

MONTHLY
INJECTION

July 9, 2024



LATEST NEWS



Permanent Injunction Issued Preventing Launch of EYLEA[®] Biosimilar Yesafili[™]

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

On June 11, 2024, the Court in Case No. 1:22-cv-00061 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) issued a permanent injunction against the launch of Biocon and Mylan's Yesafili[™] (afibercept-jbvf), a recently approved interchangeable biosimilar of Regeneron's EYLEA[®] (afibercept).



PTAB Grants Institution of IPR Challenging The Johns Hopkins University Pembrolizumab Patent

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

On June 13, 2024, the PTAB granted institution of IPR2024-00240 that Merck filed in November 2023 challenging claims 1-42 of The Johns Hopkins University's U.S. Patent No. 11,591,393 ("the '393 patent") on anticipation and obviousness (35 U.S.C. §§ 102 and 103) grounds. The '393 patent is directed to treating cancer patients with high mutational burdens, such as microsatellite instable (MSI) cancer, by using anti-PD-1 antibodies, which includes pembrolizumab, sold by Merck under the trade name Keytruda[®].

PTAB Issues Final Written Decision Invalidating Regeneron's EYLEA[®] Patent (IPR2023-00442)

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



On June 14, 2024, the PTAB issued a [Final Written Decision in Samsung Bioepis's IPR2023-00442](#) determining that the challenged claims of [Regeneron's U.S. Patent No. 10,130,681](#) ("the '681 patent) that covers [EYLEA[®] \(aflibercept\)](#) are unpatentable as obvious. The '681 patent is directed to methods for treating angiogenic eye disorders by sequentially administering multiple doses of a vascular epithelial growth factor (VEGF) antagonist to a patient.



[FDA Revises Guidance on Switching Studies for Biosimilar Interchangeability](#)

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

On June 20, 2024, the FDA issued a draft guidance, "[Considerations for Demonstrating Interchangeability with a Reference Product: Update](#)" that revises the need for switching studies to demonstrate a biosimilar is interchangeable. The [initial guidance on interchangeability](#) was published in 2019, before the FDA had received and reviewed any applications for interchangeable biosimilars. The update is based on the FDA's experience gained in approving 13 interchangeable biosimilars and current scientific thinking and analytical assessment techniques.

Under the [updated draft guidance](#), instead of conducting a switching study "Applicants may choose to provide an assessment of why the comparative analytical and clinical data provided in the application or supplement support a showing that the switching standard set forth in section 351(k)(4)(B) of the PHS Act has been met."



[Preliminary Injunctions Issued Preventing Launch of EYLEA[®] Biosimilars](#)

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

In June 2024, the Court granted preliminary injunctions against the commercial launch of three [EYLEA[®] \(aflibercept\)](#) biosimilars, [Samsung Bioepis's Opuviz[™] \(aflibercept-yszy\)](#), [Formycon's Ahzantive[®] \(aflibercept-mrbb\)](#), and [Celltrion's CT-P42 \(aflibercept\)](#) (FDA-approval pending).

While the preliminary injunction orders for [Ahzantive[®]](#) and [CT-P42](#) currently remain sealed, on June 24, 2024, the Court unsealed portions of its preliminary injunction relating to [Opuviz[™]](#).

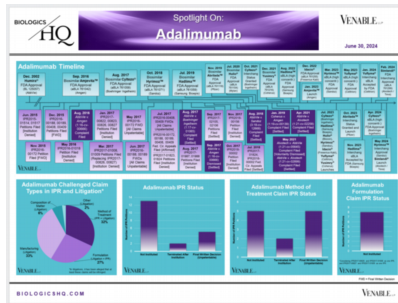


[FDA Approves Three Biosimilars – Ahzantive[®] \(aflibercept-mrbb\), Nypozi[™] \(filgrastim-txid\), and Pyzchiva[®] \(ustekinumab-ttwe\)](#)

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

On June 28, 2024, the FDA approved three new biosimilars, [Formycon and Klinge Biopharma's Ahzantive[®] \(aflibercept-mrbb\)](#), a biosimilar of [Regeneron's EYLEA[®] \(aflibercept\)](#); [Tanvex Biopharma's Nypozi[™] \(filgrastim-txid\)](#), a biosimilar of [Amgen's](#)

Neupogen[®] (filgrastim); and Samsung Bioepis and Sandoz's Pyzchiva[®] (ustekinumab-ttwe), an interchangeable biosimilar of Janssen / Johnson & Johnson's Stelara[®] (ustekinumab).



