BIOLOGICS HQ®

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LATEST NEWS

VIDEO: Biosimilar Developers' Concerns About Litigation

By: Ha Kung Wong

Ha Kung Wong discusses whether patent litigation could deter drug makers from developing biosimilars.

VIDEO: Healthcare Reform Efforts and the BPCIA

By: Ha Kung Wong

As part of the *The Center for Biosimilars*™ *Peer Exchange*®, Ha Kung Wong, Molly Burich, Amanda Forys, and Angus Worthing discuss the potential fate of the Biologics Price Competition and Innovation Act (BPCIA) in health care reform efforts, and remark on negative feedback related to the Affordable Care Act (ACA) provision for an Independent Payment Advisory Board (IPAB).

View New 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**

View Additional Videos by Ha Kung Wong:

- **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?**

Supreme Court Hears Oral Argument on Constitutionality of *Inter Partes* Review in *Oil States*

By: Christopher Loh

On November 27, 2017, the Supreme Court heard oral argument in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, No. 16-712. The Supreme Court's decision in this case will either spare or strike down *inter partes* review as a means for challenging the validity of issued patents in the United States.

Read More News

UPDATES

IPRs

- **Rituxan® (rituximab):**
  - On November 2, 2017, Pfizer filed IPR2018-00086.
  - On November 6, 2017, institution was denied in IPR2017-01167 filed by Pfizer.
  - On November 6, 2017, institution was granted in IPR2017-01168 filed by Pfizer.
  - On November 13, 2017, institution was denied in IPR2017-01166 filed by Pfizer.

- **Humira® (adalimumab):**
  - On November 6, 2017, Sandoz filed IPR2018-00156.

- **Herceptin® (trastuzumab):**
  - On November 30, 2017, Samsung Bioepis filed IPR2018-00192.

LITIGATIONS

- **Neulasta (pegfilgrastim):** On November 13, 2017, the Federal Circuit affirmed the district court decision in *Amgen v. Apotex*, Case No. 17-1010.

- **Herceptin® (trastuzumab):** On November 17, 2017, Genentech filed Case No. 1:17-cv-01672 (D. Del.) against Pfizer related to Pfizer's proposed Herceptin® biosimilar.

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aBLA APPLICATIONS AND APPROVALS

- **PF-05280014 (trastuzumab):** On November 17, 2017, Genentech filed Case No. 1:17-cv-01672 against Pfizer noting in the complaint that Pfizer's aBLA for its proposed Herceptin® biosimilar, PF-05280014, had been accepted by the FDA in August 2017.

CDER PURPLE BOOK UPDATES

- **Fasenra™ (benralizumab):** On November 14, 2017, the FDA approved AstraZeneca's Fasenra™.

- **Mepsevii™ (vestronidase alfa-vjbk):** On November 15, 2017, the FDA approved Ultragenyx Pharmaceutical's Mepsevii™.

- **Hemlibra® (emicizumab):** On November 16, 2017, the FDA approved Genentech's Hemlibra®.

NON-U.S. BIOSIMILARS / FOLLOW-ON BIOLOGICS

- **Cyltezo® (adalimumab):** On November 13, 2017, Boehringer Ingelheim announced that Cyltezo®, its biosimilar of Humira®, was approved in the E.U.

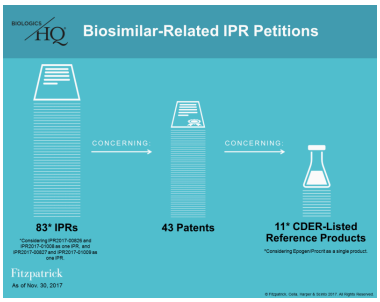
- **Ontruzant® (trastuzumab):** On November 20, 2017, Samsung Bioepis announced that Ontruzant®, its biosimilar of Herceptin®, was approved in the E.U.

STATISTICS

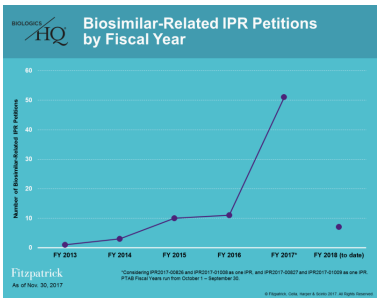
Biosimilar-Related IPR Petitions

Biosimilar-Related IPR Petitions by Fiscal Year

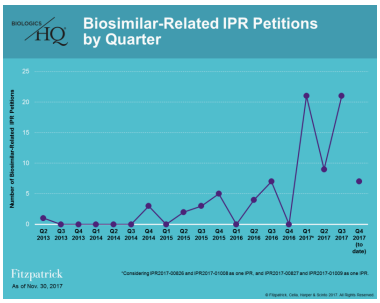
Biosimilar-Related IPR Petitions by Quarter



