

MONTHLY
INJECTION



November 14, 2022



LATEST NEWS



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) / Yusimry[™] (adalimumab-aqvh)

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

Spotlight On: Lantus[®] / Lantus[®] SoloSTAR[®] (insulin glargine recombinant) / Basaglar[®] (insulin glargine) / Semglee[®] (insulin glargine-yfgn) / Rezvoglar[™] (insulin glargine-aglr)

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 \(Herceptin[®], Ogivri[®], Herzuma[®], Ontruzant[®], Trazimera[®], Kanjinti[®], and EG12014\)](#), [rituximab \(Rituxan[®], Truxima[®], and Ruxience[®]\)](#), [adalimumab \(Humira[®], Amjevita[™], Cyltezo[®], Hyrimoz[™], Hadlima[™], Abrilada[™], Hulio[®], and Yusimry[™]\)](#), [etanercept \(Enbrel[®], Erelzi[®], and Eticovo[®]\)](#), and [insulin glargine \(Lantus[®] / Lantus[®] SoloSTAR[®], Basaglar[®], Semglee[®], and Rezvoglar[™]\)](#) have been updated with activity through October 31, 2022.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through October 31, 2022.

Read
More
News

UPDATES

IPRs and PGRs

[Actemra[®]](#) (tocilizumab):

- On October 4, 2022, [Fresenius Kabi](#) and [Chugai Seiyaku Kabushiki Kaisha](#) requested to terminate IPR2021-01024, IPR2021-01025, IPR2021-01288, IPR2021-01336, IPR2021-01542, IPR2022-00201, and IPR2022-01065 due to settlement.

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

- On October 14, 2022, the PTAB instituted [Eli Lilly's](#) IPR2022-00796 against [Teva](#).

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

- On October 25, 2022, the PTAB issued a final written decision finding all challenged claims unpatentable in [Regeneron v. Novartis](#) IPR2021-00816.

[Eylea[®]](#) (aflibercept):

- On October 28, 2022, [Mylan](#) filed IPR2023-00099 against [Regeneron](#).

Litigations

[Forteo[®]](#) (teriparatide):

- On October 14, 2022, [Eli Lilly](#) filed Case No. 1:22-cv-01355 (D. Del.) against [Dr. Reddy's](#).

aBLA Applications and FDA Activity

[Cimerli[™]](#) (ranibizumab-eqrn):

- On October 3, 2022, [Coherus](#) announced the launch of [Cimerli[™]](#) (ranibizumab-eqrn), an interchangeable biosimilar of [Genentech's Lucentis[®]](#) (ranibizumab).

[Alymsys[®]](#) (bevacizumab-maly):

- On October 3, 2022, **Amneal** and **mAbxience** announced the launch of **Alymsys[®]** (bevacizumab-maly), a biosimilar of **Genentech's Avastin[®]** (bevacizumab).

CDER Purple Book Updates

Imjudo[®] (tremelimumab-actl):

- On October 21, 2022, the FDA approved **AstraZeneca's Imjudo[®]** (tremelimumab-actl).

Tecvayli[™] (teclistamab-cqyv):

- On October 25, 2022, the FDA approved **Janssen Biotech's Tecvayli[™]** (teclistamab-cqyv).

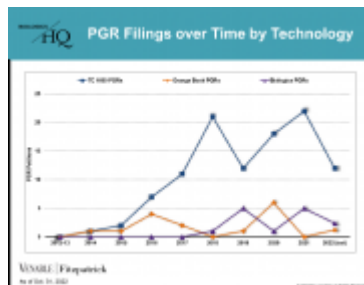
Non-U.S. Biosimilars / Follow-On Biologics

LucenBS (ranibizumab):

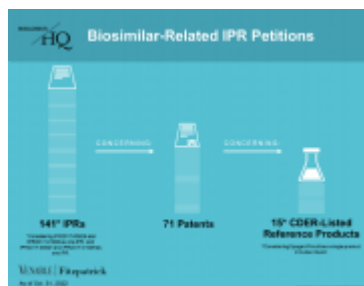
- On October 21, 2022, **Chong Kun Dang Pharmaceutical** announced the approval of **LucenBS** (ranibizumab), a biosimilar of **Genentech's Lucentis[®]** (ranibizumab), in South Korea.

