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December 11, 2018

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MONTHLY INJECTION



LATEST NEWS



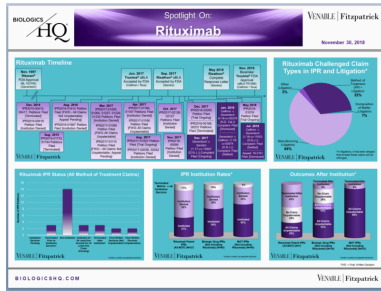
VIDEO: Noteworthy Ongoing Biosimilar Litigation

By: Ha Kung Wong

Ha Kung Wong addresses ongoing biosimilar cases that stakeholders are watching closely as part of a video series for the Center for Biosimilars.

View Additional New Videos from Ha Kung Wong:

- [Changes to IPRs and PGRs for Biologics](#)
 - [The BPCIA One Year After *Sandoz v. Amgen*](#)
 - [Biosimilar Manufacturer's Approach to the Patent Dance](#)
 - [The Importation of Biologics and Biosimilars](#)
 - [FDA and FTC Cooperation to Address Anticompetitive Behavior](#)
 - [The FDA's Biosimilar Action Plan](#)
-



Spotlight On: Rituxan[®] (rituximab) / Truxima[®] (rituximab-abbs)

Spotlight On: Humira[®] (adalimumab) / Amjevita[™] (adalimumab-atto) / Cyltezo[™] (adalimumab-adbm) / Hyrimoz[™] (adalimumab-adaz)

Spotlight On: Enbrel[®] (etanercept) / Erelzi (etanercept-szsz)

BiologicsHQ's "Spotlight On" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning rituximab (Rituxan[®] and Truxima[®]), adalimumab (Humira[®], Amjevita[™], Cyltezo[™], and Hyrimoz[™]), and etanercept (Enbrel[®] and Erelzi[™]) have been updated with activity through November 30, 2018.

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UPDATES

IPRs and PGRs

- **Humira[®] (adalimumab):** On November 2, 2018, IPR2017-01987, IPR2017-01988, IPR2017-02105, and IPR2017-02106 filed by [Sandoz](#) were terminated due to settlement.
- **Rituxan[®] (rituximab):**
 - On November 6, 2018, Federal Circuit Appeal No. 18-1924 filed by [Celltrion](#) appealing the Final Written Decision in IPR2016-01614 was dismissed.
 - On November 8, 2018, IPR2018-00186 was dismissed after institution at the joint request of [Biogen](#) and [Pfizer](#).
- **Herceptin[®] (trastuzumab):**
 - On November 8, 2018, [Hospira](#) and [Samsung Bioepis](#) filed Federal Circuit Case No. 19-1174 appealing the Final Written Decisions finding no instituted claims unpatentable in IPR2017-00804 and joined IPR2017-01958.
 - On November 8, 2018, [Hospira](#) and [Samsung Bioepis](#) filed Federal Circuit Case No. 19-1173 appealing the Final Written Decisions finding no instituted claims unpatentable in IPR2017-00805 and joined IPR2017-01959.
 - On November 29, 2018, Final Written Decisions finding some instituted claims unpatentable were entered in IPR2017-01488 filed by [Pfizer](#) and joined IPR2017-02139 filed by [Samsung Bioepis](#).
 - On November 29, 2018, a Final Written Decision finding some instituted

claims unpatentable was entered in IPR2017-01374 filed by [Celltrion](#) and [Teva](#).

- On November 30, 2018, [Genentech](#) filed Notices of Appeal in IPR2017-00731, IPR2017-00737, IPR2017-01121, and IPR2017-01122.
 - **Lantus[®] / Lantus[®] SoloSTAR[®] (insulin glargine recombinant):** On November 8, 2018, [Mylan](#) and [Biocon](#) requested dismissal of IPR2018-01677.
-

LITIGATIONS

- **Rituxan[®] (rituximab):**
 - On November 1, 2018, dismissal due to settlement was requested in [Genentech v. Celltrion](#) Case Nos. 1:18-cv-11553 (D.N.J.) and 1:18-cv-00574 (D.N.J.).
 - On November 30, 2018, Federal Circuit Case No. 18-2161 appealing [Celltrion v. Genentech](#) Case No. 4:18-cv-00276 (N.D. Cal.) was voluntarily dismissed.
 - **Herceptin[®] (trastuzumab):** On November 30, 2018, Federal Circuit Case No. 18-2160 appealing [Celltrion v. Genentech](#) Case No. 4:18-cv-00274 (N.D. Cal.) was voluntarily dismissed.
-

