

MONTHLY  
INJECTION

December 11, 2024



LATEST NEWS



**Amgen Launches Pavblu™ as the First EYLEA® Biosimilar in the U.S.**

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

Amgen announced during its Q3 2024 Earnings Call that it had launched Pavblu™ (aflibercept-ayyh) as the first biosimilar of Regeneron's EYLEA® (aflibercept) to be marketed in the U.S. The launch follows the Federal Circuit's decision on October 22, 2024 (CAFC Appeal No. 24-2351) to deny a temporary injunction that would prevent Pavblu™ from launching at-risk while Regeneron appeals an earlier District Court (Case No. 1:24-cv-00039 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.)) denial of a preliminary injunction against Pavblu™ (previously reported Amgen Plans At-Risk Launch of EYLEA® Biosimilar Pavblu™ After Federal Circuit Lifts Temporary Injunction). The litigation and appeal remain ongoing.



**BPCIA Lawsuit Against Accord's Proposed Prolia® / Xgeva® Biosimilar Filed by Amgen**

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

On November 13, 2024, Amgen filed Case No. 5:24-cv-00642 (E.D.N.C.) against Accord BioPharma and Intas Pharmaceuticals, alleging INTP23, their proposed Prolia® / Xgeva® (denosumab) biosimilar, would infringe 34 of Amgen's patents. The patents asserted include two with composition claims, four with composition of matter claims, 32 with manufacturing claims, and one with claims directed to host cells.

**Biosimilar Updates: EYLEA® IPR Filings, Herceptin® Biosimilar Hercessi™ Launch, Stelara® Biosimilar Yesintek™ Approval**

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



## Two IPRs Filed Against Regeneron's EYLEA<sup>®</sup> (afibercept) Patent

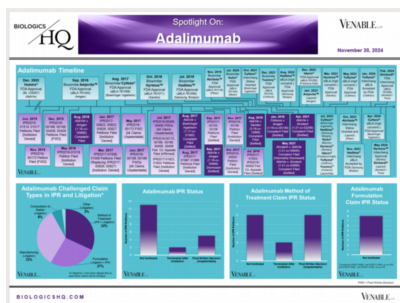
- On November 20, 2024, Samsung Bioepis filed IPR2025-00176 against Regeneron's U.S. Patent No. 11,084,865 ("the '865 patent"), challenging as obvious 48 claims (claims 1-12, 14-17, 19-20, 22-36, 39-42, 44-45, and 47-55) covering ophthalmic formulations of a vascular endothelial growth factor (VEGF) in vials and prefilled syringes. On December 2, 2024, Formycon filed IPR2025-00233 against the same patent, requesting joinder with Samsung Bioepis's petition if it is instituted.

## Herceptin<sup>®</sup> (trastuzumab) Biosimilar Hercessi<sup>™</sup> Launch Announced

- On November 29, 2024, Henlius announced that the first commercial shipment of Hercessi<sup>™</sup> (trastuzumab-strf), a biosimilar of Genentech's Herceptin<sup>®</sup> (trastuzumab), had been sent to the U.S.

## Sixth Stelara<sup>®</sup> (ustekinumab) Biosimilar Yesintek<sup>™</sup> Approved: Biocon's Yesintek<sup>™</sup>

- On November 29, 2024, the FDA approved Biocon's Yesintek<sup>™</sup> (ustekinumab-kfce) as the sixth biosimilar of Janssen / Johnson & Johnson's Stelara<sup>®</sup> (ustekinumab). Biocon previously settled with Janssen, agreeing to a launch date for Yesintek<sup>™</sup> as early as February 22, 2025 (previously reported Stelara<sup>®</sup> Biosimilar Updates: Settlement of IPR and FDA Review of Proposed Biosimilar).



