Update on Biosimilars: *Sandoz v. Amgen* and Marketing Challenges

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Janet B. Linn
Eaton & Van Winkle

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Biologics Price Competition And Innovation Act (2010) ("BPCIA")

- **Abbreviated process for FDA approval of biosimilar versions of marketed biologic drug products.**
- **Biosimilar application under Section 351(k) relies on data from approved biologic license application (BLA) (the "reference product.")**

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BPCIA

Two Sections:

- **Regulatory standards and procedures for approval of biosimilar applications.**
- **Complex procedures for identifying and resolving patent disputes.**

35 USC Sec. 271(e) (2) – artificial act of infringement to submit application under section 512

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Biosimilars

Biosimilar product

- **"highly similar to the reference product notwithstanding minor differences in clinically inactive components," and**
- **there are "no clinically meaningful differences between the [biosimilar] biological product and the reference product in terms of safety, purity and efficacy." 42 U.S.C. §262(i)**

Interchangeable product

- **"the [interchangeable] biological product . . . can be expected to produce the same clinical result as the reference product in any given patient". 42 U.S.C. §262(k)(4)**

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First Biosimilar Applications filed under Section 351(k)

Sandoz biosimilar application for Zarzio (filgrastim). reference product Amgen's Neupogen, filed May 20

Celltrion biosimilar application for infliximab, reference product Janssen's Remicabe, filed August 8, 2014.

Apotex biosimilar application for pegfilgrastim, reference product Amgen's Neulasta, filed Decemb 2014.

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Patent Procedures Under 42 U.S.C. §262: "The Patent Dance"

After the biosimilar application is accepted, the patent procedures ("patent dance") begins.

- **Within 20 days, applicant provides copy of biosimilar application and manufacturing process used to manufacture the biosimilar product.**
- **Within 60 days, sponsor must list a) potentially infringed patents, and b) patents it is willing to license to the applicant.**
- **Within 60 days, applicant a) <u>may</u> supply its own list and b) <u>must</u> supply its factual and legal basis for claims of non-infringement, invalidity or unenforceability of each patent, or agree to wait to market its product until the patent expires.**

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The Patent Dance (Cont'd)

- Within 60 days, sponsor must provide a claim by claim analysis of infringement and response to invalidity and unenforceability statement.
- Negotiation in good faith for 15 days on patents to be litigated.
- If no agreement, applicant specifies the number of patents in suit.
- Parties then exchange lists of patents to litigate.
- Sponsor limited to number of patents chosen by applicant.
- Patent Infringement suit within 30 days from agreement or from exchange of lists,

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Limitation on Declaratory Judgment Action

"If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity or enforceability of any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(l)(9)(C)

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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)." 42 USC § 262(l)(8)(A)

After receiving notice and before the date of first commercial marketing, reference sponsor may seek a preliminary injunction. 42 U.S.C. § 262(l)(8)(B)

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Amgen v. Sandoz

- **Sandoz files application for biosimilar May 2014**
- **On July 8, 2014, the day after FDA notified Sandoz its application was accepted, Sandoz notified Amgen about its application and intention to begin commercial marketing upon approval.**
- **Sandoz refuses to follow patent dance procedures and provides notice of commercial marketing "upon approval."**
- **October 2014 Amgen sues Sandoz for unfair competition, conversion, and patent infringement.**

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Sandoz v. Amgen – U.S. Supreme Court June 12, 2017

Two Questions before the Supreme Court

- **Is the requirement to provide an application and marketing information enforceable by injunction under federal or state law?**
- **Answer: Only remedy is Sponsor's immediate declaratory judgment action for artificial act of infringement.**
- **No injunction.**
- **Remand on state law.**

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Sandoz v. Amgen – U.S. Supreme Court (cont'd)

- **Must the notice of commercial marketing be after the FDA licenses the biosimilar?**
- **Answer: Notice, if given at least 180 days before marketing, can be before approval. Policy arguments are for Congress, not the Court.**

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Sandoz v. Amgen – U.S. Supreme Court (cont'd)

Concurring Opinion by Justice Breyer

FDA is delegated authority to interpret the statute

FDA may have authority to depart from or modify Supreme Court interpretation.

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Marketing Challenges

- **Nine biosimilars approved since 2015**
- **Only three available for sale at the end of September 2017.**

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Pfizer v. J & J and Janssen (E.D. Pa. September 2017)

Pfizer sues J&J and Janssen for antitrust violations relating to Pfizer's Inflectra, the biosimilar for Janssen's Remicade

- **Pfizer launches Inflectra biosimilar for Remicade in 2016.**
- **According to Pfizer, since its launch, J&J's actions have led to near total foreclosure of Inflectra from patients.**
- **Pfizer alleges J&J's anti-competitive pricing and exclusionary contracts with insurers and hospitals preserve J&J's monopoly.**

J&J's motion to dismiss currently pending

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