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 June 30, 2024.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through June 30, 2024.

UPDATES

IPRs and PGRs

Keytruda[®] (pembrolizumab):

- On June 13, 2024, the PTAB instituted **Merck Sharp & Dohme's** IPR2024-00240 against method of treatment claims of The John's Hopkins University's (JHU) U.S. Patent No. 11,591,393. On June 27, 2024, JHU filed a request for rehearing of the institution decision.

Eylea[®] (aflibercept):

- On June 14, 2024, the PTAB issued a Final Written Decision in **Samsung Bioepis's** IPR2023-00442 finding all challenged method of treatment claims of **Regeneron's** U.S. Patent No. 10,130,681 unpatentable.

Zynteglo[®] (betibeglogene autotemcel):

- On June 26 and 27, 2024, **bluebird bio** filed CAFC Appeal Nos. 24-2010 and 24-2016, appealing the Final Written Decisions in IPR2023-00070 and IPR2023-00074 finding the challenged claims of Sloan Kettering's U.S. Patent Nos. 7,541,179 and 8,058,062 are not unpatentable.

Litigations

Eylea[®] (aflibercept):

- On June 11, 2024, the Court entered a permanent injunction against the commercial launch of **Mylan / Biocon's Yesafili[™] (aflibercept-jbfv)** in Case No. 1:22-cv-00061 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.). On June 25, **Mylan / Biocon** filed CAFC Appeal No. 24-2002.
- On June 14, 2024, the Court granted a preliminary injunction against the launch of **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.) / MDL 1:24-md-03103 (N.D.W. Va.). On June 20, 2024, **Samsung Bioepis** filed CAFC Appeal Nos. 24-1965 and 24-1966.
- On June 21, 2024, the Court granted a preliminary injunction against the commercial launch of **Formycon's Ahzantive[®] (FYB203) (aflibercept-mrbb)** in Case No. 1:23-cv-00097 / MDL 1:24-md-03103 (N.D.W. Va.). On June 28, 2024, **Formycon** filed CAFC Appeal No. 24-2019.
- On June 28, 2024, the Court granted a preliminary injunction against the commercial launch of **Celltrion's** proposed biosimilar **CT-P42 (aflibercept)** in Case No. 1:23-cv-00089 / MDL 1:24-md-03103 (N.D.W. Va.).

Keytruda[®] (pembrolizumab):

- On June 29, 2024, the Court stayed **Merck Sharp & Dohme v. The Johns Hopkins University** Case No. 1:22-cv-03059 (D. Md.) pending the outcome of IPR2024-00240 that was instituted on June 13, 2024.

aBLA Applications and FDA Activity

Ahzantive[®] (aflibercept-mrbb):

- On June 28, 2024, the FDA approved **Formycon** and **Klinge Biopharma's Ahzantive[®] (afibercept-mrbb)**, a biosimilar of **Regeneron's Eylea[®] (afibercept)**.

Nypozi[™] (filgrastim-txid):

- On June 28, 2024, the FDA approved **Tanvex Biopharma's Nypozi[™] (filgrastim-txid)**, a biosimilar of **Amgen's Neupogen[®] (filgrastim)**.

Pyzchiva[®] (ustekinumab-ttwe):

- On June 28, 2024, 2024, the FDA approved **Samsung Bioepis** and **Sandoz's Pyzchiva[®] (ustekinumab-ttwe)** as an interchangeable biosimilar of **Janssen's Stelara[®] (ustekinumab)**.

CDER Purple Book Updates

PiaSky[™] (crovalimab-akkz):

- On June 20, 2024, the FDA approved **Genentech's PiaSky[™] (crovalimab-akkz)**.

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

Steqeyma[™] (CT-P43) (ustekinumab):

- On June 13, 2024, **Celltrion** announced the approval of **Steqeyma[™] (ustekinumab)**, a biosimilar of **Janssen's Stelara[®] (ustekinumab)**, in South Korea.

