BIOLOGICS HQ

VENABLE | Fitzpatrick

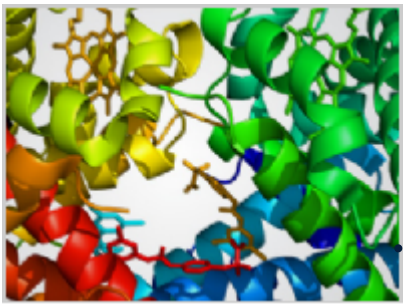

**August 6, 2019**

## LATEST NEWS

### Will Product Drift Cause a Rift?

**By: Ha Kung Wong**

**Ha Kung Wong discusses the impact of product drift on biosimilars in an article for Pharm Manufacturing, including the opportunity for product drift concerns to be addressed by the FDA as part of its Biosimilar Action Plan.**

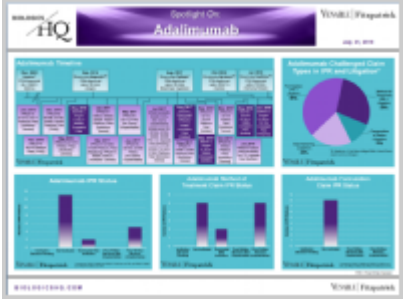


### How Can Biosimilars Make Headway in the U.S. Market?

**Ha Kung Wong spoke at ISPOR's annual conference as part of a panel that discussed the biosimilar market in the US. As a follow-up to that presentation, Ha Kung participated in a Q&A for Biosimilar Development, including providing thoughts on:**

**What we have learned from the biosimilar experience in Europe and implications for biosimilar hurdles in the U.S.;**

- **The greatest market access hurdles/challenges to overcome in the biosimilars field within the U.S. market and what could be done to address these challenges;**
- **Key areas for improvement within the biosimilar industry.**




### 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)

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

## Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (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®, Truxima®, and Ruxience®), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz™, and Hadlima™), etanercept (Enbrel®, Erelzi®, and Eticovo™), and insulin glargine (Lantus® / Lantus® SoloSTAR® and Basaglar®) have been updated with activity through July 31, 2019.**

**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, 2019.**

Read More News

# UPDATES

## IPRs and PGRs

**Herceptin® (trastuzumab):**

- On July 1, 2019, **Samsung Bioepis** and **Genentech's** motion to dismiss due to settlement was granted in Fed. Cir. Case No. 19-1173, appealing the final written decision in IPR2017-01959.
- On July 1, 2019, **Samsung Bioepis** and **Genentech's** motion to dismiss due to settlement was granted in Fed. Cir. Case No. 19-1174, appealing the final written decision in IPR2017-01958.
- On July 2, 2019, **Samsung Bioepis's** motion to withdraw as a party was granted in Fed. Cir. Case No. 19-1265, appealing the final written decision in IPR2017-01960. The case remains ongoing pending a decision from the USPTO Director on whether to intervene.

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

- On July 24, 2019, **Amgen** filed Fed. Cir. Case No. 19-2171, appealing the PTAB's decision on a request for rehearing in IPR2016-01542.

**Avastin® (bevacizumab):**

- On July 31, 2019, in Fed. Cir. Case No. 18-1959, the Federal Circuit affirmed the final written decision in ***Hospira*** *v.* ***Genentech*** IPR2016-01771.

## Litigations

**Herceptin® (trastuzumab):**

- On July 1, 2019, **Samsung Bioepis** and **Genentech's** stipulation of dismissal due to settlement was ordered in Case No. 1:18-cv-01363 (D. Del.).

- On July 18, 2019, **Genentech's** request for a temporary restraining order and preliminary injunction in Case No. 1:18-cv-00924 (D. Del.) was denied. On July 19, 2019, **Genentech** filed Fed. Cir. Case No. 19-2156 appealing this decision.

**Neupogen® (filgrastim):**

- On July 23, 2019, **Amgen** filed Case No. 3:19-cv-01374 (S.D. Cal.) against **Tanvex**.