## Spotlight On: Actemra<sup>®</sup> (tocilizumab) / Tofidence<sup>™</sup> (tocilizumab-bavi) / Tyenne<sup>®</sup> (tocilizumab-aazg)

## Spotlight On: Neulasta<sup>®</sup> (pegfilgrastim) / Fulphila<sup>®</sup> (pegfilgrastim-jmdb) / Udenyca<sup>®</sup> (pegfilgrastim-cbqv) / Ziextenzo<sup>®</sup> (pegfilgrastim-bmez) / Nyvepria<sup>®</sup> (pegfilgrastim-apgf) / Fylnetra<sup>™</sup> (pegfilgrastim-apgf) / Stimufend<sup>®</sup>

(pegfilgrastim-fpgk)

## Spotlight On: Herceptin<sup>®</sup> (trastuzumab) / Ogivri<sup>®</sup> (trastuzumab-dkst) / Herzuma<sup>®</sup> (trastuzumab-pkrb) / Ontruzant<sup>®</sup> (trastuzumab-dttb) / Trazimera<sup>®</sup> (trastuzumab-qyyp) / Kanjinti<sup>®</sup> (trastuzumab-anns) / Hercessi<sup>™</sup> (trastuzumab-strf)

## Spotlight On: Biosimilar Litigations

## Spotlight On: Rituxan<sup>®</sup> (rituximab) / Truxima<sup>®</sup> (rituximab-abbs) / Ruxience<sup>®</sup> (rituximab-pvvr) / Riabni<sup>™</sup> (rituximab-arrx)

## Spotlight On: Humira<sup>®</sup> (adalimumab) / Amjevita<sup>™</sup> (adalimumab-atto) / Cyltezo<sup>®</sup> (adalimumab-adbm) / Hyrimoz<sup>®</sup> (adalimumab-adaz) / Hadlima<sup>™</sup> (adalimumab-bwwd) / Abrilada<sup>™</sup> (adalimumab-afzb) / Hulio<sup>®</sup> (adalimumab-fkjp) / Yusimry<sup>™</sup> (adalimumab-aqvh) / Idacio<sup>®</sup> (adalimumab-aacf) / Yuflyma<sup>®</sup> (adalimumab-aaty) / Simlandi<sup>®</sup> (adalimumab-ryvk)

**Spotlight On: Enbrel<sup>®</sup> (etanercept) / Erelzi<sup>®</sup> (etanercept-szszs) / Eticovo<sup>®</sup> (etanercept-ykro)**

**Spotlight On: Lantus<sup>®</sup> / Lantus<sup>®</sup> SoloSTAR<sup>®</sup> (insulin glargine recombinant) / Basaglar<sup>®</sup> (insulin glargine) / Semglee<sup>®</sup> (insulin glargine-yfgn) / Rezvoglar<sup>™</sup> (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<sup>®</sup>, Tofidence<sup>™</sup>, Tyenne<sup>®</sup>, and CT-P47), pegfilgrastim (Neulasta<sup>®</sup>, Fulphila<sup>®</sup>, Udenyca<sup>®</sup>, Ziextenzo<sup>®</sup>, Nyvepria<sup>®</sup>, Fylnetra<sup>™</sup>, Stimufend<sup>®</sup>, Lapelga<sup>™</sup>, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin<sup>®</sup>, Ogivri<sup>®</sup>, Herzuma<sup>®</sup>, Ontruzant<sup>®</sup>, Trazimera<sup>®</sup>, Kanjinti<sup>®</sup>, Hercessi<sup>™</sup>, TX-05, and EG12014), rituximab (Rituxan<sup>®</sup>, Truxima<sup>®</sup>, Ruxience<sup>®</sup>, Riabni<sup>™</sup> and DRL RI), adalimumab (Humira<sup>®</sup>, Amjevita<sup>™</sup>, Cyltezo<sup>®</sup>, Hyrimoz<sup>®</sup>, Hadlima<sup>™</sup>, Abrilada<sup>™</sup>, Hulio<sup>®</sup>, Yusimry<sup>™</sup>, Idacio<sup>®</sup>, Yuflyma<sup>®</sup>, and Simlandi<sup>®</sup>), etanercept (Enbrel<sup>®</sup>, Erelzi<sup>®</sup>, and Eticovo<sup>®</sup>), and insulin glargine (Lantus<sup>®</sup> / Lantus<sup>®</sup> SoloSTAR<sup>®</sup>, Basaglar<sup>®</sup>, Semglee<sup>®</sup>, and Rezvoglar<sup>™</sup>) have been updated with activity through November 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 November 30, 2024.

