

MONTHLY  
INJECTION



May 12, 2021



LATEST NEWS



**Two Bills Designed to Lower Drug Prices Signed into Law**

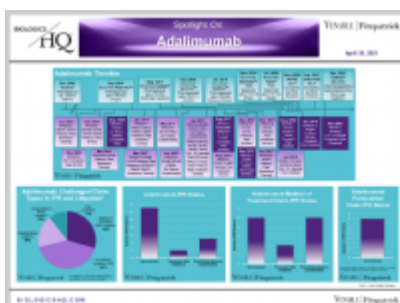
Two bipartisan bills, the Advancing Education on Biosimilars Act and the Ensuring Innovation Act, were signed into law by President Biden on April 23, 2021. According to U.S. Senator Bill Cassidy, MD (R-LA) who introduced the bills, they “both work to lower the price patients pay for their prescriptions” by increasing competition.



**Boehringer Ingelheim Applies for Interchangeability Designation for Cyltezo<sup>®</sup> (adalimumab-adbm)**

On April 23, 2021, [Boehringer Ingelheim](#) announced results from the VOLTIRE-X Phase III randomized study that evaluated switching patients with moderate-to-severe chronic plaque psoriasis between reference product [Humira<sup>®</sup> \(adalimumab\)](#) and biosimilar [Cyltezo<sup>®</sup> \(adalimumab-adbm\)](#).

According to [Boehringer Ingelheim](#), the results of the study support its application for interchangeability between [Cyltezo<sup>®</sup>](#) and [Humira<sup>®</sup>](#). If approved, [Cyltezo<sup>®</sup>](#) will be the first interchangeable product licensed in the U.S.



**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)**

**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> \(trastuzumab-anns\)](#)

## **Spotlight On: Biosimilar Litigations**

[Spotlight On: Rituxan<sup>®</sup> \(rituximab\) / Truxima<sup>®</sup> \(rituximab-abbs\) / Ruxience<sup>®</sup> \(rituximab-pvvr\)](#)

[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> \(adalimumab-fkjp\)](#)

[Spotlight On: Enbrel<sup>®</sup> \(etanercept\) / Erelzi<sup>®</sup> \(etanercept-szsz\) / 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> \(insulin glargine\)](#)

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<sup>®</sup>](#), [Lapelga<sup>™</sup>](#), [Ziextenzo<sup>®</sup>](#), [Udenyca<sup>®</sup>](#), [Fulphila<sup>®</sup>](#), [Nyvepria<sup>™</sup>](#), and [MSB11455](#)), trastuzumab ([Herceptin<sup>®</sup>](#), [Ogivri<sup>™</sup>](#), [Herzuma<sup>®</sup>](#), [Ontruzant<sup>®</sup>](#), [Trazimera<sup>™</sup>](#), and [Kanjinti<sup>®</sup>](#)), rituximab ([Rituxan<sup>®</sup>](#), [Truxima<sup>®</sup>](#), and [Ruxience<sup>®</sup>](#)), adalimumab ([Humira<sup>®</sup>](#), [Amjevita<sup>™</sup>](#), [Cyltezo<sup>®</sup>](#), [Hyrimoz<sup>™</sup>](#), [Hadlima<sup>™</sup>](#), [Abrilada<sup>™</sup>](#), and [Hulio<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>](#), and [Semglee<sup>®</sup>](#)) have been updated with activity through April 30, 2021.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through April 30, 2021.

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## **UPDATES**

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### **IPRs and PGRs**

**[Eylea<sup>®</sup> \(aflibercept\) / Lucentis<sup>®</sup> \(ranibizumab\)](#):**

- On April 16, 2021, [Regeneron](#) filed IPR2021-00816 against [Novartis](#).

**[Lantus<sup>®</sup> \(insulin glargine recombinant\)](#):**

- On April 23, 2021, [Mylan](#) withdrew cross-appeal Fed. Cir. Appeal No. 20-2139, appealing the final written decision in IPR2018-01684 (and joined IPR2019-00987).

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## **Litigations**

### **Avastin® (bevacizumab):**

- On April 14, 2021, **Genentech** and **Centus Biotherapeutics** filed a joint motion to stay deadlines and notice of settlement, with the plan to file a motion to dismiss within 30 days, in Case No. 2:20-cv-00361 (E.D. Tex.).