**Neulasta® (pegfilgrastim):**

- On July 29, 2019, in ***Amgen*** *v.* ***Coherus*** Fed. Cir. Case No. 18-1993, the Federal Circuit affirmed the dismissal of 1:17-cv-00546 (D. Del.) for failure to state a claim.

## aBLA Applications and FDA Activity

**Kanjinti™ (trastuzumab-anns):**

- On July 18, 2019, **Amgen** and **Allergan** launched **Kanjinti™ (trastuzumab-anns)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**.

**Mvasi™ (bevacizumab-awwb):**

- On July 18, 2019, **Amgen** and **Allergan** launched **Mvasi™ (bevacizumab-awwb)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**.

**Hadlima™ (adalimumab-bwwd):**

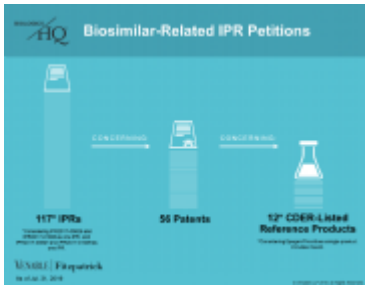
- On July 23, 2019, **Samsung Bioepis's Hadlima™ (adalimumab-bwwd)**, a biosimilar of **AbbVie's Humira® (adalimumab)**, was approved.

**Ruxience® (rituximab-pvvr):**

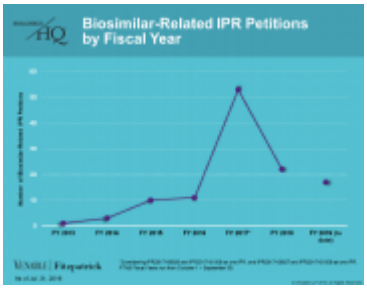
- On July 23, 2019, **Pfizer's Ruxience® (rituximab-pvvr)**, a biosimilar of **Genentech's Rituxan® (rituximab)**, was approved.

## STATISTICS

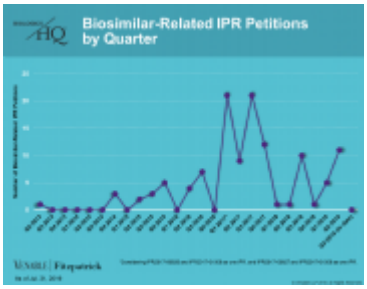
**Biosimilar-Related IPR Petitions**




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



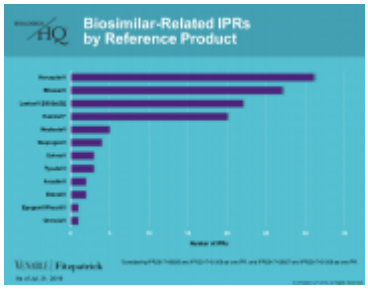

**Biosimilar-Related IPR Petitions by Quarter**



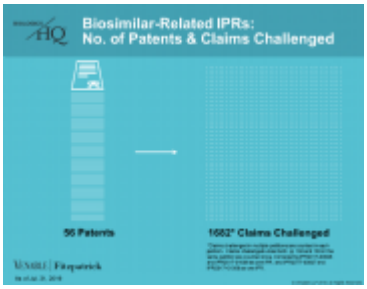

**Biosimilar-Related IPRs by Reference Product**

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

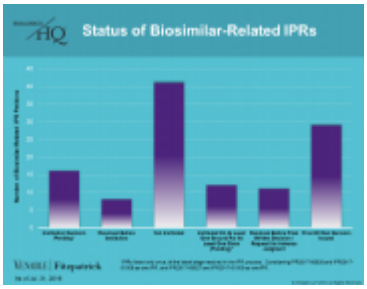
**Status of Biosimilar-Related IPRs**



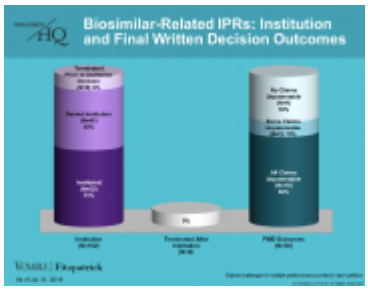

[Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes]