STATISTICS

PGR Filings over Time by Technology

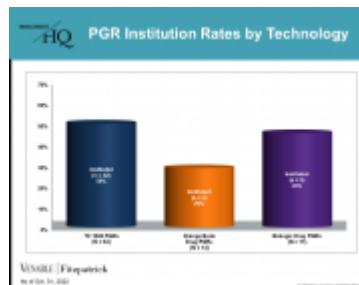


Biosimilar-Related IPR Petitions

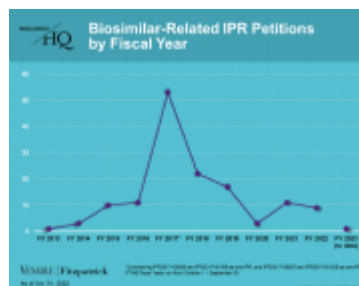


Biosimilar-Related IPRs by Reference Product

PGR Institution Rates by Technology

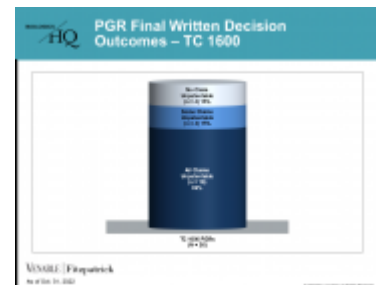


Biosimilar-Related IPR Petitions by Fiscal Year

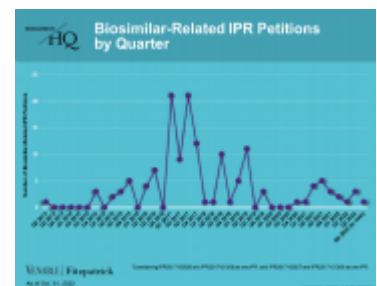


Biosimilar-Related IPRs: Number of Patents and Claims Challenged

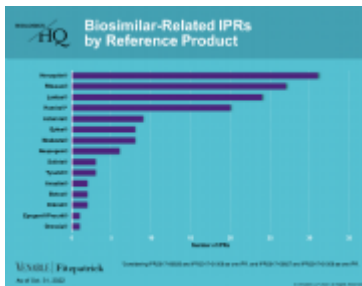
PGR Final Written Decision Outcomes - TC 1600



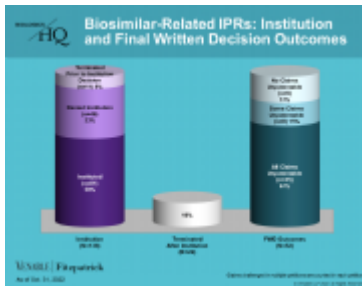
Biosimilar-Related IPR Petitions by Quarter



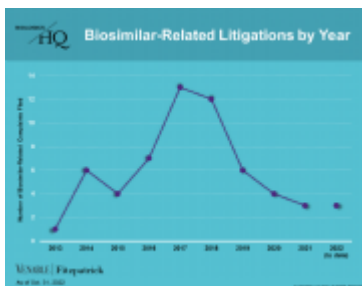
Status of Biosimilar-Related IPRs



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



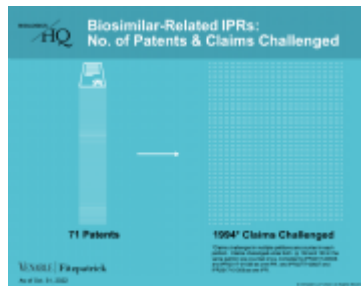
Biosimilar-Related Litigations by Year



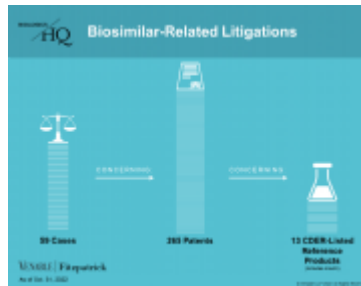
Biosimilar and Interchangeable Applications Pending in the United States

Reference Product	Biologic Name	US Approval	Priority Review	Biologics License Application (BLA) Number	US Approval
Humira	Adalimumab	2010	Priority	BLA 125181	2013
Adalimumab	Adalimumab	2010	Standard	BLA 125181	2013
Humira	Adalimumab	2010	Priority	BLA 125181	2013
Humira	Adalimumab	2010	Priority	BLA 125181	2013
Humira	Adalimumab	2010	Priority	BLA 125181	2013
Humira	Adalimumab	2010	Priority	BLA 125181	2013
Humira	Adalimumab	2010	Priority	BLA 125181	2013
Humira	Adalimumab	2010	Priority	BLA 125181	2013
Humira	Adalimumab	2010	Priority	BLA 125181	2013
Humira	Adalimumab	2010	Priority	BLA 125181	2013

