

MONTHLY
INJECTION

October 11, 2024



LATEST NEWS



Preliminary Injunction Against Amgen’s EYLEA® Biosimilar Pavblu™ Denied

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

On September 23, 2024, [Regeneron’s](#) motion for a preliminary injunction against the commercial launch of [Amgen’s EYLEA® \(afibercept\)](#) biosimilar [Pavblu™ \(afibercept-ayyh\)](#) was denied in Case No. 1:24-cv-00039 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.). [Regeneron](#) filed CAFC Appeal No. 24-2351 on the same day the Order issued. On September 24, 2024, [Regeneron](#) filed a motion for a temporary injunction pending appeal. On September 25, 2024, the Federal Circuit issued a [temporary injunction](#) preventing [Pavblu™’s](#) launch while the Court considers the motion for injunction pending appeal.



Fresenius Kabi and Formycon Announce Approval of Stelara® Biosimilar Oltufi™ in the U.S. and E.U.

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

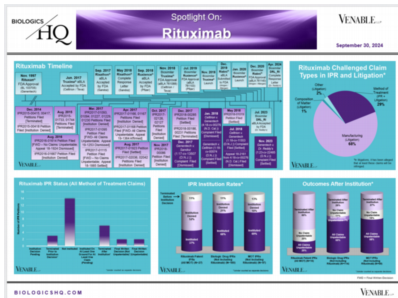
On September 27, 2024, the FDA approved a fourth biosimilar of [Janssen / Johnson & Johnson’s Stelara® \(ustekinumab\)](#): [Fresenius Kabi and Formycon’s Oltufi™ \(ustekinumab-aaaz\)](#). [Fresenius and Formycon](#) announced [Oltufi™’s](#) approval in the E.U. on the same day. [Oltufi™’s](#) FDA-approval follows [Amgen’s Wezlana™ \(ustekinumab-auub\)](#), approved as an interchangeable biosimilar in October 2023, [Alvotech and Teva’s Selarsdi™ \(ustekinumab-aekn\)](#), approved in April 2024, and [Samsung Bioepis and Sandoz’s Pyzchiva® \(ustekinumab-ttwe\)](#), approved as interchangeable in June 2024.

PTAB Grants Institution of Eight IPRs challenging The Johns Hopkins University Pembrolizumab Patents



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

Earlier this year, [Merck](#) requested *inter partes* review (“IPR”) of a number of patents owned by the Johns Hopkins University (“JHU”). The patents are directed to methods of treating cancers in patients with high mutational burdens, such as microsatellite instable (“MSI”) cancer, by using anti-PD-1 antibodies, which includes [pembrolizumab](#) that is sold by [Merck](#) under the trade name [Keytruda](#)[®]. Previously, we reported that in June 2024 the PTAB granted institution of one such IPR – IPR2024-00240 – concerning JHU’s U.S. Patent No. 11,591,393 (see [PTAB Grants Institution of IPR Challenging The Johns Hopkins University Pembrolizumab Patent](#)). The PTAB has now granted institution of all of the remaining IPRs filed by [Merck](#) based on similar grounds as the -00240 IPR, for both anticipation (35 U.S.C. § 102) and obviousness (35 U.S.C. § 103) challenges in each IPR.



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-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) / [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-yfng) / [Rezvoglar](#)[™] (insulin glargine-agrl)

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®, Riabni™ and DRL_RI), 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 September 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 September 30, 2024.

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More
News

UPDATES

IPRs and PGRs

Soliris® (eculizumab):

- On September 4, 2024, the PTAB terminated **Alexion** and **Samsung Bioepis's** IPR2023-00933 (U.S. Patent No. 9,732,149), IPR2023-00998 (U.S. Patent No. 9,718,880), IPR2023-00999 (U.S. Patent No. 9,725,504), IPR2023-01069 (U.S. Patent No. 10,590,189), and IPR2023-01070 (U.S. Patent No. 10,703,809) due to settlement after institution.

Eylea® (aflibercept) / Lucentis® (ranibizumab):

- On September 23, 2024, in CAFC Appeal No. 23-1334, the Federal Circuit affirmed the PTAB's finding that all challenged claims of **Novartis's** U.S. Patent No. 9,220,631 are unpatentable in **Regeneron's** IPR2021-00816.

Keytruda® (pembrolizumab):

- On September 23, 2024, the PTAB instituted **Merck's** IPRs against The John's Hopkin's University, including IPR2024-00622 (U.S. Patent No. 10,934,356), IPR2024-00623 (U.S. Patent No. 11,325,974), IPR2024-00624 (U.S. Patent No. 11,325,975), and IPR2024-00625 (U.S. Patent No. 11,339,219).
- On September 27, 2024, the PTAB instituted **Merck's** IPRs against The John's Hopkin's University, including IPR2024-00647 (U.S. Patent No. 11,649,287), IPR2024-00649 (U.S. Patent No. 11,629,187), and IPR2024-00650 (U.S. Patent No. 11,634,491).

