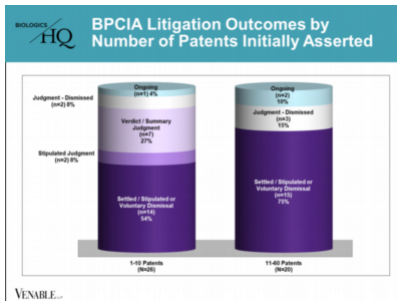




January 12, 2024



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- [First Humira Biosimilar Enters the U.S. Market](#)
- [What Do the Humira Biosimilar / Interchangeable Launches Mean for the Adalimumab Market?](#)
- [BPCIA Litigation Related to Proposed Eylea Biosimilar CT-P42 Filed](#)
- [EYLEA® \(afibercept\) IPR and BPCIA Litigation Updates](#)
- [New FDA Guidance Removes Interchangeability Statement from Product Labels](#)
- [First List of Drugs for Medicare Price Negotiations Published Includes Three Biologics](#)
- [Senators Tillis and Coons Reintroduce Patent Eligibility Reform Legislation](#)
- [PREVAIL Act Reforms at the PTAB](#)
- [PTAB Eliminates POP Review and Expands Director Review to Institution Decisions](#)



[Celltrion Completes Application for FDA Approval of CT-P41, Biosimilar of Prolia® / Xgeva®](#)

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

On November 30, 2023, [Celltrion](#) announced that it filed for an abbreviated Biologics License Application (aBLA) for FDA approval of [CT-P41 \(denosumab\)](#), a proposed biosimilar of [Amgen's Prolia® /](#)

Xgeva[®] (denosumab). There is currently another pending aBLA for a proposed biosimilar of Prolia[®] / Xgeva[®] from Sandoz for GP2411, which was accepted by the FDA in February 2023. A litigation involving GP2411 was filed in May 2023 and is currently pending. Amgen, Inc. et al v. Sandoz, Inc. et al, No. 1:23-cv-02406 (D.N.J.). No patent disputes related to Celltrion's CT-P41 have been filed yet.



EYLEA[®] (afibercept) and Soliris[®] (eculizumab) IPR and BPCIA Litigation Updates

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

On December 8, 2023, the PTAB instituted three of Samsung Bioepis's pending IPRs against Alexion's Soliris[®] (eculizumab), IPR2023-00933, IPR2023-00998, and IPR2023-00999. The challenged patents include composition of matter, formulation, and method of treatment claims.

On December 19 and 20, 2023, the PTAB instituted two additional IPRs by Samsung Bioepis against Alexion's Soliris[®] (eculizumab), IPR2023-01070 and IPR2023-01069. The challenged patents include method of treatment claims.

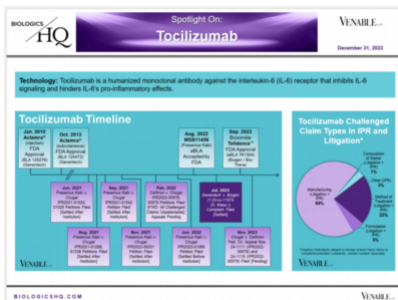
Samsung Bioepis has a pending aBLA for its Soliris[®] biosimilar candidate SB12.

The PTAB activity for EYLEA[®] (afibercept) from November (see EYLEA[®] (afibercept) IPR and BPCIA Litigation Updates) has continued into December, with the PTAB granting institution of Samsung Bioepis's IPR2023-01312 against Regeneron and its motion for joinder with Celltrion's IPR2023-00462 on December 8, 2023.

On December 14, 2023, Celltrion filed IPR2024-00260 along with a motion for joinder with Samsung Bioepis's IPR2023-00884, which was instituted in November. On December 18, 2023, Biocon Biologics, and the related parties in-interest Janssen, Johnson & Johnson, Viartis, Momenta, and Mylan, filed IPR2024-00298 along with a motion for joinder with the same Samsung Bioepis IPR2023-00884.

