



April 7, 2021



LATEST NEWS



Supreme Court Hears Argument on the Constitutionality of Administrative Patent Judge Appointments in *United States v. Arthrex*

By: [Christopher E. Loh](#)

On March 1, 2021, the Supreme Court heard oral argument in *United States v. Arthrex*, No. 19-1434, a case that will address whether administrative patent judges (APJs), who preside over *inter partes* reviews (IPRs) at the United States Patent and Trademark Office (USPTO), are unconstitutionally appointed principal officers, and, if so, whether that constitutional violation can be cured by severing “for cause” employment protections for APJs.

If the Supreme Court in *Arthrex* concludes that APJs are unconstitutionally appointed principal officers, then the remedy the Supreme Court adopts or recommends could reshape current practice and procedure for IPRs and other USPTO proceedings.



Spotlight On: Neulasta[®] (pegfilgrastim) / Fulphila[®] (pegfilgrastim-jmdb) / Udenyca[®] (pegfilgrastim-cbqv) / Ziextenzo[®] (pegfilgrastim-bmez) / Nyvepria[™] (pegfilgrastim-apgf)

Spotlight On: Herceptin[®] (trastuzumab) / Ogivri[™] (trastuzumab-dkst) / Herzuma[®] (trastuzumab-pkrb) /

Ontruzant[®] (trastuzumab-dttb) / Trazimera[™] (trastuzumab-qyyp) / Kanjinti[®] (trastuzumab-anns)

Spotlight On: Biosimilar Litigations

[Spotlight On: Rituxan[®] \(rituximab\) / Truxima[®] \(rituximab-abbs\) / Ruxience[®] \(rituximab-pvvr\)](#)

[Spotlight On: Humira[®] \(adalimumab\) / Amjevita[™] \(adalimumab-atto\) / Cyltezo[®] \(adalimumab-adbm\) / Hyrimoz[™] \(adalimumab-adaz\) / Hadlima[™] \(adalimumab-bwwd\) / Abrilada[™] \(adalimumab-afzb\) / Hulio[®] \(adalimumab-fkjp\)](#)

[Spotlight On: Enbrel[®] \(etanercept\) / Erelzi[®] \(etanercept-szsz\) / Eticovo[®] \(etanercept-ykro\)](#)

[Spotlight On: Lantus[®] / Lantus[®] SoloSTAR[®] \(insulin glargine recombinant\) / Basaglar[®] \(insulin glargine\) / Semglee[™] \(insulin glargine\)](#)

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning pegfilgrastim ([Neulasta[®]](#), [Lapelga[™]](#), [Ziextenzo[®]](#), [Udenyca[®]](#), [Fulphila[®]](#), [Nyvepria[™]](#), and [MSB11455](#)), trastuzumab ([Herceptin[®]](#), [Ogivri[™]](#), [Herzuma[®]](#), [Ontruzant[®]](#), [Trazimera[™]](#), and [Kanjinti[®]](#)), rituximab ([Rituxan[®]](#), [Truxima[®]](#), and [Ruxience[®]](#)), adalimumab ([Humira[®]](#), [Amjevita[™]](#), [Cyltezo[®]](#), [Hyrimoz[™]](#), [Hadlima[™]](#), [Abrilada[™]](#), and [Hulio[®]](#)), etanercept ([Enbrel[®]](#), [Erelzi[®]](#), and [Eticovo[®]](#)), and insulin glargine ([Lantus[®]](#) / [Lantus[®] SoloSTAR[®]](#), [Basaglar[®]](#), and [Semglee[™]](#)) have been updated with activity through March 31, 2021.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through March 31, 2021.

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News

UPDATES

IPRs and PGRs

[Dupixent[®] \(dupilumab\)](#):

- On March 11, 2021, [Immunex](#) filed a petition for writ of certiorari, Supreme Court Case No. 20-1285, from the decisions in Fed. Cir. Appeal Nos. 19-1749 and 19-1777, appealing the final written decisions in IPR2017-01884 and IPR2017-01879.

