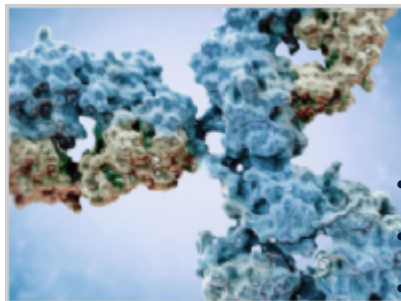


MONTHLY
INJECTION

January 10, 2023



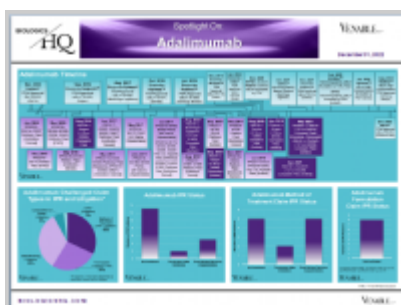
LATEST NEWS



Most Read BiologicsHQ News in 2022

In case you missed them, catch up on the BiologicsHQ most read news articles in 2022:

- [A Survey of PGR Outcomes](#)
- [Biosimilars Approved in the EU are Considered Interchangeable](#)
- [PTAB Director Review Updates](#)
- [First Interchangeable FDA Approval without a Switching Study](#)
- [The Trouble With IP for Digital Health and Precision Medicine](#)
- [Senator Mike Lee Introduces the Biosimilar Red Tape Elimination Act to Eliminate Switching Study Requirement for Biosimilar Interchangeability](#)



[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® \(adalimumab-aacf\)](#)

[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 pegfilgrastim ([Neulasta®](#), [Fulphila®](#), [Udenyca®](#), [Ziextenzo®](#), [Nyvepria®](#), [Fylnetra™](#), [Stimufend®](#), [Lapelga™](#), and [Pegfilgrastim \(Lupin\)](#)), trastuzumab ([Herceptin®](#), [Ogivri®](#), [Herzuma®](#), [Ontruzant®](#), [Trazimera®](#), [Kanjinti®](#), [TX-05](#), and [EG12014](#)), rituximab ([Rituxan®](#), [Truxima®](#), [Ruxience®](#), and [Riabni™](#)), adalimumab ([Humira®](#), [Amjevita™](#), [Cyltezo®](#), [Hyrimoz™](#), [Hadlima™](#), [Abrilada™](#), [Hulio®](#), [Yusimry™](#), [Idacio®](#), [AVT02](#), and [Yuflyma®](#)), etanercept ([Enbrel®](#), [Erelzi®](#), and [Eticovo®](#)), and insulin glargine ([Lantus® / Lantus® SoloSTAR®](#), [Basaglar®](#), [Semglee®](#), and [Rezvoglar™](#)) have been updated with activity through December 31, 2022.

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, 2022.

Read
More
News

UPDATES

IPRs and PGRs

[Skyrizi® \(risankizumab-rzaa\)](#):

- On December 7, 2022, [Sandoz](#) requested rehearing of the PTAB's decision denying institution in PGR2022-00037 against [Boehringer Ingelheim](#).

[Eylea® \(aflibercept\) / Lucentis® \(ranibizumab\)](#):

- On December 23, 2022, [Novartis](#) filed a notice of appeal of the final written decision finding all challenged claims unpatentable in IPR2021-00816 against [Regeneron](#).

[Opdivo® \(nivolumab\)](#):

- On December 29, 2022, Dana-Farber Cancer Institute filed IPR2023-00249 and IPR2023-00252 against [Bristol-Myers Squibb](#).

aBLA Applications and FDA Activity

[BLB800 \(tocilizumab\)](#):

- On December 9, 2022, **Biogen** and **Bio-Thera Solutions** announced the FDA acceptance of the aBLA for **BIIB800 (tocilizumab)**, a proposed biosimilar of **Genentech's Actemra® (tocilizumab)**.

Idacio® (adalimumab-aacf):

- On December 13, 2022, the FDA approved **Fresenius Kabi's Idacio® (adalimumab-aacf)**, a biosimilar of **AbbVie's Humira® (adalimumab)**.

Remsima® SC (infliximab):

- On December 23, 2022, **Celltrion** announced the submission of a BLA for **Remsima® SC (infliximab)**, a subcutaneous version of its biosimilar infliximab, **Inflectra® (infliximab)**.

CDER Purple Book Updates

Lunsumio™ (mosunetuzumab-axgb):

- On December 22, 2022, the FDA approved **Genentech's Lunsumio™ (mosunetuzumab-axgb)**.

