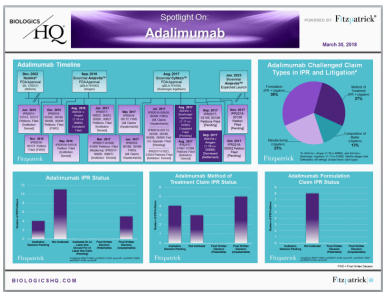
View this email online

BIOLOGICS HQ®

POWERED BY Fitzpatrick®

April 6, 2018 Forward Contact Us Visit Our Website Download PDF

LATEST NEWS



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

Updated 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™).

FEATURED VIDEO: Biosimilars, Interchangeability, and Perceptions of Safety

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 interchangeability as biosimilars enter the rheumatology market in the United States, and remark on perceptions of efficacy and safety of an interchangeable biosimilar versus a biosimilar.

View Videos by Ha Kung Wong:

- **Biosimilars and the STRONGER Patents Act**
- **Might Congress Revisit the BPCIA?**
- **The PTAB's Role in Biosimilar Patent Disputes**
- **Upcoming Patent Litigation in Biosimilars**
- **State Laws and Biosimilar Substitution**
- **Healthcare Reform Efforts and the BPCIA**
- **Biosimilar Developers' Concerns About Litigation**
- **Biosimilars, Formularies, Contracting, and PBMs**
- **Reforms at the FDA Level**
- **Inspection Reports and Proprietary Information**
- **Global Reference Products in Biosimilar Development**
- **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?**

Read More News 

UPDATES

IPRs

- **Herceptin® (trastuzumab):**
  - On March 6, 2018, a Final Written Decision was issued in IPR2016-01837, filed by Hospira, finding all claims challenged under § 102 anticipated and all claims challenged under § 103 obvious.
  - On March 12, 2018, IPR2017-02019 and IPR2017-02020, filed by Pfizer, were instituted.

- **Humira® (adalimumab):**
  - On March 9, 2018, Sandoz filed a motion for rehearing of the decision not to institute IPR2017-01824.
  - On March 12, 2018, institution was denied in IPR2017-01987 and IPR2017-01988, filed by Sandoz.

- **Avastin® (bevacizumab):** On March 9, 2018, a Final Written Decision was issued in IPR2016-01771, filed by Hospira, finding all challenged claims obvious and not anticipated.

- **Enbrel® (etanercept):** On March 9, 2018, institution was denied in IPR2017-01916 and IPR2017-02066 filed by Coherus.

- **Neupogen® (filgrastim) / Neulasta® (pegfilgrastim):** On March 16, 2018, Apotex filed a request for rehearing of the Final Written Decision issued in IPR2016-01542.

- **Rituxan® (rituximab):** On March 22, 2018, Pfizer's request for rehearing of the decision not to institute IPR2017-01167 was denied.

LITIGATIONS

- **Neupogen® (filgrastim):** On March 8, 2018, Amgen filed Case No. 2:18-cv-03347 (D.N.J.) against Adello Biologics related to Adello's proposed biosimilar TPI G-CSF.
- **Eylea® (aflibercept) / Lucentis® (ranibizumab) / Zaltrap® (ziv-aflibercept):** On March 19, 2018, Novartis and Grifols filed Case No. 7:18-cv-02434 (S.D.N.Y.) against Regeneron.
- **Herceptin® (trastuzumab):** On March 28, 2018, *Genentech v. Pfizer*, Case No. 1:17-cv-01672 (D. Del.), was dismissed for certain patents (6,417,335; 6,489,447; 6,586,206; 6,620,918; 6,716,602; 7,390,660; 7,449,184; 7,501,122; 8,044,017; 8,460,895; 8,512,983; 8,633,302; 8,691,232; 8,710,196; 8,771,988; 8,822,655; 9,428,766; 9,487,809; 9,493,744; and 9,714,293).

CDER PURPLE BOOK UPDATES

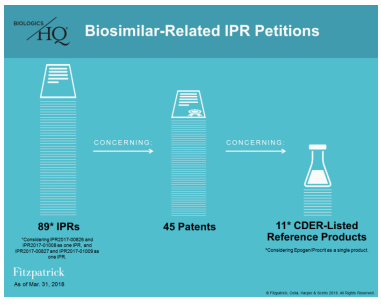
- **Trogarzo™ (ibalizumab-uiyk):** On March 6, 2018, the FDA approved TaiMed Biologics USA's Trogarzo™.

