

MONTHLY  
INJECTION

July 8, 2022



LATEST NEWS



**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) / Yusimry<sup>™</sup> (adalimumab-aqvh)**

**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-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 pegfilgrastim ([Neulasta<sup>®</sup>](#), [Lapelga<sup>™</sup>](#), [Ziextenzo<sup>®</sup>](#),

[Udenyca<sup>®</sup>](#), [Fulphila<sup>®</sup>](#), [Nyvepria<sup>®</sup>](#), [MSB11455](#), and [Pegfilgrastim \(Lupin\)](#)), [trastuzumab \(Herceptin<sup>®</sup>\)](#), [Ogivri<sup>®</sup>](#), [Herzuma<sup>®</sup>](#), [Ontruzant<sup>®</sup>](#), [Trazimera<sup>®</sup>](#), [Kanjinti<sup>®</sup>](#), and [EG12014](#)), [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>](#), [Hulio<sup>®</sup>](#), and [Yusimry<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 June 30, 2022.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through June 30, 2022.

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News

## UPDATES

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### IPRs and PGRs

#### [Actemra<sup>®</sup>](#) (tocilizumab):

- On June 3, 2022, the PTAB instituted [Fresenius Kabi](#) v. [Chugai Seiyaku Kabushiki Kaisha](#) IPR2022-00201.
- On June 7, 2022, [Fresenius Kabi](#) filed IPR2022-01065 against [Chugai Seiyaku Kabushiki Kaisha](#).

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### Litigations

#### [Herceptin<sup>®</sup>](#) (trastuzumab):

- On June 2, 2022, [Genentech](#) filed Case No. 3:22-cv-00809 (S.D. Cal.) against [Tanvex](#) related to proposed biosimilar [TX-05 \(trastuzumab\)](#).

#### [Erbix<sup>®</sup>](#) (cetuximab):

- On June 28, 2022, The Trustees of The University of Pennsylvania voluntarily dismissed Case No. 2:15-cv-06133 (E.D. Pa.) against [Eli Lilly](#) and [Bristol-Myers Squibb](#).

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### aBLA Applications and FDA Activity

#### [Byooviz<sup>™</sup>](#) (ranibizumab-nuna):

- On June 2, 2022, [Samsung Bioepis](#) and [Biogen](#) announced they began commercial marketing of [Byooviz<sup>™</sup>](#) (ranibizumab-nuna), a biosimilar of [Genentech's Lucentis<sup>®</sup>](#) (ranibizumab). [Byooviz](#) will be commercially available starting July 1, 2022 at a 40% discount to [Lucentis](#).

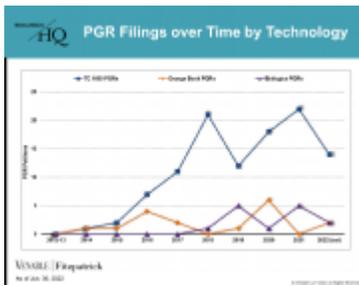
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## STATISTICS

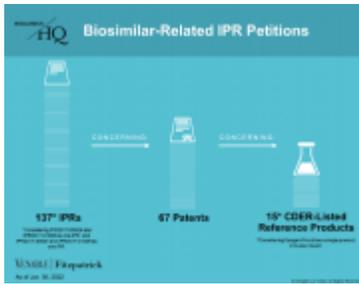
[PGR Filings  
over Time  
by Technology](#)

[PGR Institution  
Rates by  
Technology](#)

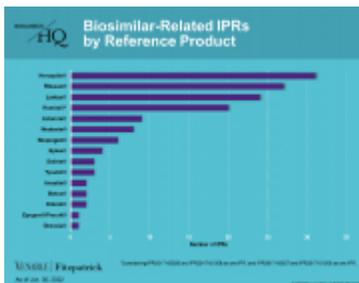
[PGR Final  
Written Decision  
Outcomes - TC 1600](#)



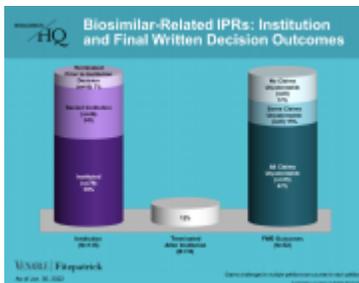
**Biosimilar-Related IPR Petitions**



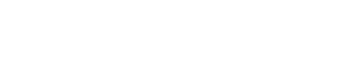
**Biosimilar-Related IPRs by Reference Product**



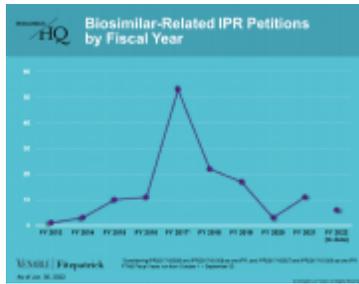
**Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes**



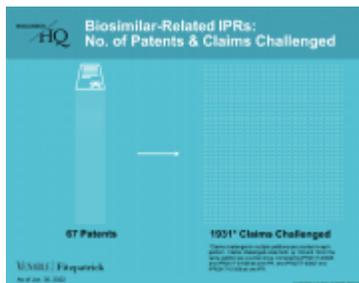
**Biosimilar-Related Litigations by Year**