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News

## UPDATES

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### IPRs and PGRs

**Eylea<sup>®</sup> (afibercept):**

- On November 20, 2024, Samsung Bioepis filed IPR2025-00176 Regeneron's U.S. Patent No. 11,084,865.
- 

### Litigations

**Prolia<sup>®</sup> / Xgeva<sup>®</sup> (denosumab):**

- On November 13, 2024, Amgen filed Case No. 5:24-cv-00642 (E.D.N.C.) against Accord and Intas's proposed biosimilar INTP23 (denosumab).

**Lucentis<sup>®</sup> (ranibizumab) / Eylea<sup>®</sup> (afibercept):**

- On November 13, 2024, the Court granted Novartis and Regeneron's stipulation of dismissal of Case No. 1:20-cv-00690 (N.D.N.Y.), after the claims of the sole asserted patent (U.S. Patent No. 9,220,631) were found unpatentable in IPR2021-00816.
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### aBLA Applications and FDA Activity

**Pavblu<sup>™</sup> (ABP 938) (afibercept-ayyh):**

- On its Q3 2024 Earnings Call, Amgen announced the launch of Pavblu<sup>™</sup> (afibercept-ayyh) as the first marketed biosimilar of Regeneron's Eylea<sup>®</sup> (afibercept) in the U.S.

### **INTP23 (denosumab):**

- A November 13, 2024 BPCIA litigation Complaint (Case No. 5:24-cv-00642 (E.D.N.C.)) noted that the FDA accepted **Accord** and **Intas's** aBLA for **INTP23 (denosumab)**, a proposed biosimilar of **Amgen's Prolia® / Xgeva® (denosumab)**, on an undisclosed date.

### **Hercessi™ (trastuzumab-strf):**

- On November 29, 2024, **Henlius** announced the commercial launch of **Hercessi™ (trastuzumab-strf)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**.

### **Yesintek™ (Bmab 1200) (ustekinumab-kfce):**

- On November 29, 2024, the FDA approved **Biocon's Yesintek™ (ustekinumab-kfce)** as a biosimilar of **Janssen / Johnson & Johnson's Stelara® (ustekinumab)**.

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## **CDER Purple Book Updates**

### **Auctazy!® (obecabtagene autoleucel):**

- On November 8, 2024, the FDA approved **Autolus's Auctazy!® (obecabtagene autoleucel)**.

### **Kebilidi® (eladocagene exuparvovec-tneq):**

- On November 13, 2024, the FDA approved **PTC Therapeutics' Kebilidi® (eladocagene exuparvovec-tneq)**.

### **Regenecyte™ (HPC, Cord Blood):**

- On November 20, 2024, the FDA approved **StemCyte's Regenecyte™ (HPC, Cord Blood)**.

### **Ziihera® (zanidatamab-hrii):**

- On November 20, 2024, the FDA approved **Jazz Pharmaceuticals' Ziihera® (zanidatamab-hrii)**.

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

### **Afqlir® (afibercept-abzy):**

- On November 15, 2024, **Sandoz** announced the approval of **Afqlir® (afibercept-abzy)**, a biosimilar of **Regeneron's Eylea® (afibercept)**, in the E.U.

### **Opuviz™ (afibercept-yszy):**

- On November 18, 2024, **Samsung Bioepis** and **Biogen** announced the approval of **Opuviz™ (afibercept-yszy)**, a biosimilar of **Regeneron's Eylea® (afibercept)**, in the E.U.

