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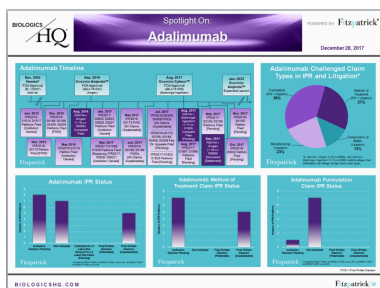
January 8, 2018

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## MONTHLY INJECTION



## LATEST NEWS



### Spotlight On: Humira® (adalimumab) / Amjevita™ (adalimumab-atto) / Cyltezo™ (adalimumab-adbm)

BiologicsHQ's "Spotlight On" dashboard provides, at a glance, an overview of the status of U.S. patent proceedings concerning adalimumab (Humira®, Amjevita™, and Cyltezo™).



### VIDEO: The PTAB's Role in Biosimilar Patent Disputes

By: Ha Kung Wong

As part of the *The Center for Biosimilars™ Peer Exchange®*, Ha Kung Wong and Amanda Forsy provide an overview of the Patent Trial and Appeal Board's role in patent disputes over biologics.



## VIDEO: Upcoming Patent Litigation in Biosimilars

By: Ha Kung Wong

As part of the *The Center for Biosimilars™ Peer Exchange®*, Ha Kung Wong, Amanda Forys, and Angus Worthing discuss upcoming litigation that affects biosimilars stakeholders.

### View New Videos by Ha Kung Wong:

- [The Need for Clarity After Sandoz v. Amgen](#)
- [State Laws and Biosimilar Substitution](#)

### View Additional Videos by Ha Kung Wong:

- [Biosimilars, Formularies, Contracting, and PBMs](#)
- [Reforms at the FDA Level](#)
- [Inspection Reports and Proprietary Information](#)
- [Global Reference Products in Biosimilar Development](#)
- [Biosimilars, Interchangeability, and Perceptions of Safety](#)
- [How Important is \*Inter Partes\* Review to Biosimilars?](#)
- [Might the FDA Clarify Its Stance on the BPCIA?](#)
- [Might PTAB Invalidate More Method of Treatment Patents?](#)
- [Will Biosimilar Applicants Still Participate in the Patent Dance?](#)
- [What Questions Did SCOTUS Leave Unresolved in Sandoz v. Amgen?](#)

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## UPDATES

### IPRs

- **Herceptin® (trastuzumab):**
  - On December 1, 2017, institution was granted in IPR2017-01373 and IPR2017-01374 filed by [Celltrion](#) and [Teva](#).
  - On December 1, 2017, institution was granted in IPR2017-01958 filed by [Samsung Bioepis](#) and Samsung's motion for joinder with IPR2017-00804 was granted.
  - On December 1, 2017, institution was granted in IPR2017-01959 filed by [Samsung Bioepis](#) and Samsung's motion for joinder with IPR2017-00805 was granted.
  - On December 1, 2017, institution was granted in IPR2017-01960 filed by [Samsung Bioepis](#) and Samsung's motion for joinder with IPR2017-00737 was granted.

- On December 18, 2017, [Pfizer](#) filed IPR2018-00330 and IPR2018-00331.
  - On December 28, 2017, [Pfizer](#) filed a motion for joinder of IPR2018-00330 with IPR2017-02019, and a motion for joinder of IPR2018-00331 with IPR2017-02020.
- **Rituxan<sup>®</sup> (rituximab):**
  - On December 1, 2017, [Pfizer](#) filed IPR2018-00186 and IPR2018-00231.
  - On December 14, 2017, [Pfizer](#) filed IPR2018-00285.
- **Lantus<sup>®</sup> / Lantus<sup>®</sup> SoloSTAR<sup>®</sup> (insulin glargine recombinant):**
  - On December 13, 2017, trial was instituted in IPR2017-01526 and IPR2017-01528 filed by [Mylan](#) and [Biocon](#).

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## LITIGATIONS

- **Praluent<sup>®</sup> (alirocumab) / Repatha<sup>®</sup> (evolocumab):** On December 6, 2017, [Amgen](#) filed a petition for rehearing *en banc* in [Amgen v. Sanofi](#), Case No. 17-1480.
- **Avastin<sup>®</sup> (bevacizumab):** On December 6, 2017, U.S. Patent No. 9,795,672 was added to [Genentech v. Amgen](#), Case Nos. 1:17-cv-01407 (D. Del.) and 1:17-cv-01471 (D. Del.).
- **Neupogen<sup>®</sup> (filgrastim):** On December 13, 2017, on remand from the Supreme Court, the Federal Circuit affirmed the district court's dismissal of [Amgen's](#) state law claims in [Amgen v. Sandoz](#), Case No. 15-1499.
- **Rituxan<sup>®</sup> (rituximab):** On December 21, 2017, [Genentech](#) and [Biogen](#) filed Case No. 2:17-cv-13507 (D.N.J.) against [Sandoz](#) related to [Rixathon<sup>®</sup>](#), Sandoz's proposed [Rituxan<sup>®</sup>](#) biosimilar.

