

MONTHLY
INJECTION

June 10, 2024



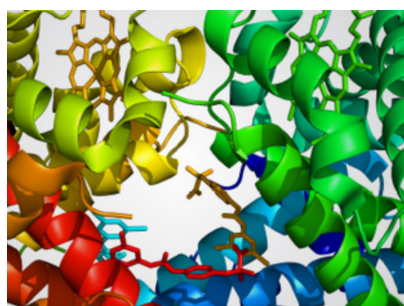
LATEST NEWS



FDA Approves High-Concentration Formulation of Boehringer Ingelheim's Humira[®] Biosimilar Cyltezo[®] (adalimumab-adbm)

By: [Monica Chou](#) and [Robert S. Schwartz, Ph.D.](#)

According to a May 1, 2024 [press release](#), the high-concentration (100 mg/mL), citrate-free formulation of [Boehringer Ingelheim's Cyltezo[®]](#) ([adalimumab-adbm](#)) was approved by the FDA as interchangeable with [AbbVie's Humira[®]](#) ([adalimumab](#)) to treat multiple chronic inflammatory diseases.



Regeneron Files Second BPCIA Complaint Against Celltrion's Proposed EYLEA[®] Biosimilar CT-P42

By: [Robert S. Schwartz, Ph.D.](#)

On May 17, 2024, [Regeneron](#) filed a second [infringement litigation](#) against [Celltrion's](#) proposed [EYLEA[®]](#) ([afibercept](#)) biosimilar [CT-P42](#), Case No. 1:24-cv-00053 (N.D.W. Va.). [Regeneron's Complaint](#) listed 25 patents, including 8 patents with method of treatment claims, 5 patents with formulation/composition claims, 4 patents with composition of matter claims, 12 patents with manufacturing claims, one patent with device claims, and one patent with packaging claims.

FDA Approves First Two Interchangeable EYLEA[®] Biosimilars – Biocon's Yesafili[™] (afibercept-jbvf) and Samsung Bioepis's Opuviz[™] (afibercept-yszy)

By: [Robert S. Schwartz, Ph.D.](#)



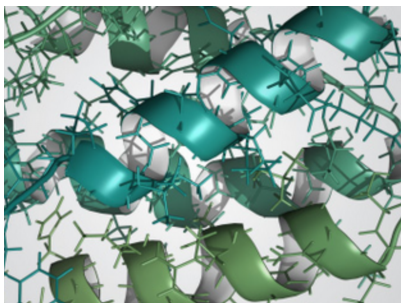
On May 20, 2024, the FDA approved the first two interchangeable biosimilars of Regeneron's EYLEA[®] (aflibercept) – Biocon Biologics and Mylan's Yesafili[™] (aflibercept-jbvf) and Samsung Bioepis's Opuviz[™] (aflibercept-yszy).



The First Biosimilar Disputes at the Unified Patent Court (UPC)

By: [Damineh Morsali, Ph.D.](#) and [Robert S. Schwartz, Ph.D.](#)

The first two biosimilar disputes were filed in Europe's Unified Patent Court (UPC) in March and April. On March 19, 2024, Alexion Pharmaceuticals (a subsidiary of AstraZeneca specializing in rare disease treatment) filed for provisional measures in the Hamburg Local Division against Amgen and Samsung Bioepis, asserting patent application EP 3167888 claiming antibodies corresponding to Alexion's blockbuster Soliris[®] (eculizumab). On April 9, 2024, Novartis and Genentech applied to the Düsseldorf Local Division of the UPC for provisional measures against Celltrion's proposed Xolair[®] (omalizumab) biosimilar CT-P39.



Fresenius Kabi Announces FDA Acceptance of aBLA for Prolia[®] / Xgeva[®] (denosumab) Biosimilar Candidate FKS518

By: [Robert S. Schwartz, Ph.D.](#)

On May 27, 2024, Fresenius Kabi announced the FDA acceptance of its aBLA for FKS518 (denosumab), a proposed biosimilar of Amgen's Prolia[®] / Xgeva[®] (denosumab). This is the third publicly announced aBLA for a Prolia[®] / Xgeva[®] biosimilar.



