

MONTHLY
INJECTION



June 10, 2021



LATEST NEWS



IP and Antitrust Litigation in the Pharmaceutical Industry – Pre-Litigation Strategies

[Ha Kung Wong](#), Daisy R. Muzzio, Shane Brunner, Joshua Resiburg, Jeffrey Lewis, and Neill Clark discuss antitrust issues relating to IP litigations in the pharmaceutical industry. This is the first webinar in a three-part series, discussing pre-litigation strategies from the perspectives of innovators, generics, and biosimilars. Topics include information on the Orange and Purple Books, selecting products to develop as a generic/biosimilar, the CREATES Act, skinny labels, and preparing for Paragraph IV letters and other pre-litigation exchanges in the BPCIA patent dance.

preparing for Paragraph IV letters



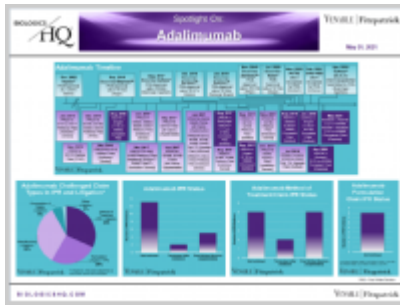
IP and Antitrust Litigation in the Pharmaceutical Industry – Patent Infringement Lawsuit

[Ha Kung Wong](#) participated in a panel discussion of antitrust issues relating to IP litigations in the pharmaceutical industry. This is the second webinar in a three-part series, discussing patent infringement lawsuits from the perspectives of innovators, generics, and biosimilars. Topics include information on ANDAs, 502(b) applications, biosimilars and Paragraph IV notices; confidential access; Hatch-Waxman case timing, venue, court rules and mandatory disclosures; inducement of infringement; unlisted patents; and manufacturing patents.

infringement; unlisted patents; and manufacturing patents.

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 May 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 May 31, 2021.

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UPDATES

IPRs and PGRs

[Eylea[®] \(aflibercept\) / Lucentis[®] \(ranibizumab\):](#)

- On May 3, 2021, [Regeneron](#) withdrew its request for rehearing of the decision denying institution in IPR2020-01317.

[Eylea[®] \(aflibercept\):](#)

- On May 5, 2021, [Mylan](#), [Viartis](#), [Momenta](#), and [Johnson & Johnson](#) filed IPR2021-00880 and IPR2021-00881 against [Regeneron](#).

[Lantus[®] \(insulin glargine recombinant\):](#)

- On May 28, 2021, [Sanofi](#) filed Fed. Cir. Appeal No. 21-1981, appealing the final written decision finding all instituted claims unpatentable in IPR2019-01657.

Litigations

Humira® (adalimumab):

- On May 11, 2021, **Alvotech** filed a declaratory judgment lawsuit, Case No. 1:21-cv-00589 (E.D. Va.) against **AbbVie**, related to **Alvotech's** proposed biosimilar **AVT02 (adalimumab)**.
- On May 28, 2021, **AbbVie** filed a second phase infringement lawsuit, Case No. 1:21-cv-02899 (N.D. Ill.) against **Alvotech**, alleging infringement of 58 patents related to **Alvotech's** proposed biosimilar **AVT02 (adalimumab)**.

Enbrel® (etanercept):

- On May 17, 2021, the Supreme Court denied certiorari in **Amgen v. Sandoz**, Supreme Court Appeal No. 20-1110, appealing Case No. 2:16-cv-01118 (D.N.J.), Fed. Cir. Appeal. No. 20-1037.

