What's going on in US Biosimilars Litigation?

Choreographing US & European Biosimilar Dances
New Developments on Patenting, Similarity & Interchangeability
Copenhagen Biotech & Pharma Forum (CPHF) Seminar
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So, what is the US “patent dance”?

Two-Phase Patent Information Exchange Process (BPCIA*)

- **Before FDA approval of the biosimilar application) (§262 (l)(2)-l(7))**
- **After FDA approval of the biosimilar application (§262(l)(8))**

*** BIOLOGICS PRICE COMPETITION AND INNOVATION ACT (2010)**

Major Questions Before the US Supreme Court Oral Arguments, April 26, 2017*

- **Is it mandatory for the "subsection (k) applicant" to share application information with the "reference product sponsor"?**

(§262 (l) (2)(A)) **(U.S. Code § 262 - Regulation of biological products)**

- **Can the 180-day notice of first commercial marketing by the biosimilars applicant to the reference product sponsor be given prior to FDA approval of the application? §262 (l) (8)(A))**

* decision expected before end of October 2016 term

Question 1

Is it mandatory for the “subsection (k) applicant” to share application information with the “reference product sponsor”?

Amgen v. Sandoz (2014 – ongoing)

- **July 7, 2014 – FDA accepts Sandoz's biosimilar application for filgrastin (Amgen's Neupogen) for review**
- **Next day, Sandoz informed Amgen about this acceptance but refused to share the information required under** §262 (l) (2)(A)) which states that "Not later than 20 days after . . . the application has been accepted for review, [Sandoz]

(A) <u>shall</u> provide to [Amgen] a copy of the application submitted . . . and such other information that describes the process or processes used to manufacture the biological product . . ." (emphasis added)

Amgen v. Sandoz (2014 – ongoing) (cont'd)

Amgen's Options:

- **It "may bring an action . . . for a declaration of infringement, validity, or enforceability of <u>any</u> patent that claims the biological product or a use of the biological product."[§262(l)(9)(C)] (emphasis added), and/or**
- **Bring a patent infringement action under 35 U.S.C. § 271 (e)(2)(c)(ii)**

Question 2

Can the 180-day notice of first commercial marketing by the biosimilars applicant to the reference product sponsor be given prior to FDA approval? § 262 (l) (8)(A))

Amgen v. Sandoz (2014 – ongoing) (cont'd)

- Sandoz also informed Amgen that it plans to market its biosimilar version (Zarxio) upon FDA approval.

- This raised the second issue because "[Sandoz] shall provide notice to [Amgen] not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." [§262(l)(9)(C)] (emphasis added)

DISTRICT COURT (ND-CA)

October 2014: Amgen Files Suit (only issues being discussed here are included).

- **Question 1: Sandoz does not have to submit information stated in §262(l)(2)(A) because Amgen has a remedy in §262(l)(9)(C).**
- **Question 2: The court also held that Sandoz's initial notice of commercial marketing before FDA approval of its application met the notice requirement under §262(l)(8)(A).**

DISTRICT COURT (ND-CA) (cont'd)

Sponsor has two remedies:

(1) "may seek a court order enjoining such market entry until a court can decide issues of patent validity or infringement. 42 U.S.C. § 262(l)(8)(B)."

(2) "It may also initiate a declaratory judgment action. 42 U.S.C. § 262(l)(9)(B)."

COURT OF APPEALS FOR THE FEDERAL CIRCUIT
July 21, 2015

Question 1

- **The 3-judge panel was divided**
- **Majority held that "[b]ecause Sandoz took a path expressly contemplated by the BPCIA, it did not violate the [paragraph l(2)(A) of the Act]."**
- **"42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies as those being based on a claim of patent infringement."**

COURT OF APPEALS FOR THE FEDERAL CIRCUIT
July 21, 2015 (cont'd)

Question 2

- **The 3-judge panel unanimously held that notice can come only after FDA approval because after "licensure . . . the product, its therapeutic uses, and its manufacturing processes are fixed."**

- **"Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the [sponsor] to effectively determine whether, and on which patents, to seek a preliminary injunction from the court." § 262(l)(8)(B)**

QUESTIONS? COMMENTS?

Speaker's Publications on Biosimilars

1. Chapter 5: Landscape and Consideration of Intellectual Property for Development of Biosimilars in *Biological Drug Products: Development and Strategies, Eds. W. Wang and M. Singh, John Wiley Press, 2014*
2. http://lawandscience.com/wp-content/uploads/2014/09/BSFG-Newsletter-2015-The-Biologics-Price-Competition-and-Innovation-Act-of-2009.pdf