Amgen Files BPCIA Lawsuit Against Celltrion's Proposed Prolia[®] / Xgeva[®] (Denosumab) Biosimilar CT-P41

By: [Robert S. Schwartz, Ph.D.](#)

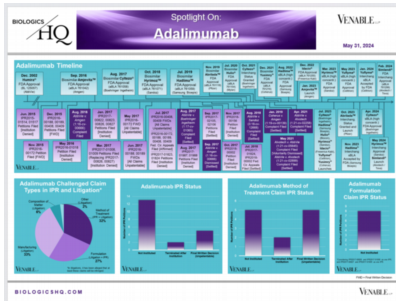
On May 28, 2024, Amgen filed a BPCIA litigation, Case No. 1:24-cv-06497 (D.N.J.), against Celltrion's proposed Prolia[®] / Xgeva[®] (denosumab) biosimilar CT-P41 alleging infringement of 29 of Amgen's patents, including one patent with formulation/composition claims, three patents with composition of matter claims, and 27 patents with manufacturing claims.

FDA Approves First Interchangeable Biosimilar of Alexion's Soliris[®] (eculizumab) – Amgen's Bkemb[™] (eculizumab-aeeb)



By: [Robert S. Schwartz, Ph.D.](#)

On May 28, 2024, the FDA approved [Amgen's Bkempv™ \(eculizumab-aeab\)](#), the first interchangeable biosimilar of [Alexion's Soliris® \(eculizumab\)](#). [Bkempv™](#) was approved with a skinny label for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS).



Spotlight On: Actemra® (tocilizumab) / Tofidence™ (tocilizumab-bavi) / Tyenne® (tocilizumab-aazg)

Spotlight On: Neulasta® (pegfilgrastim) / Fulphila® (pegfilgrastim-jmdb) / Udenyca® (pegfilgrastim-cbqv) / Ziextenzo® (pegfilgrastim-bmez) / Nyvepria® (pegfilgrastim-ppgf) / Fylnetra™ (pegfilgrastim-ppgf) / Stimufend® (pegfilgrastim-fpgk)

Spotlight On: Herceptin® (trastuzumab) / Ogivri® (trastuzumab-dkst) / Herzuma® (trastuzumab-pkrb) / Ontruzant® (trastuzumab-dttb) / Trazimera® (trastuzumab-qyyp) / Kanjinti® (trastuzumab-anns) / Hercessi™ (trastuzumab-strf)

Spotlight On: Biosimilar Litigations

Spotlight On: Rituxan® (rituximab) / Truxima® (rituximab-abbs) / Ruxience® (rituximab-pvvr) / Riabni™ (rituximab-arrx)

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) / Idacio® (adalimumab-aacf) / Yuflyma® (adalimumab-aaty) / Simlandi® (adalimumab-ryvk)

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 tocilizumab ([Actemra®](#), [Tofidence™](#), [Tyenne®](#), and [CT-P47](#)), pegfilgrastim ([Neulasta®](#), [Fulphila®](#), [Udenyca®](#), [Ziextenzo®](#), [Nyvepria®](#), [Fylnetra™](#), [Stimufend®](#), [Lapelga™](#), and [Pegfilgrastim \(Lupin\)](#)), trastuzumab ([Herceptin®](#), [Ogivri®](#), [Herzuma®](#), [Ontruzant®](#), [Trazimera®](#), [Kanjinti®](#), [Hercessi™](#), [TX-05](#), and [EG12014](#)), rituximab ([Rituxan®](#), [Truxima®](#), [Ruxience®](#), and [Riabni™](#)), adalimumab ([Humira®](#), [Amjevita™](#), [Cyltezo®](#), [Hyrimoz®](#), [Hadlima™](#), [Abrilada™](#), [Hulio®](#), [Yusimry™](#), [Idacio®](#),

Yuflyma[®], and Simlandi[®]), etanercept (Enbrel[®], Erelzi[®], and Eticovo[®]), and insulin glargine (Lantus[®] / Lantus[®] SoloSTAR[®], Basaglar[®], Semglee[®], and Rezvoglar[™]) have been updated with activity through May 31, 2024.

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, 2024.