### **Praluent® (alirocumab) / Repatha® (evolocumab):**

- On April 14, 2021, **Amgen** filed a request for an en banc rehearing of the Federal Circuit's affirmation in Fed. Cir. Appeal No 20-1074, appealing the district court determination in Case No. 1:14-cv-01317 (D. Del.) and consolidated Case Nos. 1:14-cv-01349 (D. Del.), 1:14-cv-01393 (D. Del.), and 1:14-cv-01414 (D. Del.) against **Regeneron**.

### **Taltz® (ixekizumab):**

- On April 22, 2021, **Eli Lilly** filed Fed. Cir. Appeal No. 21-1874, appealing the denial of attorney fees in Case No. 3:18-cv-01518 (S.D. Cal.).

### **Humira® (adalimumab):**

- On April 27, 2021, **AbbVie** filed Case No. 1:21-cv-02258 (N.D. Ill.) against **Alvotech** related to its proposed biosimilar **AVT02 (adalimumab)**.

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## **aBLA Applications and FDA Activity**

### **Cyltezo® (adalimumab-adbm):**

- On April 23, 2021, **Boehringer Ingelheim** announced results from a Phase III switching study between **Cyltezo® (adalimumab-adbm)** and **Humira® (adalimumab)** to support its supplemental BLA to designate **Cyltezo® (adalimumab-adbm)** as an interchangeable biosimilar to **AbbVie's Humira® (adalimumab)**. The action date on the supplemental BLA is the 4th quarter of 2021.

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## **CDER Purple Book Updates**

### **Jemperli™ (dostarlimab-gxly):**

- On April 22, 2021, the FDA approved **GlaxoSmithKline's Jemperli™ (dostarlimab-gxly)**.

### **Zynlonta™ (loncastuximab tesirine-lpyl):**

- On April 23, 2021, the FDA approved **ADC Therapeutics' Zynlonta™ (loncastuximab tesirine-lpyl)**.

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

### **Abevmy (bevacizumab):**

- On April 26, 2021, **Biocon Biologics** and **Viatris** announced **Abevmy (bevacizumab)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, was approved in the E.U.

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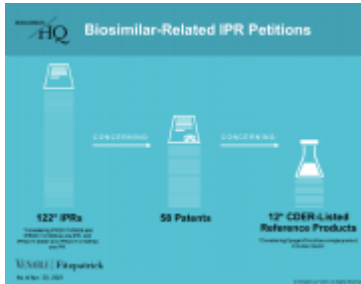
## **STATISTICS**

**Biosimilar-  
Related IPR**

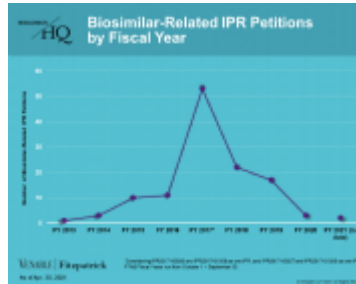
**Biosimilar-Related  
IPR Petitions**

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IPR Petitions**

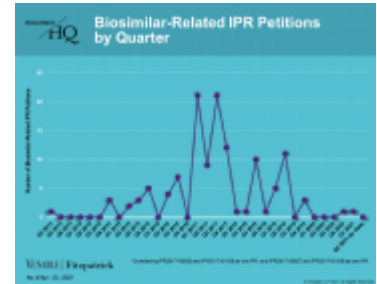
## Petitions



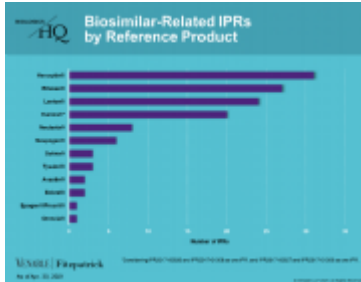
## by Fiscal Year



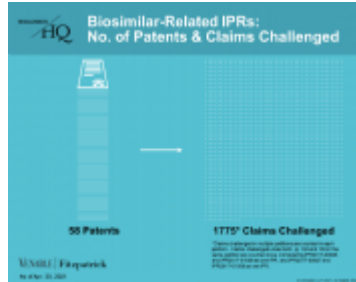
## by Quarter



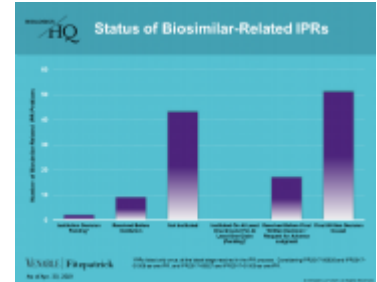
## Biosimilar-Related IPRs by Reference Product



