

MONTHLY
INJECTION

August 9, 2024



LATEST NEWS



Implications of Loper Bright for FDA-Regulated Products

By: [Todd Harrison](#), [Claudia Lewis](#), [Justin Coen](#), and [Jeremiah Kelly](#)

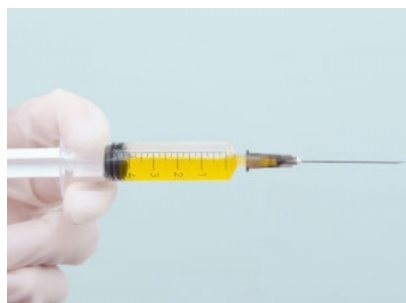
After the Supreme Court's reversal of the long-standing *Chevron* deference principle in *Loper Bright*, Venable's FDA Group offers some of its thoughts on the potential impact on the FDA.



FDA Approves Second Soliris® (eculizumab) Interchangeable Biosimilar – Samsung Bioepis's Epysqli® (eculizumab-aagh)

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

On July 19, 2024, the FDA approved the second biosimilar of [Alexion / AstraZeneca's Soliris® \(eculizumab\)](#), [Samsung Bioepis's Epysqli® \(eculizumab-aagh\)](#), approximately one year after [Samsung Bioepis](#) announced the FDA acceptance of its aBLA. [Epysqli®](#) was approved as an interchangeable.



Regeneron Dismisses IPR Appeals and Disclaims EYLEA® (afibercept) Patents

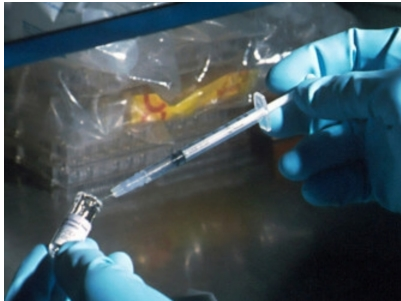
By: [Robert S. Schwartz, Ph.D.](#)

On July 8, 2024, [Regeneron](#), [Mylan](#), [Celltrion](#), and [Apotex](#) jointly stipulated to the dismissal of CAFC Appeal Nos. 23-1395 and 23-1396, appealing the

Final Written Decisions finding all challenged claims of U.S. Patent Nos. 9,254,338 and 9,669,069 unpatentable in [IPR2021-00880](#) (IPR2022-00257 and IPR2022-00301 joined) and [IPR2021-00881](#) (IPR2022-00258 and IPR2022-00298 joined). The patents recite method of treatment claims for the use of a VEGF antagonist such as [EYLEA® \(aflibercept\)](#) in angiogenic eye disorders.

On July 23, 2024, the PTAB granted [Regeneron's](#) request for adverse judgment after disclaiming the claims of U.S. Patent No. 11,253,572 challenged by [Samsung Bioepis](#) in IPR2023-00884 (and joined IPR2024-00260 ([Celltrion](#)) and IPR2024-00298 ([Biocon](#))). The patent also recited method of treatment claims using aflibercept to treat angiogenic eye disorders.

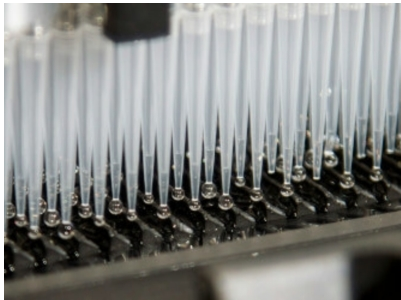
On July 30, 2024, the PTAB granted [Regeneron's](#) request for adverse judgment after disclaiming claims 10-12, 17-19, 21, 25-28, and 33 of U.S. Patent No. 10,888,601, challenged by [Samsung Bioepis](#) in IPR2023-00739 ([Biocon](#) IPR2024-00201 joined). Similar to the other patents, this patent recited method of treatment claims using aflibercept to treat angiogenic eye disorders.



[FDA Accepts Bio-Thera's aBLA for Proposed Stelara® \(ustekinumab\) Interchangeable BAT2206](#)

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

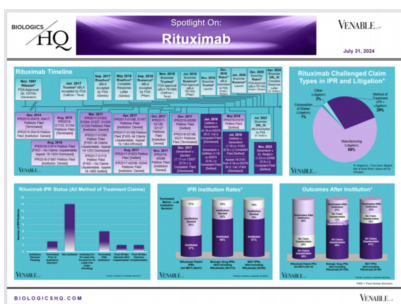
On July 24, 2024, [Bio-Thera Solutions](#) announced the FDA acceptance of its aBLA for [BAT2206 \(ustekinumab\)](#), a proposed biosimilar of [Janssen](#) and [Johnson & Johnson's Stelara® \(ustekinumab\)](#), with a request for interchangeability. This aBLA is the seventh publicly announced aBLA filing for a [Stelara®](#) biosimilar. There are currently no pending patent disputes related to BAT2206.