Tofidence[™] (tocilizumab-bavi):

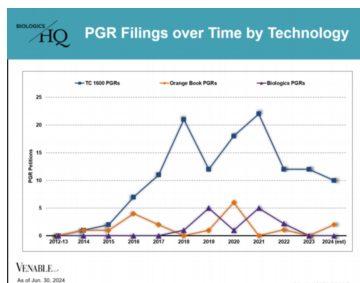
- On June 24, 2024, **Biogen** and **Bio-Thera** announced the approval of **Tofidence[™] (tocilizumab-bavi)**, a biosimilar of **Genentech's Actemra[®] (tocilizumab)**, in the E.U.

Omlyclo[®] (CT-P39) (omalizumab):

- On June 25, 2024, **Celltrion** announced the approval of **Omlyclo[®] (omalizumab)**, a biosimilar of **Genentech's Xolair[®] (omalizumab)**, in South Korea.

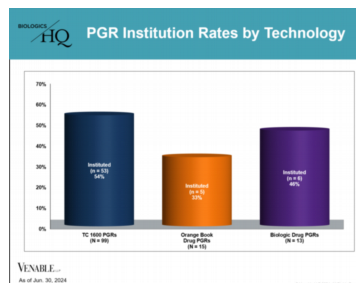
STATISTICS

PGR Filings Over Time by Technology



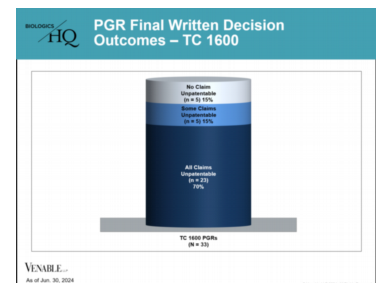
Biosimilar-Related IPR Petitions

PGR Institution Rates by Technology

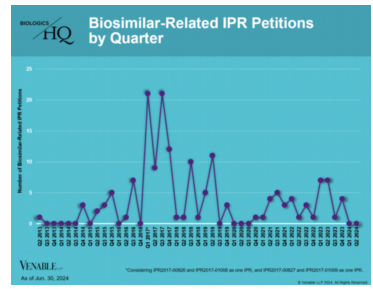
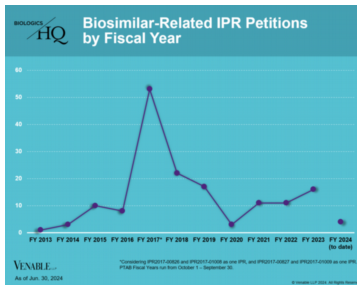
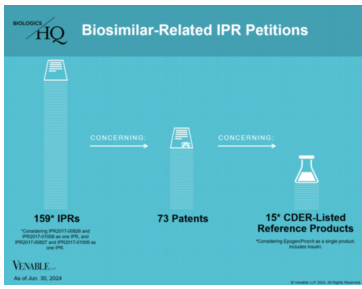


Biosimilar-Related IPR Petitions by Fiscal Year

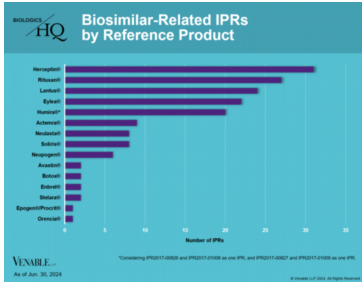
PGR Final Written Decision Outcomes – TC 1600



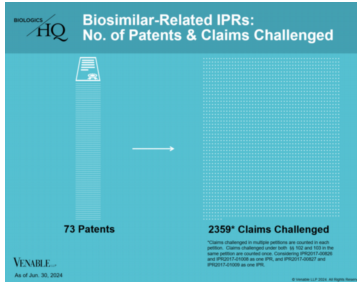
Biosimilar-Related IPR Petitions by Quarter



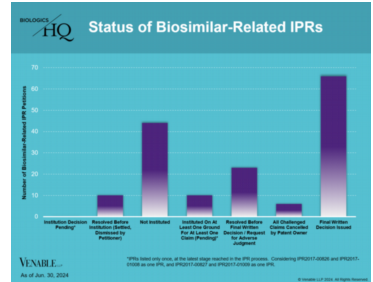
Biosimilar-Related IPRs by Reference Product



