

Boston Seminar Series: Latest Developments in Post-Grant Proceedings for Biosimilars



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Biosimilars and IPR

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



IPR Overview

Biosimilars and IPR

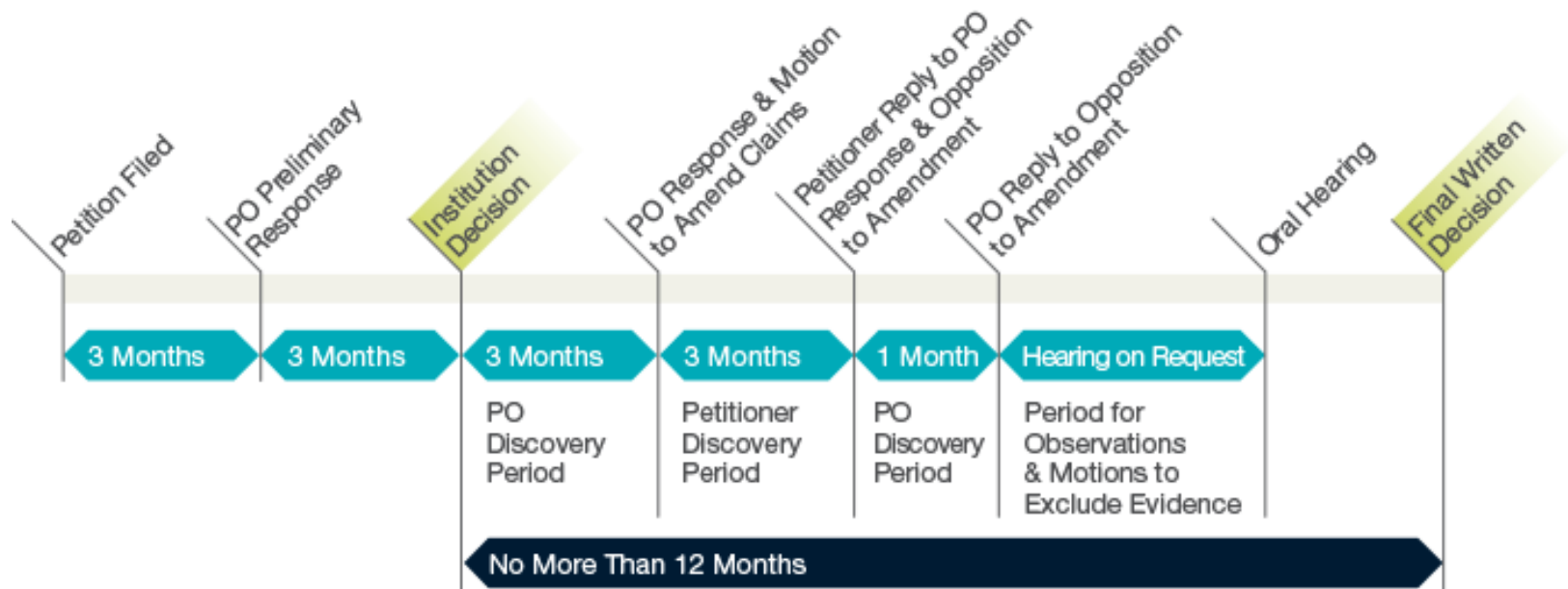
IPR Overview

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

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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!

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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

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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

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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

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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

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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

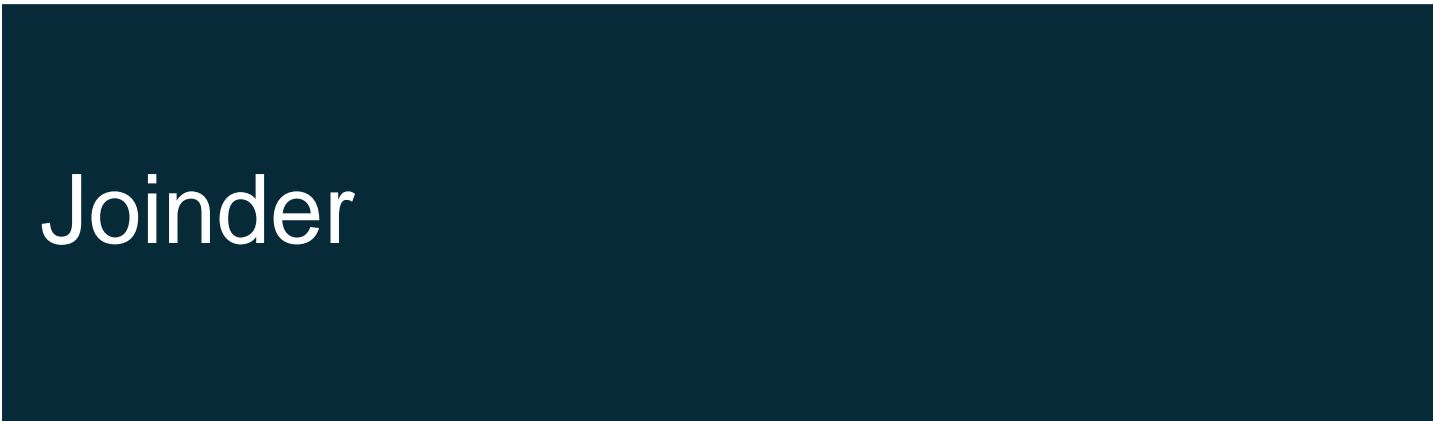
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Biosimilars IPR Petitions

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, Boehringer 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®



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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)

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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

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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

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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

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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?

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Thank you!



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