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Subject: ABA Biotech Law Committee -- News & Developments

Biotechnology Law Committee, ABA Section of Science & Technology
Week of December 11, 2016 to December 17, 2016

Developments of Note.

- **Patent Law.** Two things here, not specifically related to biotech, but probably important to biotech companies. First, the enormous damages award by the jury in the Gilead patent case, Idenix v. Gilead (D. Del. 14-cv-00846). The case relates to four patents covering Hepatitis-C treatment, and the jury awarded Idenix an eye-popping and record-setting $2.54 billion. Bloomberg coverage here. Second, the Supreme Court granted certiorari in TC Heartland, which relates to the patent litigation venue statute. The plain English explanation of the controversy follows. The statute (1400) says actions may be brought either (a) in the judicial district where the defendant resides, or (b) where the defendant has committed acts of infringement and has a regular and established place of business. A separate provision of law (1391) expands the definition of a corporation's residence to all districts where it has minimum contacts. The Federal Circuit found that 1391 expands the scope of 1400. Why does this matter to biotech? The Federal Circuit approach allows plaintiffs to file their suits in E.D. Texas, which is perceived to be plaintiff-friendly, but most defendants have only minimal contacts there. (Reportedly, 44 percent of the patent suits filed in 2015 were filed in E.D. Texas.)
- **Biosimilars**. On Monday, December 12, the Supreme Court declined certiorari in 16–332, Apotex v. Amgen. The questions presented were (a) whether the Federal Circuit erred in holding that biosimilar applicants that make all disclosures necessary under the BPCIA for the resolution of patent disputes must also provide the reference product sponsor with a notice of commercial marketing under 42 U.S.C. § 262(l)(8)(A), and (b) whether the Federal Circuit improperly extended the statutory 12-year exclusivity period to 12½ years by holding that a biosimilar applicant cannot give effective notice of commercial marketing under 42 U.S.C. § 262(l)(8)(A) for its biosimilar product until it receives an FDA license and therefore may not commercially market its biosimilar product for 180 days after receiving its license.
- **Biosimilars.** This is not the same as the two cases between Amgen and Sandoz in which the Solicitor General weighed in, last week. Those are 15–1039 and 15–1195, and certiorari is still pending. As noted last week, the questions in the original petition in that case 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.
- **21st Century Cures Act.** President Obama signed the 21st Century Cures Act on December 13. On December 14, the Biotech Committee had a lunchtime presentation from Prof. Rachel Sachs at Washington University School of Law. She discussed ten provisions of interest to biotech: Section 2002 (Eureka Prize), 2014 (Data Sharing), 3011 (Qualification of Drug Development Tools), 3016 (Continuous Drug Manufacturing), 3021 (Novel

Clinical Trial Designs), 3022 (Real World Evidence), 3031 (Summary Level Review), 3032 (Expanded Access Policy), 3038 (Combination Product Innovation), 3051 (Breakthrough Devices). Here are links to the blog entries from Hyman Phelps on the drug and biologic provisions (Part 1 and Part 2) and here is their discussion of the device provisions.

- **HHS OIG Final Rule, Anti–Kickback Law.** On December 7, the HHS OIG published its final rule amending the safe harbor regulations under the federal Anti-Kickback law. It's a chore to read, 42 Federal Register pages; here is the Hyman Phelps summary.
- **Nagoya Protocol.** By January 2017, the Nagoya Protocol to the Conventional on Biological Diversity will be in force in 89 countries. It creates an international regulatory system affecting all life science companies that conduct research and development on biological material. It covers "genetic resources" and "associated traditional knowledge," and the basic idea is that Parties may adopt "provider–country" rules on access and benefit sharing and must adopt "user country" rules to enforce compliance with provider–country rules. In simple terms, for example, a country that is rich in genetic resources might require public permits to obtain those resources from that country. Countries with advanced technological capabilities (where companies engage in R&D to develop products) will have to ensure that genetic resources have been acquired in compliance with the rules of the providing jurisdiction. Here is a short high–level summary from Covington, issued about ten days ago.
- **President-Elect Trump's Health Policy Agenda.** The Petrie–Flom Center is hosting a free webinar at noon tomorrow on President-Elect Trump's Health Policy Agenda, including the future of the Affordable Care Act, but also drug pricing, innovation policy, and support for scientific research.
- **Finally, a nice essay from a history of medicine professor at Hopkins**, that the "hype around medical genetics is a public enemy." He makes a thoughtful case that we should "encourage science, not just cheerleading."

Committee News.

- **Call for Volunteers.** Can you help me put together a list of the top 10 developments in biotechnology law in 2016? Please email me, if you can help me put together the list.
- **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.

Committee Network.

- **Introduction: Jeff Licitra.** Jeff is a member of the D.C. bar (admission pending in NY) and a 2015 graduate of the American University Washington College of Law, where in addition to his legal studies, he completed graduate courses in Molecular Biology, Genomics, and FDA Regulatory Science. He interned for the Honorable Tanya S. Chutkan in the United States District Court for the District of Columbia. Prior to law school, Jeff ran after-school education programs in public housing developments for the Harlem Children's Zone. He is a former National Science Talent Search Finalist for his research on biodiversity and was admitted to the State University of New York Stony Brook on a full scholarship, receiving a B.S. in Mathematics in 2008. Jeff lives in the Cleveland Park section of Washington, D.C and is an avid pick-up basketball player, proving that

longevity does not necessarily translate to greatness. Jeff is working with committee leadership to put together a directory of biotech-law resources for committee members.