BIOLOGICS HQ®

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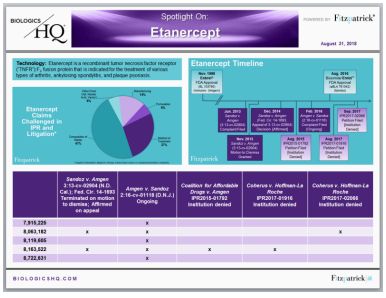
## LATEST NEWS


### VIDEO: The FDA's Biosimilar Action Plan

By: Ha Kung Wong

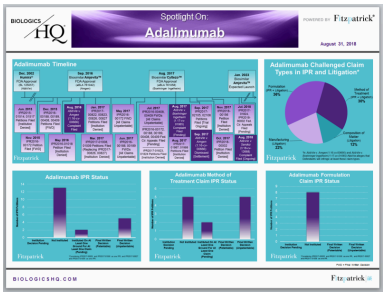
Ha Kung Wong discusses key features of the FDA's Biosimilar Action Plan and potential implications for litigations and inter partes review (IPR) proceedings for biologic drugs as part of a video series for the Center for Biosimilars.

Stay tuned to BiologicsHQ for new videos coming out each week!




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

BiologicsHQ's "Spotlight On" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. A new dashboard concerning Enbrel® (etanercept) and Erelzi® (etanercept-szzs) is now available.




## Spotlight On: Rituxan® (rituximab)

## Spotlight On: Humira® (adalimumab) / Amjevita™ (adalimumab-atto) / Cyltezo® (adalimumab-adbm)

BiologicsHQ's "Spotlight On" dashboards concerning rituximab (Rituxan®) and adalimumab (Humira®, Amjevita™, and Cyltezo®) have been updated with activity through August 31, 2018.

**Read More News**

# UPDATES

### IPRs

- **Avastin® (bevacizumab):** On August 2, 2018, institution was denied in IPR2018-00373 filed by Pfizer.

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### LITIGATIONS

- **Neupogen® (filgrastim) / Neulasta® (pegfilgrastim):** On August 7, 2018, Amgen filed Case No. 0:18-cv-61828 (S.D. Fla.) against Apotex related to Apotex's proposed biosimilars Grastfil™ (filgrastim) and Lapelga™ (pegfilgrastim).
- **Humira® (adalimumab):** On August 10, 2018, AbbVie filed Case No. 3:18-cv-12668 (D.N.J.) against Sandoz related to Sandoz's proposed biosimilar GP2017 (adalimumab).

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### CDER PURPLE BOOK UPDATES

- **Poteligeo® (mogamulizumab-kpkc):** On August 8, 2018, the FDA approved Kyowa Kirin's Poteligeo®.
- **Takhzyro™ (lanadelumab-flyo):** On August 23, 2018, the FDA approved Dyax Corp.'s Takhzyro™.

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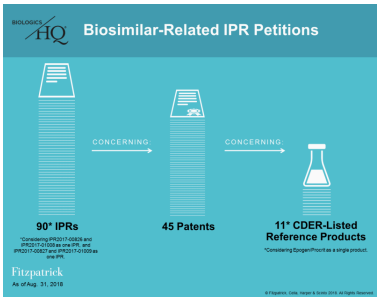
### NON-U.S. BIOSIMILARS / FOLLOW-ON BIOLOGICS

- **Herzuma® (trastuzumab):**

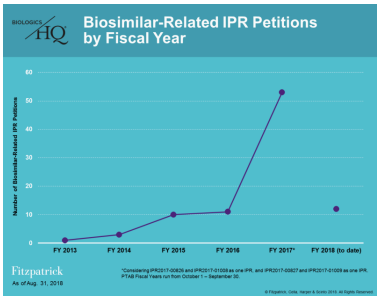
- On August 6, 2018, Celltrion announced that Herzuma®, its biosimilar of Herceptin®, was approved in Australia.
- On August 20, 2018, Celltrion and Nippon Kayaku announced that CT-P6 their biosimilar of Herceptin®, was launched in Japan.