[Genzyme Files Complaint Against Sarepta Concerning Gene Therapy Elevidys®](#)

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

On July 26, 2024, [Genzyme](#) filed a complaint against [Sarepta Therapeutics](#) in the District of Delaware, Case No. 1:24-cv-00882 (D. Del.). In its complaint, [Genzyme](#) alleges that [Sarepta](#) infringed [Genzyme's](#) U.S. Patent Nos. 7,704,721 and 9,051,542 by making, using, offering for sale, and/or selling [Elevidys® \(delandistrogene moxeparvovec-rokl\)](#) in the U.S.



[Spotlight On: Actemra® \(tocilizumab\) / Tofidence™ \(tocilizumab-bavi\) / Tyenne® \(tocilizumab-aazg\)](#)

[Spotlight On: Neulasta® \(pegfilgrastim\) / Fulphila® \(pegfilgrastim-jmdb\) / Udenyca® \(pegfilgrastim-cbqv\) / Ziextenzo® \(pegfilgrastim-bmez\) / Nyvepria® \(pegfilgrastim-appg\) / Fylnetra™ \(pegfilgrastim-appg\) / 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 July 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 July 31, 2024.

[Read More News](#)

UPDATES

IPRs and PGRs

Eylea[®] (aflibercept):

- On July 8, 2024, **Regeneron**, **Mylan**, **Celltrion**, and **Apotex** stipulated to the voluntary dismissal of CAFC Appeal Nos. 23-1395 and 23-1396, appealing the Final Written Decisions finding all challenged claims of U.S. Patent Nos. 9,669,069 and 9,254,338 unpatentable in IPR2021-00880 (IPR2022-00257 and IPR2022-00301 joined) and IPR2021-00881 (IPR2022-00258 and IPR2022-00298 joined).

- On July 23, 2024, the PTAB granted **Regeneron's** request for adverse judgement after institution due to disclaimer of the challenged claims of U.S. Patent No. 11,253,572 challenged by **Samsung Bioepis** in IPR2023-00884 (IPR2024-00260 (**Celltrion**) and IPR2024-00298 (**Biocon**) joined).
- On July 30, 2024, the PTAB granted **Regeneron's** request for adverse judgement after institution due to disclaimer of the remaining claims (10-12, 17-19, 21, 25-28, and 33) of U.S. Patent No. 10,888,601 challenged by **Samsung Bioepis** in IPR2023-00739 (**Biocon** IPR2024-00201 joined). **Regeneron** previously disclaimed the other challenged claims (13-16, 20, 22-24, 29-32, and 46-47).

Keytruda[®] (pembrolizumab):

- On July 31, 2024, the PTAB denied The Johns Hopkins University's (JHU) request for rehearing of the decision instituting **Merck Sharp & Dohme's** IPR2024-00240 against JHU's U.S. Patent No. 11,591,393.
-

Litigations

Eylea[®] (aflibercept):

- On July 10, 2024, **Celltrion** filed CAFC Appeal No. 24-2058, appealing the preliminary injunction granted in Case No. 1:23-cv-00089 (N.D.W. Va.) / 1:24-cv-03103 (N.D.W. Va.). On July 31, 2024, **Celltrion** filed a second appeal, CAFC Appeal No. 24-2147, appealing the July 10, 2024 order setting the terms of the preliminary injunction.
- On July 16, 2024, **Samsung Bioepis** filed CAFC Appeal Nos. 24-2082 and 24-2083 appealing the July 10, 2024 orders setting the terms of the preliminary injunctions issued in Case Nos. 1:23-cv-00094 (N.D.W. Va.) and 1:23-cv-00106 (N.D.W. Va.) / 1:24-md-03103 (N.D.W. Va.).

Elevidys[®] (delandistrogene moxeparvovec-rokl):

- On July 26, 2024, **Genzyme** filed Case No. 1:24-cv-00882 (D. Del.) against **Sarepta**.