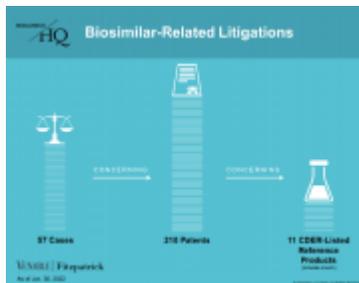
**Biosimilar-Related IPR Petitions by Fiscal Year**



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



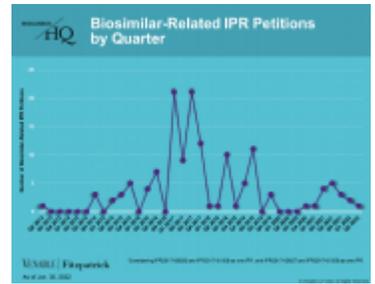
**Biosimilar-Related Litigations**



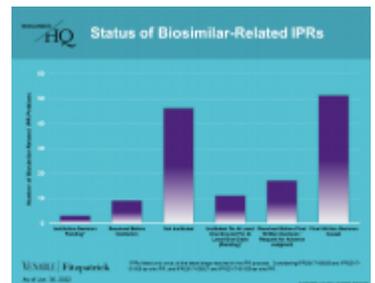
**Patents Subject to Biosimilar-Related IPRs and Litigations**



**Biosimilar-Related IPR Petitions by Quarter**



**Status of Biosimilar-Related IPRs**

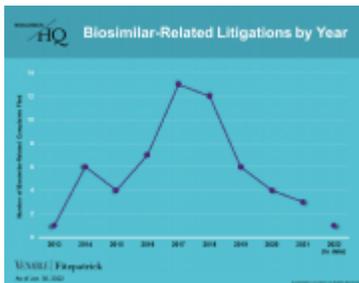


**Biosimilar-Related Litigations by Reference Product**

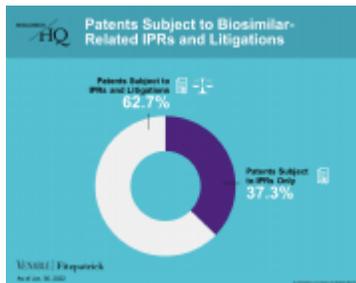


**Biosimilars and Interchangeables Approved in the United States**





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



**Biologic Drug IPR Petitions**

**Biosimilars and Interchangeables Approved in the United States**

ANDA No.	Reference Product	Generic Product Name	Applicant	Approval Date	Approval Type	Reference Product (Trade Name)	U.S. Reference Product
ANDA 141-0101	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0102	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0103	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0104	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0105	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0106	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0107	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0108	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0109	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0110	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0111	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0112	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0113	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0114	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0115	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0116	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0117	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0118	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0119	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0120	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0121	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0122	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0123	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0124	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0125	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0126	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0127	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0128	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0129	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog
ANDA 141-0130	Humalog	Humalog	Novartis	Feb 22, 2011	ANDA	Humalog	Humalog

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**Biologic Drug IPRs by Reference Product**

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

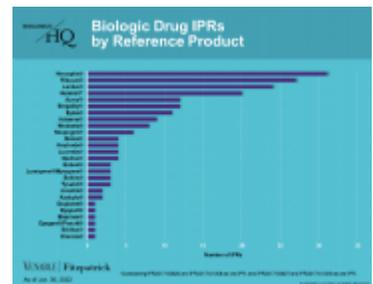
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Humalog	Humalog	ANDA 141-0106	Feb 22, 2011	ANDA	Humalog	Humalog
Humalog	Humalog	ANDA 141-0107	Feb 22, 2011	ANDA	Humalog	Humalog
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Humalog	Humalog	ANDA 141-0127	Feb 22, 2011	ANDA	Humalog	Humalog
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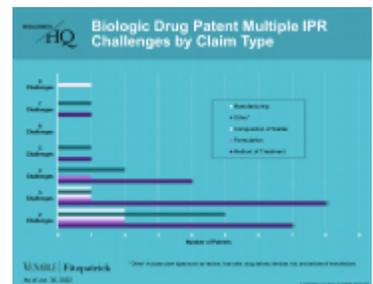
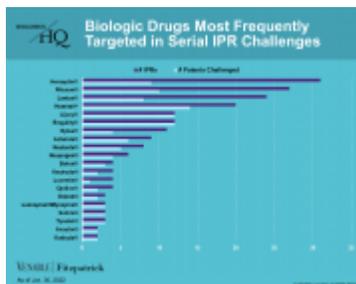
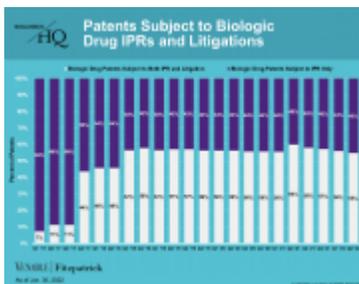
**Patents Subject to Biologic Drug IPRs and Litigations**



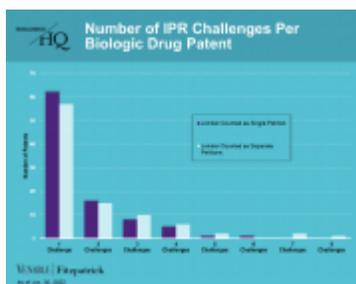
**Biologic Drugs Most Frequently Targeted in Serial IPR Challenges**



**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.

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