



February 6, 2020



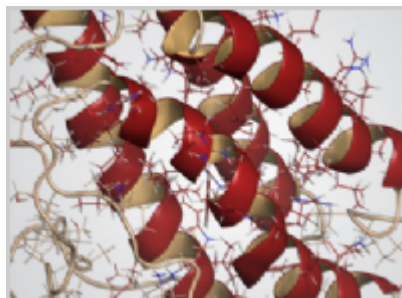
## LATEST NEWS



**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)**

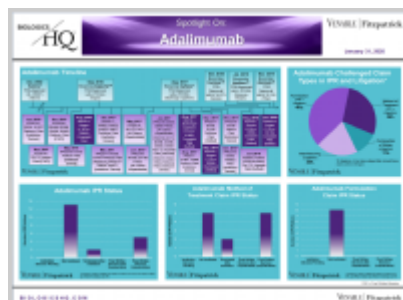
BioLogicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. A new dashboard concerning trastuzumab (Herceptin<sup>®</sup>, Ogivri<sup>™</sup>, Herzuma<sup>®</sup>, Ontruzant<sup>®</sup>,

Trazimera<sup>™</sup>, and Kanjinti<sup>™</sup>) is now available.



## **Biosimilar Makers Must Plan for Originator Firms Gaming the Patent System, Panel Says**

Ha Kung Wong spoke at the Specialty Therapies and Biosimilars Conference as part of a panel that discussed biosimilar litigation and patent issues. He focused on the impact of *inter partes* reviews (IPRs) and post grant reviews (PGRs) on how patents are challenged in the U.S.



## **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)**

**Spotlight On: Enbrel<sup>®</sup> (etanercept) / Erelzi<sup>®</sup> (etanercept-szzs) / Eticovo<sup>™</sup> (etanercept-ykro)**

**Spotlight On: Lantus<sup>®</sup> / Lantus<sup>®</sup> SoloSTAR<sup>®</sup> (insulin glargine recombinant) / Basaglar<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 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>, and Abrilada<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> and Basaglar<sup>®</sup>) have been updated with activity through January 31, 2020.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through January 31, 2020.

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News

## UPDATES

### IPRs and PGRs

#### Humira<sup>®</sup> (adalimumab).

- On January 7, 2020, the Federal Circuit affirmed the PTAB's findings that all instituted claims were unpatentable in IPR2016-00172, IPR2016-00188, IPR2016-00189, IPR2016-00408, and IPR2016-00409 in consolidated Appeal Nos. 17-2304, 17-2305, 17-2306, 17-2362, and 17-2363.

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

- On January 10, 2020, in Appeal No. 18-1933, the Federal Circuit affirmed the PTAB's finding that all instituted claims were unpatentable in Hospira v. Genentech IPR2016-01837.

#### Lantus<sup>®</sup> (insulin glargine recombinant):

- On January 28, 2020, the Federal Circuit denied Mylan and Sanofi's petitions for panel rehearing and en banc rehearing in consolidated Federal Circuit Appeal Nos. 19-1368 and 19-1369, which affirmed the final written decisions finding all instituted claims unpatentable in IPR2017-01526 and IPR2017-01528. On January 31, 2020, Sanofi filed a motion to stay the execution of the mandate until the Supreme Court decides its forthcoming writ of certiorari.

## Litigations

#### Epogen<sup>®</sup> / Procrit<sup>®</sup> (epoetin alfa):

- On January 15, 2020, Hospira filed a petition for en banc rehearing in Amgen v. Hospira, Fed. Cir. Case No. 19-1067, appealing the decision in Case No. 1:15-cv-00839 (D. Del.).

## aBLA Applications and FDA Activity

## Zirabev™ (bevacizumab-bvzr):

- On January 6, 2020, **Pfizer** announced that it had launched **Zirabev™ (bevacizumab-bvzr)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, on December 31, 2019 at a 23% discount.

## Ruxience® (rituximab-pvvr):

- On January 23, 2020, **Pfizer** announced that it had launched **Ruxience® (rituximab-pvvr)**, a biosimilar of **Genentech's Rituxan® (rituximab)**, at a 24% discount.

## CDER Purple Book Updates

### Tepezza™ (teprotumumab-trbw):

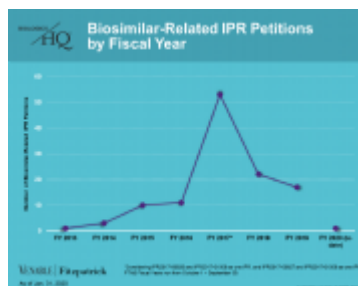
- On January 21, 2020, the FDA approved **Horizon Therapeutics' Tepezza™ (teprotumumab-trbw)**.

## STATISTICS

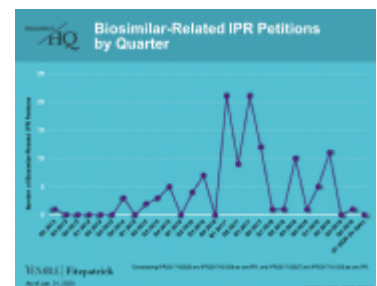
### Biosimilar-Related IPR Petitions



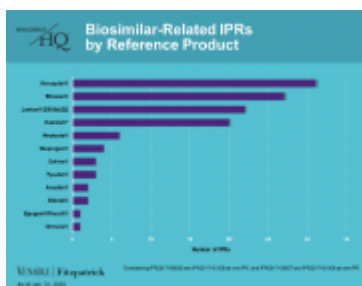
### Biosimilar-Related IPR Petitions by Fiscal Year