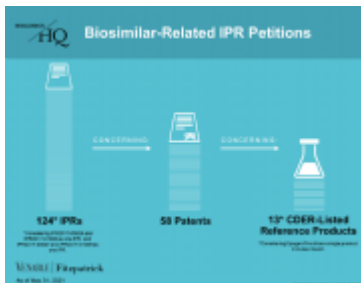
CDER Purple Book Updates

Rybrevent™ (amivantamab-vmjw):

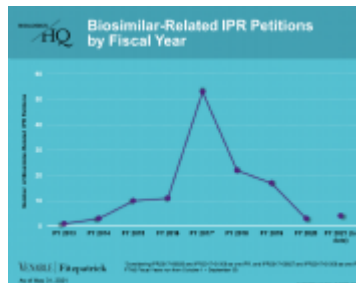
- On May 21, 2021, the FDA approved **Janssen's Rybrevent™ (amivantamab-vmjw)**.

STATISTICS

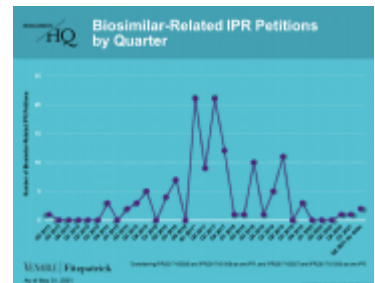
Biosimilar-Related IPR Petitions



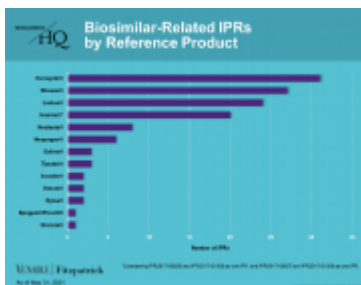
Biosimilar-Related IPR Petitions by Fiscal Year



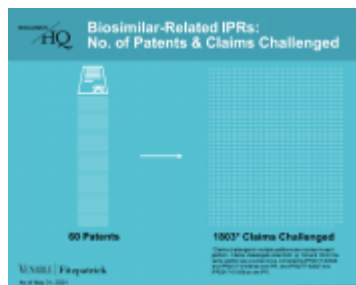
Biosimilar-Related IPR Petitions by Quarter



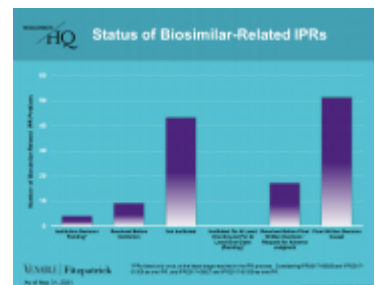
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



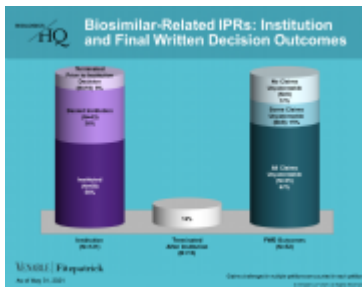
Status of Biosimilar-Related IPRs



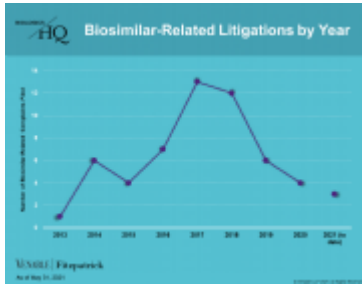
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

Biosimilar-Related Litigations

Biosimilar-Related Litigations by Reference Product



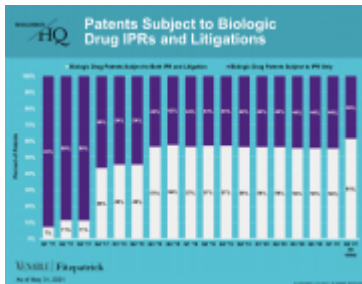
Biosimilar-Related Litigations by Year



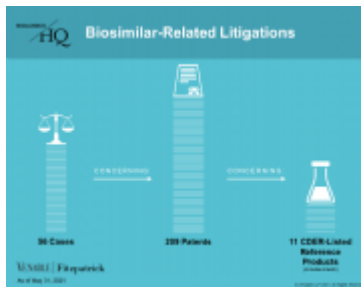
Biosimilar and Interchangeable Applications Pending in the United States