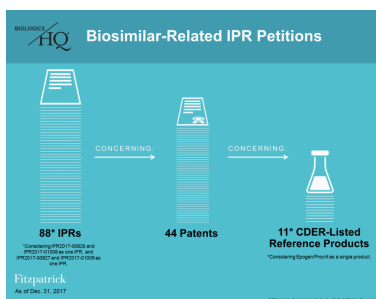
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## aBLA APPLICATIONS AND APPROVALS

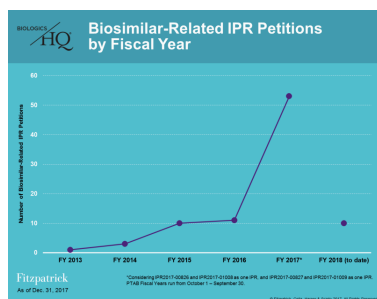
- **Ogivri<sup>™</sup> (trastuzumab-dkst):** On December 1, 2017, the FDA approved [Mylan](#) and [Biocon's](#) Ogivri<sup>™</sup>, a biosimilar of [Genentech's Herceptin<sup>®</sup>](#) (trastuzumab).
- **Ixifi<sup>™</sup> (infliximab-qbtx):** On December 13, 2017, the FDA approved [Pfizer's](#) Ixifi<sup>™</sup>, a biosimilar of [Centocor's Remicade<sup>®</sup>](#) (infliximab).
- **SB3 (trastuzumab):** On December 20, 2017, [Samsung Bioepis](#) announced the FDA accepted its aBLA for SB3, its proposed biosimilar of [Genentech's Herceptin<sup>®</sup>](#) (trastuzumab).

## STATISTICS

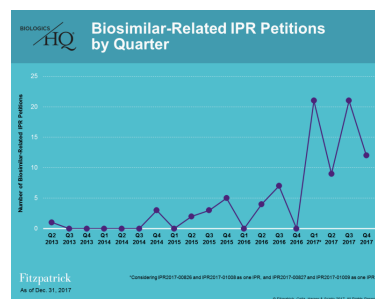
## Biosimilar-Related IPR Petitions



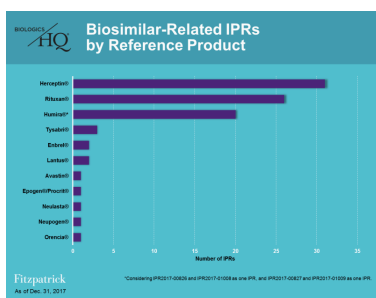
## Biosimilar-Related IPR Petitions by Fiscal Year



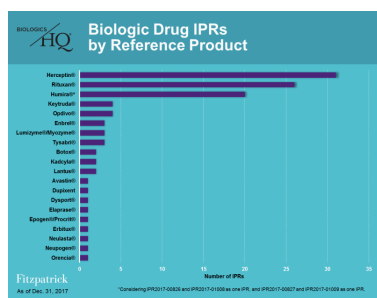
## Biosimilar-Related IPR Petitions by Quarter



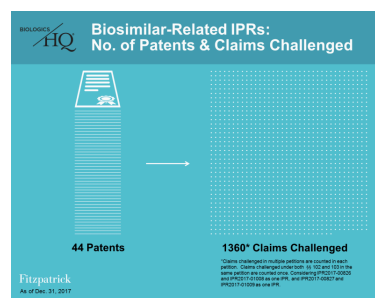
## Biosimilar-Related IPRs by Reference Product



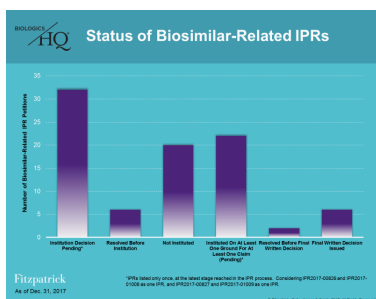
## Biologic Drug IPRs by Reference Product



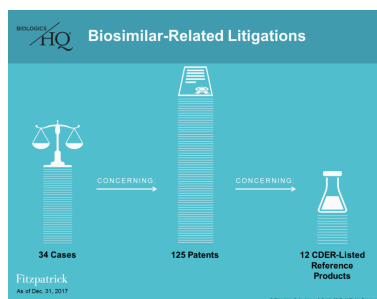
## Biosimilar-Related IPRs: Number of Patents and Claims Challenged