Litigations

[Avonex[®] \(interferon beta-1a\) / Betaseron[®] \(interferon beta-1b\) / Extavia[®] \(interferon beta-1b\) / Rebif[®] \(interferon beta-1a\)](#):

- On March 8, 2021, [Bayer](#) filed a petition for writ of mandamus, Fed. Cir. Appeal No. 21-120, requesting the entry of final judgment of infringement in Case No. 2:10-cv-02734 (D.N.J.). This followed the February 26, 2021 petition for writ of mandamus by [EMD Serono](#), Fed. Cir. Appeal No. 21-117, with the same request. On the same day as [Bayer's](#) petition, the District Court entered final judgment. On March 11, 2021, Fed. Cir. Appeal Nos. 21-117 and 21-120 were voluntarily dismissed by [EMD Serono](#) and [Bayer](#).
-

CDER Purple Book Updates

Abecma® (idecabtagene vicleucel):

- On March 26, 2021, the FDA approved **Celgene** and **Bristol-Myers Squibb's Abecma® (idecabtagene vicleucel)**, a CAR-T therapy.

Non-U.S. Biosimilars / Follow-On Biologics

Adalimumab BS MA (adalimumab):

- On March 24, 2021, LG Chem and Mochida Pharmaceutical announced **Adalimumab BS MA (adalimumab)**, a biosimilar of **AbbVie's Humira® (adalimumab)**, was approved in Japan.

Oyavas (bevacizumab):

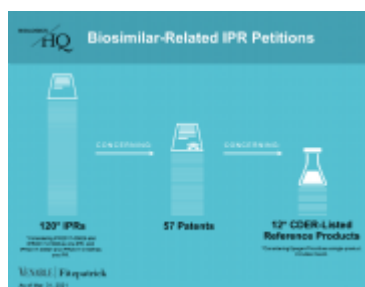
- On March 30, 2021, STADA announced that **Oyavas (bevacizumab)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, was approved and launched in the E.U.

Alymsys (bevacizumab):

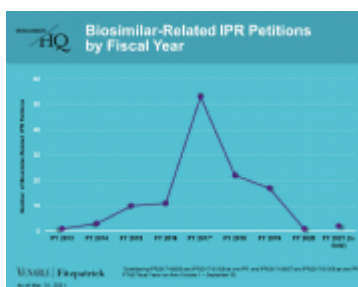
- On March 31, 2021, mAbxience announced that **Alymsys (bevacizumab)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, was approved in the E.U.

STATISTICS

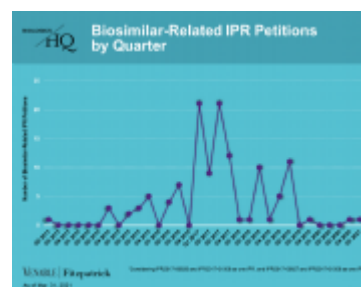
Biosimilar-Related IPR Petitions



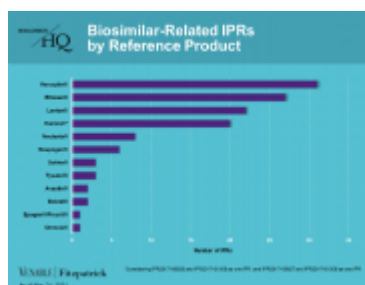
Biosimilar-Related IPR Petitions by Fiscal Year



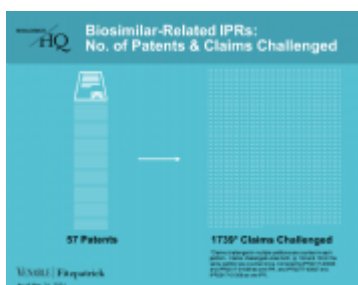
Biosimilar-Related IPR Petitions by Quarter



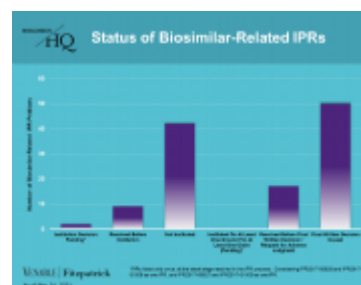
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