Reference Product	Company Name	USDA/USDA	Reference Product	Patent Status	Comments
Humira	AbbVie	AbbVie	Humira	Patent	Patent expiration 2016
Enbrel	Amgen	Amgen	Enbrel	Patent	Patent expiration 2016
Actemra	Novartis	Novartis	Actemra	Patent	Patent expiration 2016
Remicade	Novartis	Novartis	Remicade	Patent	Patent expiration 2016
Humira	AbbVie	AbbVie	Humira	Patent	Patent expiration 2016
Enbrel	Amgen	Amgen	Enbrel	Patent	Patent expiration 2016
Actemra	Novartis	Novartis	Actemra	Patent	Patent expiration 2016
Remicade	Novartis	Novartis	Remicade	Patent	Patent expiration 2016
Humira	AbbVie	AbbVie	Humira	Patent	Patent expiration 2016
Enbrel	Amgen	Amgen	Enbrel	Patent	Patent expiration 2016
Actemra	Novartis	Novartis	Actemra	Patent	Patent expiration 2016
Remicade	Novartis	Novartis	Remicade	Patent	Patent expiration 2016
Humira	AbbVie	AbbVie	Humira	Patent	Patent expiration 2016
Enbrel	Amgen	Amgen	Enbrel	Patent	Patent expiration 2016
Actemra	Novartis	Novartis	Actemra	Patent	Patent expiration 2016
Remicade	Novartis	Novartis	Remicade	Patent	Patent expiration 2016

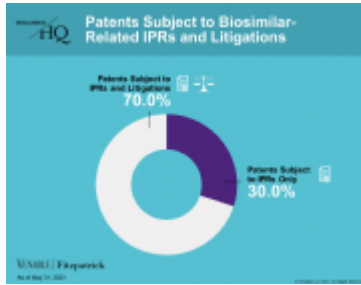
Patents Subject to Biologic Drug IPRs and Litigations



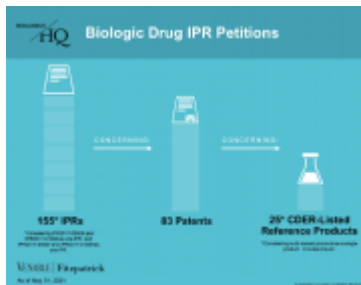
Patents Subject to Biosimilar-Related IPRs and Litigations



Patents Subject to Biologic Drug IPR Petitions



Biologic Drug IPR Petitions

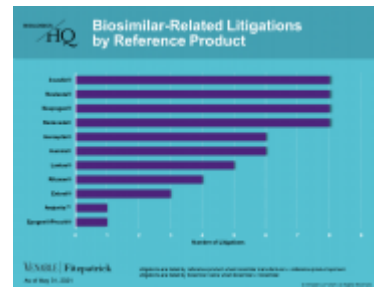


Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Number of IPR Challenges Per Biologic Drug Patent

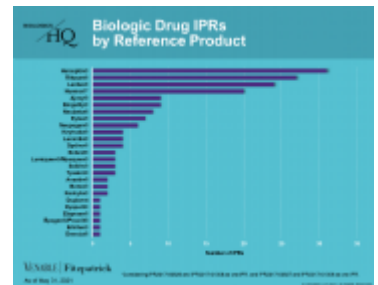
Biosimilars Approved in the United States



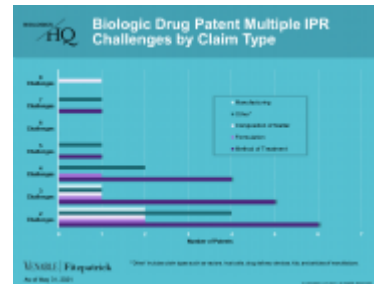
Biosimilars Approved in the United States

