March 24, 2016

Webinar Series: Biosimilars

Biosimilars & IPR

Dorothy P. Whelan
Principal
Twin Cities

Brian D. Coggio
Of Counsel
New York

FISH.
FISH & RICHARDSON

Overview

- Biosimilars Series
  - Introduction to the area of biosimilars
  - Explore key developments and trends
- CLE Credit
  - Contact: Jane Lundberg
    - lundberg@fr.com
- Materials will be made available
  - fr.com/industries/life-sciences
- Follow us on Twitter @FishRichardson
  - #fishwebinar

Join Us For Our Next Biosimilars Webinar

1:00 PM ET
April 21, 2014

Biosimilars and IPR

I. IPR Overview
II. Biosimilars IPR Petitions
III. Joinder
IV. Timing Issues Where There are Multiple Filers

IPR Overview

FISH.

Biosimilars and IPR

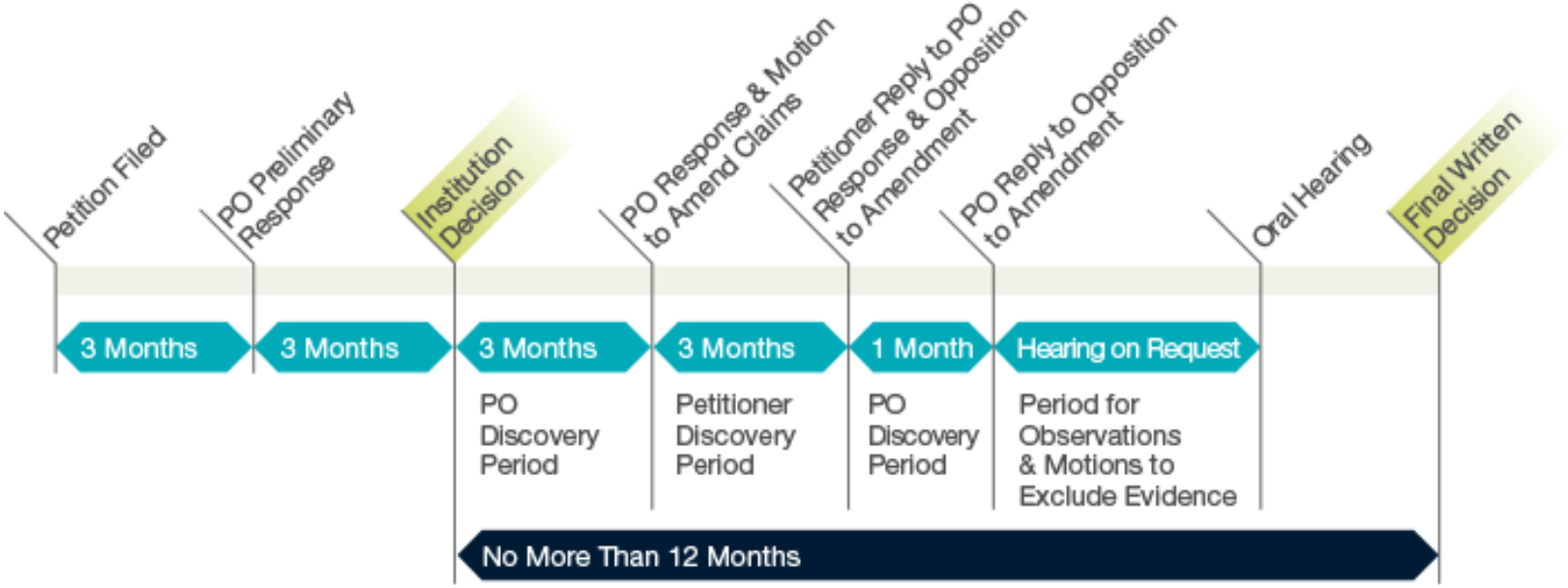
IPR Overview

IPR Essential Features:

- Claim construction: Broadest reasonable interpretation (currently being challenged in *Cuozzo* at the U.S. Supreme Court)
- Burden of proof: Preponderance of the evidence
- Limited discovery
- Limited ability to amend claims
- Fast relative to reexamination and district court litigation
- Estoppel
- Can be settled

Biosimilars and IPR

IPR Overview



Biosimilars and IPR

IPR Overview

How difficult is it to gain institution?

- Applicable Standards
  - Reasonable likelihood that petitioner would prevail on at least 1 challenged claim
- Intentionally low threshold
  - No presumption of validity - PTAB reviews prior art *de novo* (Even CRU decisions may be revisited, if justified) *Macauto U.S.A. v. Bos GmbH & KG*, slip. op. IPR2012-00004 (PTAB Jan. 24, 2013)
- Institution decisions are not appealable!