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

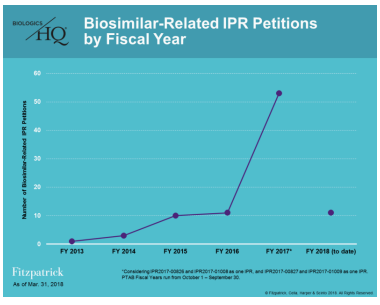
- **Semglee™ (insulin glargine):** On March 28, 2018, Mylan and Biocon announced that Semglee™, a Lantus® biosimilar, was approved in the E.U. and Australia.

STATISTICS

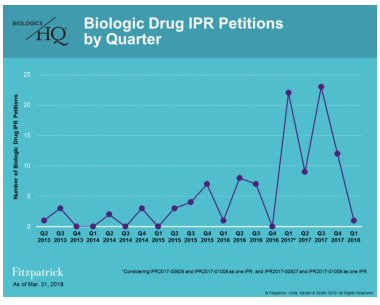
Biosimilar-Related IPR Petitions



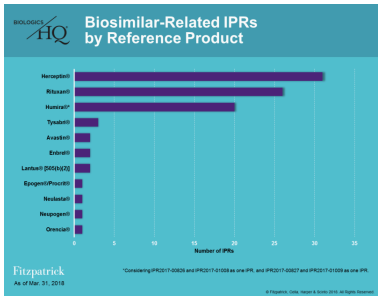
Biosimilar-Related IPR Petitions by Fiscal Year



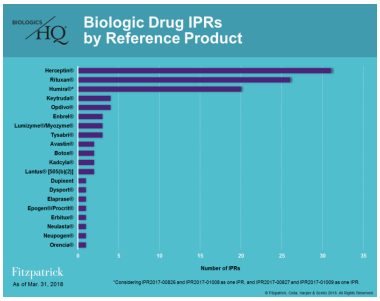
Biosimilar-Related IPR Petitions by Quarter



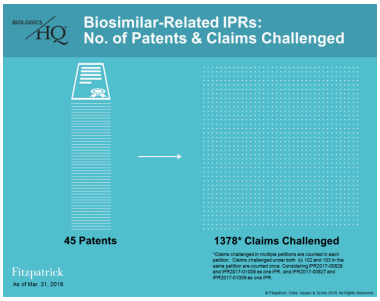
Biosimilar-Related IPRs by Reference Product



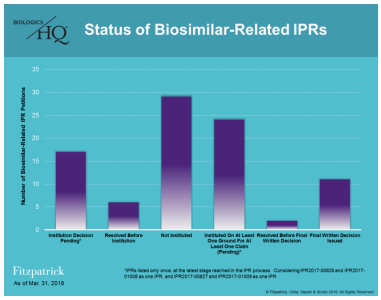
Biologic Drug IPRs by Reference Product



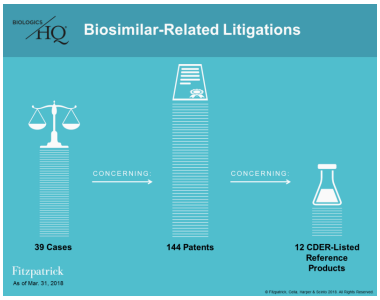
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



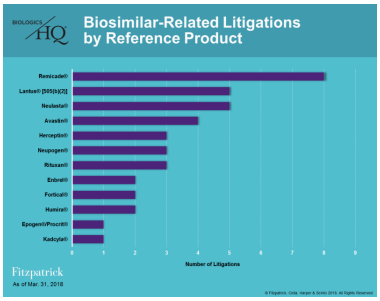
Status of Biosimilar-Related IPRs



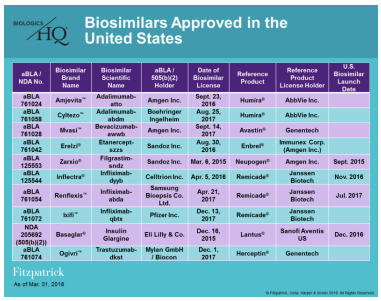
Biosimilar-Related Litigations



Biosimilar-Related Litigations by Reference Product

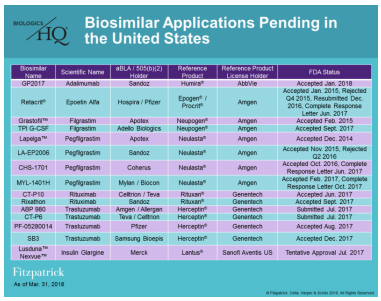


Biosimilars Approved in the U.S.

