

MONTHLY
INJECTION



September 8, 2021



LATEST NEWS



Lack of standing dooms high court challenge to ACA individual mandate California v. Texas

[Ha Kung Wong's](#) expert opinion was cited in an article by Thomson Reuters Westlaw about the Supreme Court's opinion in *California v. Texas*, upholding the Affordable Care Act (ACA). According to [Wong](#), it remains to be seen how future constitutional attacks, such as those in *Kelley v. Becerra*, will fare.



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[™]](#), [MSB11455](#), and [Pegfilgrastim \(Lupin\)](#)), 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 August 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 August 31, 2021.

Read
More
News

UPDATES

IPRs and PGRs

[Ajovy[®] \(fremanezumab-vfrm\) / Emgality[®] \(galcanezumab-gnlm\)](#):

- On August 16, 2021, the Federal Circuit affirmed the PTAB's final written decisions finding all challenged claims unpatentable in [Teva v. Eli Lilly](#) Fed. Cir. Appeal Nos. 20-1747 (appealing IPR2018-01422), 20-1748 (appealing IPR2018-01423), 20-1749 (appealing IPR2018-01424), 20-1750 (appealing IPR2018-01425), 20-1751 (appealing IPR2018-01426), and 20-1752 (appealing IPR2018-01427).
- On August 16, 2021, the Federal Circuit affirmed the PTAB's final written decisions finding no challenged claims unpatentable in [Eli Lilly v. Teva](#) Fed. Cir. Appeal Nos. 20-1876 (appealing IPR2018-01710), 20-1877 (appealing IPR2018-01711), and 20-1878 (appealing IPR2018-01712).

[Botox[®] \(onabotulinumtoxinA\)](#):

- On August 16, 2021, [Medy-Tox](#) requested Director review or panel rehearing of the decision denying its non-contingent motion to amend in PGR2019-00062.

[Neupogen[®] \(filgrastim\) / Neulasta[®] \(pegfilgrastim\)](#):

- On August 17, 2021, [Pfizer v. Amgen](#) IPR2021-00528 was instituted.

[Actemra[®] \(tocilizumab\)](#):

- On August 18, 2021, [Fresenius Kabi](#) filed IPR2021-01288 and IPR2021-01336 against [Chugai Seiyaku Kabushiki Kaisha](#).

[Keytruda[®] \(pembrolizumab\)](#):

- On August 23, 2021, [Merck Sharp & Dohme](#) filed requests for rehearing of the decisions denying institution in PGR2021-00036 and PGR2021-00039.

Litigations

Taltz® (ixekizumab):

- On August 25, 2021, **Eli Lilly's** motion to voluntarily dismiss Fed. Cir. Appeal No. 21-1874, appealing the denial of attorney fees in Case No. 3:18-cv-01518 (S.D. Cal.), was granted.

aBLA Applications and FDA Activity

FYB201 (also known as CHS-201) (ranibizumab):

- On August 5, 2021, **Formycon**, **Bioeq**, and **Coherus** announced the resubmission of an aBLA for **FYB201 (ranibizumab)**, a proposed biosimilar of **Genentech's Lucentis® (ranibizumab)**, to the FDA.

CDER Purple Book Updates

Nexviazyme™ (avalglucosidase alfa-ngpt):

- On August 6, 2021, the FDA approved **Genzyme's Nexviazyme™ (avalglucosidase alfa-ngpt)**.

Skytrofa™ (lonapegsomatropin-tcgd):

- On August 25, 2021, the FDA approved **Acendis Pharma Endocrinology's Skytrofa™ (lonapegsomatropin-tcgd)**.