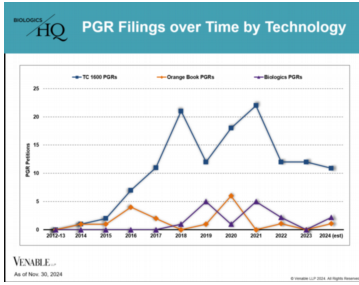
### **Stoboclo® / Osenvelt® (CT-P41) (denosumab):**

- On November 22, 2024, **Celltrion** announced the approval of **Stoboclo® / Osenvelt® (CT-P41) (denosumab)**, biosimilars of **Amgen's Prolia® / Xgeva® (denosumab)**, in South Korea.

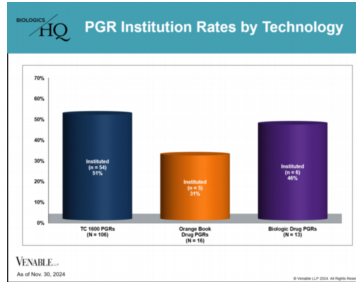
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## **STATISTICS**

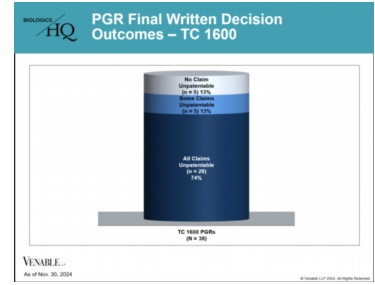
## PGR Filings Over Time by Technology



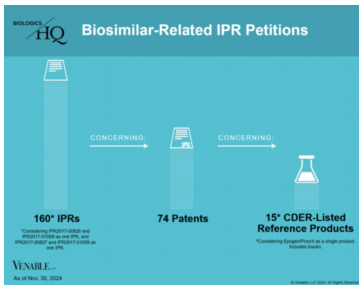
## PGR Institution Rates by Technology



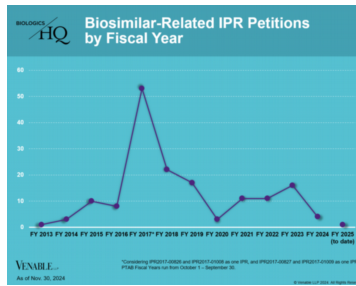
## PGR Final Written Decision Outcomes – TC 1600



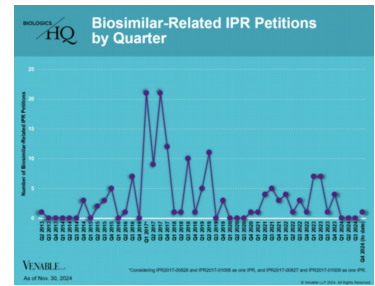
## Biosimilar-Related IPR Petitions



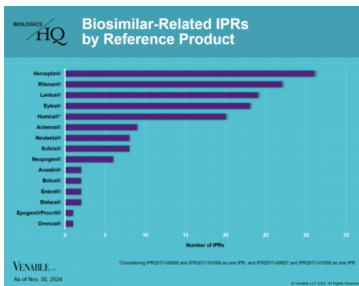
## Biosimilar-Related IPR Petitions by Fiscal Year



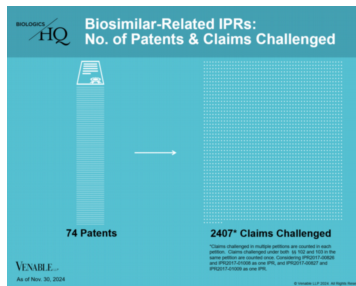
## Biosimilar-Related IPR Petitions by Quarter



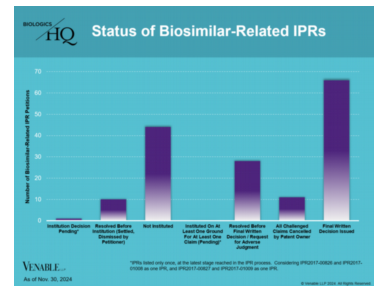
## Biosimilar-Related IPRs by Reference Product