Biosimilars and IPR

IPR Overview

- Types of permissible evidence:
  - In the petition and patent owner response, expert declarations are commonplace/critical to success
  - Expert will be subject to deposition
  - No live testimony of experts
  - As Patent Owner, prior to institution, expert declarations may not be submitted, leaving the institution decision unbalanced in favor of Petitioner
  - Important to back-up expert testimony with documentary evidence

IPR Overview

Estoppel

What happens to the loser?

Petitioner:

- Any ground raised or reasonably could have been raised
- Attaches at the time the final written decision issues
- Applies to district court, ITC, and PTO proceedings
- Applies to petitioner and its privies

IPR Overview

Appeal

Either party may appeal a final written decision directly to the Federal Circuit. 35 USC §319

Appeal statistics (through 2/16):

- Affirmance rate: 92.8%
- Rule 36 rate: 56.6%
- Reversal/vacate rate: 7.2%

Biosimilars IPR Petitions

FISH.

Biosimilars and IPR

Biosimilars IPR Petitions

Types of claims being challenged

~ 17% targeted core patents:

Drug composition claims (13% drugs; 4% biologics)

~ 84% targeted follow-on patents:

Claims to drug product uses/dosing (41%), formulations (34%), or manufacturing processes (8%)

Source: 34 Biotechnology Law Report 185(5) Nov. 5, 2015

Biosimilars and IPR

Biosimilars IPR Petitions

Types of Claims Being Challenged

- Challenged core patents
  - 30% institution rate
  - 2% of these IPR settled
  - Final decision has been reached in only one of the analyzed IPRs challenging a core patent
    - Majority of claims were held unpatentable
- Challenged follow-on patents
  - 48% institution rate
  - 18% of these challenges settled
  - Final decision reached in 23 analyzed follow-on patent IPR challenges
    - In 65%, all or most claims were held unpatentable

34 Biotechnology Law Report 185(5) Nov. 5, 2015

Biosimilars and IPR

Biosimilars IPR Petitions

Who is filing?

- A number of biosimilar makers have turned to IPR to challenge pioneer patents prior to submitting their biosimilar applications to the FDA
- Examples include
  - Boehringer Ingelheim
    - IPR2015-00415, -417, -418 challenging patents covering Rituxan®
  - Hospira
    - IPR2013-00365 challenging patents covering dosing regimens for administering erythropoietin (EPO)IPR2013-00365 challenging Eprex (epoetin alfa), a biologic used to treat anemia
  - Amgen, Coherus, Boerhinger Ingelheim
    - IPR2015-01514, 2015-01517, 2016-00172, 2016-00188, 2016-00189, 2016-00408, 2016-00409 challenging patents covering Humira®
  - Momenta
    - IPR2015-01537 challenging patent covering Orencia®

Joinder

FISH.

Biosimilars and IPR

Joinder

- PTAB has the discretion to join multiple petitions. 35 U.S.C. § 314
  - Multiple petitions by a single party
  - Multiple petitions by multiple parties.
- Motion for joinder must be filed no later than one month after the institution date of the first IPR petition. 37 CFR § 42.122(b)

Biosimilars and IPR

Joinder

- PTAB has a liberal policy with respect to joinder
  - 2015: 174 motions filed. 74% granted
  - Reflects PTAB's desire to simplify and streamline proceedings

Biosimilars and IPR

Joinder

How does a joined proceeding work?

- Trend has been toward more limited role by joined party
  - "[Joined Party] not permitted to file papers, engage in discovery, or participate in any deposition or oral hearing. [Joined Party], however, is permitted to appear so that it may receive notification of filings and may attend depositions and oral hearing. Should [Joined Party] believe it necessary to take any further action, [Joined Party] should request a conference call to obtain authorization from the Board." IPR2015-00565
- Effectively, a backseat passenger unless/until original Petitioner settles out

Biosimilars and IPR

Joinder

Should you join an existing proceeding or simply file a separate petition?

- Similarity of grounds?
- PTAB joinder
- Timing

Timing Issues Where There Are Multiple Filers

FISH.

Biosimilars and IPR

Timing issues where there are multiple potential filers

When should you file in a multiple filer situation?

- Should you be the first filer?
- Should you file shortly after the first filer?
- Should you wait until the patent owner files a preliminary response to file?
- Should you wait until the PTAB decides whether to grant the first petition?
  - Need to file within one month of institution, along with a motion for joinder, if you wish to join the instituted proceedings

Questions?

FISH.

Thank you!

Dorothy P. Whelan
Principal
Twin Cities
612-337-2509
whelan@fr.com

Brian D. Coggio
Of Counsel
New York
212-765-5070
coggio@fr.com

Please send your NY CLE forms or questions about the webinar to marketing at lundberg@fr.com.

A replay of the webinar will be available for viewing at fr.com/industries/life-sciences.