Soliris[®] (eculizumab):

- On July 29, 2024, in CAFC Case No. 24-1829, the Federal Circuit denied **Alexion's** motion for a temporary injunction pending the appeal of the District Court decision in Case No. 1:24-cv-00005 (D. Del.) to deny a motion for a preliminary injunction against the commercial launch of **Samsung Bioepis's Epysqli[®] (eculizumab-aagh)**.
-

aBLA Applications and FDA Activity

Epysqli[®] (eculizumab-aagh):

- On July 19, 2024, the FDA approved **Samsung Bioepis's Epysqli[®] (eculizumab-aagh)** as an interchangeable biosimilar of **Alexion's Soliris[®] (eculizumab)**.

BAT2206 (ustekinumab):

- On July 24, 2024, **Bio-Thera Solutions** announced the FDA acceptance of an aBLA, with a request for interchangeability, for **BAT2206 (ustekinumab)**, a proposed biosimilar of **Janssen / Johnson & Johnson's Stelara[®] (ustekinumab)**.
-

CDER Purple Book Updates

Kisunla[™] (donanemab-azbt):

- On July 2, 2024, the FDA approved **Eli Lilly's Kisunla[™] (donanemab-azbt)** for Alzheimer's disease.

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

Lytenava™ (bevacizumab):

- On July 8, 2024, **Outlook Therapeutics** announced the approval of **Lytenava™ (bevacizumab)**, the first biosimilar of **Genentech's Avastin® (bevacizumab)** approved for an on-label ophthalmic condition, the treatment of wet AMD, in the U.K.

Omlyclo® (CT-P39) (omalizumab):

- On July 9, 2024, **Celltrion** announced the approval of **Omlyclo® (omalizumab)**, a biosimilar of **Genentech's Xolair® (omalizumab)**, in the U.K.

Avzivi® (bevacizumab-tjnj):

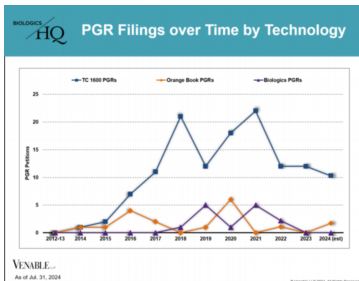
- On July 30, 2024, **Bio-Thera Solutions** announced the approval of **Avzivi® (bevacizumab-tjnj)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, in the E.U.

Steqeyma™ (CT-P43) (ustekinumab):

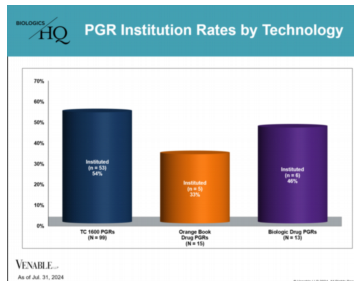
- On July 31, 2024, **Celltrion** announced the approval of **Steqeyma™ (ustekinumab)**, a biosimilar of **Janssen / Johnson & Johnson's Stelara® (ustekinumab)**, in Canada.

STATISTICS

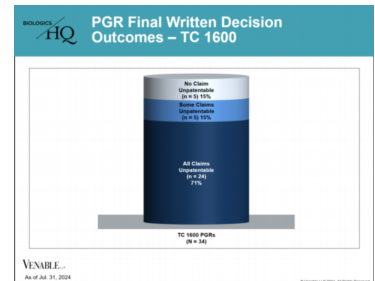
PGR Filings Over Time by Technology



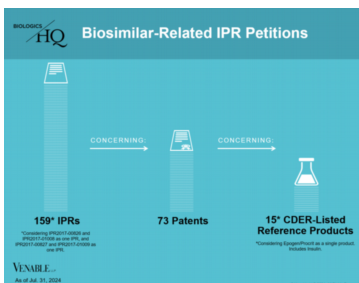
PGR Institution Rates by Technology



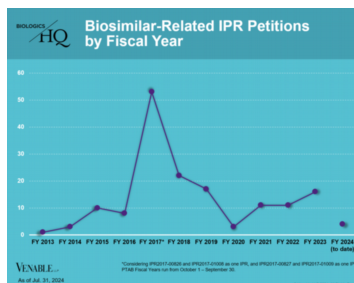
PGR Final Written Decision Outcomes – TC 1600



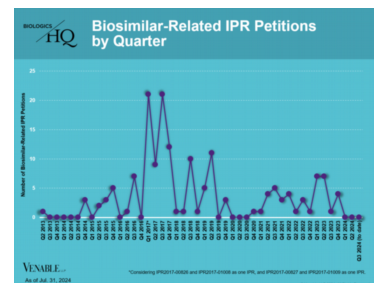
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