aBLA APPLICATIONS AND FDA ACTIVITY

- **Udenyca[™] (pegfilgrastim-cbqv):** On November 2, 2018, the FDA approved [Coherus's Udenyca[™]](#), a biosimilar of [Amgen's Neulasta[®] \(pegfilgrastim\)](#).
 - **Retacrit[®] (epoetin alfa-epbx):** On November 14, 2018, [Pfizer](#) announced it launched [Retacrit[®]](#), its biosimilar of [Amgen's Epogen[®] \(epoetin alfa\)](#) on November 12, 2018.
 - **Truxima[®] (rituximab):** On November 28, 2018, the FDA approved [Celltrion](#) and [Teva's Truxima[®]](#), a biosimilar of [Genentech's Rituxan[®] \(rituximab\)](#).
-

CDER PURPLE BOOK UPDATES

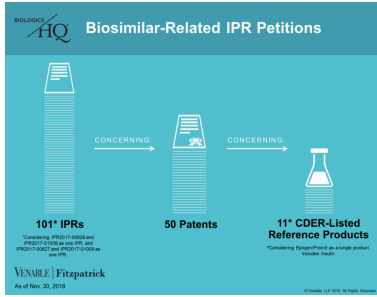
- **Gamifant[®] (emapalumab-lzsg):** On November 20, 2018, the FDA approved [Novimmune's Gamifant[®]](#).
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NON-U.S. BIOSIMILARS / FOLLOW-ON BIOLOGICS

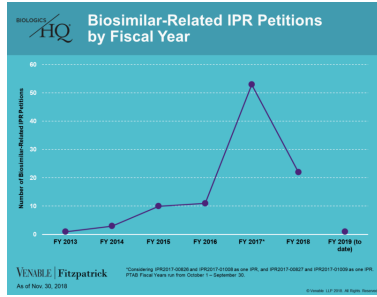
- **Pelmeg (pegfilgrastim):** On November 23, 2018, [Cinfa Biotech](#) and [Mundipharma](#) announced that [Pelmeg](#), their biosimilar of [Neulasta[®] \(pegfilgrastim\)](#) was approved in the E.U.
- **Ziextenzo[®] (pegfilgrastim):** On November 27, 2018, [Sandoz](#) announced that [Ziextenzo[®]](#), its biosimilar of [Neulasta[®] \(pegfilgrastim\)](#) was approved in the E.U.

STATISTICS

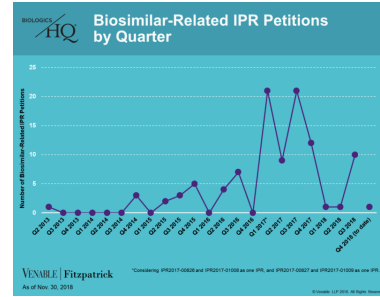
Biosimilar-Related IPR Petitions



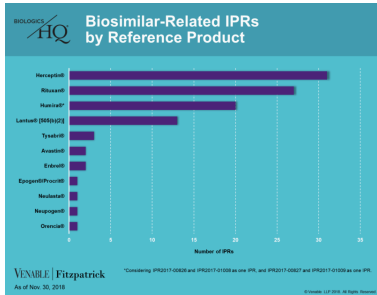
Biosimilar-Related IPR Petitions by Fiscal Year



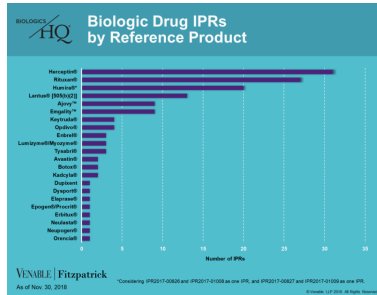
Biosimilar-Related IPR Petitions by Quarter



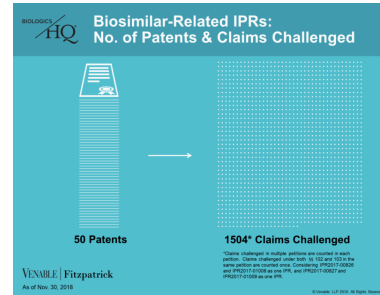
Biosimilar-Related IPRs by Reference Product



