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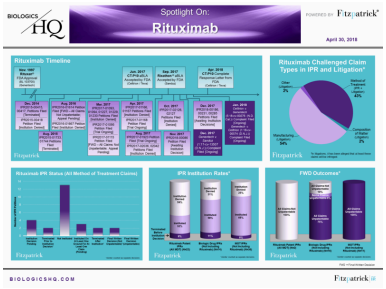
LATEST NEWS



Spotlight On: Rituxan® (rituximab)

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

BiologicsHQ's "Spotlight On" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. A new dashboard concerning rituximab (Rituxan®) is now available.

The dashboard concerning adalimumab (Humira®, Amjevita™, and Cyltezo™) has been updated with activity through April 30, 2018.

Supreme Court Upholds Constitutionality of *Inter Partes* Review in *Oil States*

By: Christopher Loh and Jordan Klimek

On April 24, 2018, the Supreme Court in *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC,* No. 16-712, held 7-2 that the *inter partes* review procedure created by the

America Invents Act of 2011 (AIA) does not violate Article III or the Seventh Amendment of the U.S. Constitution, because patents are public rights, and public rights need not be adjudicated before an Article III court or in a jury trial. Justice Gorsuch wrote a dissenting opinion that was joined by Chief Justice Roberts.

IPR Patentability of All Challenged Claims - *SAS Institute v. Iancu*

By: Douglas Sharrott and Shannon Clark

On April 24, 2018, in a 5-4 decision the Supreme Court held in *SAS Institute Inc. v. Iancu* that when the U.S. Patent and Trademark Office ("USPTO") institutes an *inter partes* review, it must decide the patentability of *all* of the claims the petitioner challenged, based on the plain text of 35 U.S.C. § 318(a).

Read More News

UPDATES

IPRs

- **Humira® (adalimumab):**
  - On April 3, 2018, institution was granted in IPR2017-02105 and IPR2017-02106 filed by Sandoz.
  - On April 6, 2018, Sandoz filed motions for rehearing of the decisions not to institute IPR2017-01987 and IPR2017-01988.

- **Rituxan® (rituximab):**
  - On April 4, 2018, institution was denied in IPR2017-02036 and IPR2017-02042 filed by Sandoz.
  - On April 4, 2018, institution was granted in IPR2017-01923 filed by Pfizer.
  - On April 19, 2018, institution was denied in IPR2017-02127 filed by Pfizer.
  - On April 26, 2018, Pfizer filed an appeal of the final written decision in IPR2016-01614 and IPR2017-01115, Federal Circuit Case No. 18-1885.
  - On April 30, 2018, institution was denied in IPR2017-02126 filed by Pfizer.
  - On April 30, 2018, the institution decision in IPR2017-01095, filed by Celltrion and Teva, was revised to institute all challenged claims under all challenged grounds.

- **Enbrel® (etanercept):** On April 9, 2018, Coherus filed Requests for Rehearing of the decisions denying institution of IPR2017-01916 and IPR2017-02066.

LITIGATIONS

- **Neulasta® (pegfilgrastim):** On April 18, 2018, *Amgen v. Coherus*, Case No. 1:17-cv-00546 (D. Del.) was dismissed.

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aBLA APPLICATIONS AND APPROVALS

- **CT-P10 (rituximab):** On April 5, 2018, Celltrion announced that it had received a Complete Response Letter from the FDA related to its application for CT-P10, a proposed biosimilar of Genentech's Rituxan® (rituximab).

- **Herzuma® (trastuzumab):** On April 5, 2018, Celltrion announced that it had received a Complete Response Letter from the FDA related to its application for Herzuma®, a proposed biosimilar of Genentech's Herceptin® (trastuzumab).

- **PF-05280014 (trastuzumab):** On April 23, 2018, Pfizer announced that it had received a Complete Response Letter from the FDA related to its application for PF-05280014, a proposed biosimilar of Genentech's Herceptin® (trastuzumab).

CDER PURPLE BOOK UPDATES

- **Crysvita® (burosumab-twza):** On April 17, 2018, the FDA approved Ultragenyx Pharmaceutical's Crysvita®.