Status of Biosimilar-Related IPRs

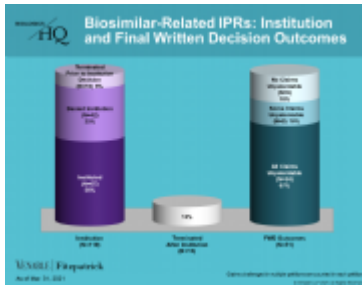


Biosimilar-Related IPRs: Institution and Final

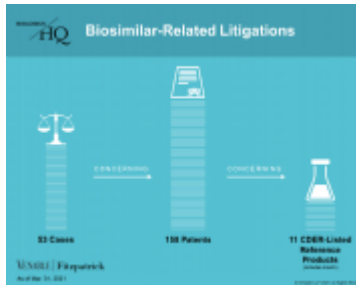
Biosimilar-Related

Biosimilar-Related Litigations

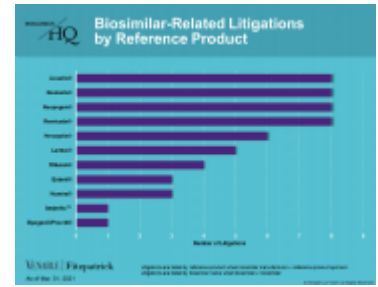
Written Decision Outcomes



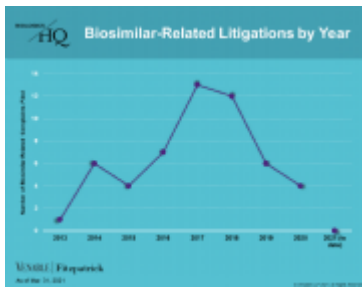
Litigations



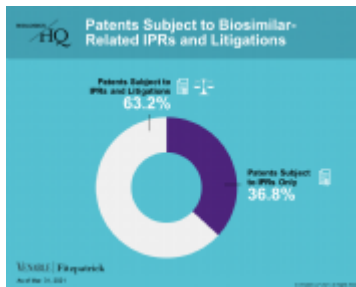
by Reference Product



Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



Biosimilars Approved in the United States

Biosimilars Approved in the United States

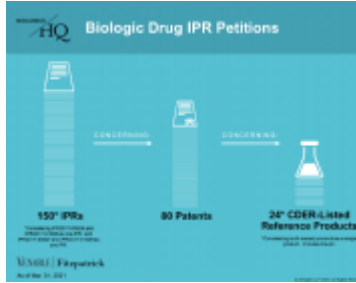
NDA No.	Reference Product	Applicant	Approval Date	Patent Status	Reference Product Status	U.S. Marketing
ANDA 141224	Humira	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141225	Enbrel	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141226	Actemra	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141227	Avastin	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141228	Keytruda	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141229	Opdivo	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141230	Imbruvica	Amgen Inc.	May 25, 2016	Granted	Granted	Yes

Biosimilar Applications Pending in the United States

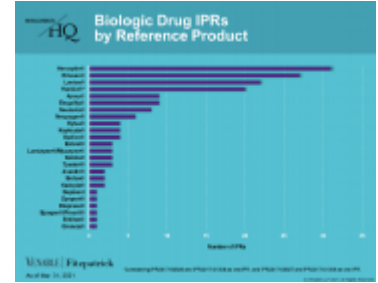
Biosimilar Applications Pending in the United States*

NDA No.	Reference Product	Applicant	Approval Date	Patent Status	Reference Product Status	U.S. Marketing
ANDA 141231	Humira	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141232	Enbrel	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141233	Actemra	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141234	Avastin	Amgen Inc.	May 25, 2016	Granted	Granted	Yes
ANDA 141235	Keytruda	Amgen Inc.	May 25, 2016	Granted	Granted	Yes

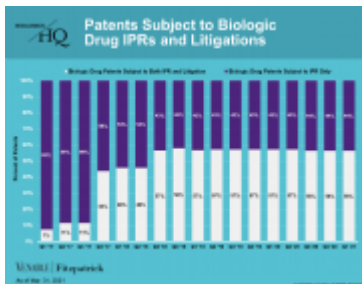
Biologic Drug IPR Petitions



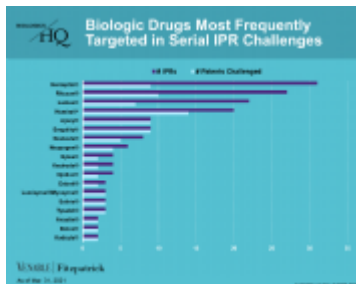
Biologic Drug IPRs by Reference Product



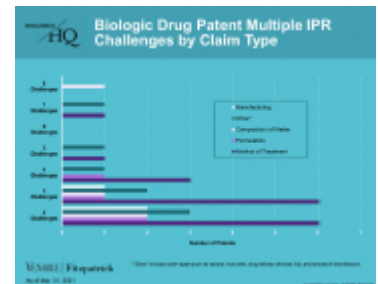
Patents Subject to Biologic Drug IPRs and Litigations



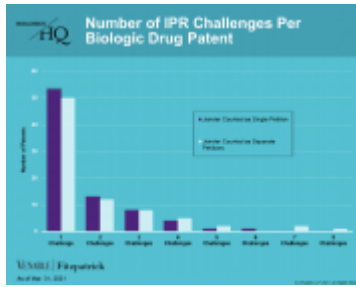
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent



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.

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