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UPDATES

IPRs and PGRs

Enhertu[®] (fam-trastuzumab deruxtecan-nxki) / Adcetris[®] (brentuximab vedotin):

- On May 28, 2024, Seagen filed CAFC Appeal No. 24-1878 appealing the final written decision in PGR2021-00030 finding all challenged composition of matter claims of U.S. Patent No. 10,808,039 unpatentable.

Litigations

Soliris[®] (eculizumab):

- On May 6, 2024, the Court denied Alexion's motion for a preliminary injunction against Samsung Bioepis's SB12 (eculizumab), a proposed biosimilar of Alexion's Soliris[®] (eculizumab), in Case No. 1:24-cv-00005 (D. Del.). The Court found that each of the asserted claims for which Alexion sought a preliminary injunction (U.S. Patent No. 9,447,176, claim 1 and U.S. Patent No. 10,590,189, claim 1) faced a substantial question of validity, and therefore Alexion failed to demonstrate a reasonable likelihood of success.
 - On May 20, 2024, Alexion filed CAFC Appeal No. 24-1829, appealing the decision denying the preliminary injunction.

Eylea[®] (aflibercept):

- On May 17, 2024, Regeneron filed Case No. 1:24-cv-00053 (N.D.W. Va.) against Celltrion alleging infringement of 25 patents by Celltrion's proposed biosimilar CT-P42.
- On May 17, 2024, the Court granted Temporary Restraining Orders against Mylan / Biocon's Yesafili[™] (aflibercept-jbfv) in Case No. 1:22-cv-00061 (N.D.W. Va.) and against Samsung Bioepis's Opuviz[™] (aflibercept-yszy) in Case Nos. 1:23-cv-00094 (N.D.W. Va.) and 1:23-cv-00106 (N.D.W. Va.). On May 30, 2024, the Court extended the Temporary Restraining Orders through June 14, 2024.

Prolia[®] / Xgeva[®] (denosumab):

- On May 28, 2024, Amgen filed Case No. 1:24-cv-06497 (D.N.J.) alleging infringement of 29 patents by Celltrion's proposed Prolia[®] / Xgeva[®] (denosumab) biosimilar CT-P41 (denosumab).

aBLA Applications and FDA Activity

Hyrimoz[®] (adalimumab-adaz):

- On May 13, 2024, the FDA approved Sandoz's sBLA for Hyrimoz[®] (adalimumab-adaz), deeming it interchangeable with AbbVie's Humira[®] (adalimumab) for the 10 mg/0.1 mL, 20 mg/0.2 mL, and 80 mg/0.8 mL

strengths. A provisional determination was also made for 40mg/0.4 mL strength due to interchangeable exclusivity of **Alvotech** and **Teva's Simlandi[®] (adalimumab-ryvk)**.

Yesafili[™] (afibercept-jbvf):

- On May 20, 2024, the FDA approved **Mylan** and **Biocon's Yesafili[™] (afibercept-jbvf)** as an interchangeable biosimilar of **Regeneron's Eylea[®] (afibercept)**.

Opuviz[™] (afibercept-yszy):

- On May 20, 2024, the FDA approved **Samsung Bioepis's Opuviz[™] (afibercept-yszy)** as an interchangeable biosimilar of **Regeneron's Eylea[®] (afibercept)**.

Simlandi[®] (adalimumab-ryvk):

- On May 21, 2024, **Alvotech** and **Teva** announced the launch of **Simlandi[®] (adalimumab-ryvk)**, a high-concentration, citrate-free interchangeable biosimilar of **AbbVie's Humira[®] (adalimumab)**.

FKS518 (denosumab):

- On May 27, 2024, **Fresenius Kabi** announced the FDA acceptance of an aBLA for **FKS518 (denosumab)**, a proposed biosimilar of **Amgen's Prolia[®] / Xgeva[®] (denosumab)**.

Bkemv[™] (eculizumab-aeab):

- On May 28, 2024, the FDA approved **Amgen's Bkemv[™] (eculizumab-aeab)** as an interchangeable biosimilar of **Alexion's Soliris[®] (eculizumab)**.

CDER Purple Book Updates

Imdelltra[™] (tarlatamab-dlle):

- On May 16, 2024, the FDA approved **Amgen's Imdelltra[™] (tarlatamab-dlle)**.