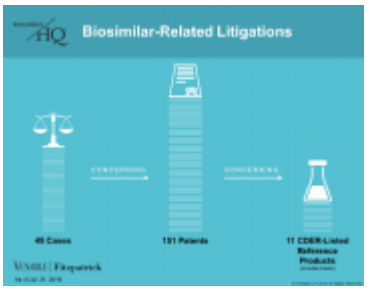

[Biosimilar-Related Litigations]



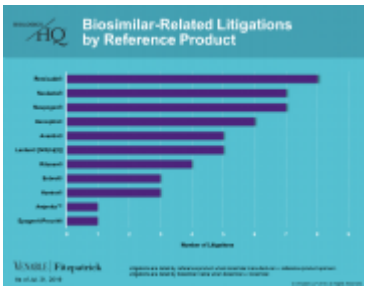

[Biosimilar-Related Litigations by Reference Product]



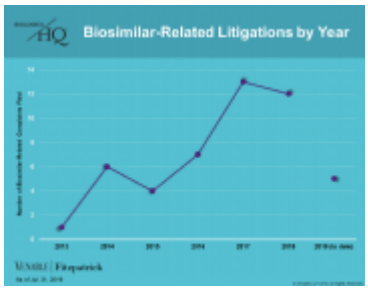

[Biosimilar-Related Litigations by Year]



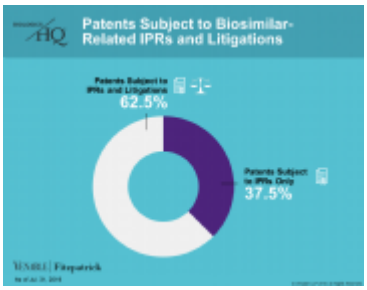

[Patents Subject to Biosimilar-Related IPRs and Litigations]



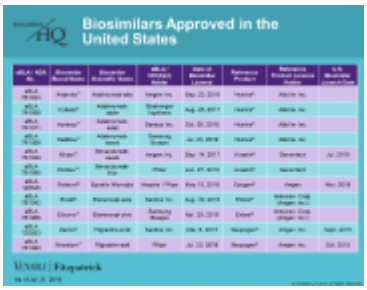

[Biosimilars Approved in the United States]



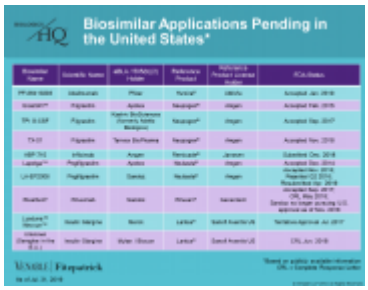

[Biosimilar Applications Pending in the United States]



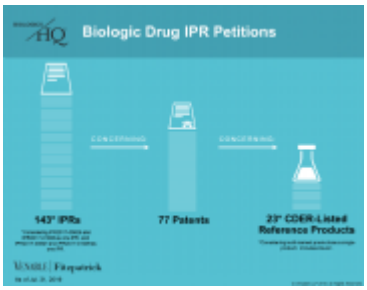

[Biologic Drug IPR Petitions]



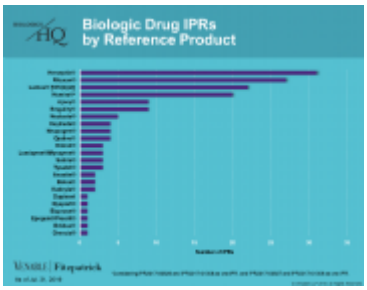

[Biologic Drug IPRs by Reference Product]



