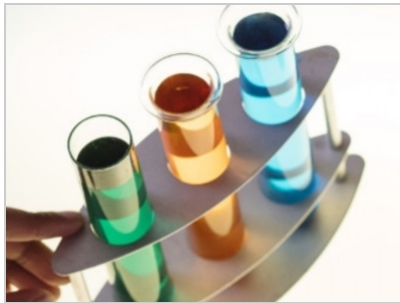


MONTHLY
INJECTION

October 10, 2023



LATEST NEWS

**New FDA Guidance Removes Interchangeability Statement from Product Labels**By: [Robert S. Schwartz, Ph.D.](#)

On September 18, 2023, the FDA issued a new draft guidance "[Labeling for Biosimilar and Interchangeable Biosimilar Products](#)," updating the previous labeling guidance "[Labeling for Biosimilar Products](#)" from July 2018. In the most recent guidance, the FDA changed its recommendation

of inclusion of an interchangeability statement in the labeling for interchangeable products rather than a biosimilarity statement. It now recommends both biosimilars and interchangeables include a biosimilarity statement, regardless of whether the product is a biosimilar or interchangeable.

**Complimentary Life Sciences Webinar Series**

We are excited to announce Venable's inaugural Life Sciences Webinar Series. This month-long series will explore the intricacies and latest developments that shape the life sciences industry. Join us as we hear from our seasoned attorneys across various practices who will share insights and provide a framework for navigating the relevant legal landscape.

Join us on Tuesday, October 17, 2023, from 1:00 p.m. - 2:00 p.m. ET for "[IPRs, PGRs, and the BPCIA.](#)"

This presentation will provide an update on PTAB challenges to biologics patents and their interplay with district court litigation. We will discuss recent IPR and PGR decisions, focusing on those most relevant to biologics patents. We will explore how challengers in the biologics space are using PTAB proceedings as a tool and how their use of PTAB proceedings has changed over time, compare outcomes at the PTAB vs. district courts, and look at how the Board and district courts are currently approaching parallel proceedings and motions to stay litigation pending IPRs or PGRs.

Speakers:



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

[Spotlight On: Neulasta[®] \(pegfilgrastim\) / Fulphila[®] \(pegfilgrastim-jmdb\) / Udenyca[®] \(pegfilgrastim-cbqv\) / Ziextenzo[®] \(pegfilgrastim-bmez\) / Nyvepria[®] \(pegfilgrastim-appg\) / Fylnetra[™] \(pegfilgrastim-appgf\) / 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 September 30, 2023.

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, 2023.

Read
More

UPDATES

IPRs and PGRs

Eylea[®] (afibercept):

- On September 1, 2023, the PTAB issued a decision denying institution in **Celltrion v. Regeneron** IPR2023-00620 because all challenged claims had been cancelled by **Regeneron**.

Ajovy[®] (fremanezumab-vfrm) / Emgality[®] (galcanezumab-gnlm):

- On September 25, 2023, the PTAB issued final written decisions in **Eli Lilly v. Teva** IPR2022-00738 and IPR2022-00739 finding all challenged claims unpatentable.
-

Litigations

Hemlibra[®] (emicizumab-kxwh):

- On September 20, 2023, the Federal Circuit affirmed the District Court's summary judgment of invalidity and found the District Court did not err by finding a lack of enablement in **Baxalta v. Chugai**, Appeal No. 22-1461, appealing Case No. 1:17-cv-00509 (D. Del.).

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

- On September 26, 2023, Federal Circuit Appeal No. 23-2424, appealing **Seagen v. Daiichi** Case No. 2:20-cv-00337 (E.D. Tex.), was filed by **Daiichi**.