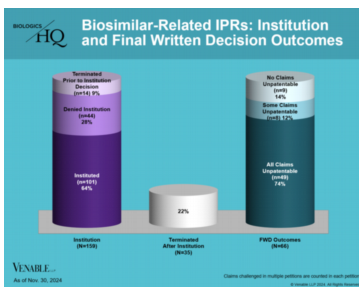
## Biosimilar-Related IPRs: Number of Patents and Claims Challenged



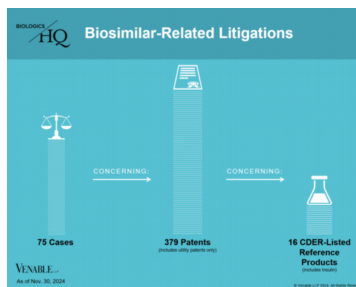
## Status of Biosimilar-Related IPRs



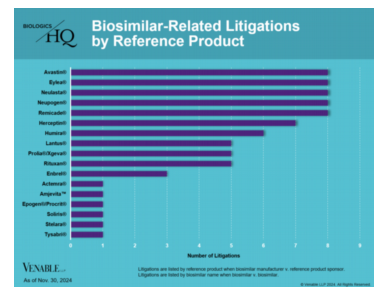
## Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



## Biosimilar-Related Litigations



## Biosimilar-Related Litigations by Reference Product

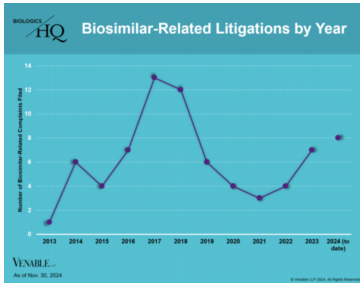


## Biosimilar-Related Litigations by Year

## Patents Subject to Biosimilar-Related IPRs and Litigations

## Biosimilars and Interchangeables Approved in the United States





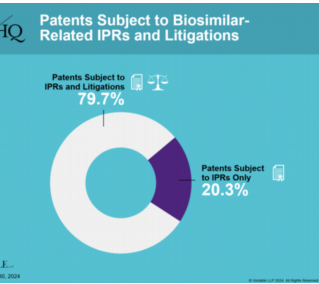
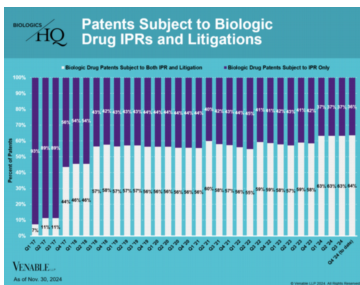
## Biosimilar and Interchangeable Applications Pending in the United States

### Biosimilar and Interchangeable Applications Pending in the United States\*

Biosimilar Name	Reference Product	U.S. Status	Reference Product	U.S. Status	FDA Status
CTCF42	Atenolol	Approved	Ezetimibe	Approved	Submitted Jun. 2023
FKS328	Brevinabant	Orphan Drug	Genentech	Approved Nov. 2019	Accepted Nov. 2019
888	Biosimilar	Orphan Drug	Genentech	Approved Nov. 2019	Accepted Nov. 2019
MPX1482C	Biosimilar	Orphan Drug	Genentech	Approved Mar. 2020, CRL Feb. 2023	Accepted Mar. 2020, CRL Feb. 2023
CTCF41	Biosimilar	Orphan Drug	Genentech	Approved Nov. 2023	Submitted Nov. 2023
FKS516	Biosimilar	Orphan Drug	Genentech	Approved May 2024	Accepted May 2024
SB19	Biosimilar	Orphan Drug	Genentech	Approved Aug. 2024	Submitted Aug. 2024
TB505P	Biosimilar	Orphan Drug	Genentech	Approved Oct. 2024	Submitted Oct. 2024
14314	Biosimilar	Orphan Drug	Genentech	Approved Oct. 2024	Submitted Oct. 2024
INTF23	Biosimilar	Orphan Drug	Genentech	Approved Feb. 2025	Submitted Feb. 2025
Orasmet	Figivatin	Approved	Neovigam	Approved Feb. 2019	Submitted Feb. 2019
Accur	Figivatin	Approved	Neovigam	Approved Jan. 2024	Submitted Jan. 2024
MPX1981D	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthR	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthG	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthA	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthB	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthC	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthD	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthE	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthF	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthG	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthH	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthI	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthJ	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthK	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthL	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthM	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthN	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthO	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthP	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthQ	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthR	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthS	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthT	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthU	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthV	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthW	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthX	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthY	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023
HealthZ	Health Aspect	Orphan Drug	Novartis	Approved Oct. 2023, CRL Oct. 2023	Accepted Oct. 2023, CRL Oct. 2023

