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LATEST NEWS

VIDEO: Biosimilar Manufacturer's Approach to the Patent Dance

By: Ha Kung Wong

Ha Kung Wong discusses how biosimilar manufacturers now approach the “patent dance” in light of *Sandoz v. Amgen* as part of a video series for the Center for Biosimilars.

VIDEO: The BPCIA One Year After *Sandoz v. Amgen*

By: Ha Kung Wong

Ha Kung Wong discusses lessons learned about the Biologics Price Competition and Innovation Act in the year following *Sandoz v. Amgen* as part of a video series for the Center for Biosimilars.

View Additional New Videos from Ha Kung Wong:

- **The Importation of Biologics and Biosimilars**
- **FDA and FTC Cooperation to Address Anticompetitive Behavior**

CRISPR-Cas9: Federal Circuit Says No Interference-in-Fact Between University of California and Broad Institute

By: Christopher E. Loh

On September 10, 2018, Judges Prost, Schall and Moore of the Federal Circuit, in *University of California v. Broad Institute, Inc.*, No. 2017-1907, affirmed the Patent Trial and Appeal Board's determination that there was no interference-in-fact between the University of California's patent application No. 13/842,859 and twelve patents and one patent application owned by the Broad Institute, MIT, and Harvard (collectively "Broad"), concerning CRISPR-Cas9 technology. In so doing, the Federal Circuit upheld the PTAB's underlying finding that, "given the differences between eukaryotic and prokaryotic systems, a person of ordinary skill in the art would not have had a reasonable expectation of success in applying the CRISPR-Cas9 system in eukaryotes."

Read More News

UPDATES

IPRs

- **Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant):** On September 10, 2018, Mylan and Biocon filed IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, and IPR2018-01696.

- **Erbitux® (cetuximab):** On September 17, 2018, in Case No. 17-2397, the Federal Circuit affirmed the PTAB's final written decision finding all instituted claims unpatentable in IPR2016-00458 filed by Eli Lilly.

- **Ajovy™ (fremanezumab-vfrm) / Emgality™ (galcanezumab-gnlm):**
  - On September 28, 2018, Eli Lilly filed IPR2018-01710.
  - Prior to the September 2018 FDA approvals of Ajovy™ and Emgality™, Eli Lilly filed IPR2018-01422, IPR2018-01423, IPR2018-01424, IPR2018-01425, IPR2018-01426, and IPR2018-01427.

LITIGATIONS

- **Herceptin® (trastuzumab):** On September 4, 2018, Genentech filed Case No.

1:18-cv-01363 (D. Del.) against Samsung Bioepis related to Samsung's proposed biosimilar SB3 (trastuzumab).

- **Avonex® / Betaseron® / Extavia® / Rebif® (interferon beta-1a / interferon beta-1b):** On September 7, 2018, Biogen's judgment as a matter of law (JMOL) motions were granted in *Bayer v. Biogen*, Case No. 2:10-cv-02734 (D.N.J.), and a new trial will be granted.

- **Epogen® / Procrit® (epoetin alfa):** On September 11, 2018, final judgment was entered in *Amgen v. Hospira*, Case No. 1:15-cv-00839 (D. Del.).

- **Ajovy™ (fremanezumab-vfrm) / Emgality™ (galcanezumab-gnlm):**
  - On September 27, 2018, *Teva v. Eli Lilly* Case Nos. 1:17-cv-12087 (D. Mass.) and 1:18-cv-10242 (D. Mass.) were dismissed.
  - On September 27, 2018 Teva filed Case No. 1:18-cv-12029 (D. Mass.) against Eli Lilly.

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aBLA APPLICATIONS AND FDA ACTIVITY

- **SB5 (adalimumab):** On September 27, 2018, Samsung Bioepis announced that the FDA had accepted its application for SB5, a proposed biosimilar of AbbVie's Humira® (adalimumab).

CDER PURPLE BOOK UPDATES

- **Lumoxiti™ (moxetumomab pasudotox-tdfk):** On September 13, 2018, the FDA approved AstraZeneca's Lumoxiti™.