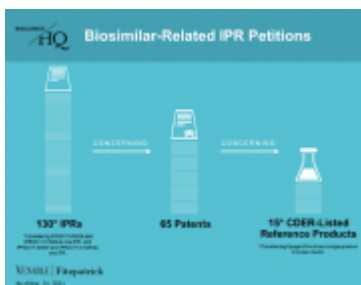
Non-U.S. Biosimilars / Follow-On Biologics

Byooviz™ (ranibizumab):

- On August 23, 2021, **Samsung Bioepis** and **Biogen** announced **Byooviz™ (ranibizumab)**, a biosimilar of **Genentech's Lucentis® (ranibizumab)**, was approved in the E.U.

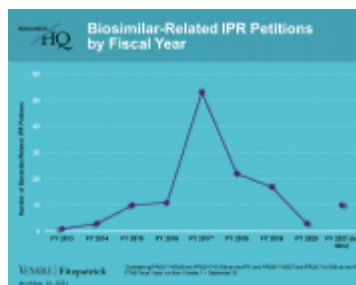
STATISTICS

Biosimilar-Related IPR Petitions



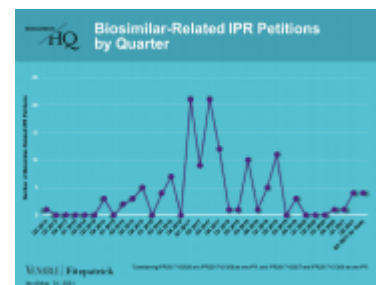
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPR Petitions by Fiscal Year

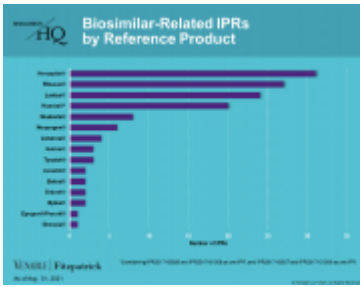


Biosimilar-Related IPRs: Number of Patents and Claims Challenged

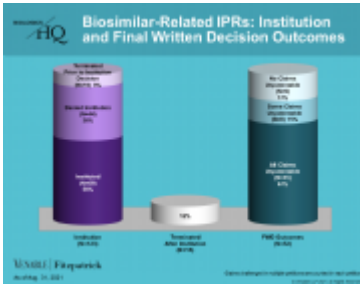
Biosimilar-Related IPR Petitions by Quarter



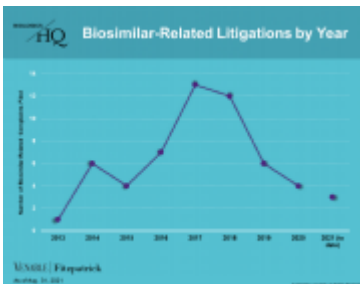
Status of Biosimilar-Related IPRs



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



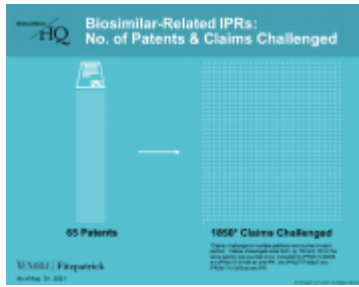
Biosimilar-Related Litigations by Year



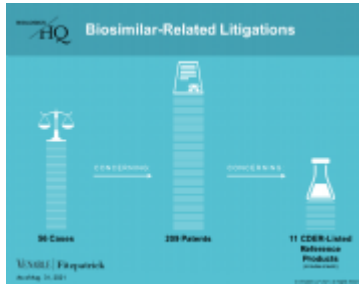
Biosimilar and Interchangeable Applications Pending in the United States

Reference Product	Quantity	Brand Name	U.S. Brand	Reference Product Category	IPR Status
Humira	1,200	AbbVie	Humira	Tumor Necrosis Factor Inhibitor	IPR Pending
Enbrel	400	Amgen	Enbrel	Tumor Necrosis Factor Inhibitor	IPR Pending
Actemra	300	Novartis	Actemra	Interleukin-6 Inhibitor	IPR Pending

