UNITED STATES

BioPharma Patents

QUICK NEWS & PRACTICE TIPS

Harness Dickey will be attending IPO in Chicago 27-29 Sept 2015! Will you? Please let us know!

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A. U.S. Litigation Updates:

1. **See our July 2015 Newsletter...the Federal Circuit didn't wait for Congress to broaden the scope of direct infringement!** Sitting *en banc*, the Federal Circuit in *Akamai v. Limelight*[1] held that a "mastermind" is liable for the acts of third-parties who perform step(s) of a claimed method if the "mastermind" conditions the third-parties' **receipt of a benefit** on their performing the method steps.

   This new basis of direct infringement scored a victory for Eli Lilly in their lawsuit against Teva[2] relating to ALIMTA (pemetrexed). Lilly's ALIMTA label (which Teva must copy exactly, if it wants to get regulatory approval through the abbreviated pathway) instructs patients to take folic acid before pemetrexed treatment begins. Lilly's patents recite a method in which folic acid supplementation is step 1, and pemetrexed administration is step 3. Teva had sought to avoid liability by saying that the patient performs step 1, and the physician performs step 3, so there is no single actor performing all steps. Under *Akamai*, however, the physician is the "mastermind" who conditions a benefit (pemetrexed administration) on the patient's performing step 1. Therefore, the physician infringes directly, making Teva liable for induced infringement.

2. **Can my method claim block importation of a product into the U.S.? Answer = Yes.** In *Suprema v. ITC*[3], the Federal Circuit, sitting *en banc*, held that "articles that infringe" (9 U.S.C. §1337) means **"articles that will infringe after importation."** This is important, because a previous Federal Circuit panel had held that method claims could not be used to prevent importation of a product that performs the patented method unless the product is performing the method at the time of importation. Now, under the *en banc* holding, a patentee who owns a method of treatment claim can use that claim to prevent importation of a drug product into the U.S. that would infringe the method claim when administered to a patient after importation.

B. U.S. Biosimilar Update:

In *Amgen v. Sandoz*[4], a split panel of the Federal Circuit made two important holdings:

1. **Exchange of information provisions ("the patent dance") is voluntary. Win for Sandoz.**
2. **Notice to the holder of the reference product of an intention to begin commercial marketing in 180 days can occur *only* after the biosimilar is licensed. Win for Amgen.**

Subsequently, Sandoz launched the first biosimilar licensed under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") on 3 September 2015. Sandoz's ZARXIO (filgrastim-sndz) is a biosimilar version of Amgen's NEUPOGEN (filgrastim). The FDA licensed ZARXIO on 6 March 2015 under BLA 125553.

But controversy still remains. Amgen and Sandoz have already petitioned on 20 Aug 2015 for rehearing *en banc* at the Federal Circuit and the amicus briefs for both sides are rolling in as we speak. Stay tuned!

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[1] *Akamai Tech. v. Limelight Networks*, No. 2009-1372 (Fed. Cir. Aug. 13, 2015)
[2] *Eli Lilly & Co. v. Teva Pharma*, No. 1:10-cv-01376-TWP-DKL (S.D. Ind. Aug. 25, 2015)
[3] *Suprema Inc. v. ITC*, No. 2012-1170 (Fed. Cir. Aug. 10, 2015)
[4] *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015)