In the ongoing Northern district of West Virginia litigation (1:22-cv-00061), judgment against Mylan's proposed biosimilar M710 issued on December 27, 2023 after a bench trial. Also on December 27, 2023, Regeneron filed a second lawsuit against Samsung Bioepis, 1:23-cv-00106 (N.D.W. Va.).

Samsung Bioepis, Celltrion, and Biocon have filed aBLAs for their EYLEA[®] biosimilar candidates SB15, CT-P42, and M710 respectively.



Spotlight On: Actemra[®] (tocilizumab) / Tofidence[™] (tocilizumab-bavi)

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

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) / 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)

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[™]](#), and [MSB11456](#)), pegfilgrastim ([Neulasta[®]](#), [Fulphila[®]](#), [Udenyca[®]](#), [Ziextenzo[®]](#), [Nyvepria[®]](#), [Fylnetra[™]](#), [Stimufend[®]](#), [Lapelga[™]](#), and [Pegfilgrastim \(Lupin\)](#)), trastuzumab ([Herceptin[®]](#), [Ogivri[®]](#), [Herzuma[®]](#), [Ontruzant[®]](#), [Trazimera[®]](#), [Kanjinti[®]](#), [TX-05](#), [EG12014](#), and [HLX02](#)), rituximab ([Rituxan[®]](#), [Truxima[®]](#), [Ruxience[®]](#), and [Riabni[™]](#)), adalimumab ([Humira[®]](#), [Amjevita[™]](#), [Cyltezo[®]](#), [Hyrimoz[®]](#), [Hadlima[™]](#), [Abrilada[™]](#), [Hulio[®]](#), [Yusimry[™]](#), [Idacio[®]](#), [Yuflyma[®]](#), and [AVT02](#)), etanercept ([Enbrel[®]](#), [Erelzi[®]](#), and [Eticovo[®]](#)), and insulin glargine ([Lantus[®]](#) / [Lantus[®] SoloSTAR[®]](#), [Basaglar[®]](#), [Semglee[®]](#), and [Rezvoglar[™]](#)) have been updated with activity through December 31, 2023.

BiologicsHQ's "[Spotlight On Biosimilar Litigations](#)" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through December 31, 2023.

Read
More
News

UPDATES

IPRs and PGRs

Soliris[®] (eculizumab):

- On December 8, 2023, the PTAB granted institution of [Samsung Bioepis's](#) IPR2023-00933, IPR2023-00998 and IPR2023-00999 against [Alexion](#).
- On December 19, 2023, the PTAB granted institution of [Samsung Bioepis's](#) IPR2023-01070 against [Alexion](#).
- On December 20, 2023, the PTAB granted institution of [Samsung Bioepis's](#) IPR2023-01069 against [Alexion](#).

Eylea[®] (aflibercept):

- On December 8, 2023, the PTAB granted institution of [Samsung Bioepis's](#) IPR2023-01312 against [Regeneron](#) and granted its motion for joinder with [Celltrion's](#) IPR2023-00462.

- On December 14, 2023, **Celltrion** filed IPR2024-00260 against **Regeneron** along with a motion for joinder with **Samsung Bioepis's** IPR2023-00884.
- On December 18, 2023, **Biocon Biologics**, and the related parties in-interest **Janssen**, **Johnson & Johnson**, **Viartis**, **Momenta**, and **Mylan** filed IPR2024-00298 against **Regeneron** along with a motion for joinder with **Samsung Bioepis's** IPR2023-00884.

Litigations

Eylea® (afibercept):

- On December 27, 2023, the Court issued a sealed judgment in **Regeneron v. Mylan**, Case No. 1:22-cv-00061 (N.D.W. Va.), finding claims 4, 7, 9, 11, and 14-17 of U.S. Patent No. 11,084,865 valid and infringed, and claims 6 and 25 of U.S. Patent No. 11,253,572 patent and claims 11 and 19 of U.S. Patent No. 10,888,601 infringed, but invalid as obvious.
- On December 27, 2023, **Regeneron** filed a second lawsuit against **Samsung Bioepis**, 1:23-cv-00106 (N.D.W. Va.) related to its proposed biosimilar **SB15**.

aBLA Applications and FDA Activity

Avzivi® (bevacizumab-tjnj):

- On December 6, 2023, the FDA approved **Bio-Thera Solutions** and **Sandoz's Avzivi® (bevacizumab-tjnj)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**.

