BIOLOGICS HQ

VENABLE | Fitzpatrick


August 11, 2021

## LATEST NEWS

### FDA Approves Semglee® (Insulin Glargine) as the First Interchangeable Biosimilar in the U.S.

By: April Breyer Menon

On July 28, 2021, the FDA approved Viatris (formerly Mylan) and Biocon Biologics' Semglee® (insulin glargine-yfgn) as the first interchangeable biosimilar in the U.S. Semglee is both biosimilar to, and interchangeable with Sanofi's Lantus® (insulin glargine).

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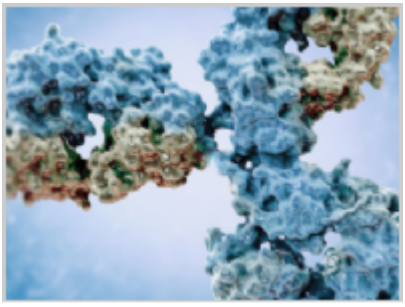

### How a Surge of PGRs for Biologics Could Challenge PTAB Counsel

Ha Kung Wong spoke with Managing IP about the current rate of biologic drug post grant reviews (PGRs) at the Patent Trial and Appeal Board (PTAB) and a potential uptick in the future. He also discussed reasons PGRs may be filed instead of *inter partes* reviews (IPRs) or challenges at the district court, and potential concerns, like estoppel.

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

### 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)

## Spotlight On: Humira® (adalimumab) / Amjevita™ (adalimumab-atto) / Cyltezo® (adalimumab-adbm) / Hyrimoz™ (adalimumab-adaz) / Hadlima™ (adalimumab-bwwd) / Abrilada™ (adalimumab-afzb) / Hulio® (adalimumab-fkjp)

## Spotlight On: Enbrel® (etanercept) / Erelzi® (etanercept-szzs) / Eticovo® (etanercept-ykro)

## Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (insulin glargine) / Semglee® (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®, Lapelga™, Ziextenzo®, Udenyca®, Fulphila®, Nyvepria™, MSB11455, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin®, Ogivri™, Herzuma®, Ontruzant®, Trazimera™, and Kanjinti®), rituximab (Rituxan®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, Hadlima™, Abrilada™, and Hulio®), etanercept (Enbrel®, Erelzi®, and Eticovo®), and insulin glargine (Lantus® / Lantus® SoloSTAR®, Basaglar®, and Semglee®) have been updated with activity through July 31, 2021.**

**BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through July 31, 2021.**

**Read More News**

## UPDATES

### IPRs and PGRs

**Botox® (onabotulinumtoxinA):**

- On July 1, 2021, **Revance Theapeutics** filed IPR2021-01203 and IPR2021-01204 against **Medy-Tox**.

**Neupogen® (filgrastim) / Neulasta® (pegfilgrastim):**

- On July 12, 2021, the PTAB denied institution in **Lupin** v. **Amgen** IPR2021-00326.

**Botox® (onabotulinumtoxinA) / Dysport® (abobotulinumtoxinA):**

- On July 16, 2021, the PTAB issued a final written decision in **Galderma** v. **Medy-Tox** PGR2019-00062, denying **Medy-Tox's** non-contingent motion to amend.

**Keytruda® (pembrolizumab):**

- On July 24, 2021, the PTAB denied institution in **Merck Sharp & Dohme** v. **Genentech** PGR2021-00036 and PGR2021-00039.

**Enhertu® (fam-trastuzumab deruxtecan-nxki):**

- On July 26, 2021, **Daiichi Sankyo** filed requests for rehearing of the decisions denying institution in PGR2021-00030 and PGR2021-00042.

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## Litigations

**Avastin® (bevacizumab):**

- On July 2, 2021, **Genentech** v. **Centus Biotherapeutics**, Case No. 2:20-cv-00361 (E.D. Tex.) was dismissed due to settlement.

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## aBLA Applications and FDA Activity

**Semglee® (insulin glargine-yfgn):**

- On July 28, 2021, the FDA approved **Viatris** (formerly **Mylan**) and **Biocon's Semglee® (insulin gargine-yfgn)**, as biosimilar to and interchangeable with **Sanofi's Lantus® (insulin glargine recombinant)**. This is the first drug to be approved as an interchangeable biosimilar in the U.S.

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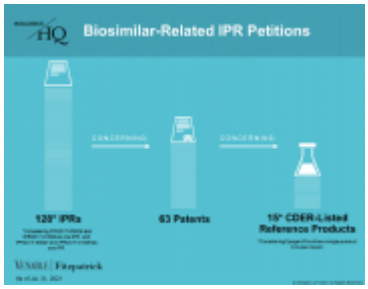
## CDER Purple Book Updates

**Saphnelo™ (anifrolumab-fnia):**

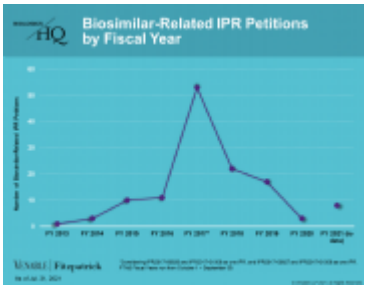
- On July 30, 2021, the FDA approved **AstraZeneca's Saphnelo™ (anifrolumab-fnia)**.