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

Jubbonti[®] / Wyost[®] (denosumab-bbdz):

- On May 22, 2024, **Sandoz** announced the approval of **Jubbonti[®]** and **Wyost[®] (denosumab-bbdz)**, biosimilars of **Amgen's Prolia[®] / Xgeva[®] (denosumab)**, in the E.U.

Omlyclo[®] (CT-P39) (omalizumab):

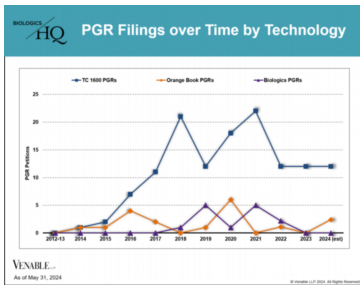
- On May 23, 2024, **Celltrion** announced the approval of **Omlyclo[®] (omalizumab)**, a biosimilar of **Genentech's Xolair[®] (omalizumab)**, in the E.U.

STATISTICS

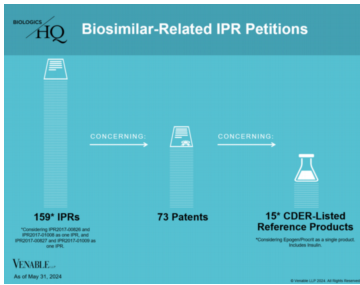
**PGR Filings
Over Time
by Technology**

**PGR Institution
Rates by
Technology**

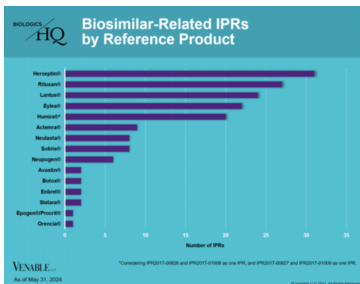
**PGR Final Written
Decision Outcomes –
TC 1600**



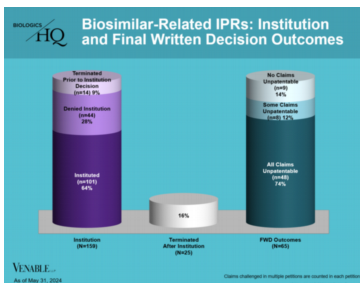
Biosimilar-Related IPR Petitions



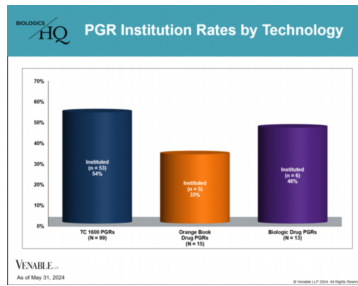
Biosimilar-Related IPRs by Reference Product



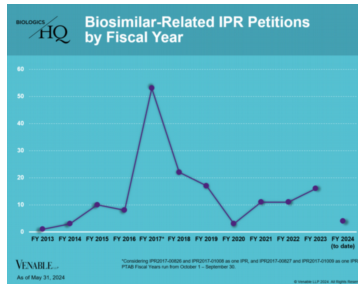
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



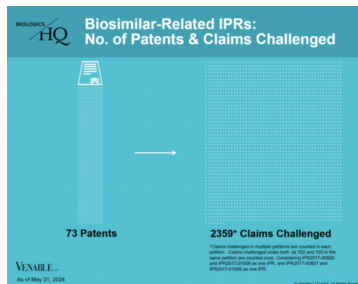
Biosimilar-Related Litigations by Year



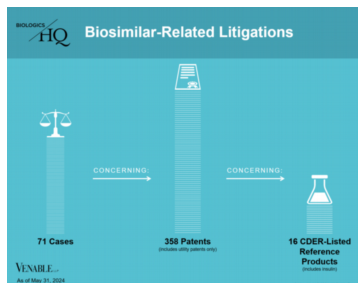
Biosimilar-Related IPR Petitions by Fiscal Year



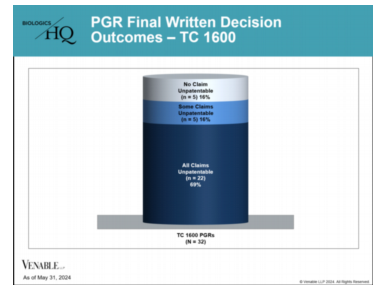
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