Ajovy[®] (fremanezumab-vfrm) / Emgality[®] (galcanezumab-gnlm):

- On September 26, 2023, the Court granted judgment as a matter of law in **Teva v. Eli Lilly** Case No. 1:18-cv-12029 (D. Mass.), finding the asserted claims of U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908 invalid for lack of written description and enablement. At trial, the jury found the claims infringed. The parties previously stipulated to dismissal of all other challenged patents.
-

aBLA Applications and FDA Activity

Tofidence[™] (tocilizumab-bavi):

- On September 29, 2023, the FDA approved **Biogen** and **Bio-Thera's Tofidence[™] (tocilizumab-bavi)**, a biosimilar of **Genentech's Actemra[®] (tocilizumab)**.
-

CDER Purple Book Updates

Pombiliti[™] (cipaglucoisidase alfa-atga):

- On September 28, 2023 the FDA approved **Amicus Therapeutics' Pombiliti[™] (cipaglucoisidase alfa-atga)**.
-

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

Vegzelma[®] (bevacizumab-adcd):

- On September 4, 2023, **Celltrion** announced the approval of **Vegzelma[®] (bevacizumab-adcd)**, a biosimilar of **Genentech's Avastin[®] (bevacizumab)**, in Australia.

Tyenne[®] (tocilizumab):

- On September 19, 2023, **Fresenius Kabi** announced the approval of **Tyenne[®] (tocilizumab)**, a biosimilar of **Genentech's RoActemra[®] (tocilizumab)**, in the E.U.

Yesafili[®] (afibercept):

- On September 20, 2023, **Biocon Biologics** announced the approval of **Yesafili[®] (afibercept)**, a biosimilar of **Regeneron's Eylea[®] (afibercept)**, in the E.U.

Tyruko[®] (natalizumab-sztn):

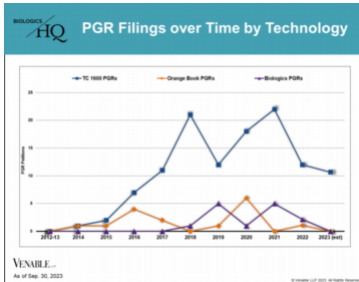
- On September 22, 2023, **Sandoz** and **Polpharma** announced approval of **Tyruko[®] (natalizumab-sztn)**, a biosimilar of **Biogen's Tysabri[®] (natalizumab)**, in the E.U.

AVT04 (ustekinumab):

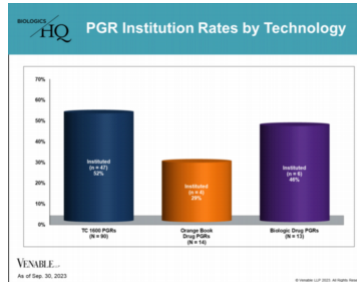
- On September 25, 2023, **Alvotech** and **Fuji Pharma** announced approval of **AVT04 (ustekinumab)**, a biosimilar of **Janssen's Stelara[®] (ustekinumab)**, in Japan.

STATISTICS

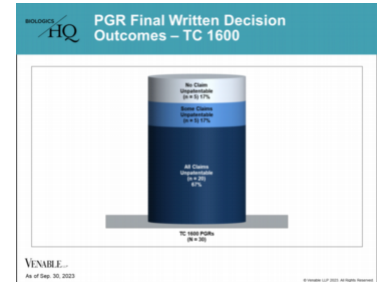
PGR Filings Over Time by Technology



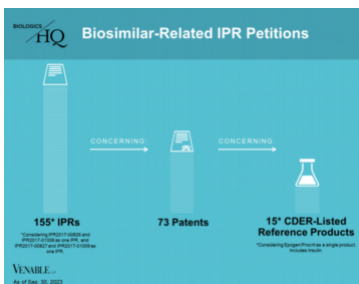
PGR Institution Rates by Technology



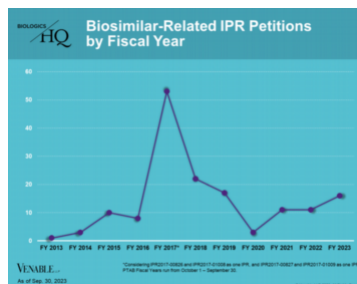
PGR Final Written Decision Outcomes – TC 1600



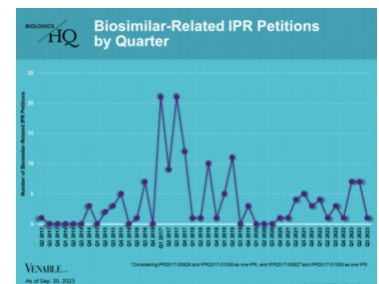
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