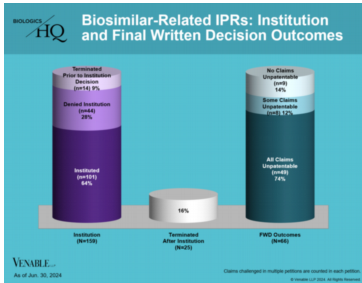
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



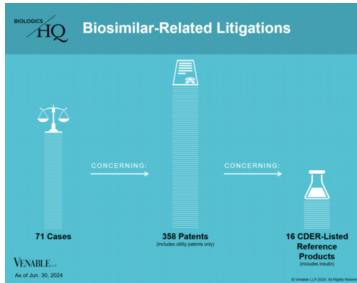
Status of Biosimilar-Related IPRs



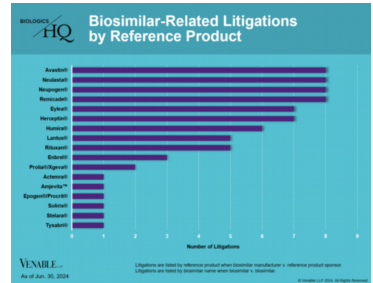
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



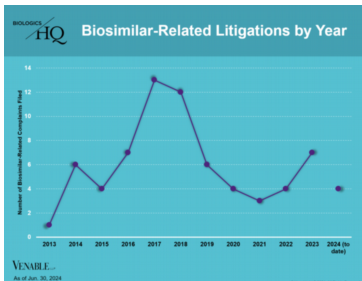
Biosimilar-Related Litigations



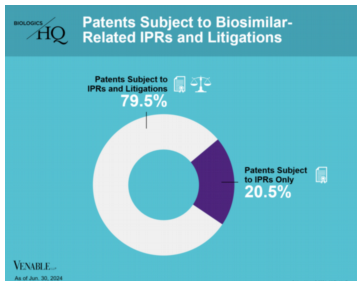
Biosimilar-Related Litigations by Reference Product



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

USLA No.	Reference Brand Name	Biosimilar/ Interchangeable Name	USLA Holder	Date of Biologics License	Reference Product	Reference Product LAJ	U.S. Reference Product Launch Date
USLA 710184	Humira®	Adalimumab-actem	Amgen	Aug. 29, 2017 Oct. 10, 2018 Apr. 30, 2024 (to date)	Humira®	ABBVIA	Jul. 2012
USLA 710185	Cytotec®	Adalimumab-actem	Boehringer Ingelheim	Humira®	ABBVIA	Jul. 2012	
USLA 710171	Humira®	Adalimumab-actem	Sandoz	Oct. 30, 2018 May 20, 2020 Mar. 11, 2024 (to date)	Humira®	ABBVIA	Jul. 2012
USLA 710188	Humira®	Adalimumab-actem	Samsung Biopharm	Aug. 17, 2022	Humira®	ABBVIA	Jul. 2012
USLA 710189	Humira®	Adalimumab-actem	Amgen	Nov. 18, 2018 Oct. 5, 2021	Humira®	ABBVIA	Oct. 2012
USLA 710184	Humira®	Adalimumab-actem	Mylan (Eli Lilly)	Jul. 6, 2020	Humira®	ABBVIA	Jul. 2012
USLA 710216	Humira®	Adalimumab-actem	Celastor	Dec. 17, 2023	Humira®	ABBVIA	Jul. 2012
USLA 710255	Humira®	Adalimumab-actem	Pharmacia Inc.	Dec. 15, 2023	Humira®	ABBVIA	Jul. 2012
USLA 710212	Humira®	Adalimumab-actem	Celastor	May 23, 2023	Humira®	ABBVIA	Jul. 2012
USLA 710269	Humira®	Adalimumab-actem	Alkermes Inc.	Feb. 23, 2024 (to date)	Humira®	ABBVIA	May 2024