Litigations

Soliris® (eculizumab):

- On September 3, 2024, the Court ordered **Alexion** and **Samsung Bioepis's** joint motion to voluntarily dismiss Case No. 1:24-cv-00005 (D. Del.) and terminated the case. On September 3, 2024, the Court ordered **Alexion** and **Samsung Bioepis's** joint motion to voluntarily dismiss the related CAFC Appeal No. 24-1829 appealing the preliminary injunction issued against the commercial launch of **Epysqli® (eculizumab-aagh)**.

Eylea® (aflibercept):

- On September 23, 2024, the Court denied **Regeneron's** motion for a preliminary injunction against **Amgen's** biosimilar **Pavblu™ (aflibercept-ayyh)** in Case No. 1:24-cv-00039 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.). On the same day, **Regeneron** filed CAFC Appeal No. 24-2351 appealing the denial, along with a motion for

an injunction pending appeal. On September 25, 2024, the Federal Circuit issued a temporary injunction while it considers the injunction pending appeal motion.

aBLA Applications and FDA Activity

Otulfi™ (ustekinumab-aaaz):

- On September 27, 2024, the FDA approved **Fresenius Kabi** and **Formycon's Otulfi™ (ustekinumab-aaaz)**, a biosimilar of **Janssen** and **Johnson & Johnson's Stelara® (ustekinumab)**.

CDER Purple Book Updates

Ebglyss™ (mosunetuzumab-axgb):

- On September 13, 2024, the FDA approved **Eli Lilly's Ebglyss™ (lebrikizumab-lbkz)**.

Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq):

- On September 13, 2024, the FDA approved **Genentech's Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq)**.

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

Tuznue™ (trastuzumab):

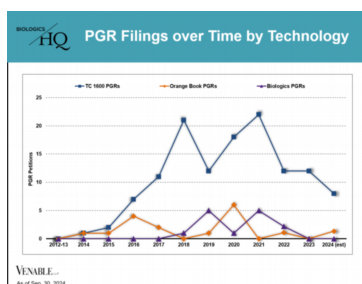
- On September 23, 2024, **Prestige BioPharma** announced the approval of **Tuznue™ (trastuzumab)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, in the E.U.

Otulfi™ (ustekinumab-aaaz):

- On September 27, 2024, **Fresenius Kabi** and **Formycon** announced the approval of **Otulfi™ (ustekinumab-aaaz)**, a biosimilar of **Janssen** and **Johnson & Johnson's Stelara® (ustekinumab)**, in the E.U.

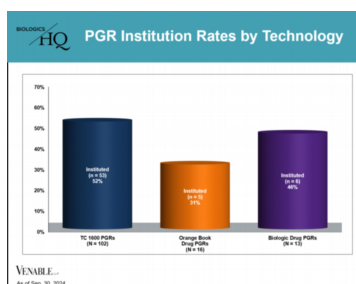
STATISTICS

PGR Filings Over Time by Technology



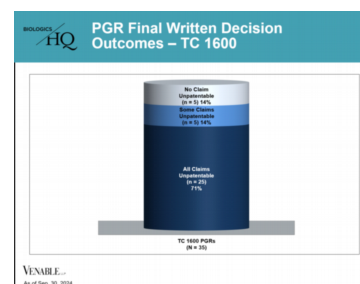
Biosimilar- Related IPR Petitions

PGR Institution Rates by Technology

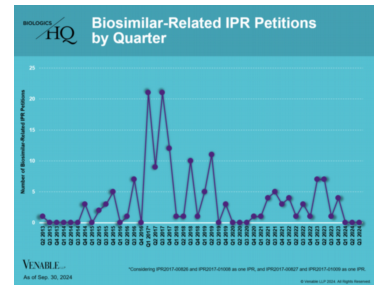
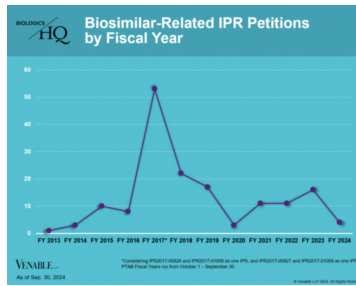
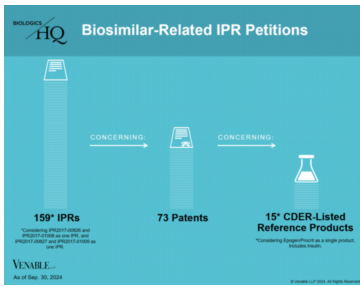