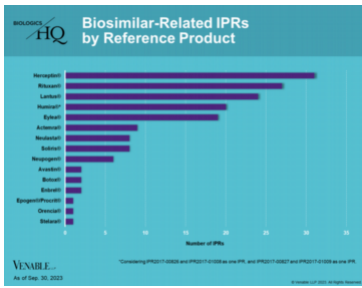
Biosimilar-Related IPR Petitions by Quarter



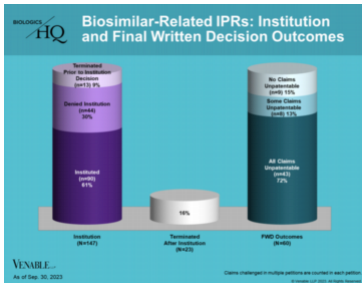
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPRs: Number of Patents and Claims Challenged

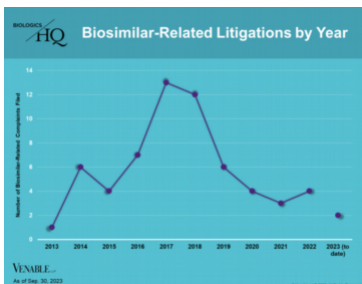
Status of Biosimilar-Related IPRs



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



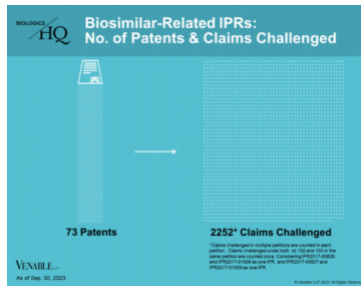
Biosimilar-Related Litigations by Year



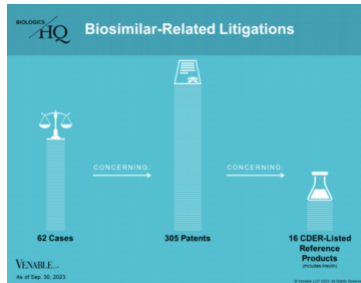
Biosimilar and Interchangeable Applications Pending in the United States

Biosimilar Name	Reference Name	ABX Active	Reference Product	Reference Product U.S. Approval	FDA Status
AV702	Adalimumab	Adalimumab	Humira®	Adilve	Approved Nov 2022; ABX for interchangeability accepted Feb 2023; CRL; Aug 2023; Apr 2023 and Jun 2023 Pre-emptive; Aug 2023 ABX for interchangeability; approved Feb 2023
Abravix™	Adalimumab-akx	Pflizer	Humira®	Adilve	ABX for interchangeability; approved Feb 2023
MT10	AbobotulinumtoxinA	Moderna	Eubea®	AbobotulinumtoxinA	Approved Dec 2021
FR0203	AbobotulinumtoxinA	Moderna	Eubea®	Regeneron	Submitted Jan 2023
OT142	AbobotulinumtoxinA	Regeneron	Eubea®	Regeneron	Submitted Jan 2023
FR0218	Brezovanolone	Cardinal Pharm	Avastin	Cardemstat	Submitted Nov 2018
SB0	Brevantolone	Samyang Biotech	Avastin	Cardemstat	Approved Nov 2018
ML13023	Brezovanolone	Moderna	Avastin	Cardemstat	Approved Nov 2018; CRL; Feb 2023
SM1108	Brezovanolone	Moderna	Avastin	Cardemstat	Approved Nov 2018
SP241	Dexamethasone	Sanofi	Previa® / Ignitor®	Angion	Approved Feb 2023
OS041™	Fligastin	Amgen	Neupogen®	Angion	Approved Feb 2015
TX-01	Fligastin	Teva BioPharma	Neupogen®	Angion	Approved Nov 2018; CRL; Sep 2018; Resubmitted Nov 2020; CRL; May 2021
ML1-16010	Insulin Aspart	Novo Nordisk	NovoRapid®	Novo Nordisk	Approved 2001; CRL; Jun 2022