- **Ajovy™ (fremanezumab-vfrm):** On September 14, 2018, the FDA approved Teva's Ajovy™.

- **Emgality™ (galcanezumab-gnlm):** On September 27, 2018, the FDA approved Eli Lilly's Emgality™.

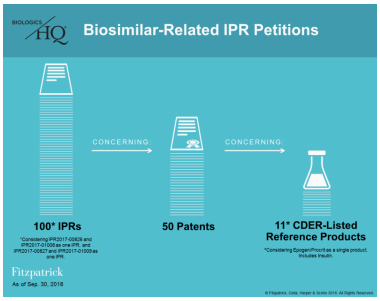
- **Libtayo® (cemiplimab-rwlc):** On September 28, 2018, the FDA approved Regeneron Pharmaceuticals' Libtayo®.

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

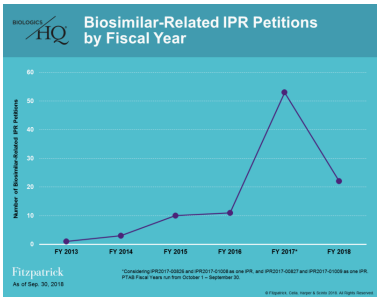
- **Hulio® (adalimumab):** On September 20, 2018, Mylan and Fujifilm Kyowa Kirin Biologics announced that Hulio®, their biosimilar of Humira®, was approved in the E.U.

STATISTICS

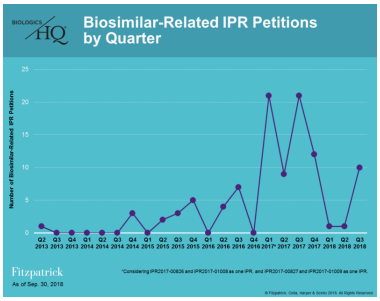
Biosimilar-Related IPR Petitions



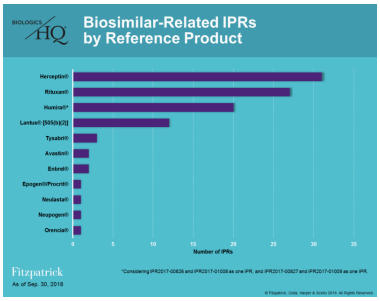
Biosimilar-Related IPR Petitions by Fiscal Year



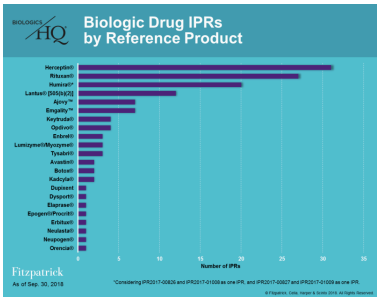
Biosimilar-Related IPR Petitions by Quarter



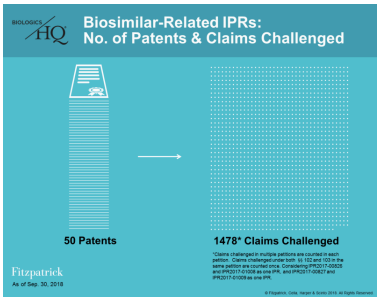
Biosimilar-Related IPRs by Reference Product



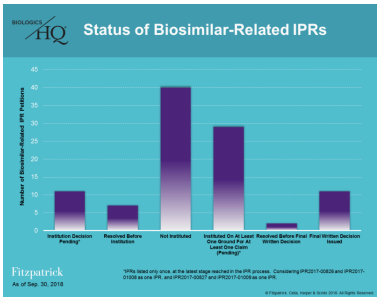
Biologic Drug IPRs by Reference Product



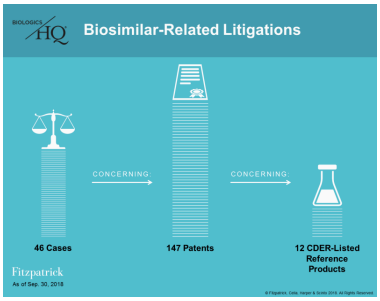
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