Biosimilar-Related IPR Petitions by Fiscal Year

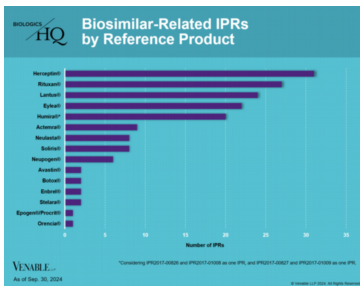
PGR Final Written Decision Outcomes – TC 1600



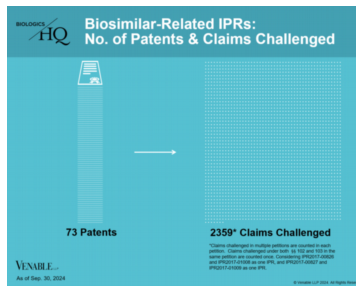
Biosimilar-Related IPR Petitions by Quarter



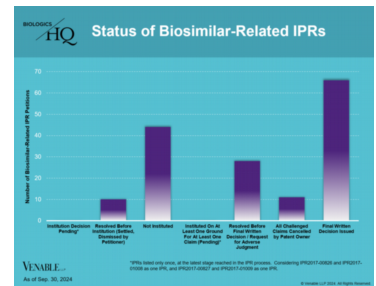
Biosimilar-Related IPRs by Reference Product



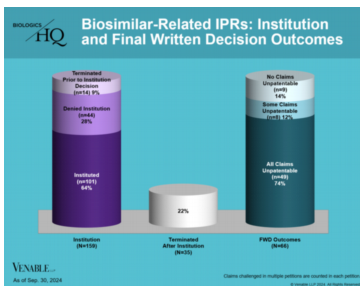
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



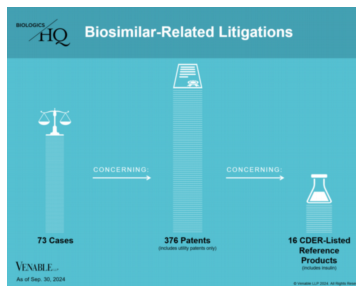
Status of Biosimilar-Related IPRs



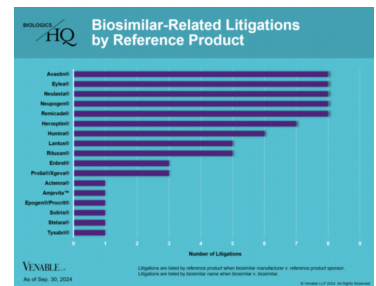
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



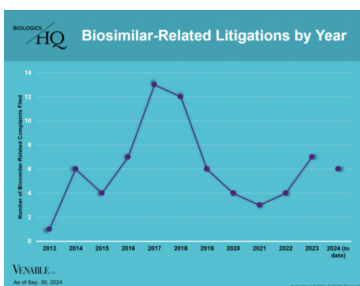
Biosimilar-Related Litigations



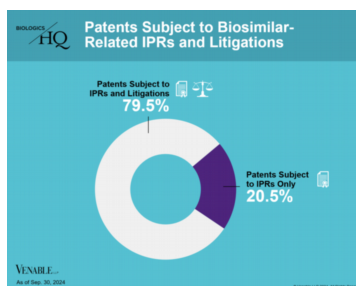
Biosimilar-Related Litigations by Reference Product



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

ANDA No.	Biosimilar Brand Name	Reference Product Name	ANDA Holder	Date of Approval	Reference Product First Approved	Reference Product First Approved	U.S. Marketing Launch Date
ANDA 791024	Amgen [®]	Abatacept [®]	Amgen	Dec. 23, 2019	Humira [®]	AbbVie	Jan. 2013
ANDA 791028	Cytel [®]	Adalimumab-actem	Boehringer Ingelheim	Aug. 22, 2017 Oct. 12, 2017 Apr. 30, 2020	Humira [®]	AbbVie	Jan. 2013
ANDA 791071	Hytrin [®]	Adalimumab-actem	Sandoz	Oct. 30, 2018 Apr. 23, 2021 Mar. 25, 2022	Humira [®]	AbbVie	Jan. 2013
ANDA 791039	Heldring [®]	Adalimumab-actem	Samsung Biopharma	Jul. 23, 2019 Apr. 17, 2020 Apr. 17, 2020	Humira [®]	AbbVie	Jan. 2013
ANDA 791118	Actavis [®]	Adalimumab-actem	Pfizer	May. 31, 2019 Feb. 2, 2023	Humira [®]	AbbVie	Jan. 2013
ANDA 791164	Hytrin [®]	Adalimumab-actem	Mylan / Bristol	Jan. 6, 2020	Humira [®]	AbbVie	Jan. 2013
ANDA 791216	Hytrin [®]	Adalimumab-actem	Celgene	Dec. 17, 2021	Humira [®]	AbbVie	Jan. 2013
ANDA 791202	Stantec [®]	Adalimumab-actem	Penentec	Dec. 13, 2022	Humira [®]	AbbVie	Jan. 2013
ANDA 791219	Tulyp [®]	Adalimumab-actem	Celltrion	Apr. 23, 2020	Humira [®]	AbbVie	Jan. 2013
ANDA 791289	Stantec [®]	Adalimumab-actem	Novartis / Teva	Nov. 14, 2023	Humira [®]	AbbVie	May 2014