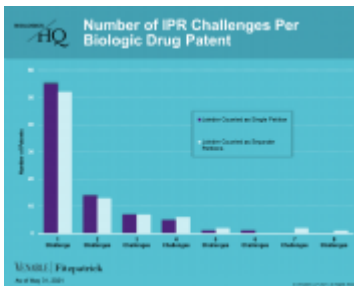
USDA No.	Reference Product	Reference Product Name	Reference Product Class	USDA No.	Reference Product	Reference Product Name	Reference Product Class	USDA No.
USDA 18000	Humira	Humira (Adalimumab)	Anti-TNF	USDA 18000	Humira	Humira (Adalimumab)	Anti-TNF	USDA 18000
USDA 18001	Enbrel	Enbrel (Etanercept)	Anti-TNF	USDA 18001	Enbrel	Enbrel (Etanercept)	Anti-TNF	USDA 18001
USDA 18002	Actemra	Actemra (Tocilizumab)	Anti-IL6	USDA 18002	Actemra	Actemra (Tocilizumab)	Anti-IL6	USDA 18002
USDA 18003	Remicade	Remicade (Infliximab)	Anti-TNF	USDA 18003	Remicade	Remicade (Infliximab)	Anti-TNF	USDA 18003
USDA 18004	Humira	Humira (Adalimumab)	Anti-TNF	USDA 18004	Humira	Humira (Adalimumab)	Anti-TNF	USDA 18004
USDA 18005	Enbrel	Enbrel (Etanercept)	Anti-TNF	USDA 18005	Enbrel	Enbrel (Etanercept)	Anti-TNF	USDA 18005
USDA 18006	Actemra	Actemra (Tocilizumab)	Anti-IL6	USDA 18006	Actemra	Actemra (Tocilizumab)	Anti-IL6	USDA 18006
USDA 18007	Remicade	Remicade (Infliximab)	Anti-TNF	USDA 18007	Remicade	Remicade (Infliximab)	Anti-TNF	USDA 18007
USDA 18008	Humira	Humira (Adalimumab)	Anti-TNF	USDA 18008	Humira	Humira (Adalimumab)	Anti-TNF	USDA 18008
USDA 18009	Enbrel	Enbrel (Etanercept)	Anti-TNF	USDA 18009	Enbrel	Enbrel (Etanercept)	Anti-TNF	USDA 18009
USDA 18010	Actemra	Actemra (Tocilizumab)	Anti-IL6	USDA 18010	Actemra	Actemra (Tocilizumab)	Anti-IL6	USDA 18010
USDA 18011	Remicade	Remicade (Infliximab)	Anti-TNF	USDA 18011	Remicade	Remicade (Infliximab)	Anti-TNF	USDA 18011
USDA 18012	Humira	Humira (Adalimumab)	Anti-TNF	USDA 18012	Humira	Humira (Adalimumab)	Anti-TNF	USDA 18012
USDA 18013	Enbrel	Enbrel (Etanercept)	Anti-TNF	USDA 18013	Enbrel	Enbrel (Etanercept)	Anti-TNF	USDA 18013
USDA 18014	Actemra	Actemra (Tocilizumab)	Anti-IL6	USDA 18014	Actemra	Actemra (Tocilizumab)	Anti-IL6	USDA 18014
USDA 18015	Remicade	Remicade (Infliximab)	Anti-TNF	USDA 18015	Remicade	Remicade (Infliximab)	Anti-TNF	USDA 18015

Biologic Drug IPRs by Reference Product



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.

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Contact the BiologicsHQ Team



Robert S. Schwartz, Ph.D.
Chair
+1 212.218.2298
RSchwartz@Venable.com



Ha Kung Wong
Partner
+1 212.218.2571
HWong@Venable.com

CALIFORNIA | DELAWARE | ILLINOIS | MARYLAND | NEW YORK | VIRGINIA | WASHINGTON, DC

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