## STATISTICS

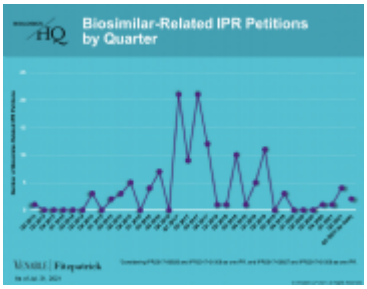
**Biosimilar-Related IPR Petitions**




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



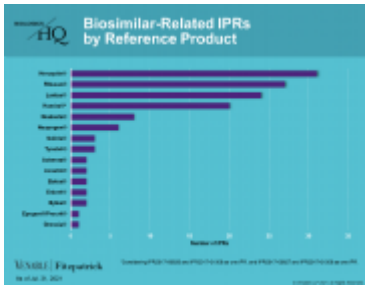

**Biosimilar-Related IPR Petitions by Quarter**



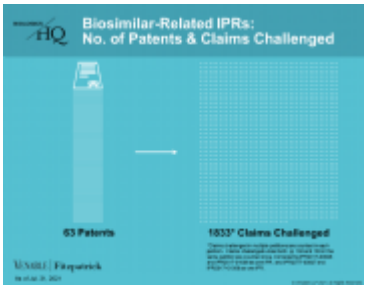

**Biosimilar-Related IPRs by Reference Product**

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

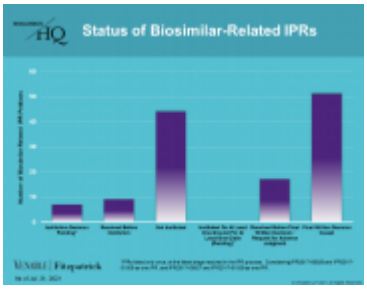
**Status of Biosimilar-Related IPRs**



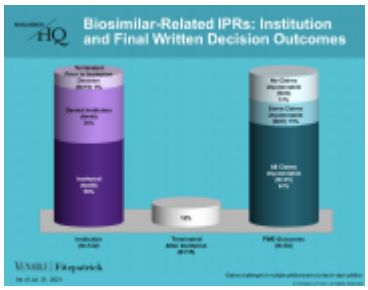

[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



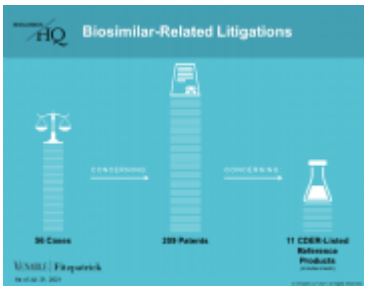

[Biosimilar-Related Litigations]



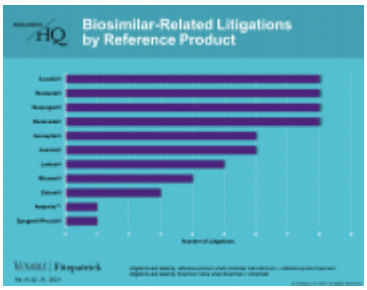

[Biosimilar-Related Litigations by Reference Product]



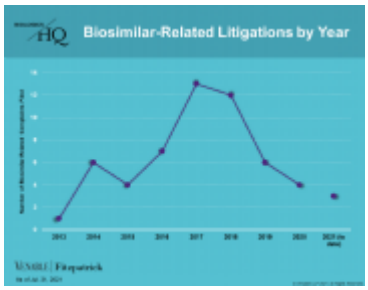

[Biosimilar-Related Litigations by Year]



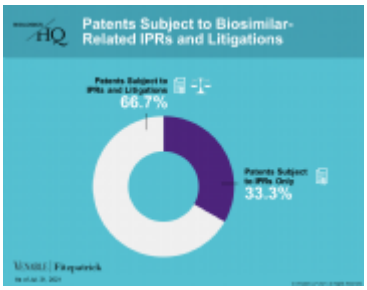

[Patents Subject to Biosimilar-Related IPRs and Litigations]



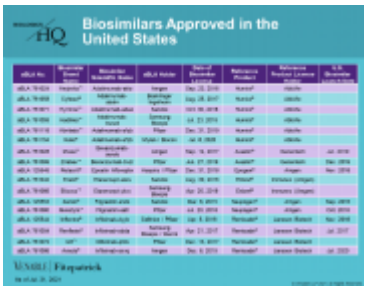

[Biosimilars Approved in the United States]