NexoBrid™ (anacaulase-bcdb):

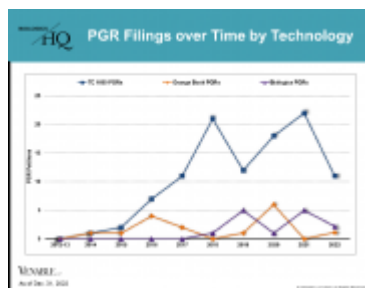
- On December 28, 2022, the FDA approved **Mediwound's NexoBrid™ (anacaulase-bcdb)**.

Briumvi™ (ublituximab):

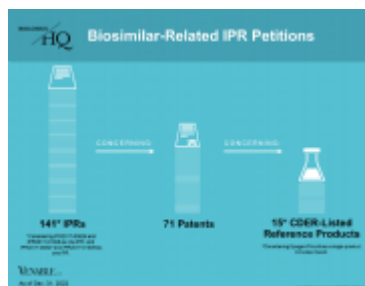
- On December 28, 2022, the FDA approved **TG Therapeutics' Briumvi™ (ublituximab)**.

STATISTICS

PGR Filings Over Time by Technology

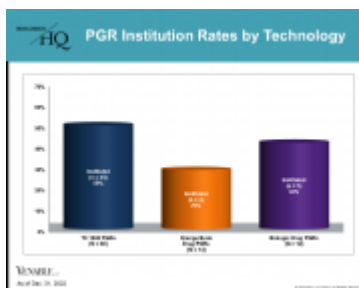


Biosimilar-Related IPR Petitions

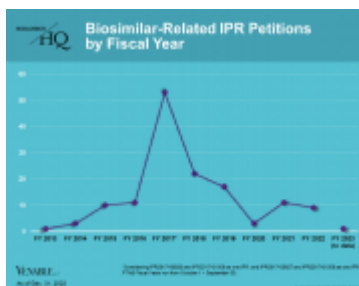


Biosimilar-Related IPRs by Reference

PGR Institution Rates by Technology

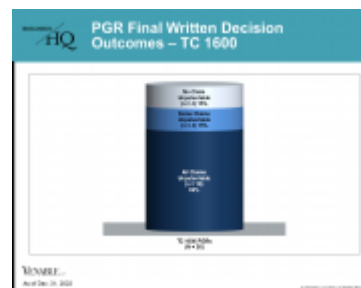


Biosimilar-Related IPR Petitions by Fiscal Year

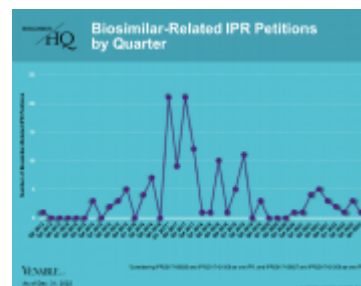


Biosimilar-Related IPRs: Number of Patents

PGR Final Written Decision Outcomes – TC 1600

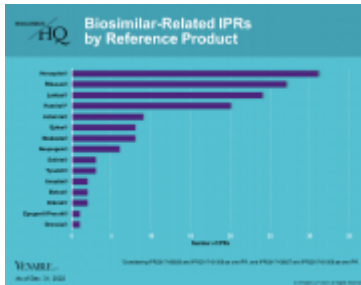


Biosimilar-Related IPR Petitions by Quarter

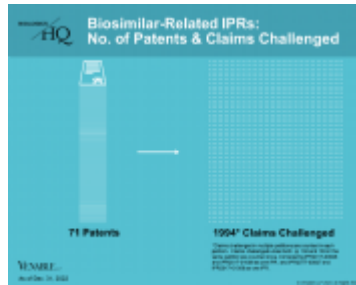


Status of Biosimilar-

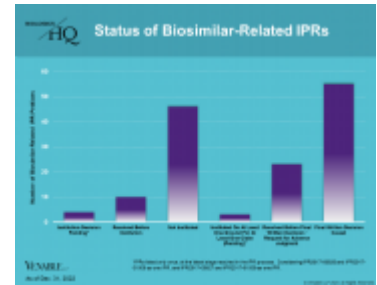
Product



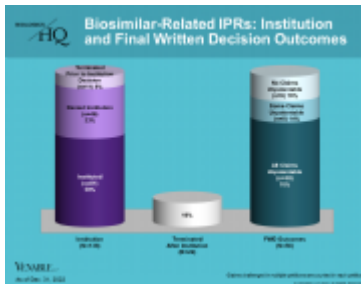
and Claims Challenged



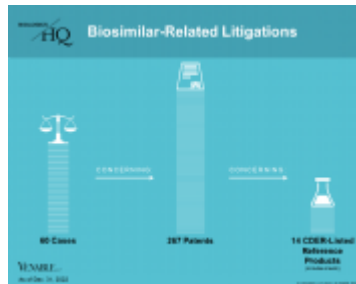
Related IPRs



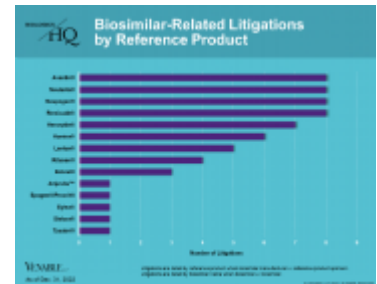
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