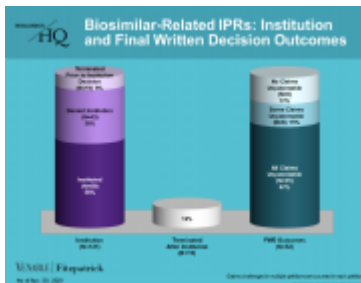
## Biosimilar-Related IPRs: Number of Patents and Claims Challenged



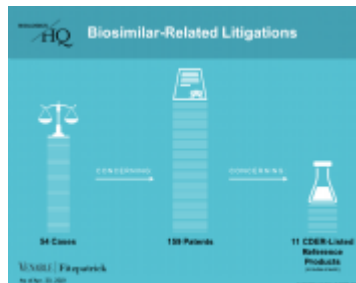
## Status of Biosimilar-Related IPRs



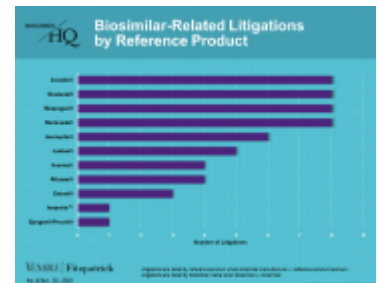
## Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



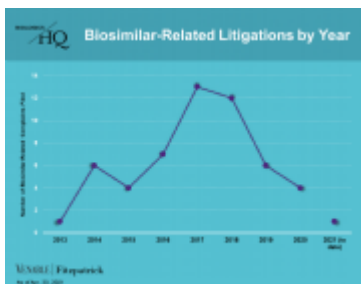
## Biosimilar-Related Litigations



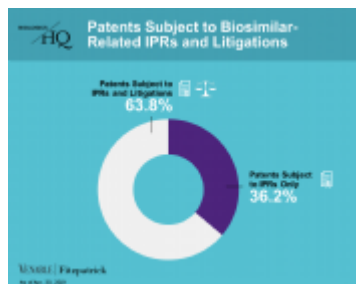
## Biosimilar-Related Litigations by Reference Product



## Biosimilar-Related Litigations by Year



## Patents Subject to Biosimilar-Related IPRs and Litigations



## Biosimilars Approved in the United States

**Biosimilars Approved in the United States**

ANDA No.	Reference Product	Biosimilar Name	USDA Brand	Approval Date	Reference Product Approval Date	U.S. Approval
ANDA 191201	Humalog	Humalog	Humalog	Jul 25, 2014	Humalog	2014
ANDA 191202	Humalog	Humalog	Humalog	Jul 28, 2014	Humalog	2014
ANDA 191203	Humalog	Humalog	Humalog	Aug 19, 2014	Humalog	2014
ANDA 191204	Humalog	Humalog	Humalog	Oct 21, 2014	Humalog	2014
ANDA 191205	Humalog	Humalog	Humalog	Dec 22, 2014	Humalog	2014
ANDA 191206	Humalog	Humalog	Humalog	Jan 23, 2015	Humalog	2015
ANDA 191207	Humalog	Humalog	Humalog	Mar 16, 2015	Humalog	2015
ANDA 191208	Humalog	Humalog	Humalog	Apr 17, 2015	Humalog	2015
ANDA 191209	Humalog	Humalog	Humalog	May 18, 2015	Humalog	2015
ANDA 191210	Humalog	Humalog	Humalog	Jun 19, 2015	Humalog	2015
ANDA 191211	Humalog	Humalog	Humalog	Jul 20, 2015	Humalog	2015
ANDA 191212	Humalog	Humalog	Humalog	Aug 21, 2015	Humalog	2015
ANDA 191213	Humalog	Humalog	Humalog	Sep 22, 2015	Humalog	2015
ANDA 191214	Humalog	Humalog	Humalog	Oct 23, 2015	Humalog	2015
ANDA 191215	Humalog	Humalog	Humalog	Nov 24, 2015	Humalog	2015
ANDA 191216	Humalog	Humalog	Humalog	Dec 25, 2015	Humalog	2015
ANDA 191217	Humalog	Humalog	Humalog	Jan 26, 2016	Humalog	2016
ANDA 191218	Humalog	Humalog	Humalog	Feb 27, 2016	Humalog	2016
ANDA 191219	Humalog	Humalog	Humalog	Mar 28, 2016	Humalog	2016
ANDA 191220	Humalog	Humalog	Humalog	Apr 29, 2016	Humalog	2016
ANDA 191221	Humalog	Humalog	Humalog	May 30, 2016	Humalog	2016
ANDA 191222	Humalog	Humalog	Humalog	Jun 30, 2016	Humalog	2016
ANDA 191223	Humalog	Humalog	Humalog	Jul 31, 2016	Humalog	2016
ANDA 191224	Humalog	Humalog	Humalog	Aug 31, 2016	Humalog	2016
ANDA 191225	Humalog	Humalog	Humalog	Sep 30, 2016	Humalog	2016
ANDA 191226	Humalog	Humalog	Humalog	Oct 31, 2016	Humalog	2016
ANDA 191227	Humalog	Humalog	Humalog	Nov 30, 2016	Humalog	2016
ANDA 191228	Humalog	Humalog	Humalog	Dec 31, 2016	Humalog	2016