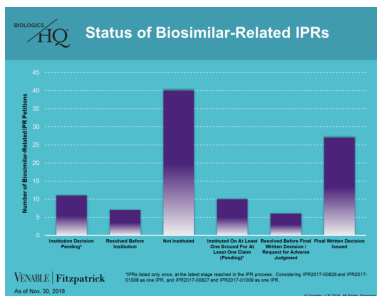
Biologic Drug IPRs by Reference Product



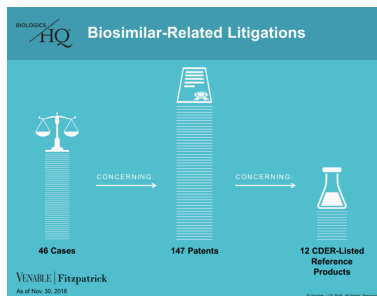
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



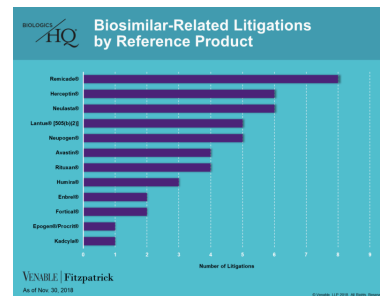
Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations



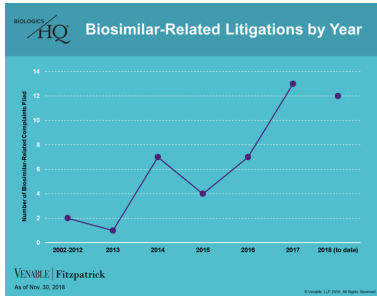
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year

Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

Biosimilars Approved in the U.S.



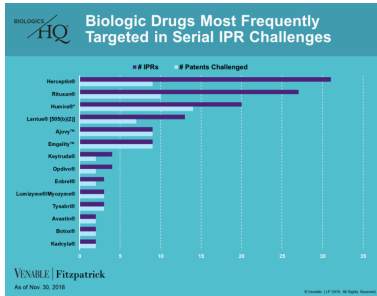
Biosimilar Applications Pending in the U.S.

Biosimilar Applications Pending in the United States

Biosimilar Name	Scientific Name	aBLA / 505(b)(2) Number	Reference Product	Reference Product Licensee	Referred Product Licensee	FDA Status
ABB	Adalimumab	Sermung Biologics	Humira®	AbbVie	AbbVie	Accepted Sep. 2018
CoatJel®	Fibrinogen	Adcino	Neugogen	Angen	Angen	Accepted Feb. 2015
TPX (t-CSP)	Fibrinogen	Adcino Biologics	Neugogen	Angen	Angen	Accepted Sep. 2017
TK-01	Fibrinogen	Adcino	Neugogen	Angen	Angen	BLA Submitted Oct. 2018
Lasigle®	Pioglitazone	Aplicor	Neustat®	Angen	Angen	Accepted Dec. 2014
LA-EP2006	Pioglitazone	Sandoz	Neustat®	Angen	Angen	Accepted Nov. 2015
Ranoh®	Rituximab	Sandoz	Rituxan®	Genentech	Genentech	Accepted Sep. 2017
ASP-800	Trastuzumab	Amgen / Alkermes	Herceptin®	Genentech	Genentech	Submitted Jul. 2017
Herzuma®	Trastuzumab	Teva / Celltech	Herceptin®	Genentech	Genentech	Submitted Jul. 2017; CRL Apr. 2018; Resubmitted Jan. 2018
PF-0280014	Trastuzumab	Pfizer	Herceptin®	Genentech	Genentech	Accepted Aug. 2017; CRL Apr. 2018
SB3	Trastuzumab	Sermung Biologics	Herceptin®	Genentech	Genentech	Accepted Dec. 2017
Lisiana™	Insulin Glargine	Merck	Lantus®	Sandoz	Sandoz	Tentative Approval Jul. 2017
Lisiana™	Insulin Glargine	Mylan / Boehringer	Lantus®	Sandoz	Sandoz	CRL Jun. 2018

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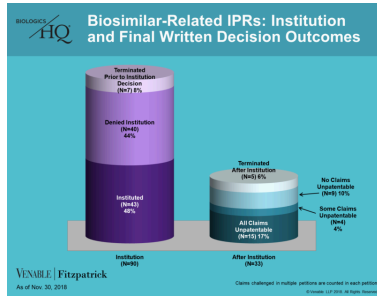
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



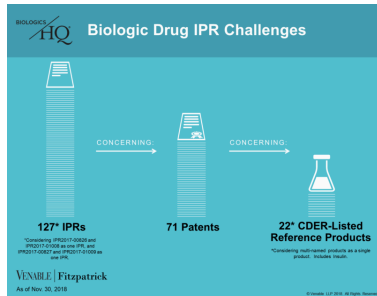
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Robert S. Schwartz