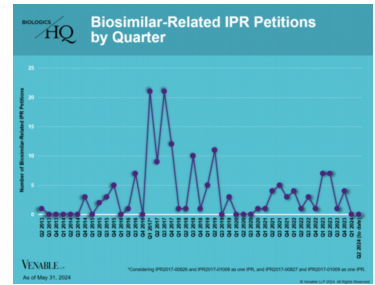
Biosimilar-Related Litigations



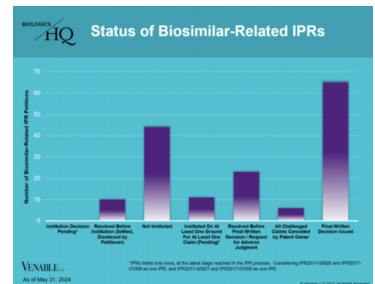
Patents Subject to Biosimilar-Related IPRs and Litigations



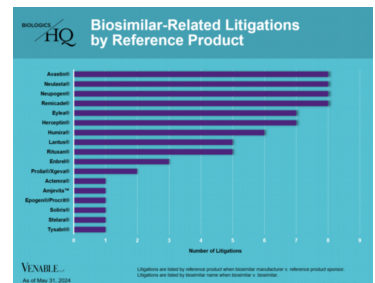
Biosimilar-Related IPR Petitions by Quarter



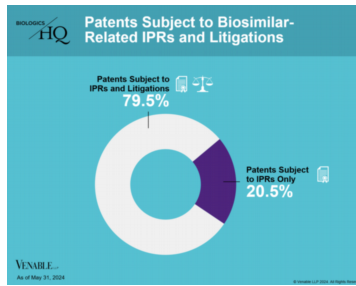
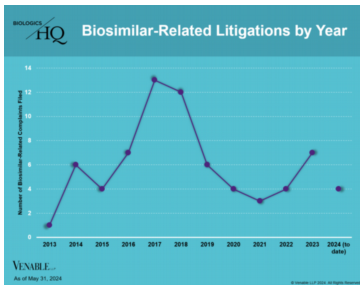
Status of Biosimilar-Related IPRs



Biosimilar-Related Litigations by Reference Product



Biosimilars and Interchangeables Approved in the United States



Biosimilars and Interchangeables Approved in the United States

BLA No.	Brand Name	Biosimilar/ Interchangeable Name	BLA Holder	Date of Approval	Reference Product	Reference Product's Launch Date	U.S. Market Entry Date
BLA 761024	Aranesp®	Adalimumab-adsb	Amgen	Dec. 23, 2014	Humira®	AAV14	Jan. 2012
BLA 761058	Cyltezo®	Adalimumab-adsb	BioCryst/ Regeneron	Oct. 15, 2014	Humira®	AAV14	Jan. 2012
BLA 761071	Humira®	Adalimumab-adsb	Sandoz	Apr. 20, 2015	Humira®	AAV14	Jan. 2012
BLA 761028	Hytrinra®	Adalimumab-bvrd	Sanofi/ Biogen	Mar. 20, 2015	Humira®	AAV14	Jan. 2012
BLA 761118	Abrysvo®	Adalimumab-adsb	Pfizer	Oct. 1, 2015	Humira®	AAV14	Oct. 2012
BLA 761154	Hytrinra®	Adalimumab-bvrd	Novartis/ Biogen	Jul. 8, 2015	Humira®	AAV14	Jan. 2012
BLA 761218	Humira®	Adalimumab-adsb	Centocor/ Amgen	Dec. 10, 2015	Humira®	AAV14	Jan. 2012
BLA 761219	Vyalupur®	Adalimumab-adsb	Cellgene	May 23, 2015	Humira®	AAV14	Jan. 2012
BLA 761289	Enstetap®	Adalimumab-ryrh	Alkermes/ Teva	Feb. 20, 2016	Humira®	AAV14	May 2014
BLA 761350	Opovir®	Aflibercept-zyzj	Novartis/ Biogen	May 20, 2016	Eylea®	Regeneron	
BLA 761351	Yessur®	Aflibercept-zyzj	Novartis/ Biogen	May 20, 2016	Eylea®	Regeneron	