# STATISTICS

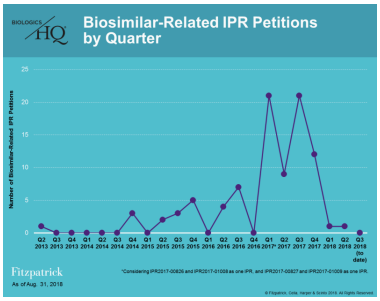
### Biosimilar-Related IPR Petitions



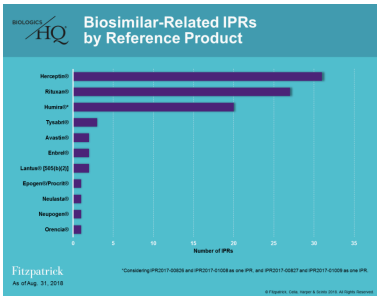

### Biosimilar-Related IPR Petitions by Fiscal Year



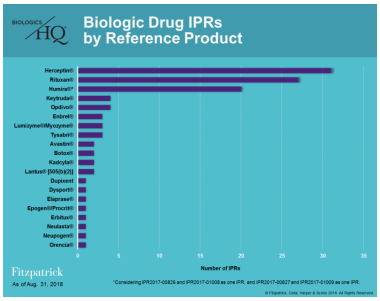

### Biosimilar-Related IPR Petitions by Quarter



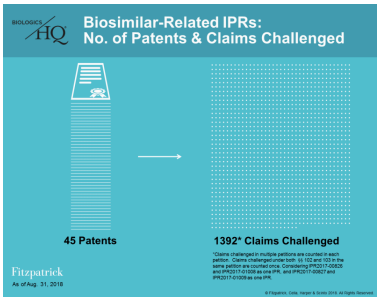

### Biosimilar-Related IPRs by Reference Product



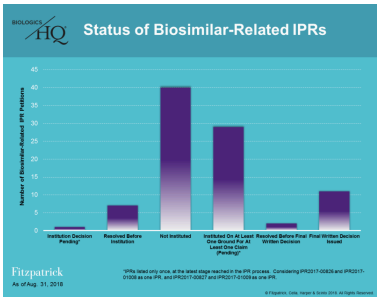

### Biologic Drug IPRs by Reference Product



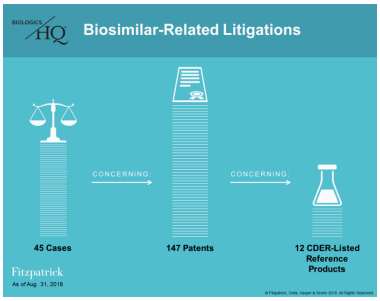

### Biosimilar-Related IPRs: Number of Patents and Claims Challenged



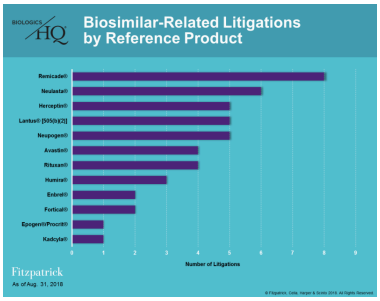

### Status of Biosimilar-Related IPRs



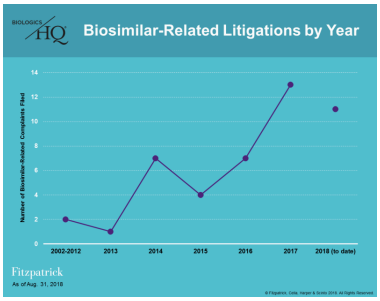

### Biosimilar-Related Litigations



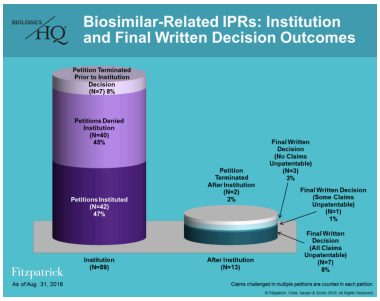

### Biosimilar-Related Litigations by Reference Product



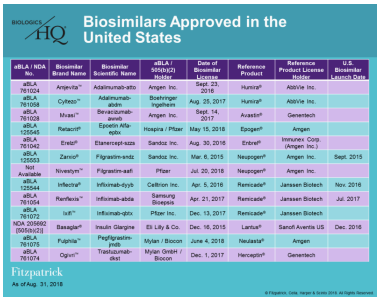
## Biosimilar-Related Litigations by Year




