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DENTONS

Janssen Biotech v. Celltrion: The Balance Between the BPCIA and Litigation

Presented by Kerisha A. Bowen, Ph.D.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA)

- **The BPCIA includes three major elements:**
  1) The BPCIA creates a pathway for submitting an abbreviated biologics license application (aBLA) for approval of biosimilars
  2) The BPCIA creates a term of regulatory exclusivity for the applicant that is the first to demonstrate an interchangeable biosimilar
  3) The BPCIA creates a distinct patent dispute resolution procedure for use by brand name and biosimilar manufacturers.

BPCIA: The Varying Definitions of "SHALL"

- **42 U.S.C. § (l)(2)(A) Application Information:** Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) **applicant shall provide** to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
- **42 U.S.C. § (l)(8)(A) Notice of Commercial Marketing:** The subsection (k) **applicant shall provide** notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

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Effect Notice of Commercial Marketing Under BPCIA

- The Federal Circuit decided “shall” in this context is mandatory, and effective notice of commercial marketing may only occur after the product is licensed by the FDA.

- In it's decision in *Amgen Inc. v. Sandoz Inc*. 794 F.3d 1347 (Fed. Cir. 2015) , the Federal Circuit stated that **notice of commercial marketing prior to licensing by the FDA is premature and ineffective**.

Janssen Biotech v. Celltrion: Timeline

- **Sep 1998 - U.S. Patent No. 5,807,715 issues (expired 15-Sep-2015)**
  - A method for producing a functional immunoglobin.
- **Sep 2001 - U.S. Patent No. 6,284,471 issues (expires 4-Sep-2018)**
  - A chimeric antibody comprising at least a part of human immunoglobin constant region and at least a part of a non-human immunoglobin variable region.
- **May 2007 - U.S. Patent No. 7,223,396 issued (expires 29-Jun-2016)**
  - A method for inhibiting TNFα in a human patient.
- Mar 2013 - Celltrion files Complaint for Declaratory Judgement to invalidate the '715, '471, and '396 patents. (in the District Court for the District of Massachusetts)
- Oct 2014 - the FDA accepts the application for review
- Oct 2014 - Declaratory Judgment voluntary dismissed
- Mar 2015 - Janssen files a complaint against Celltrion for not obeying BPCIA

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Janssen Biotech v. Celltrion: Update as of 28-Sep-2015

- *In light of Sandoz…*
- Defendants will not launch any biosimilar infliximab product in the United States until after September 15, 2015 (when the ‘715 patent expired).
- All claims and defenses pending between Janssen and Celltrion related to alleged infringement of the ‘715 patent under 35 U.S.C. § 271(e)(2)(C)(i) are dismissed as moot.
- All claims and defenses pending between the parties related to alleged infringement of the ‘056 patent under 35 U.S.C. § 271(e)(2)(C)(ii) are dismissed, and that dismissal is with prejudice only with respect to all claims and defenses related to the cell growth media described in the Cell Growth Media Spreadsheet.

The Take Home Message…

Do not file a notice of commercial marketing until **AFTER** the product is licensed by the FDA!!!

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Thank you

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