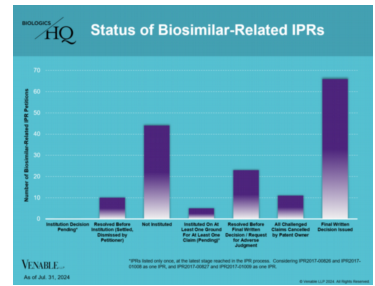
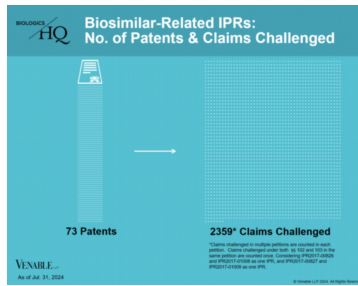
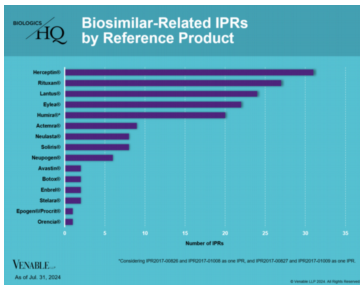
Biosimilar-Related IPR Petitions by Quarter



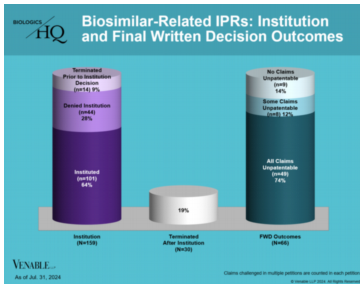
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPRs: Number of Patents and Claims Challenged

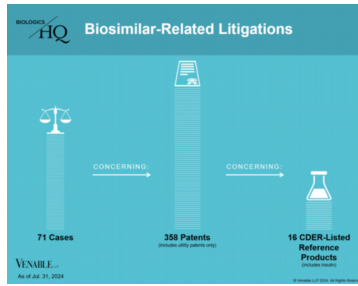
Status of Biosimilar-Related IPRs



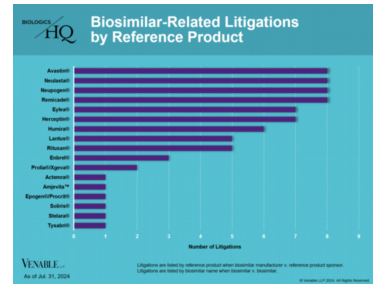
Biosimilar-Related Institution and Final Written Decision Outcomes



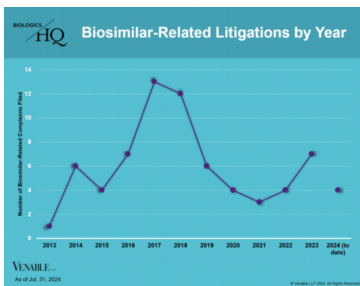
Biosimilar-Related Litigations



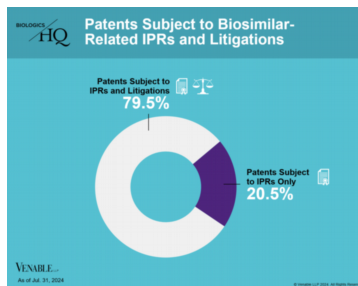
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



Biosimilars and Interchangeables Approved in the United States

Biosimilars and Interchangeables Approved in the United States

USDA No.	Reference Name	Biosimilar Name	USDA Status	Date of Approval	Reference Product	Biosimilar Product	U.S. Biologics License Date
USDA 791001	Humira®	Humira-biosimilars	Approved	Aug. 20, 2017	Humira®	Humira	Jul 2023
USDA 791008	Cytosol®	Adalimumab-adal	Approved	Apr. 30, 2024	Humira®	ABNVA	Jul 2023
USDA 791011	Humira®	Adalimumab-adal	Approved	Apr. 30, 2024	Humira®	ABNVA	Jul 2023
USDA 791009	Humira®	Adalimumab-biosimilars	Approved	Aug. 17, 2022	Humira®	ABNVA	Jul 2023
USDA 791118	Actemra®	Actemra-biosimilars	Approved	Nov. 15, 2019	Actemra®	ABNVA	Oct 2023
USDA 791154	Humira®	Adalimumab-agg	Approved	Jul. 6, 2023	Humira®	ABNVA	Jul 2023
USDA 791201	Humira®	Adalimumab-agg	Approved	Dec. 12, 2023	Humira®	ABNVA	Jul 2023
USDA 791210	Humira®	Adalimumab-agg	Approved	Dec. 12, 2023	Humira®	ABNVA	Jul 2023
USDA 791028	Humira®	Adalimumab-agg	Approved	Feb. 23, 2024	Humira®	ABNVA	May 2024