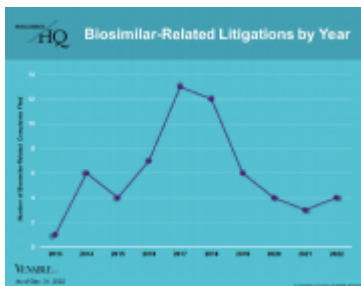
Biosimilar-Related Litigations



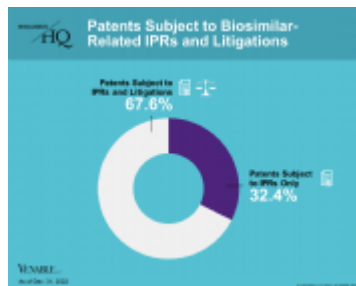
Biosimilar-Related Litigations by Reference Product



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

Approval No.	Reference Product	Manufacturer	Approval Date	Approval Type	Reference Product	U.S. Approval Date
1A-171-104	Humira	AbbVie	Aug 12, 2013	Approval	Humira	Aug 2013
1A-171-105	Enbrel	Amgen	Aug 12, 2013	Approval	Enbrel	Aug 2013
1A-171-106	Actemra	Roche	Aug 12, 2013	Approval	Actemra	Aug 2013
1A-171-107	Avastin	Roche	Aug 12, 2013	Approval	Avastin	Aug 2013
1A-171-108	Keytruda	Bristol-Myers Squibb	Aug 12, 2013	Approval	Keytruda	Aug 2013
1A-171-109	Herceptin	Roche	Aug 12, 2013	Approval	Herceptin	Aug 2013
1A-171-110	Trastuzumab	Roche	Aug 12, 2013	Approval	Trastuzumab	Aug 2013
1A-171-111	Adalimumab	AbbVie	Aug 12, 2013	Approval	Adalimumab	Aug 2013
1A-171-112	Infliximab	Roche	Aug 12, 2013	Approval	Infliximab	Aug 2013
1A-171-113	Humira	AbbVie	Aug 12, 2013	Approval	Humira	Aug 2013
1A-171-114	Enbrel	Amgen	Aug 12, 2013	Approval	Enbrel	Aug 2013
1A-171-115	Actemra	Roche	Aug 12, 2013	Approval	Actemra	Aug 2013
1A-171-116	Avastin	Roche	Aug 12, 2013	Approval	Avastin	Aug 2013
1A-171-117	Keytruda	Bristol-Myers Squibb	Aug 12, 2013	Approval	Keytruda	Aug 2013
1A-171-118	Herceptin	Roche	Aug 12, 2013	Approval	Herceptin	Aug 2013
1A-171-119	Trastuzumab	Roche	Aug 12, 2013	Approval	Trastuzumab	Aug 2013
1A-171-120	Adalimumab	AbbVie	Aug 12, 2013	Approval	Adalimumab	Aug 2013
1A-171-121	Infliximab	Roche	Aug 12, 2013	Approval	Infliximab	Aug 2013
1A-171-122	Humira	AbbVie	Aug 12, 2013	Approval	Humira	Aug 2013
1A-171-123	Enbrel	Amgen	Aug 12, 2013	Approval	Enbrel	Aug 2013
1A-171-124	Actemra	Roche	Aug 12, 2013	Approval	Actemra	Aug 2013
1A-171-125	Avastin	Roche	Aug 12, 2013	Approval	Avastin	Aug 2013
1A-171-126	Keytruda	Bristol-Myers Squibb	Aug 12, 2013	Approval	Keytruda	Aug 2013
1A-171-127	Herceptin	Roche	Aug 12, 2013	Approval	Herceptin	Aug 2013
1A-171-128	Trastuzumab	Roche	Aug 12, 2013	Approval	Trastuzumab	Aug 2013
1A-171-129	Adalimumab	AbbVie	Aug 12, 2013	Approval	Adalimumab	Aug 2013
1A-171-130	Infliximab	Roche	Aug 12, 2013	Approval	Infliximab	Aug 2013