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As of Sep. 30, 2024

Biosimilar and Interchangeable Applications Pending in the United States

Biologic Drug IPR Petitions

Biologic Drug IPRs by Reference Product

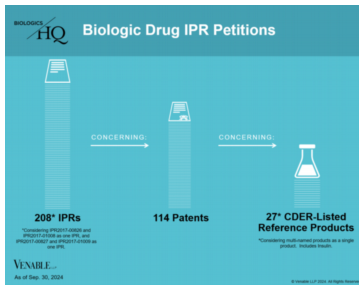
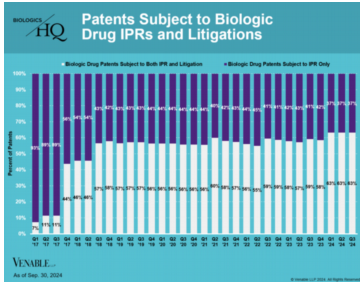
Biosimilar and Interchangeable Applications Pending in the United States*

Biosimilar Name	Scientific Name	aBLA Holder	Reference Product	Reference Product License Holder	FDA Status
CTP42	Atenolol	Celgene	Eltrop [®]	Regeneron	Submitted Jan. 2023
FK236	Benevolon	Celgene / Fujifilm Kyowa Kirin	Asustop [®]	Genentech	Accepted Nov. 2019
S88	Benevolon	Samsung Biologics	Asustop [®]	Genentech	Accepted Nov. 2019
MYL1402	Benevolon	Merck / Biogen	Asustop [®]	Genentech	Accepted Mar. 2020, CDL Feb. 2023
CT341	Denosumab	Celgene	Proton [®] / Xgep [®]	Amgen	Submitted Nov. 2023
FK216	Denosumab	Freemove Kabi	Proton [®] / Xgep [®]	Amgen	Accepted May 2024
S816	Denosumab	Samsung Biologics	Proton [®] / Xgep [®]	Amgen	Undisclosed filing date prior to Aug. 2024
Grasim [®]	Figivatin	Astellas	Neupogen [®]	Amgen	Accepted Feb. 2015
Accord	Figivatin	Astellas	Neupogen [®]	Amgen	Undisclosed filing date prior to Apr. 2024
MYL1610	Insulin Aspart	Viatris / Biogen	Novolog [®]	Novo Nordisk	Accepted 2021, CDL Jan. 2022, CDL Oct. 2023
Insulin-R	Insulin Human	Biogen	Humalog [®]	Eli Lilly	Acceptance date unknown, CDL Oct. 2023
Insulin [®] Novolog [®]	Insulin Glargine	Merck	Lantus [®]	Sandoz America	Terminated Approval Jul. 2017, Merck vs. Sandoz pending approval

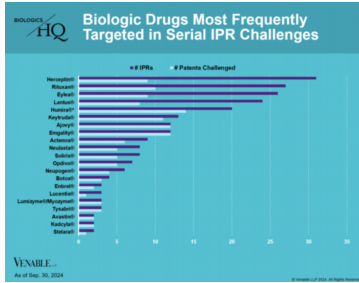
*Based on publicly available information CDL = Complete Response Letter

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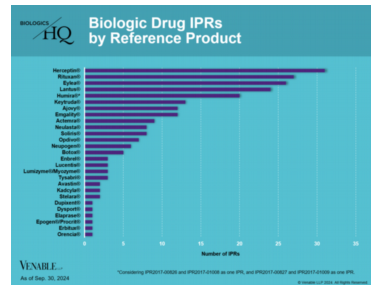
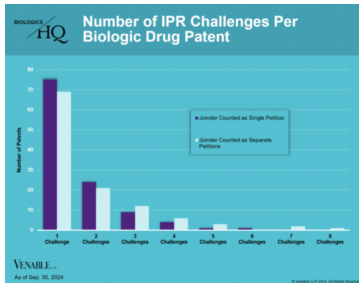
Patents Subject to Biologic Drug IPRs and Litigations



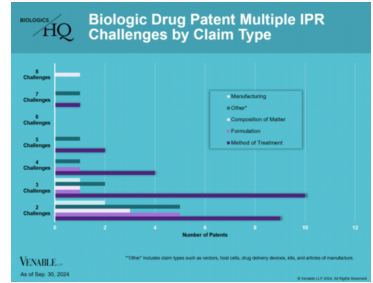
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



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.

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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

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