

Biosimilars in an AIA World



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Biosimilar Applications Accepted for Filing

- Sandoz – Amgen Neupogen (\$1B+ US)
- Celltrion – Johnson & Johnson Remicade (\$4B+ US)
- Apotex – Amgen Neulasta (\$3B+ US)
- Hospira – Amgen Epogen/J&J Procrit (\$2B+ US)
- Apotex – Amgen Neupogen (\$1B+ US)

BPCIA Patent Dispute Resolution Procedure



FDA Accepts Biosimilar Application
20 Days

Biosimilar Applicant Provides Information
60 Days

Reference Sponsor Provides Patent List
60 Days

Biosimilar Applicant Provides List and Defenses
60 Days

Reference Sponsor Provides Response
15 Days

Negotiation [If Agreement, Sponsor Begins Litigation]
5 Days

Biosimilar Applicant Provides # of Patents
Sponsor Begins Litigation

Biosimilar Applicants: Three Little DJ Actions



**Sandoz v. Amgen
(Fed. Cir. Aff'd)**

Hospira



Celltrion



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AIA to the Rescue, But at a Cost

	Post Grant Review	Inter Partes Review
Eligible Patents	First-inventor-to-file patents (filed on Mar. 16, 2013 or later); patents involved in an interference; and certain business method patents	No restrictions
Prior Art	NOT limited to printed publications and patents.	Only printed publications and patents
Petition Standard	More likely than not that at least one claim is unpatentable (higher standard than the IPR standard)	Reasonable likelihood that petitioner will prevail
Grounds for challenging	Almost any ground (§§ 101, 102, 103, 112)	35 U.S.C. §§102 or 103
Estoppel	Any ground raised or reasonably could have been raised, unless settled	Any ground raised or reasonably could have been raised, unless settled

Questions???

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