VENABLE
As of Jul. 31, 2024

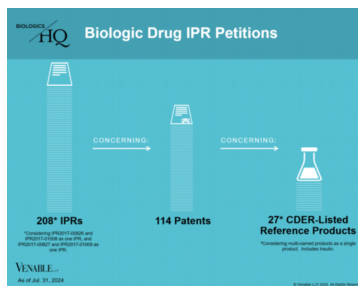
Biosimilar and Interchangeable Applications Pending in the United States

Biosimilar and Interchangeable Applications Pending in the United States*

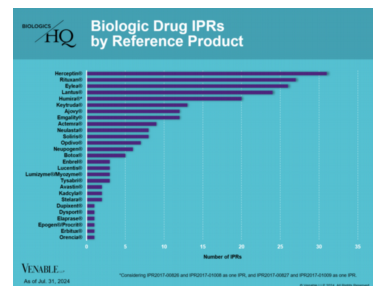
Biosimilar Name	Scientific Name	USDA Holder	Reference Product	Reference Product License Holder	FDA Status
EVK003	Abiraterone	Abiraterone	Abiraterone	Roche	Submitted Jun. 2023
FKS328	Biosimilars	Cartisro / Fulflex / Kymris	Avastin®	Genentech	Accepted Nov. 2019
388	Biosimilars	Genentech Biosimilars	Avastin®	Genentech	Accepted Nov. 2019
MYL14020	Biosimilars	Mylan Biosimilars	Avastin®	Genentech	Accepted Mar. 2020, CRN, Feb. 2022
CTP41	Denosumab	Cellgene	Prokin® / Agnos®	Amgen	Submitted Nov. 2023
FKS319	Denosumab	Freemove Kabi	Prokin® / Agnos®	Amgen	Submitted May 2024
GranHR	Figivatin	Aptalis	Neogenen®	Amgen	Accepted Feb. 2019
Accor	Figivatin	Accord	Neogenen®	Amgen	Underscored filing date prior to Jan. 2024
MYL16012	Insulin Aspart	Novo / Basoon	NovoRapid®	Novo Nordisk	Accepted 2021, CRN, Jan. 2022, CRN, Oct. 2023
Insulin-R	Insulin Human	Biosimilars	Humulin® R	Novo Nordisk	Accepted 2017, CRN, Oct. 2023
Lodopin®	Insulin Glargine	Novo	Lantus®	Sandoz America	Terminated Approval Jul. 2017, Marked as longer pending approval

VENABLE
As of Jul. 31, 2024

Biologic Drug IPR Petitions



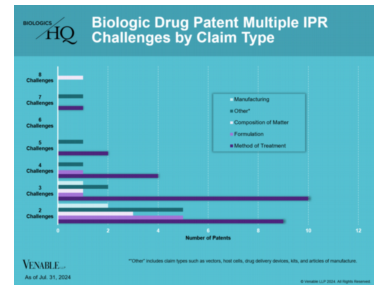
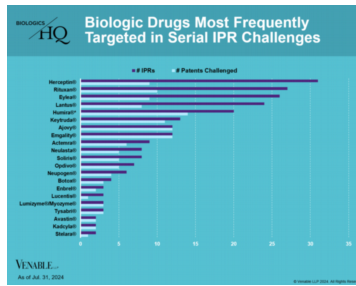
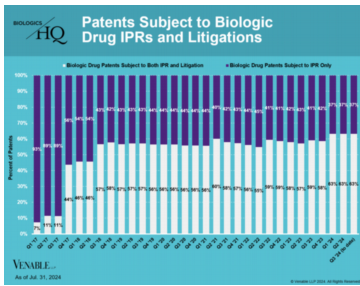
Biologic Drug IPRs by Reference Product



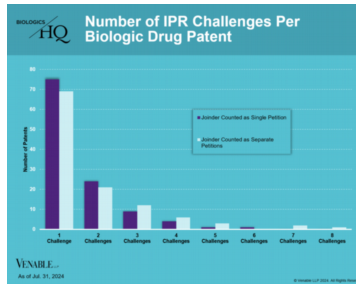
Patents Subject to Biologic Drug IPRs and Litigations

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 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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