VENABLE
As of Jan. 30, 2024

Biosimilar and Interchangeable Applications Pending in the United States

Biologic Drug IPR Petitions

Biologic Drug IPRs by Reference Product

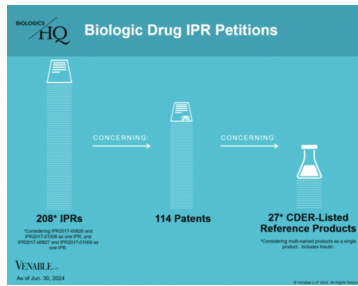
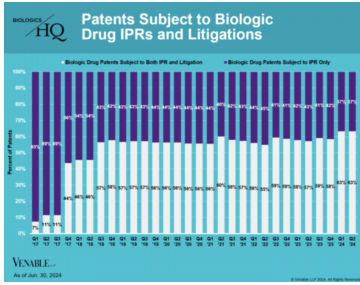
Biosimilar and Interchangeable Applications Pending in the United States*

Biosimilar Name	Scientific Name	aBLA Holder	Reference Product	Reference Product License Holder	FDA Status
FYB023	Atenolol	Avanco	Eliquis®	Regeneron	Submitted Jan. 2023
FYB026	Benzocaine	Corticeo / Fialin	Asustin®	Generon	Accepted Nov. 2019
888	Benzocaine	Samsung Biotech	Asustin®	Generon	Accepted Nov. 2019
MYL14020	Benzocaine	Mylan / Biocan	Asustin®	Generon	Accepted Mar. 2020, CRL Feb. 2023
CS141	Denosumab	Cellgene	Prograf®/Rapam®	Amgen	Submitted Nov. 2023
FYB016	Denosumab	Freemira Kabi	Prograf®/Rapam®	Amgen	Accepted May 2024
SB12	Eculizumab	Samsung Biotech	Sutab®	Astellas	Submitted Jul. 2023
Grasim®	Figiratinib	Academe	Neupogen®	Amgen	Accepted Feb. 2015
Accord®	Figiratinib	Accord	Neupogen®	Amgen	Underscored filing date prior to Apr. 2024
MYL16102	Insulin Aspart	Viatris / Biocan	Novolog®	Novo Nordisk	Accepted 2021, CRL Jan. 2022, CRL Oct. 2023
Insulin-R	Insulin Human	Biocan	Humulin® R	Eli Lilly	Accelerated data submission, CRL Oct. 2023
Levulin®/NovoR®	Insulin Glargine	Merck	Lantus®	Sandoz Aventis	Terminative Approval Jul. 2017, Merck US drug pending approval

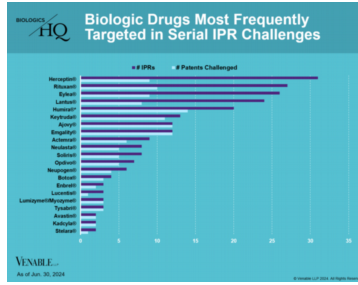
*Based on publicly available information. CRL = Complete Response Letter

VENABLE
As of Jan. 30, 2024

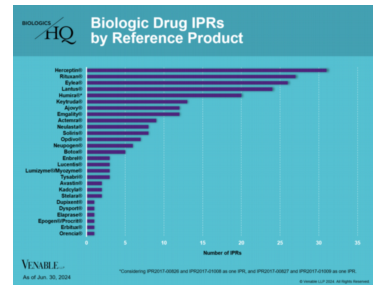
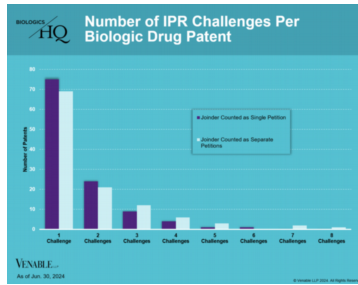
Patents Subject to Biologic Drug IPRs and Litigations



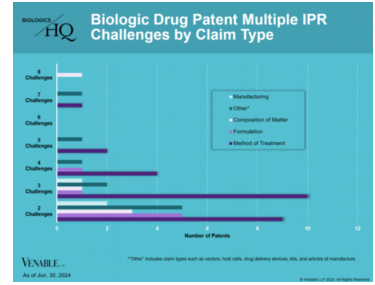
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Number of IPR Challenges Per Biologic Drug Patent



Biologic Drug Patent Multiple IPR Challenges by Claim Type



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 305(b)(2) activity, approved foreign biosimilars, IPRs and U.S. litigations.

Enter Keywords

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