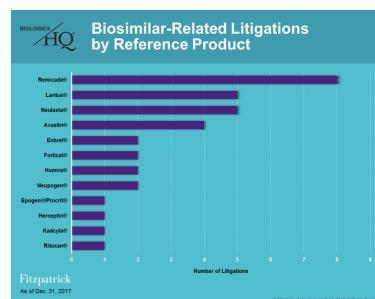
## Status of Biosimilar-Related IPRs



## Biosimilar-Related Litigations



## Biosimilar-Related Litigations by Reference Product



## Biosimilars Approved in the U.S.

## Biosimilar Applications Pending in the U.S.

aBLA / NDA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Number	Date of Biosimilar License	Reference Product	Reference Product License Holder	U.S. Biotech Launch Date
aBLA 781334	Anjex <sup>®</sup>	Adelimumab-ahs	Angen Inc.	Sept. 23, 2016	Humira <sup>®</sup>	AbbVie Inc.	
aBLA 781338	Cyltezo <sup>®</sup>	Adelimumab-ahs	Angen Inc.	Aug. 25, 2017	Humira <sup>®</sup>	AbbVie Inc.	
aBLA 781338	Muesi <sup>®</sup>	Adelimumab-ahs	Angen Inc.	Sept. 14, 2017	Humira <sup>®</sup>	AbbVie Inc.	
aBLA 781342	Erelzi <sup>®</sup>	Etanercept-ahs	Sandoz Inc.	Aug. 30, 2016	Enbrel <sup>®</sup>	Immune Corp. (Pfizer Inc.)	
aBLA 123503	Zenpezi <sup>®</sup>	Filgrastim-ahs	Sandoz Inc.	Mar. 4, 2015	Neupogen <sup>®</sup>	Amgen Inc.	Sept. 2015
aBLA 123504	Inflectra <sup>®</sup>	Infliximab-dyy	Celltrion Inc.	Apr. 5, 2016	Remicade <sup>®</sup>	Centocor Inc.	Nov. 2016
aBLA 781354	Reclifex <sup>®</sup>	Infliximab-ahs	Samsung Biopharm Co. Ltd.	Apr. 21, 2017	Remicade <sup>®</sup>	Centocor Inc.	Jul. 2017
aBLA 781372	Isulf <sup>®</sup>	Infliximab-dys	Pfizer Inc.	Dec. 13, 2017	Remicade <sup>®</sup>	Centocor Inc.	
NDA 205482 (505(b)(2))	Biosiglar <sup>®</sup>	Insulin Glargine	EU Lilly & Co.	Dec. 16, 2015	Lantus <sup>®</sup>	Berndt Aventis US	Dec. 2016
aBLA 781374	Ogylvi <sup>®</sup>	Trastuzumab-dxt	Mylan GenH / Bioson	Dec. 1, 2017	Herceptin <sup>®</sup>	Genentech	

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As of Dec. 31, 2017

Biosimilar Name	Scientific Name	aBLA / 505(b)(2) Number	Reference Product	Reference Product License Holder	FDA Status
Rituximab <sup>®</sup>	Eporep Alfa	Hospira / Pfizer	Eporep <sup>®</sup>	Amgen	Accepted Jan. 2015, Rejected Oct. 2015, Resubmitted Dec. 2016, Complete Response Letter Jan. 2017
Granix <sup>®</sup>	Filgrastim	Apotex	Neupogen <sup>®</sup>	Amgen Inc.	Accepted Feb. 2015
Umevac <sup>®</sup>	Filgrastim	Abate Biologics	Neupogen <sup>®</sup>	Amgen Inc.	Accepted Feb. 2017
Lapiga <sup>®</sup>	Pegfilgrastim	Apotex	Neulasta <sup>®</sup>	Amgen	Accepted Dec. 2014
LA-EP2006	Pegfilgrastim	Sandoz	Neulasta <sup>®</sup>	Amgen	Accepted Nov. 2015, Rejected Oct. 2016
ChS-1751	Pegfilgrastim	Cohesus	Neulasta <sup>®</sup>	Amgen	Accepted Oct. 2016, Complete Response Letter Jan. 2017
MFL-1421H	Pegfilgrastim	Myon / Bocon	Neulasta <sup>®</sup>	Amgen	Accepted Feb. 2017, Complete Response Letter Oct. 2017
CT-P10	Rhumab	Celltrion / Teva	Rhume <sup>®</sup>	Genentech	Accepted Jan. 2017
Rhumab	Rhumab	Sandoz	Rhume <sup>®</sup>	Genentech	Accepted Sept. 2017
ASP 383	Trastuzumab	Amgen / Alkermes	Herceptin <sup>®</sup>	Genentech	Submitted Jul. 2017
CT-P2	Trastuzumab	Teva / Celltrion	Herceptin <sup>®</sup>	Genentech	Submitted Jul. 2017
PF-03280214	Trastuzumab	Pfizer	Herceptin <sup>®</sup>	Genentech	Accepted Aug. 2017
383	Trastuzumab	Samsung Biopharm	Herceptin <sup>®</sup>	Genentech	Accepted Dec. 2017
Lankang <sup>®</sup> Nucova <sup>®</sup>	Insulin Glargine	Merck	Lantus <sup>®</sup>	Sandoz Aventis US	tentative Approval Jul. 2017

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As of Dec. 31, 2017

## BiologicsHQ Search

Information contained in the Fitzpatrick BiologicsHQ database relates to FDA-approved drug products listed in the CDER Purple Book. Product and Company page search results are reported for FDA-approved indications, aBLA and 505(b)(2) activity, approved foreign biosimilars, IPRs and U.S. litigations.



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