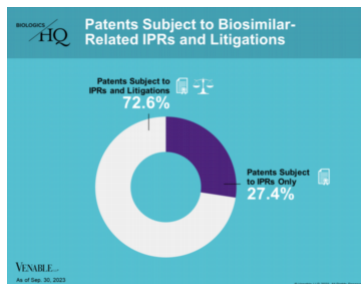
Patents Subject to Biologic Drug IPRs and Litigations



Biosimilar-Related Litigations



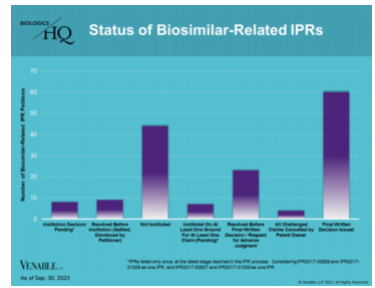
Patents Subject to Biosimilar-Related IPRs and Litigations



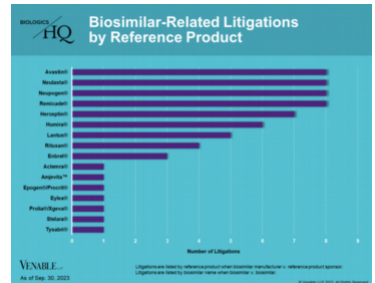
Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



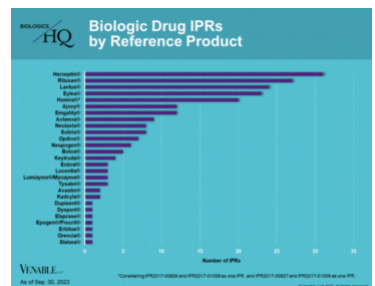
Biosimilar-Related Litigations by Reference Product



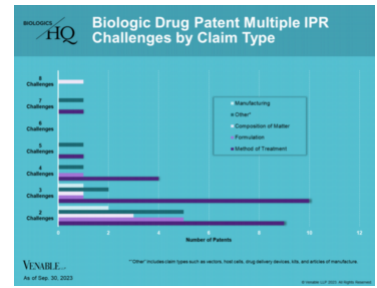
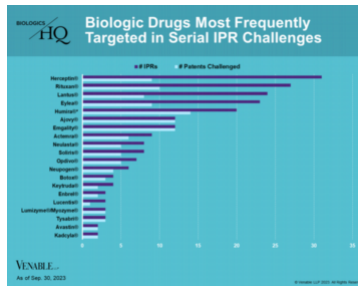
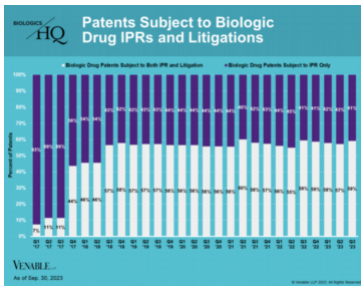
Biosimilars and Interchangeables Approved in the United States

ABX No.	Biosimilar Name	Reference Name	ABX Active	Date of U.S. Approval	Reference Product	Reference Product U.S. Approval	U.S. Approval Launch Date
ABX-11124	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Aug 22, 2021	Humira®	Adilve	Jul 2013
ABX-11018	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Aug 22, 2021	Humira®	Adilve	Jul 2013
ABX-11017	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11016	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11015	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11014	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11013	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11012	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11011	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11010	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11009	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11008	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11007	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11006	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11005	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11004	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11003	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11002	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11001	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013
ABX-11000	AbobotulinumtoxinA	AbobotulinumtoxinA	Humira®	Jul 14, 2021	Humira®	Adilve	Jul 2013

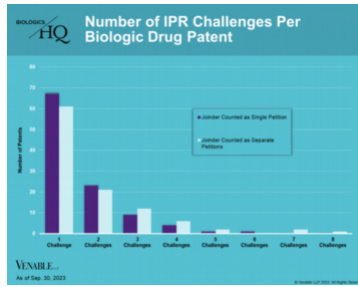
Biologic Drug IPRs by Reference Product



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

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