VENABLE
As of May 31, 2024

Biosimilar and Interchangeable Applications Pending in the United States

Biologic Drug IPR Petitions

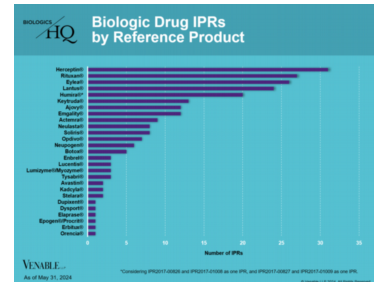
Biologic Drug IPRs by Reference Product

Biosimilar and Interchangeable Applications Pending in the United States*

Biosimilar Name	Scientific Name	BLA Holder	Reference Product	Reference Product's Launch Date	IPR Status
PR003	Atanesep®	Amgen	Eylea®	Regeneron	Submitted Jan. 2023
CT142	Atanesep®	Amgen/ Kenvue	Eylea®	Regeneron	Submitted Jan. 2023
FK328	Bencicizumab	Carinca/ Tigenix/ Kineta/KCJ	Avastin®	Genentech	Accepted Nov. 2019
S88	Bencicizumab	Samsung Biologics	Avastin®	Genentech	Accepted Nov. 2019
MPL14202	Bencicizumab	Mylan/ Biogen	Avastin®	Genentech	Accepted Mar. 2020, CRL Feb. 2023
CT141	Dicoumab	Cellgene	Prograf®/ Rapam®	Amgen	Submitted Nov. 2022
FK3318	Dicoumab	Freemove/KCJ	Prograf®/ Rapam®	Amgen	Accepted May 2024
S812	Eucoumab	Samsung Biologics	Soliris®	Alexion	Submitted Jul. 2023
Gravim®	Filgrastim	Apotex	Neupogen®	Amgen	Accepted Feb. 2015
TX-01	Filgrastim	Texas BioPharma	Neupogen®	Amgen	Accepted Nov. 2018, CRL Sep. 2019, Resubmitted Nov. 2022, CRL May 2023
Asuor®	Filgrastim	Accord	Neupogen®	Amgen	Undisclosed filing date prior to Apr. 2024
MYS-10102	Insulin Aspart	Viatris/ Biogen	Novolog®	Novo Nordisk	Accepted 2021, CRL Jan. 2022, CRL Oct. 2023
Insulin-R	Insulin Human	Biogen	Humulin®/ E/Lily	Accordance/ Lilly/ Amgen, CRL Jan. 2023	

*Based on publicly available information: CRL = Complete Response Letter

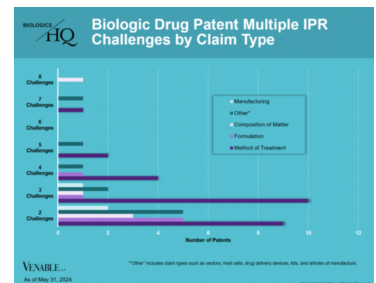
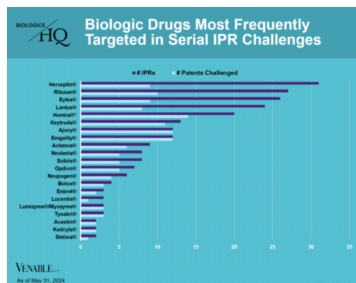
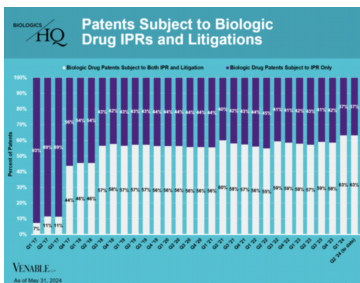
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As of May 31, 2024



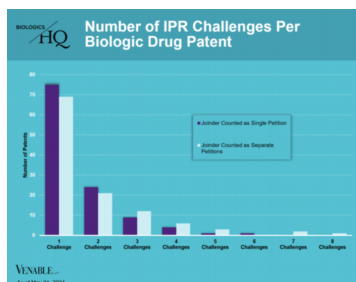
Patents Subject to Biologic Drug IPRs and Litigations

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 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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