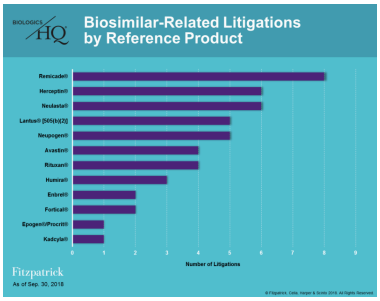
Status of Biosimilar-Related IPRs



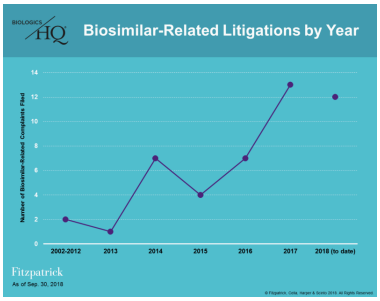
Biosimilar-Related Litigations



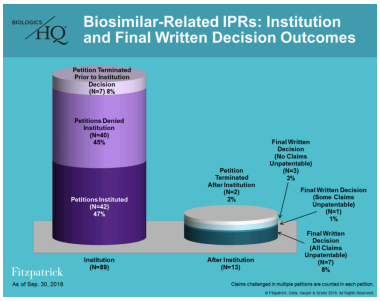
Biosimilar-Related Litigations by Reference Product



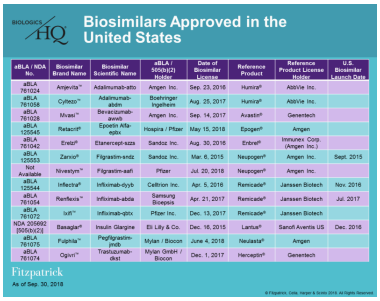
Biosimilar-Related Litigations by Year



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilars Approved in the U.S.

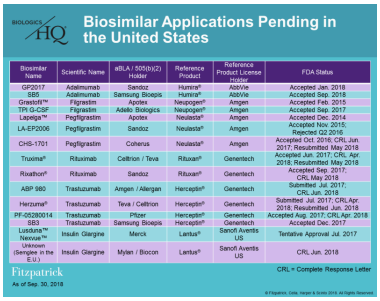


aBLA / NDA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Holder	Date of Biosimilar License	Reference Product	Reference Product License Holder	U.S. Biosimilar Launch Date
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen Inc.	Sep. 23, 2016	Humira®	AbbVie Inc.	
aBLA 761058	Cyltezo™	Adalimumab-adbm	Boehringer Ingelheim	Aug. 25, 2017	Humira®	AbbVie Inc.	
aBLA 761028	Mvasi™	Bevacizumab-awwb	Amgen Inc.	Sep. 14, 2017	Avastin®	Genentech	
aBLA 125545	Retacrit®	Epoetin Alfa-epbx	Hospira / Pfizer	May 15, 2018	Epogen®	Amgen	
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
Not Available	Nivestym™	Filgrastim-aafi	Pfizer	Jul. 20, 2018	Neupogen®	Amgen Inc.	
aBLA 125544	Inflectra®	Infliximab-dyyb	Celltrion Inc.	Apr. 5, 2016	Remicade®	Janssen Biotech	Nov. 2016
aBLA 761054	Renflexis™	Infliximab-abda	Samsung Bioepis	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 761075	Fulphila™	Pegfilgrastim-jmdb	Mylan / Biocon	June 4, 2018	Neulasta®	Amgen	
aBLA 761074	Ogivri™	Trastuzumab-dkst	Mylan GmbH / Biocon	Dec. 1, 2017	Herceptin®	Genentech	

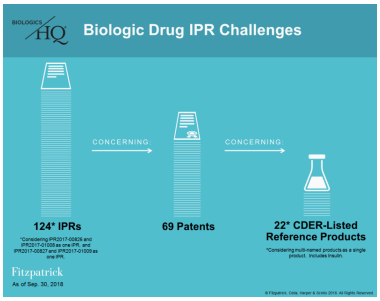
Biosimilar Applications Pending in the U.S.