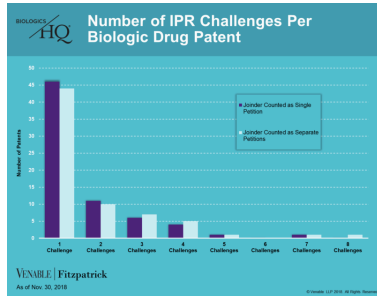
BiologicsHQ@venable.com



Biologic Drug IPR Challenges



Number of IPR Challenges Per Biologic Drug Patent



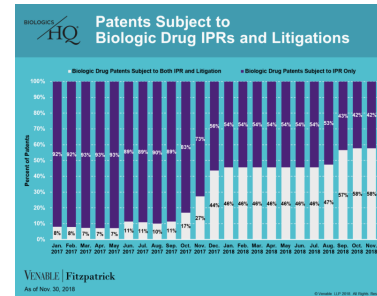
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Biosimilars Approved in the United States

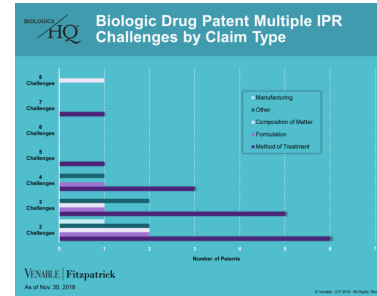
aBLA / 505(b)(2) No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA / 505(b)(2) Holder	Date of U.S. Approval	Reference Product	Reference Product Licensee	U.S. Reference Product
BLA 781024	Amgen®	Adalimumab-act	Amgen Inc.	Aug. 23, 2016	Humira®	AbbVie Inc.	Humira®
BLA 781038	Cytex®	Abatacept-actem	Boehringer Ingelheim	Aug. 25, 2016	Humira®	AbbVie Inc.	Humira®
BLA 781071	Hytrin®	Adalimumab-act	Sandoz Inc.	Oct. 30, 2016	Humira®	Genentech	Humira®
BLA 781028	Mylan®	Adalimumab-act	Amgen Inc.	Sep. 14, 2017	Humira®	Genentech	Humira®
BLA 125461	Recept®	Enbrel-act	Novartis Inc.	Nov. 15, 2016	Enbrel®	Amgen	Enbrel®
BLA 781042	Emd®	Enbrel-act	Sandoz Inc.	Aug. 30, 2016	Enbrel®	Amgen Corp. / Amgen Inc.	Enbrel®
BLA 125463	Zenati®	Enbrel-act	Sandoz Inc.	Mar. 8, 2018	Enbrel®	Amgen Inc.	Enbrel®
BLA 781050	Novartis®	Enbrel-act	Novartis Inc.	Jul. 20, 2016	Enbrel®	Amgen Inc.	Enbrel®
BLA 125464	Incept®	Enbrel-act	Cellco Inc.	Apr. 5, 2016	Enbrel®	Amgen Inc.	Enbrel®
BLA 781054	Ranexa®	Infliximab-act	Sermung Biologics	Apr. 21, 2017	Remicade®	Janssen Biotech	Remicade®
BLA 781075	Act®	Infliximab-act	Pfizer Inc.	Dec. 13, 2017	Remicade®	Janssen Biotech	Remicade®
BLA 125465	Novartis®	Infliximab-act	Cellco Inc.	Nov. 28, 2016	Remicade®	Amgen Inc.	Remicade®
BLA 781076	Fialta®	Infliximab-act	Novartis Inc.	Dec. 16, 2015	Remicade®	Sandoz Inc. / Sandoz	Remicade®
BLA 781075	Fialta®	Infliximab-act	Novartis Inc.	Jan. 4, 2018	Remicade®	Amgen	Remicade®
BLA 781039	Udenca®	Paclitaxel-act	Celgene	Nov. 2, 2016	Neulasta®	Amgen	Neulasta®
BLA 781080	Trovan®	Trovan-act	Cellco Inc.	Nov. 28, 2016	Humira®	Genentech	Humira®
BLA 781074	Ogios®	Trastuzumab-act	Mylan / Oberlin / Sandoz	Dec. 1, 2017	Herceptin®	Genentech	Herceptin®

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As of Nov. 30, 2018

Patents Subject to Biologic Drug IPRs and Litigations



Biologic Drug Patent Multiple IPR Challenges by Claim Type



BiologicsHQ Search

Information contained in the Venable 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.

Enter Keywords

SEARCH

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