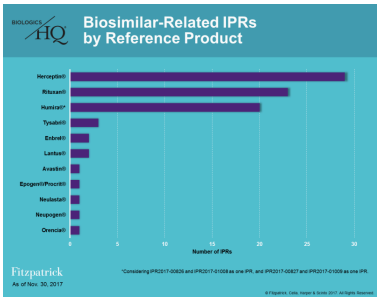
Biosimilar-Related IPRs by Reference Product



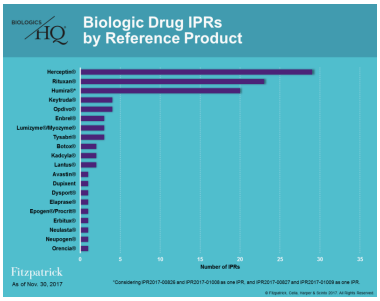
Biologic Drug IPRs by Reference Product



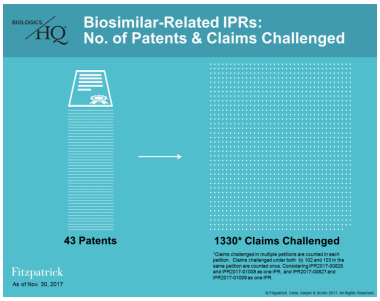
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



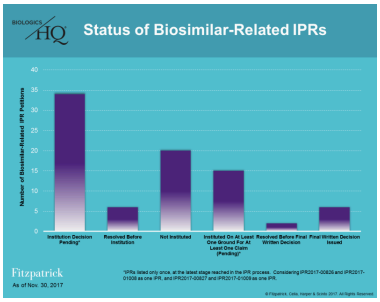
Status of Biosimilar-Related IPRs



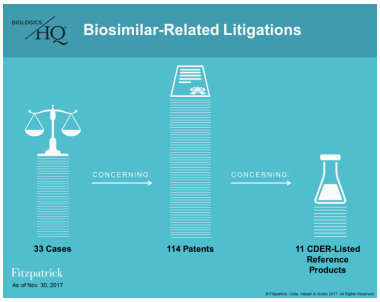
Biosimilar-Related Litigations



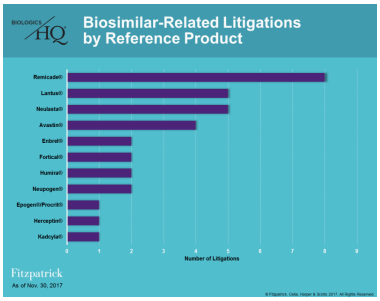
Biosimilar-Related Litigations by Reference Product

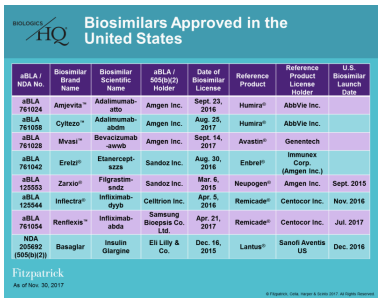


Biosimilars Approved in the U.S.

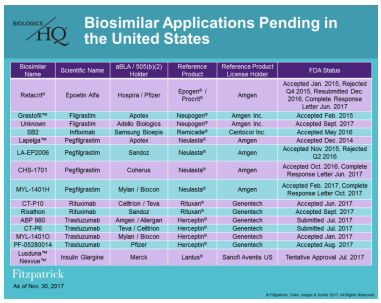


Biosimilar Applications Pending in the U.S.