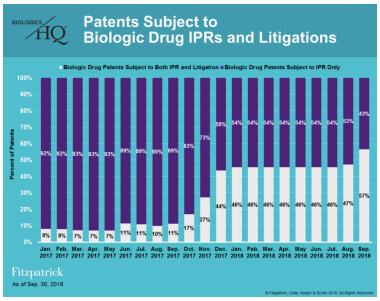
Biologic Drug IPR Challenges

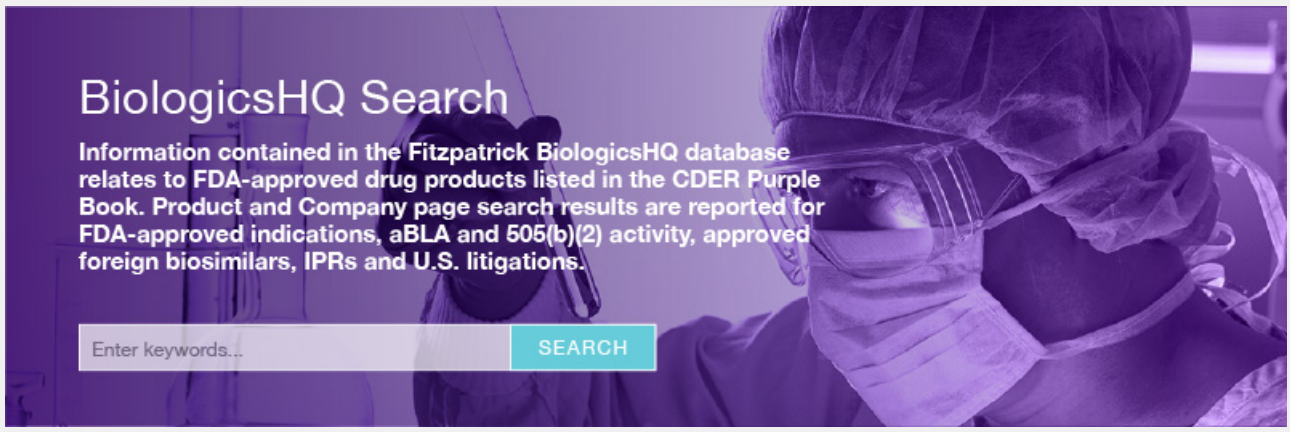
Patents Subject to Biologic Drug IPRs and Litigations



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
SB5	Adalimumab	Samsung Bioepis	Humira®	AbbVie	Accepted Sep. 2018
Grastofil™	Filgrastim	Apotex	Neupogen®	Amgen	Accepted Feb. 2015
TPI G-CSF	Filgrastim	Adello Biologics	Neupogen®	Amgen	Accepted Sep. 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; CRL Jun. 2017; Resubmitted May 2018
Truxima®	Rituximab	Celltrion / Teva	Rituxan®	Genentech	Accepted Jun. 2017; CRL Apr. 2018; Resubmitted May 2018
Rixathon®	Rituximab	Sandoz	Rituxan®	Genentech	Accepted Sep. 2017; CRL May 2018
ABP 980	Trastuzumab	Amgen / Allergan	Herceptin®	Genentech	Submitted Jul. 2017; CRL Jun. 2018
Herzuma®	Trastuzumab	Teva / Celltrion	Herceptin®	Genentech	Submitted Jul. 2017; CRL Apr. 2018; Resubmitted Jun. 2018
PF-05280014	Trastuzumab	Pfizer	Herceptin®	Genentech	Accepted Aug. 2017; CRL Apr. 2018
SB3	Trastuzumab	Samsung Bioepis	Herceptin®	Genentech	Accepted Dec. 2017
Lusduna™ Nexvue™	Insulin Glargine	Merck	Lantus®	Sanofi Aventis US	Tentative Approval Jul. 2017
Unknown (Semglee in the E.U.)	Insulin Glargine	Mylan / Biocon	Lantus®	Sanofi Aventis US	CRL Jun. 2018







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