USMRL | Fitzpatrick  
As of Apr. 30, 2020

## Biosimilar and Interchangeable Applications Pending in the United States

## Biologic Drug IPR Petitions

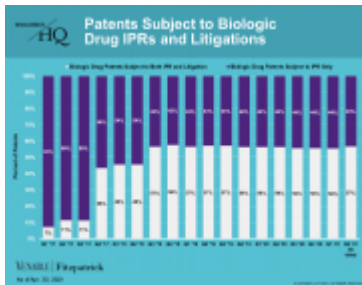
## Biologic Drug IPRs by Reference Product

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

Reference Product	Generic Name	aBLA/505(b)(2)	Reference Product	Approval/Phase 3 Start Date	Expiration
Humira	Adalimumab	2010	Humira	2010	2020
Enbrel	Etanercept	2002	Enbrel	2002	2012
Remicade	Infliximab	2006	Remicade	2006	2016
Actemra	Tocilizumab	2009	Actemra	2009	2019
Avastin	Bevacizumab	2006	Avastin	2006	2016
Herceptin	Trastuzumab	2006	Herceptin	2006	2016
Keytruda	Pembrolizumab	2014	Keytruda	2014	2024
Opdivo	Nivolumab	2015	Opdivo	2015	2025
Imbruvica	Venetoclax	2015	Imbruvica	2015	2025
Yescarta	Axicitinib	2017	Yescarta	2017	2027
Imfinzi	Erdafitinib	2018	Imfinzi	2018	2028
Keytruda	Pembrolizumab	2014	Keytruda	2014	2024
Opdivo	Nivolumab	2015	Opdivo	2015	2025
Imbruvica	Venetoclax	2015	Imbruvica	2015	2025
Yescarta	Axicitinib	2017	Yescarta	2017	2027
Imfinzi	Erdafitinib	2018	Imfinzi	2018	2028
Keytruda	Pembrolizumab	2014	Keytruda	2014	2024
Opdivo	Nivolumab	2015	Opdivo	2015	2025
Imbruvica	Venetoclax	2015	Imbruvica	2015	2025
Yescarta	Axicitinib	2017	Yescarta	2017	2027
Imfinzi	Erdafitinib	2018	Imfinzi	2018	2028

\*Based on public available information. \*\*U.S. Complete Response Letter

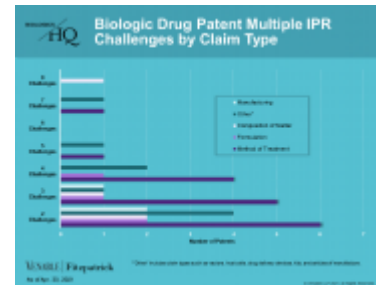
**Patents Subject to Biologic Drug IPRs and Litigations**



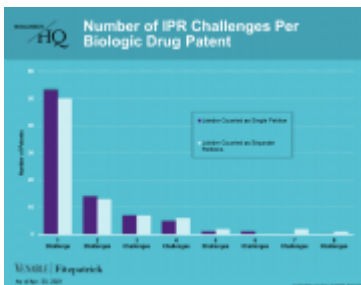
**Biologic Drugs Most Frequently Targeted in Serial IPR Challenges**



**Biologic Drug Patent Multiple IPR Challenges by Claim Type**



**Number of IPR Challenges Per Biologic Drug Patent**



## BiologicsHQ Search

Information contained in the Venable Fitzpatrick 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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