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

- **Imraldi (adalimumab):** On April 5, 2018, Samsung Bioepis and Biogen announced that they entered into a settlement agreement with AbbVie relating to Imraldi, a biosimilar of Humira® (adalimumab), delaying European launch until October 16, 2018 and U.S. launch until at least January 31, 2023. Imraldi was approved in the E.U. in August 2017. Samsung and Biogen have not yet announced FDA acceptance of an application for an adalimumab biosimilar in the U.S.

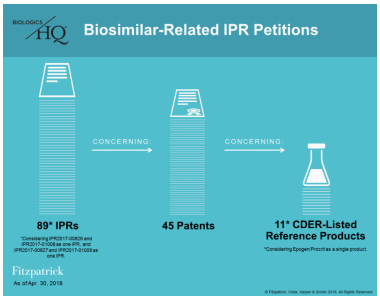
- **Truxima® (CT-P10) (rituximab):** On April 23, 2018, Celltrion announced that Truxima®, its biosimilar of Rituxan®, was approved in Australia.

STATISTICS

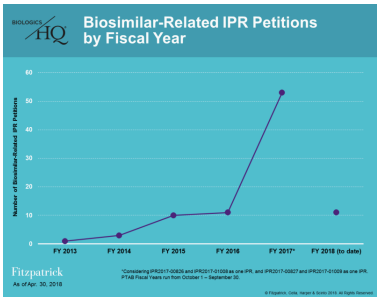
Biosimilar-Related IPR Petitions

Biosimilar-Related IPR Petitions by Fiscal Year

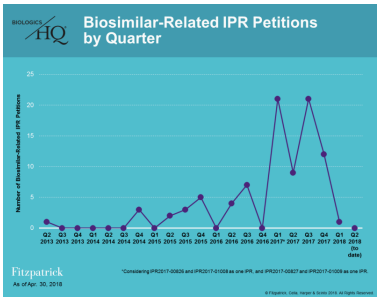
Biosimilar-Related IPR Petitions by Quarter



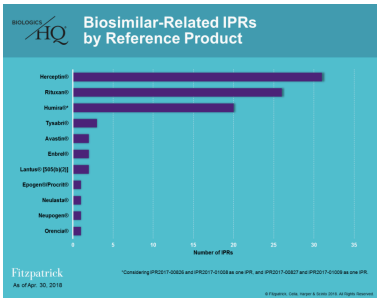
Biosimilar-Related IPRs by Reference Product



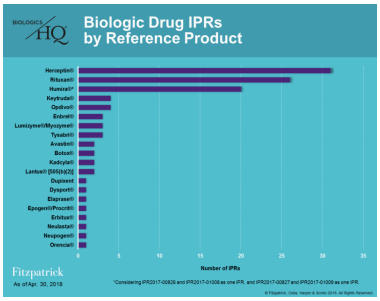
Biologic Drug IPRs by Reference Product



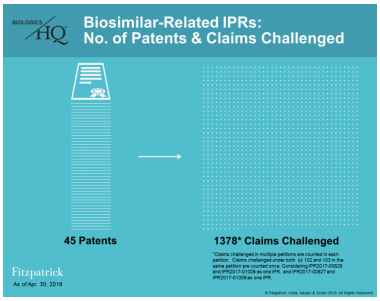
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



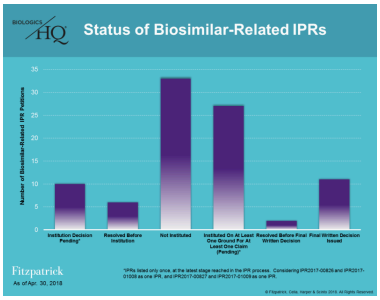
Status of Biosimilar-Related IPRs



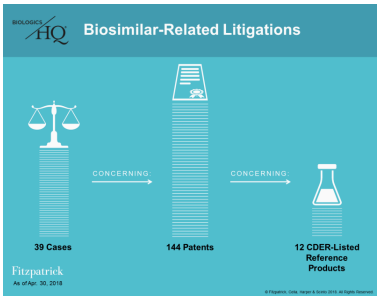
Biosimilar-Related Litigations



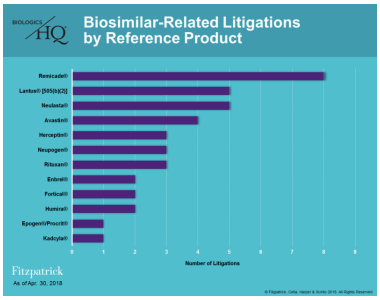
Biosimilar-Related Litigations by Reference Product

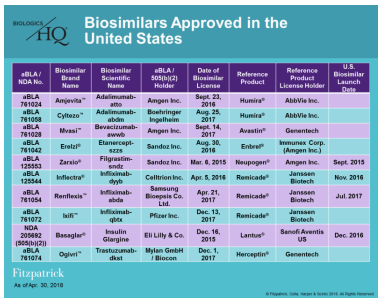


Biosimilars Approved in the U.S.