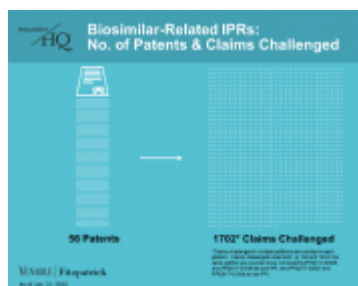
### Biosimilar-Related IPR Petitions by Quarter



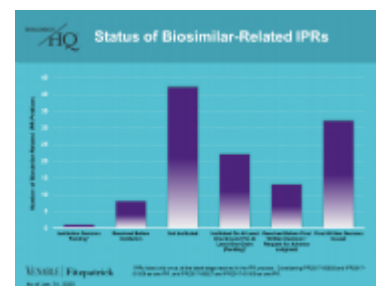
### Biosimilar-Related IPRs by Reference Product



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



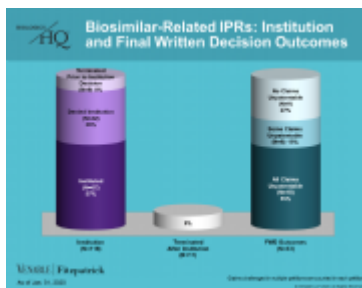
### Status of Biosimilar-Related IPRs



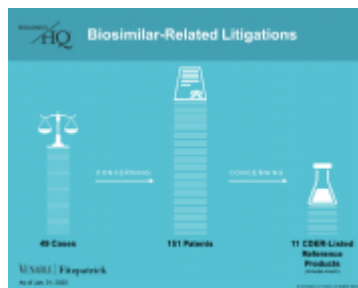
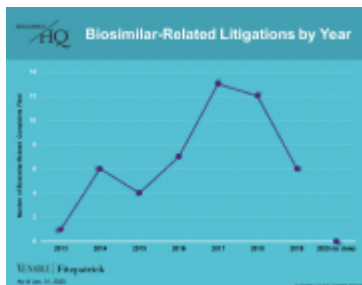
### Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

### Biosimilar-Related Litigations

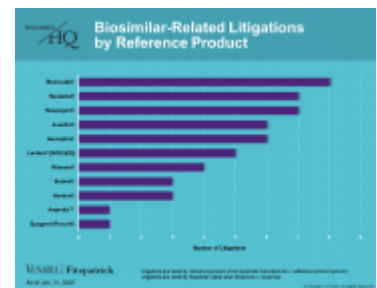
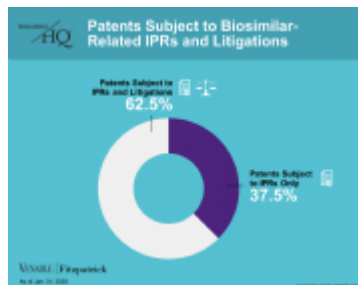
### Biosimilar-Related Litigations by Reference Product



## Biosimilar-Related Litigations by Year



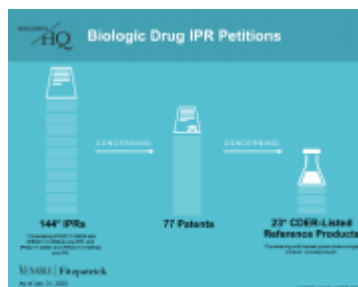
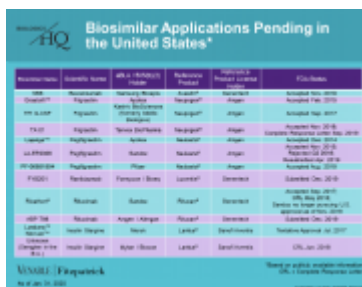
## Patents Subject to Biosimilar-Related IPRs and Litigations



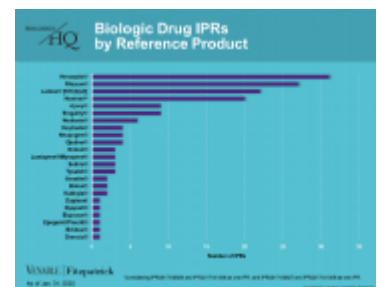
## Biosimilars Approved in the United States



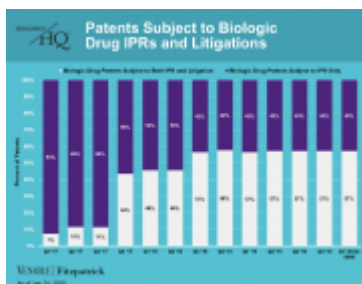
## Biosimilar Applications Pending in the United States



**Biologic Drug**  
**IPRs by Reference**  
**Product**



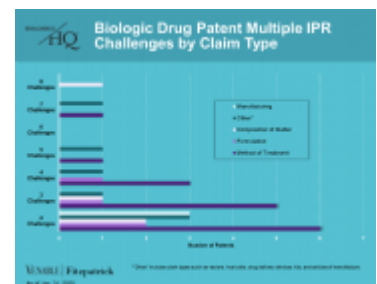
## Patents Subject to Biologic Drug IPRs and Litigations



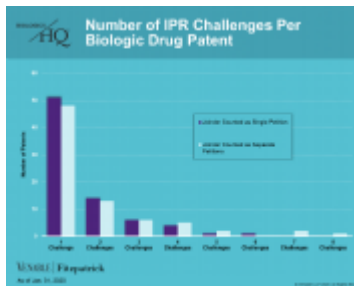
## Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



## Biologic Drug Patent Multiple IPR Challenges by Claim Type



### Number of IPR Challenges Per Biologic Drug Patent



## 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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