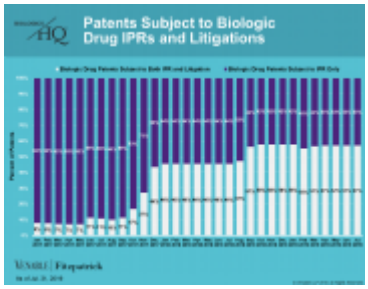

[Patents Subject to Biologic Drug IPRs and Litigations]

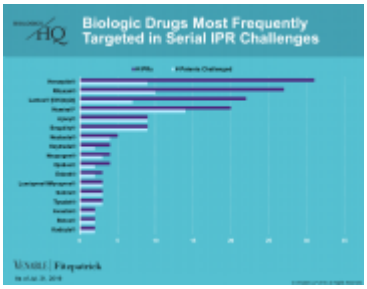


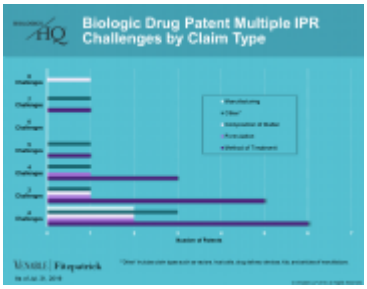

[Biologic Drugs Most Frequently Targeted in Serial IPR Challenges]



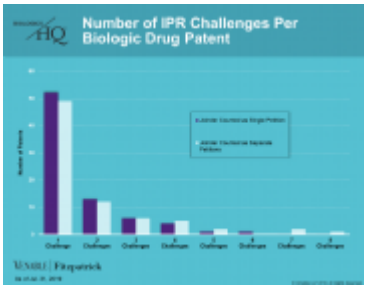

[Biologic Drug Patent Multiple IPR Challenges by Claim Type]

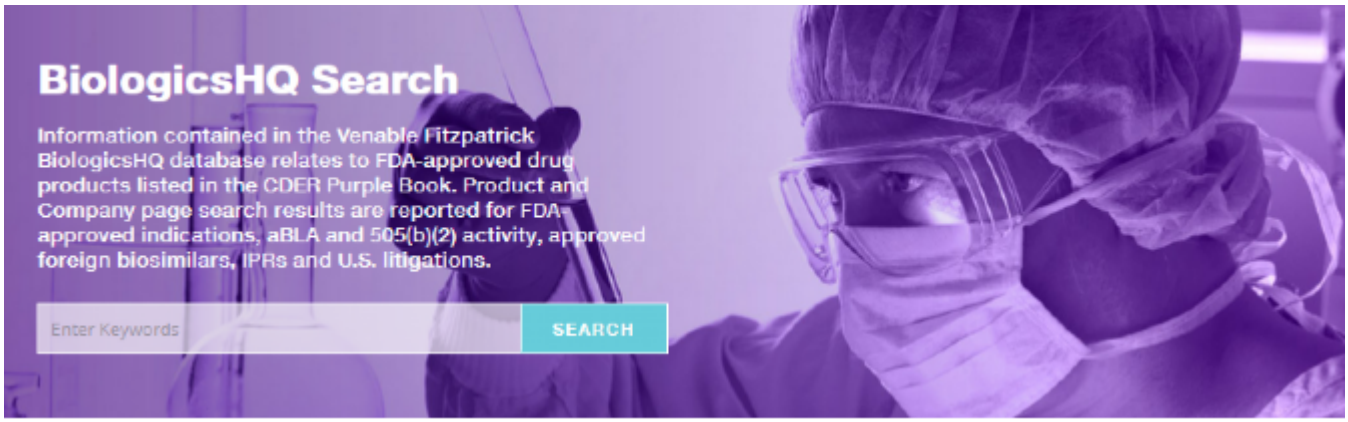



**Number of IPR Challenges Per Biologic Drug Patent**




## Contact the BiologicsHQ Team

**Robert S. Schwartz, Ph.D.**
**Chair**
**+1 212.218.2298**
**RSchwartz@Venable.com**

**Ha Kung Wong**
**Partner**
**+1 212.218.2571**
**HWong@Venable.com**