Biosimilar and Interchangeable Applications Pending in the United States

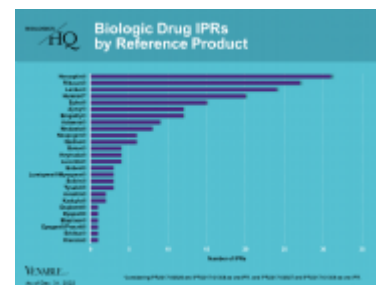
Biosimilar and Interchangeable Applications Pending in the United States*

Approval No.	Reference Product	Manufacturer	Approval Date	Approval Type	Reference Product	U.S. Approval Date
1A-171-131	Humira	AbbVie	Aug 12, 2013	Approval	Humira	Aug 2013
1A-171-132	Enbrel	Amgen	Aug 12, 2013	Approval	Enbrel	Aug 2013
1A-171-133	Actemra	Roche	Aug 12, 2013	Approval	Actemra	Aug 2013
1A-171-134	Avastin	Roche	Aug 12, 2013	Approval	Avastin	Aug 2013
1A-171-135	Keytruda	Bristol-Myers Squibb	Aug 12, 2013	Approval	Keytruda	Aug 2013
1A-171-136	Herceptin	Roche	Aug 12, 2013	Approval	Herceptin	Aug 2013
1A-171-137	Trastuzumab	Roche	Aug 12, 2013	Approval	Trastuzumab	Aug 2013
1A-171-138	Adalimumab	AbbVie	Aug 12, 2013	Approval	Adalimumab	Aug 2013
1A-171-139	Infliximab	Roche	Aug 12, 2013	Approval	Infliximab	Aug 2013
1A-171-140	Humira	AbbVie	Aug 12, 2013	Approval	Humira	Aug 2013
1A-171-141	Enbrel	Amgen	Aug 12, 2013	Approval	Enbrel	Aug 2013
1A-171-142	Actemra	Roche	Aug 12, 2013	Approval	Actemra	Aug 2013
1A-171-143	Avastin	Roche	Aug 12, 2013	Approval	Avastin	Aug 2013
1A-171-144	Keytruda	Bristol-Myers Squibb	Aug 12, 2013	Approval	Keytruda	Aug 2013
1A-171-145	Herceptin	Roche	Aug 12, 2013	Approval	Herceptin	Aug 2013
1A-171-146	Trastuzumab	Roche	Aug 12, 2013	Approval	Trastuzumab	Aug 2013
1A-171-147	Adalimumab	AbbVie	Aug 12, 2013	Approval	Adalimumab	Aug 2013
1A-171-148	Infliximab	Roche	Aug 12, 2013	Approval	Infliximab	Aug 2013
1A-171-149	Humira	AbbVie	Aug 12, 2013	Approval	Humira	Aug 2013
1A-171-150	Enbrel	Amgen	Aug 12, 2013	Approval	Enbrel	Aug 2013

Biologic Drug IPR Petitions



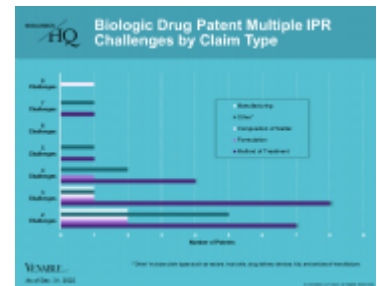
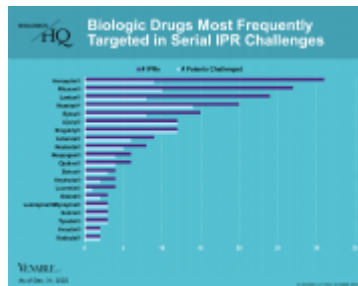
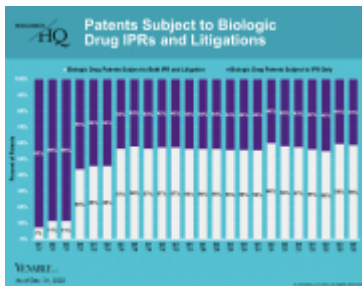
Biologic Drug IPRs by Reference Product



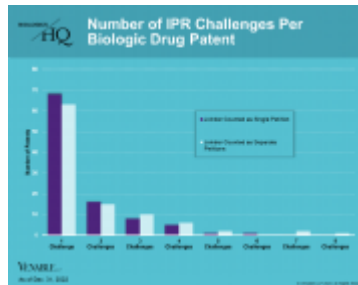
Patents Subject to Biologic Drug IPRs and Litigations

Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

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.

SEARCH

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