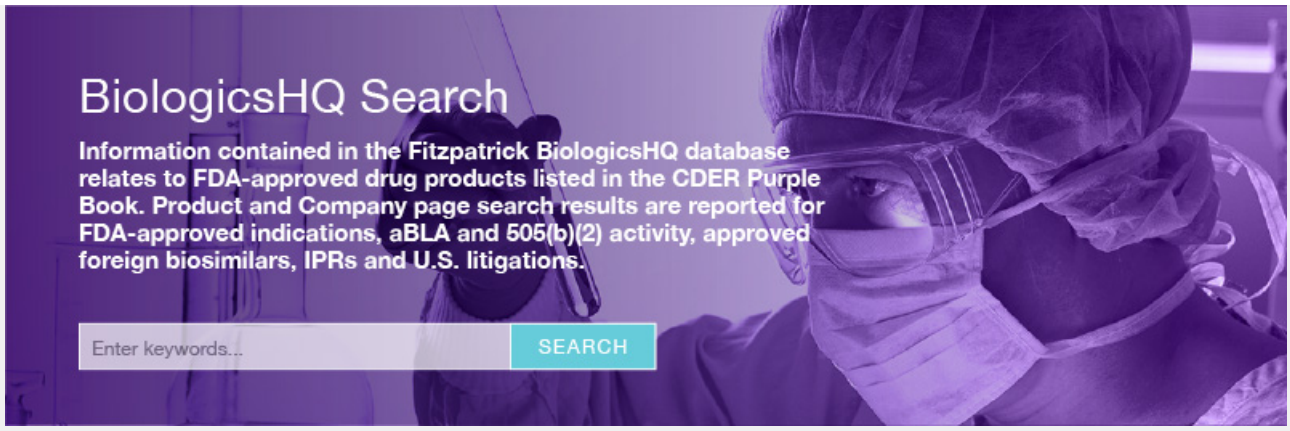




aBLA / NDA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Holder	Date of Biosimilar Licensee	Reference Product	Reference Product License Holder	U.S. Biosimilar Launch Date
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen Inc.	Sept. 23, 2016	Humira®	AbbVie Inc.	
aBLA 761058	Cyltezo™	Adalimumab-adbm	Amgen Inc.	Aug. 25, 2017	Humira®	AbbVie Inc.	
aBLA 761028	Mvasi™	Bevacizumab -awwb	Amgen Inc.	Sept. 14, 2017	Avastin®	Genentech	
aBLA 761042	Erelzi®	Etanercept-szzs	Sandoz Inc.	Aug. 30, 2016	Enbrel®	Immunex Corp. (Amgen Inc.)	
aBLA 125553	Zarxio®	Filgrastim-sndz	Sandoz Inc.	Mar. 6, 2015	Neupogen®	Amgen Inc.	Sept. 2015
aBLA 125544	Inflectra®	Infliximab-dyyb	Celltrion Inc.	Apr. 5, 2016	Remicade®	Centocor Inc.	Nov. 2016
aBLA 761054	Renflexis™	Infliximab-abda	Samsung Bioepsis Co. Ltd.	Apr. 21, 2017	Remicade®	Centocor Inc.	Jul. 2017
NDA 205692 (505(b)(2))	Basaglar	Insulin Glargine	Eli Lilly & Co.	Dec. 16, 2015	Lantus®	Sanofi Aventis US	Dec. 2016



Biosimilar Name	Scientific Name	aBLA / 505(b)(2) Holder	Reference Product	Reference Product License Holder	FDA Status
Retacrit®	Epoetin Alfa	Hospira / Pfizer	Epogen® / Procrit®	Amgen	Accepted Jan. 2015. Rejected Q4 2015. Resubmitted Dec. 2016. Complete Response Letter Jun. 2017
Grastofi™	Filgrastim	Apotex	Neupogen®	Amgen Inc.	Accepted Feb. 2015
Unknown	Filgrastim	Adello Biologics	Neupogen®	Amgen Inc.	Accepted Sept. 2017
SB2	Infliximab	Samsung Bioepis	Remicade®	Centocor Inc.	Accepted May 2016
Lapelga™	Pegfilgrastim	Apotex	Neulasta®	Amgen	Accepted Dec. 2014
LA-EP2006	Pegfilgrastim	Sandoz	Neulasta®	Amgen	Accepted Nov. 2015. Rejected Q2 2016
CHS-1701	Pegfilgrastim	Coherus	Neulasta®	Amgen	Accepted Oct. 2016. Complete Response Letter Jun. 2017
MYL-1401H	Pegfilgrastim	Mylan / Biocon	Neulasta®	Amgen	Accepted Feb. 2017. Complete Response Letter Oct. 2017
CT-P10	Rituximab	Celltrion / Teva	Rituxan®	Genentech	Accepted Jun. 2017
Rixathon	Rituximab	Sandoz	Rituxan®	Genentech	Accepted Sept. 2017
ABP 980	Trastuzumab	Amgen / Allergan	Herceptin®	Genentech	Submitted Jul. 2017
CT-P6	Trastuzumab	Teva / Celltrion	Herceptin®	Genentech	Submitted Jul. 2017
MYL-1401O	Trastuzumab	Mylan / Biocon	Herceptin®	Genentech	Accepted Jan. 2017
PF-05280014	Trastuzumab	Pfizer	Herceptin®	Genentech	Accepted Aug. 2017
Lusduna™ Nexvue™	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Tentative Approval Jul. 2017



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