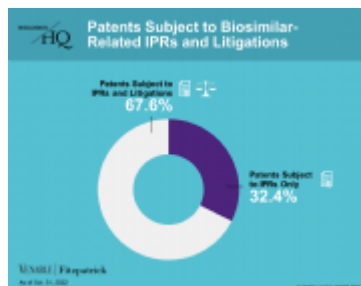
Patents Subject to Biologic Drug IPRs and Litigations



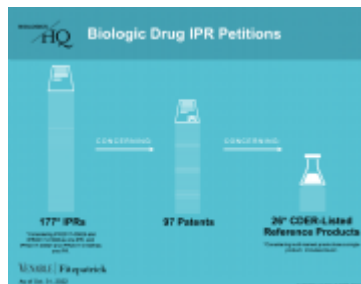
Biosimilar-Related Litigations



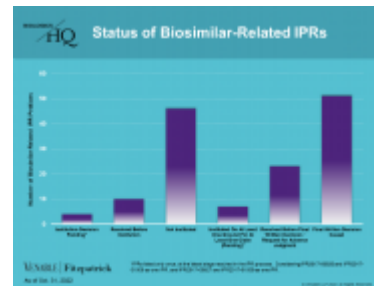
Patents Subject to Biosimilar-Related IPRs and Litigations



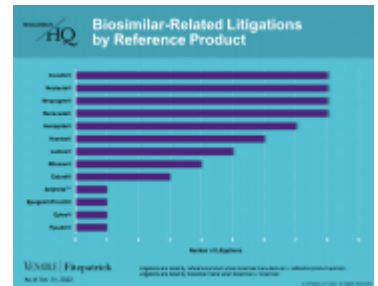
Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



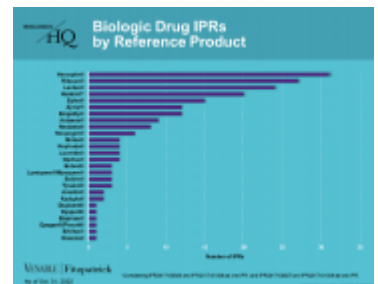
Biosimilar-Related Litigations by Reference Product



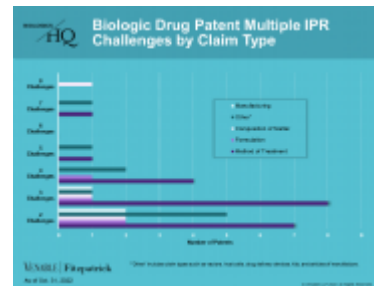
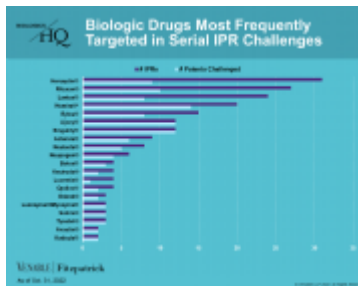
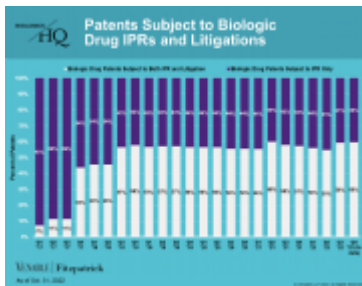
Biosimilars and Interchangeables Approved in the United States

Approval No.	Reference Product	Biologic Name	US Approval	Priority Review	Biologics License Application (BLA) Number	US Approval
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013
125181	Humira	Adalimumab	2010	Priority	BLA 125181	2013

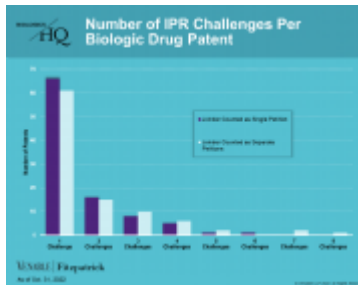
Biologic Drug IPRs by Reference Product



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.

SEARCH

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