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

Ranopto® (ranibizumab):

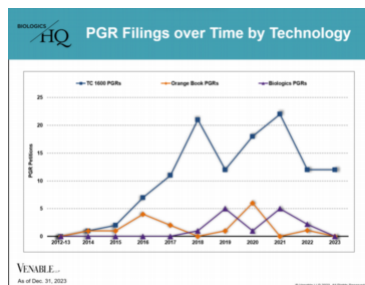
- On December 7, 2023, **Bioeq** and **Teva** announced the approval of **Ranopto® (ranibizumab)**, a biosimilar of **Genentech's Lucentis® (ranibizumab)**, in Canada.

Xelenka® (adalimumab):

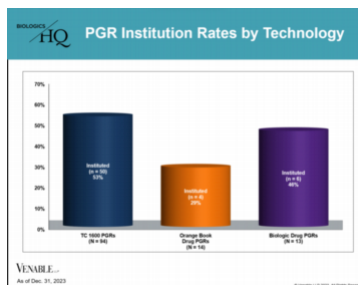
- On December 15, 2023, LG Chem announced the approval of **Xelenka® (adalimumab)**, a high-concentration biosimilar of **AbbVie's Humira® (adalimumab)**, in South Korea.

STATISTICS

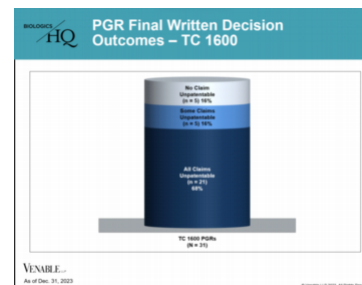
PGR Filings Over Time by Technology



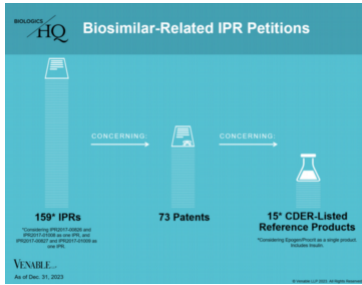
PGR Institution Rates by Technology



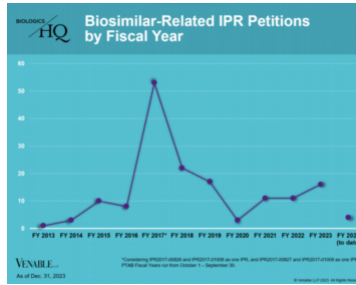
PGR Final Written Decision Outcomes – TC 1600



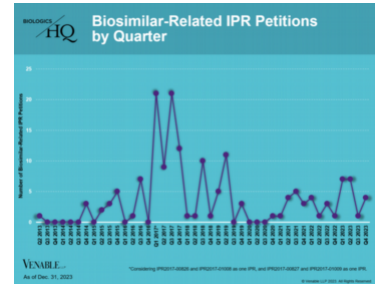
Biosimilar-Related IPR Petitions



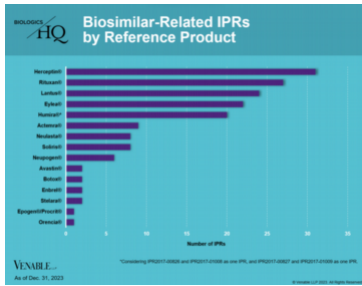
Biosimilar-Related IPR Petitions by Fiscal Year



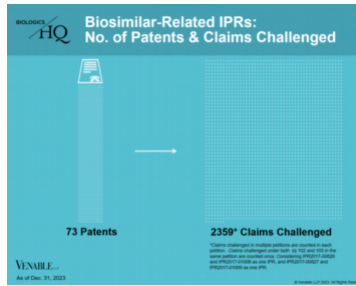
Biosimilar-Related IPR Petitions by Quarter