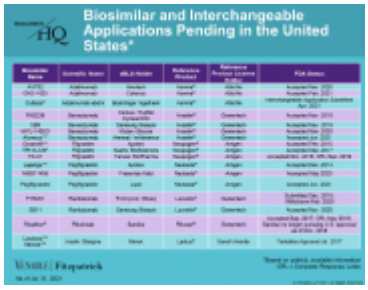

[Biosimilar and Interchangeable Applications Pending in the United States]



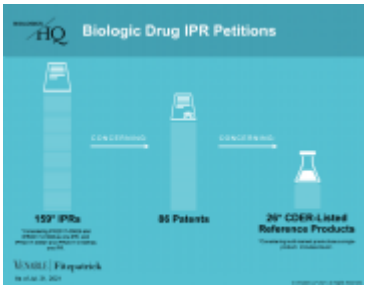

[Biologic Drug IPR Petitions]



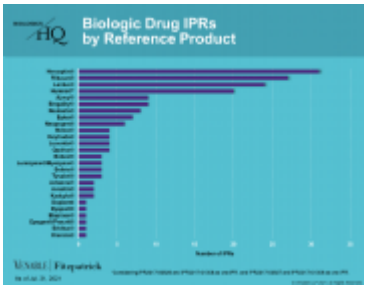

[Biologic Drug IPRs by Reference Product]



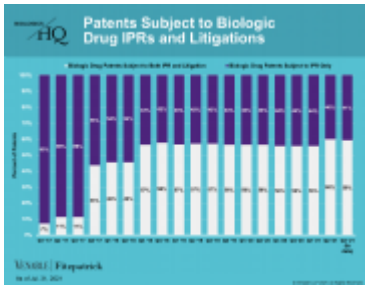

[Patents Subject to Biologic Drug IPRs and Litigations]

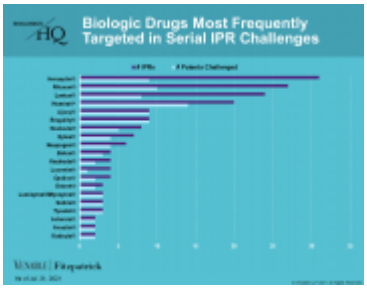


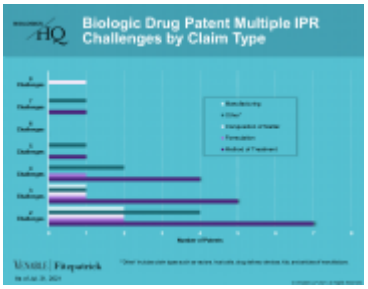

[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]



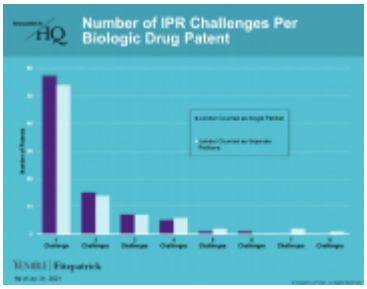

[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

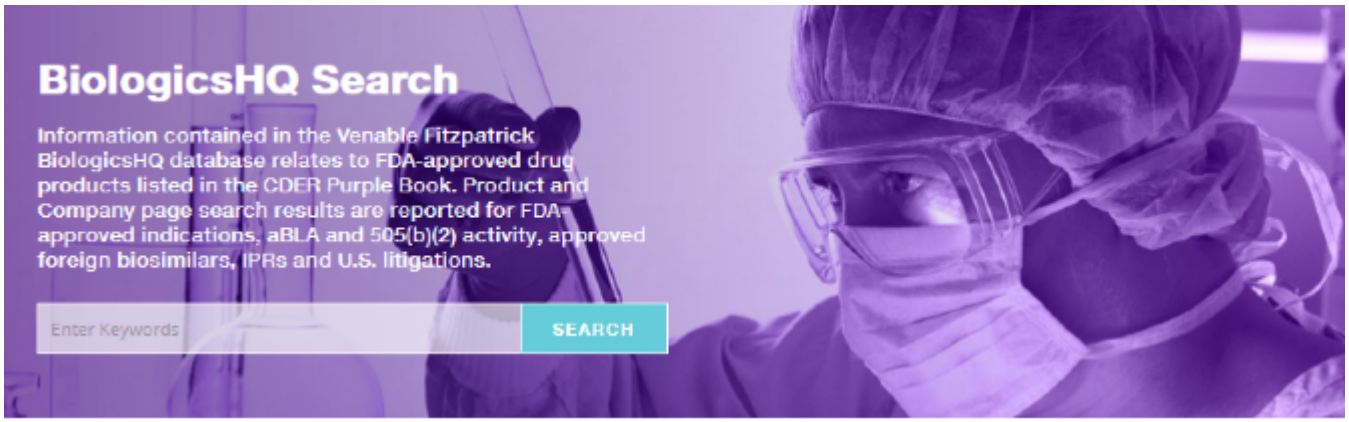



**Number of IPR Challenges Per Biologic Drug Patent**




## Contact the BiologicsHQ Team

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