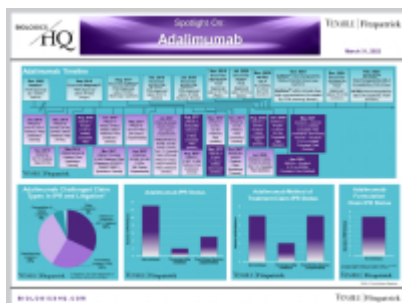


MONTHLY  
INJECTION

April 18, 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 March 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 March 31, 2022.

Read  
More  
News

## UPDATES

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### IPRs and PGRs

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

- On March 3, 2022, the PTAB instituted [Fresenius Kabi's](#) IPR2021-01542 against [Chugai Seiyaku Kabushiki Kaisha](#), [Hoffmann-La Roche](#), and [Genentech](#).

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

- On March 15, 2022, the Board declined to enter adverse judgment against [Regeneron](#) after it disclaimed all challenged claims and denied institution in PGR2021-00117.

#### [Neupogen<sup>®</sup> \(filgrastim\) / Neulasta<sup>®</sup> \(pegfilgrastim\)](#):

- On March 18, 2022, [Amgen](#) and [Pfizer](#) filed a joint motion to terminate after institution due to settlement in IPR2021-00528.

#### [Ajovy<sup>®</sup> \(fremanezumab-vfrm\) / Emgality<sup>®</sup> \(galcanezumab-gnlm\)](#):

- On March 23, 2022, [Eli Lilly](#) filed IPR2022-00738 and IPR2022-00739 against [Teva](#).

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## Litigations

#### [Humira<sup>®</sup> \(adalimumab\)](#):

- On March 9, 2022, [AbbVie](#) v. [Alvotech](#) Case Nos. 1:21-cv-02258 (N.D. Ill.) and 1:21-cv-02899 (N.D. Ill.) were dismissed due to settlement.

#### [Opdivo<sup>®</sup> \(nivolumab\) / Imfinzi<sup>®</sup> \(durvalumab\)](#):

- On March 17, 2022, [Bristol-Myers Squibb](#) filed Case No. 1:22-cv-00346 (D. Del.) against [AstraZeneca](#).

#### [Ultomiris<sup>®</sup> \(ravulizumab-cwvz\)](#):

- On March 17, 2022, [Chugai](#) and [Alexion's](#) stipulated dismissals of Case Nos. 1:18-cv-01802 (D. Del.) and 1:19-cv-02120 (D. Del.) were granted.

#### [Neulasta<sup>®</sup> \(pegfilgrastim\)](#):

- On March 21, 2022, [Amgen](#) and [Pfizer's](#) stipulated dismissal of Case No. 1:20-cv-00201 (D. Del.) was granted.

## CDER Purple Book Updates

### Opdualag™ (nivolumab; elatlimab-rmbw):

- On March 18, 2022, the FDA approved Bristol-Myers Squibb's Opdualag™ (nivolumab; elatlimab-rmbw).

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

### Byooviz™ (ranibizumab):

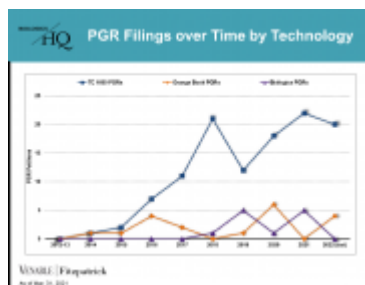
- On March 10, 2022, Samsung Bioepis and Biogen announced Byooviz™ (ranibizumab), a biosimilar of Genentech's Lucentis® (ranibizumab), was approved in Canada.

### Stimufend® (pegfilgrastim):

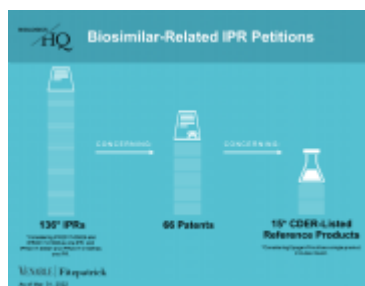
- On March 30, 2022, Fresenius Kabi announced Stimufend® (pegfilgrastim), a biosimilar of Amgen's Neulasta® (pegfilgrastim), was approved in the E.U.

## STATISTICS

### PGR Filings over Time by Technology

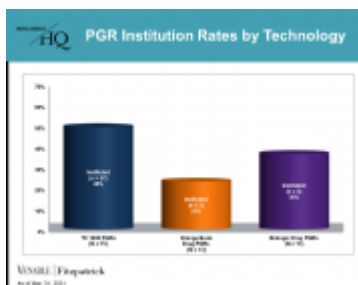


### Biosimilar-Related IPR Petitions

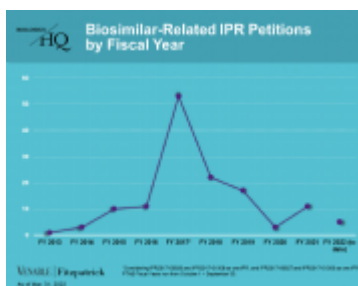


### Biosimilar-Related IPRs by Reference Product

### PGR Institution Rates by Technology

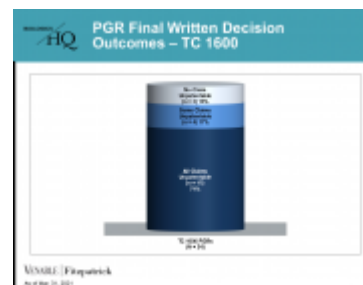


### Biosimilar-Related IPR Petitions by Fiscal Year

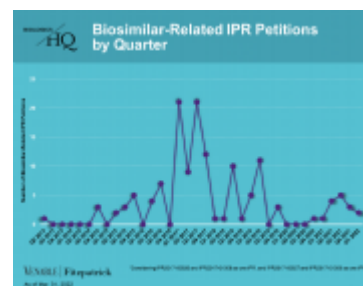


### Biosimilar-Related IPRs: Number of Patents and Claims Challenged

### PGR Final Written Decision Outcomes - TC1600

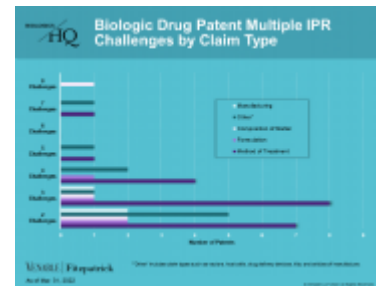
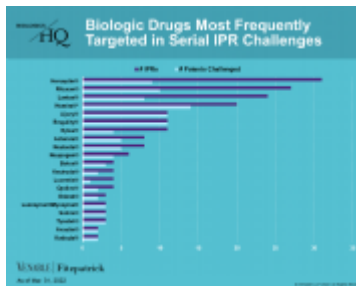
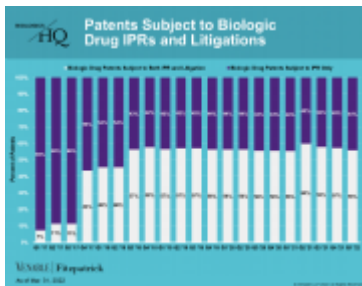


### Biosimilar-Related IPR Petitions by Quarter

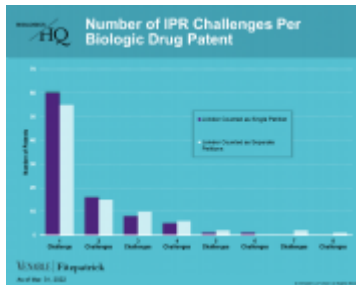


### Status of Biosimilar-Related IPRs





### 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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