**VENABLE**  
As of Nov. 30, 2024

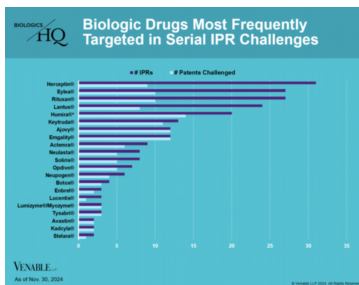
## Patents Subject to Biologic Drug IPRs and Litigations



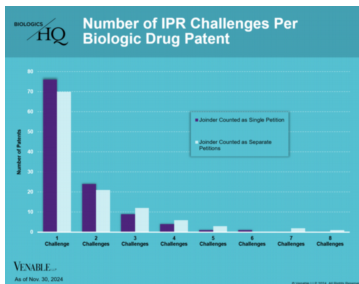
## Biologic Drug IPR Petitions



## Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



## Number of IPR Challenges Per Biologic Drug Patent

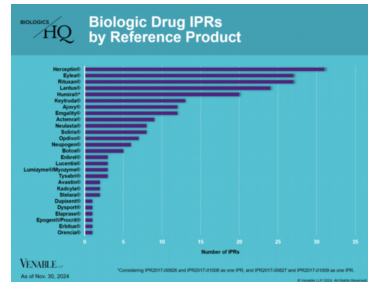


### Biosimilars and Interchangeables Approved in the United States

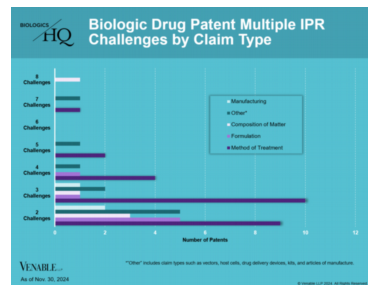
BLA No.	Reference Product	Biosimilar Name	U.S. Status	Reference Product	U.S. Status	U.S. Reference Product	U.S. Reference Product
BLA 71024	Amoxicillin	Amoxicillin	Approved	Amoxicillin	Approved	Amoxicillin	Amoxicillin
BLA 71028	Cytotec	Adalimumab-act	Approved	Adalimumab-act	Approved	Adalimumab-act	Adalimumab-act
BLA 71031	Humira	Adalimumab-act	Approved	Adalimumab-act	Approved	Adalimumab-act	Adalimumab-act
BLA 71038	Humira	Adalimumab-act	Approved	Adalimumab-act	Approved	Adalimumab-act	Adalimumab-act
BLA 71118	Humira	Adalimumab-act	Approved	Adalimumab-act	Approved	Adalimumab-act	Adalimumab-act
BLA 71124	Humira	Adalimumab-act	Approved	Adalimumab-act	Approved	Adalimumab-act	Adalimumab-act
BLA 71253	Humira	Adalimumab-act	Approved	Adalimumab-act	Approved	Adalimumab-act	Adalimumab-act
BLA 71252	Humira	Adalimumab-act	Approved	Adalimumab-act	Approved	Adalimumab-act	Adalimumab-act
BLA 71259	Humira	Adalimumab-act	Approved	Adalimumab-act	Approved	Adalimumab-act	Adalimumab-act

**VENABLE**  
As of Nov. 30, 2024

## Biologic Drug IPRs by Reference Product



## 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 505(b)(2) activity, approved foreign biosimilars, IPRs and U.S. Litigations.

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