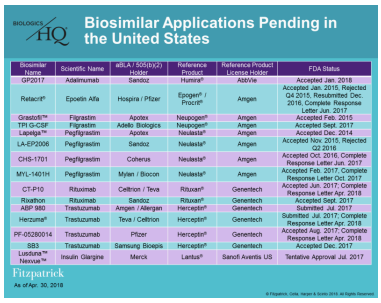


Biosimilar Applications Pending in the U.S.

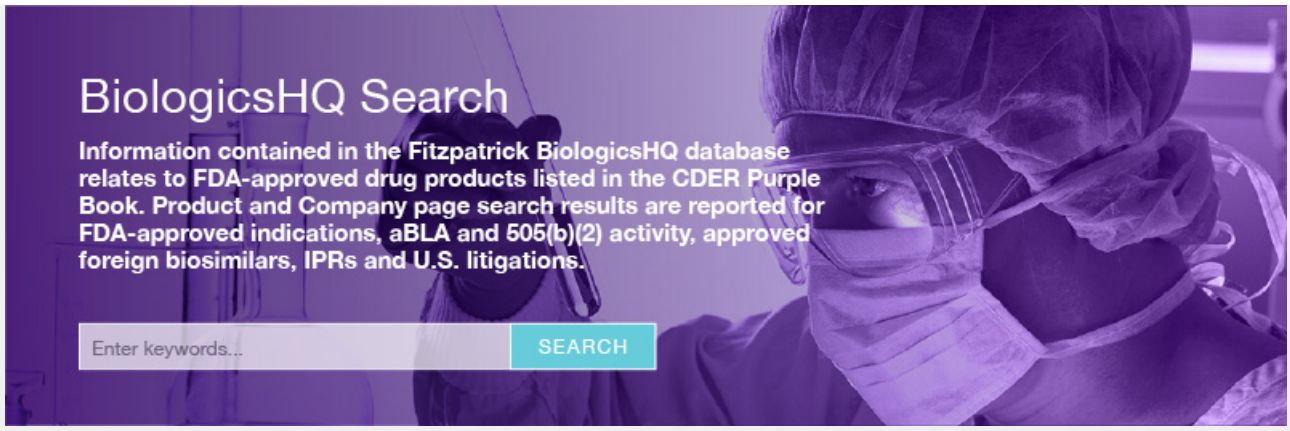




aBLA / NDA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Holder	Date of Biosimilar License	Reference Product	Reference Product License Holder	U.S. Biosimilar Launch Date
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen Inc.	Sept. 23, 2016	Humira®	AbbVie Inc.	
aBLA 761058	Cyltezo™	Adalimumab-adbm	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))	Basaglar®	Insulin Glargine	Eli Lilly & Co.	Dec. 16, 2015	Lantus®	Sanofi Aventis US	Dec. 2016
aBLA 761074	Ogivri™	Trastuzumab-dkst	Mylan GmbH / Biocon	Dec. 1, 2017	Herceptin®	Genentech	



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. 2015; 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; Complete Response Letter Apr. 2018
Rixathon	Rituximab	Sandoz	Rituxan®	Genentech	Accepted Sept. 2017
ABP 980	Trastuzumab	Amgen / Allergan	Herceptin®	Genentech	Submitted Jul. 2017
Herzuma®	Trastuzumab	Teva / Celltrion	Herceptin®	Genentech	Submitted Jul. 2017; Complete Response Letter Apr. 2018
PF-05280014	Trastuzumab	Pfizer	Herceptin®	Genentech	Accepted Aug. 2017; Complete Response Letter Apr. 2018
SB3	Trastuzumab	Samsung Bioepis	Herceptin®	Genentech	Accepted Dec. 2017
Lusduna™ Nexvue™	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Tentative Approval Jul. 2017



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