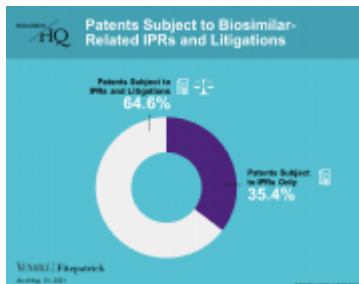
Patents Subject to Biologic Drug IPRs and Litigations



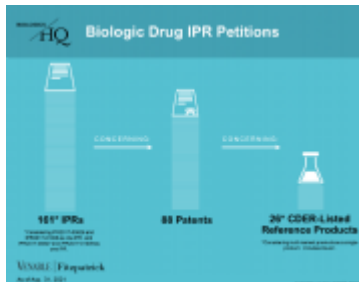
Biosimilar-Related Litigations



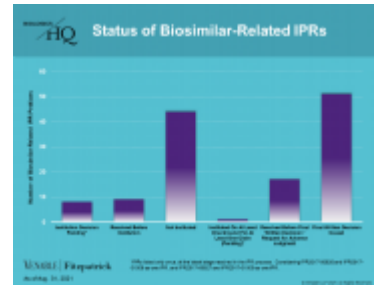
Patents Subject to Biosimilar-Related IPRs and Litigations



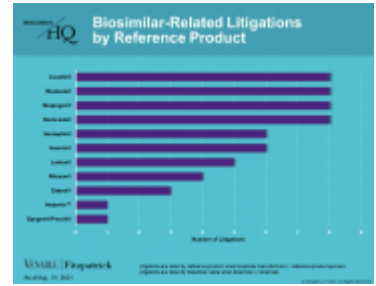
Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



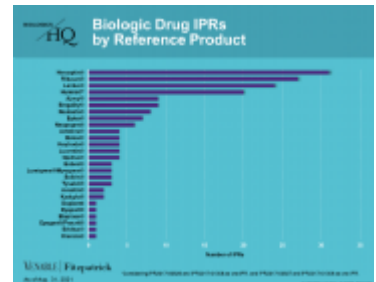
Biosimilar-Related Litigations by Reference Product



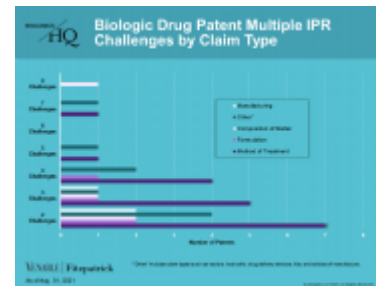
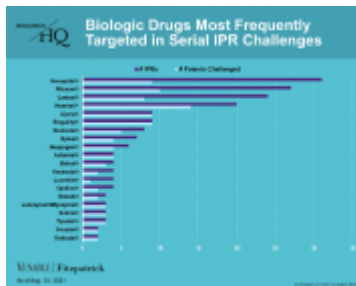
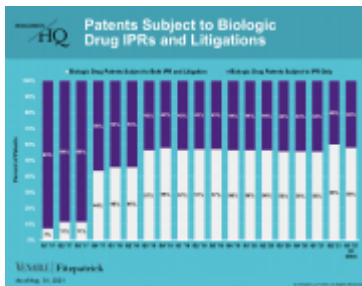
Biosimilars and Interchangeables Approved in the United States

U.S. Brand Name	Reference Product	U.S. Brand Name	U.S. Brand Name	U.S. Brand Name	U.S. Brand Name	U.S. Brand Name	U.S. Brand Name
Amgen	Humira	Amgen	Humira	Amgen	Humira	Amgen	Humira
Novartis	Actemra	Novartis	Actemra	Novartis	Actemra	Novartis	Actemra

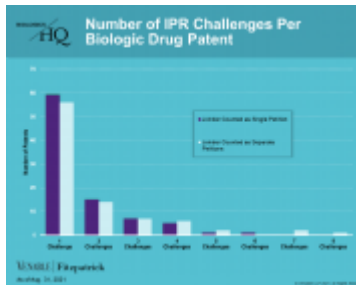
Biologic Drug IPRs by Reference Product



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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