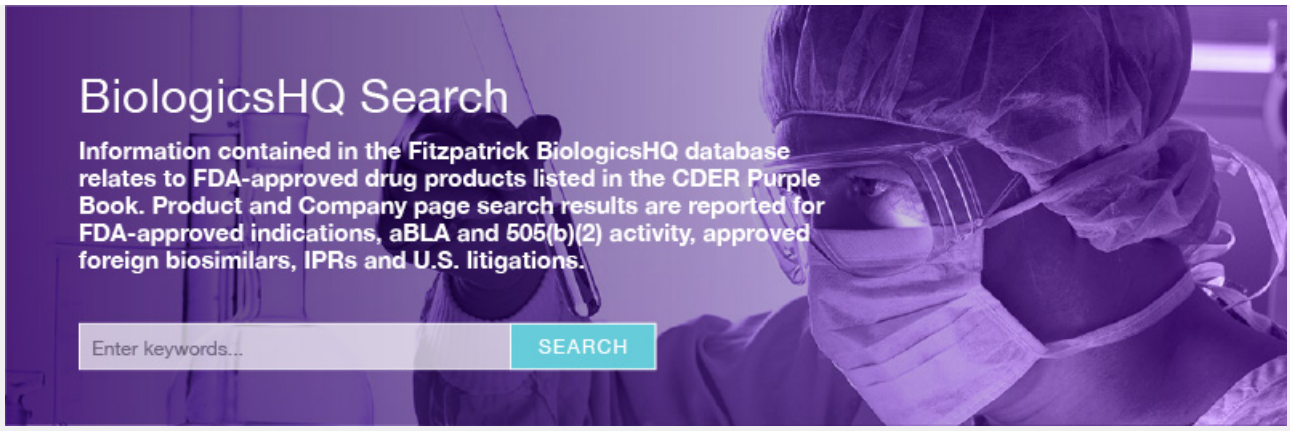


aBLA / NDA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Holder	Date of Biosimilar License	Reference Product	Reference Product License Holder	U.S. Biosimilar Launch Date
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen Inc.	Sept. 23, 2016	Humira®	AbbVie Inc.	
aBLA 761058	Cyltezo™	Adalimumab-adbm	Boehringer Ingelheim	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®	Janssen Biotech	Nov. 2016
aBLA 761054	Renflexis™	Infliximab-abda	Samsung Bioepsis Co. Ltd.	Apr. 21, 2017	Remicade®	Janssen Biotech	Jul. 2017
aBLA 761072	Ixifi™	Infliximab-qbtx	Pfizer Inc.	Dec. 13, 2017	Remicade®	Janssen Biotech	
NDA 205692 (505(b)(2)) aBLA 761074	Basaglar®	Insulin Glargine	Eli Lilly & Co.	Dec. 16, 2015	Lantus®	Sanofi Aventis US	Dec. 2016
	Ogivri™	Trastuzumab-dkst	Mylan GmbH / Biocon	Dec. 1, 2017	Herceptin®	Genentech	

Biosimilar Applications Pending in the U.S.



Biosimilar Name	Scientific Name	aBLA / 505(b)(2) Holder	Reference Product	Reference Product License Holder	FDA Status
GP2017	Adalimumab	Sandoz	Humira®	AbbVie	Accepted Jan. 2018
Retacrit®	Epoetin Alfa	Hospira / Pfizer	Epogen® / Procrit®	Amgen	Accepted Jan. 2016, Rejected Q4 2015, Resubmitted Dec. 2016, Complete Response Letter Jun. 2017
Grastofil™	Filgrastim	Apotex	Neupogen®	Amgen	Accepted Feb. 2015
TPI G-CSF	Filgrastim	Adello Biologics	Neupogen®	Amgen	Accepted Sept. 2017
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
PF-05280014	Trastuzumab	Pfizer	Herceptin®	Genentech	Accepted Aug. 2017
SB3	Trastuzumab	Samsung Bioepis	Herceptin®	Genentech	Accepted Dec. 2017
Lusduna™ Nexxue™	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Tentative Approval Jul. 2017



Contact Us

(212) 218-2100 New York
(714) 540-8700 California
(202) 530-1010 Washington DC

BiologicsHQ@fchs.com
www.fitzpatrickcella.com
www.postgranthq.com