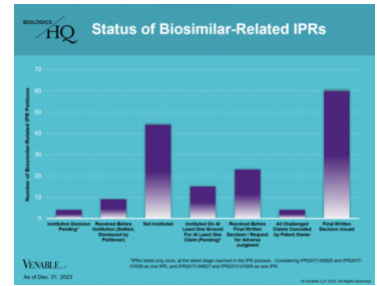
Biosimilar-Related IPRs by Reference Product



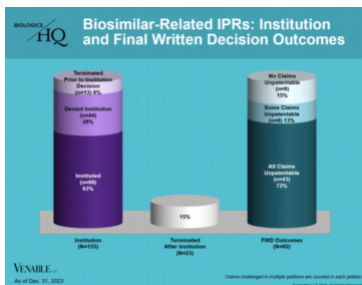
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



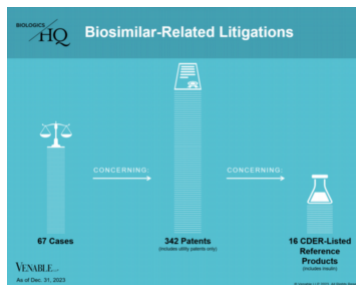
Status of Biosimilar-Related IPRs



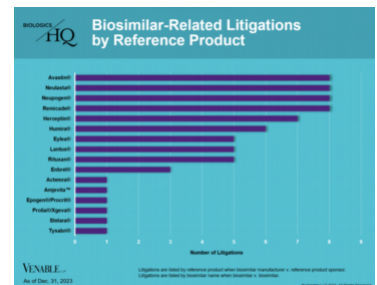
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



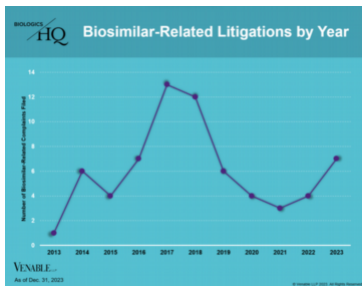
Biosimilar-Related Litigations



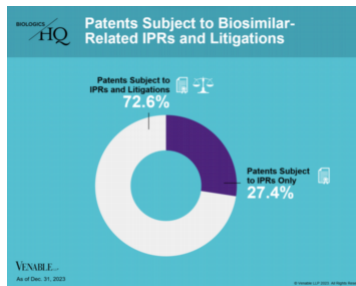
Biosimilar-Related Litigations by Reference Product



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 Product	Biosimilar Reference Product	USDA Holder	Date of Approval	Reference Product Status	USDA Status
USDA 191034	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191035	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191036	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191037	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191038	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191039	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191040	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191041	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191042	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191043	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191044	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191045	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191046	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191047	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191048	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191049	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191050	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191051	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191052	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191053	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191054	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191055	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191056	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191057	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191058	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191059	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191060	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191061	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191062	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191063	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191064	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191065	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191066	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191067	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191068	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191069	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN
USDA 191070	Avastin	Avastin-bio	Amgen	Aug. 22, 2012	Patent?	ABN

As of Dec. 31, 2023

Biosimilar and Interchangeable Applications

Biologic Drug IPR

Biologic Drug IPRs by Reference

Pending in the United States

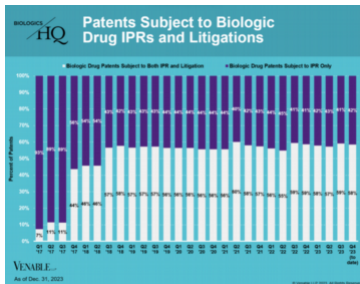
Biosimilar and Interchangeable Applications Pending in the United States*