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

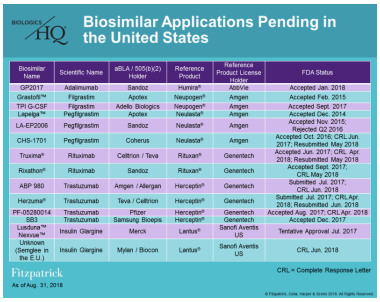



## Biosimilars Approved in the U.S.



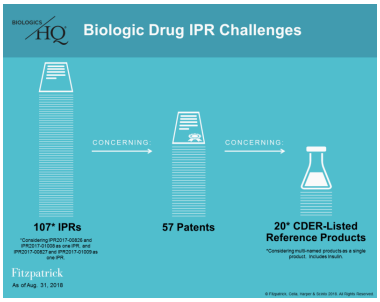

| aBLA / NDA No. | Biosimilar Brand Name | Biosimilar Scientific Name | aBLA / 505(b)(2) Holder | Date of Biosimilar License | Reference Product | Reference Product License Holder | U.S. Biosimilar Launch Date |
|---|---|---|---|---|---|---|---|
| aBLA 761024 | Amjevita™ | Adalimumab-atto | Amgen Inc. | Sept. 23, 2016 | Humira® | AbbVie Inc. | |
| aBLA 761058 | Cyltezo™ | Adalimumab-adbm | Boehringer Ingelheim | Aug. 25, 2017 | Humira® | AbbVie Inc. | |
| aBLA 761028 | Mvasi™ | Bevacizumab-awwb | Amgen Inc. | Sept. 14, 2017 | Avastin® | Genentech | |
| aBLA 125545 | Retacrit® | Epoetin Alfa-epbx | Hospira / Pfizer | May 15, 2018 | Epogen® | Amgen | |
| aBLA 761042 | Erelzi® | Etanercept-szzs | Sandoz Inc. | Aug. 30, 2016 | Enbrel® | Immunex Corp. (Amgen Inc.) | |
| aBLA 125553 | Zarxio® | Filgrastim-sndz | Sandoz Inc. | Mar. 6, 2015 | Neupogen® | Amgen Inc. | Sept. 2015 |
| Not Available | Nivestym™ | Filgrastim-aafi | Pfizer | Jul. 20, 2018 | Neupogen® | Amgen Inc. | |
| aBLA 125544 | Inflectra® | Infliximab-dyyb | Celltrion Inc. | Apr. 5, 2016 | Remicade® | Janssen Biotech | Nov. 2016 |
| aBLA 761054 | Renflexis™ | Infliximab-abda | Samsung Bioepis | Apr. 21, 2017 | Remicade® | Janssen Biotech | Jul. 2017 |
| aBLA 761072 | Ixifi™ | Infliximab-qbtx | Pfizer Inc. | Dec. 13, 2017 | Remicade® | Janssen Biotech | |
| NDA 205692 (505(b)(2)) | Basaglar® | Insulin Glargine | Eli Lilly & Co. | Dec. 16, 2015 | Lantus® | Sanofi Aventis US | Dec. 2016 |
| aBLA 761075 | Fulphila™ | Pegfilgrastim-jmdb | Mylan / Biocon | June 4, 2018 | Neulasta® | Amgen | |
| aBLA 761074 | Ogivri™ | Trastuzumab-dkst | Mylan GmbH / Biocon | Dec. 1, 2017 | Herceptin® | Genentech | |