Biosimilar Name	Reference Name	aBLA Holder	Reference Product	Reference Product Category	FDA Status
AT102	Abatacept	Abatacept	Humira®	AB01A	Accepted Nov. 2020, aBLA for Interchangeability Submitted Feb. 2022, CRLs Iss. 2022, Apr. 2023, and Jun. 2023, Resubmitted Feb. 2023
MF10	Abatacept	Merck	Humira®	Regeneron	Accepted Dec. 2021
PT9033	Abatacept	Abatacept	Humira®	Regeneron	Submitted Jan. 2023
CT192	Abatacept	Amgen/Volvo	Humira®	Regeneron	Submitted Jan. 2023
SB15	Abatacept	Sanofi/Baxter	Humira®	Regeneron	Unfiled/Not filed due prior to Nov. 2023
PR228	Enzalutamide	Novartis/Figini	Avastin®	Genentech	Accepted Nov. 2019
Q93	Enzalutamide	Novartis/Baxter	Avastin®	Genentech	Accepted Nov. 2019
MPL1420	Enzalutamide	Novartis/Baxter	Avastin®	Genentech	Accepted Mar. 2020, CRL, Feb. 2023
SP311	Enzalutamide	Baxter	Avastin®/Keytruda®	Amgen	Accepted Feb. 2023
CT141	Enzalutamide	Carlisle	Avastin®/Keytruda®	Amgen	Submitted Nov. 2023
Q9484®	Figalstatin	Aptalis	Neurosurge®	Amgen	Accepted Feb. 2015
TX-01	Figalstatin	Teva/Sunovion	Neurosurge®	Amgen	Accepted Nov. 2016, CRL, Dec. 2019, Resubmitted Nov. 2020, CRL, May 2021
MPL14010	Insulin Aspart	Novartis/Baxter	Novo Nordisk	Novo Nordisk	Accepted 2020, CRL, Jan. 2022, CRL Dec. 2023

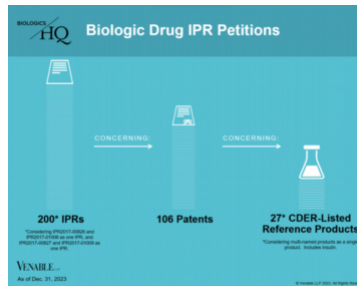
*Based on publicly available information. CRL = Complete Response Letter

VENABLE
As of Dec. 31, 2023

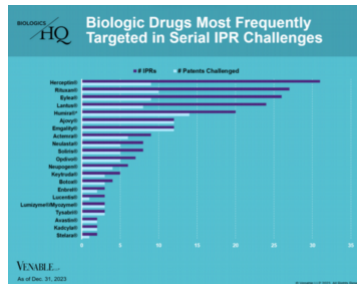
Patents Subject to Biologic Drug IPRs and Litigations



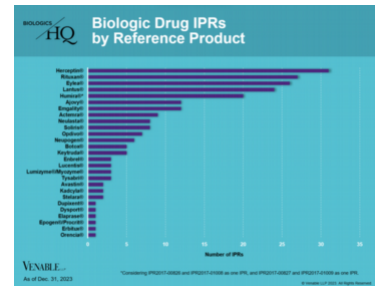
Petitions



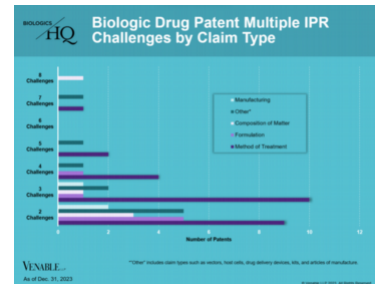
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



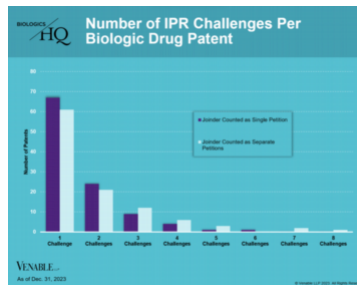
Product



Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent



BiologicsHQ Search

Information contained in the Venable 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.

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 | FLORIDA | ILLINOIS | MARYLAND | NEW YORK | VIRGINIA | WASHINGTON, DC

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