## Biosimilar Applications Pending in the U.S.

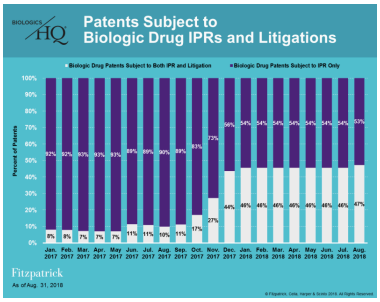


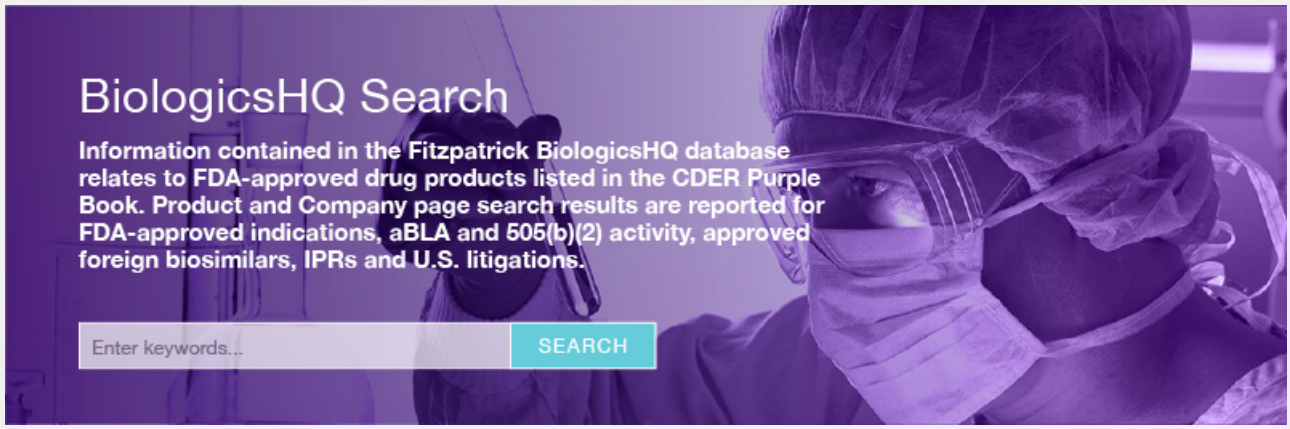

| Biosimilar Name | Scientific Name | aBLA / 505(b)(2) Holder | Reference Product | Reference Product License Holder | FDA Status |
|---|---|---|---|---|---|
| GP2017 | Adalimumab | Sandoz | Humira® | AbbVie | Accepted Jan. 2018 |
| Grastofil™ | Filgrastim | Apotex | Neupogen® | Amgen | Accepted Feb. 2015 |
| TPI G-CSF | Filgrastim | Adello Biologics | Neupogen® | Amgen | Accepted Sept. 2017 |
| Lapelga™ | Pegfilgrastim | Apotex | Neulasta® | Amgen | Accepted Dec. 2014 |
| LA-EP2006 | Pegfilgrastim | Sandoz | Neulasta® | Amgen | Accepted Nov. 2015; Rejected Q2 2016 |
| CHS-1701 | Pegfilgrastim | Coherus | Neulasta® | Amgen | Accepted Oct. 2016; CRL Jun. 2017; Resubmitted May 2018 |
| Truxima® | Rituximab | Celltrion / Teva | Rituxan® | Genentech | Accepted Jun. 2017; CRL Apr. 2018; Resubmitted May 2018 |
| Rixathon® | Rituximab | Sandoz | Rituxan® | Genentech | Accepted Sept. 2017; CRL May 2018 |
| ABP 980 | Trastuzumab | Amgen / Allergan | Herceptin® | Genentech | Submitted Jul. 2017; CRL Jun. 2018 |
| Herzuma® | Trastuzumab | Teva / Celltrion | Herceptin® | Genentech | Submitted Jul. 2017; CRL Apr. 2018; Resubmitted Jun. 2018 |
| PF-05280014 | Trastuzumab | Pfizer | Herceptin® | Genentech | Accepted Aug. 2017; CRL Apr. 2018 |
| SB3 | Trastuzumab | Samsung Bioepis | Herceptin® | Genentech | Accepted Dec. 2017 |
| Lusduna™ Nexvue™ | Insulin Glargine | Merck | Lantus® | Sanofi Aventis US | Tentative Approval Jul. 2017 |
| Unknown (Semglee in the E.U.) | Insulin Glargine | Mylan / Biocon | Lantus® | Sanofi Aventis US | CRL Jun. 2018 |

## Biologic Drug IPR Challenges




## Patents Subject to Biologic Drug IPRs and Litigations

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