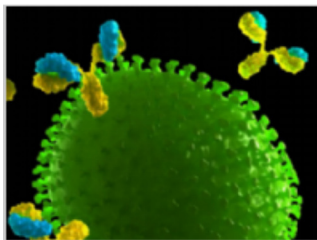




April 5, 2019



LATEST NEWS



**Biosimilars and the BPCIA: Past, Present, and Future**

By: [Ha Kung Wong](#) and [April Breyer Menon](#)

In an article for Biosimilar Development, [Ha Kung Wong](#) and [April Breyer Menon](#) discuss observations in the biosimilar space since the enactment of the 2009 Biologics Price Competition and Innovation Act (BPCIA) and possibilities for the future of biosimilars and related patent disputes.



**Spotlight On: Rituxan® (rituximab) / Truxima® (rituximab-abbs)**

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

**Spotlight On: Enbrel® (etanercept) / Erelzi® (etanercept-szss)**

**Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (insulin glargine)**

BiologicsHQ's "Spotlight On" dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning rituximab (**Rituxan®** and **Truxima®**), adalimumab (**Humira®**, **Amjevita™**, and **Cyltezo®**), etanercept (**Enbrel®** and **Erelzi®**), and insulin glargine (**Lantus® / Lantus® SoloSTAR®** and **Basaglar®**) have been updated with activity through March 31, 2019.

Read More News

UPDATES

IPRs and PGRs

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

- On March 7, 2019, [Kashiv BioSciences](#) filed IPR2019-00791 and IPR2019-00797 challenging patents owned by [Amgen](#).

**Rituxan® (rituximab):**

- On March 20, 2019, [Pfizer](#) and [Biogen](#) voluntarily dismissed Fed. Cir. Appeal No. 18-1885, appealing the final written decision in IPR2017-01115.

- On March 20, 2019, **Pfizer** notified the court it would not participate in Fed. Cir. Appeal No. 19-1364, appealing the final written decision in IPR2017-01168. The appeal remains ongoing with the U.S. requesting to intervene on March 21, 2019.
- On March 26, 2019, **Biogen** voluntarily dismissed Fed. Cir. Appeal No. 19-1253, appealing the final written decision in IPR2017-01095, which was pending with the U.S. as intervenor. **Celltrion** and **Teva** had previously been dismissed due to settlement.
- On March 26, 2019, **Pfizer** and **Genentech** submitted a joint request to terminate IPR2017-01923 due to settlement after institution.
- On March 27, 2019, **Pfizer** and **Biogen's** request to dismiss IPR2018-00285 due to settlement after institution was granted.

## Litigations

### **Amjevita (adalimumab-atto):**

- On March 5, 2019, **Coherus** filed an amended complaint in Case No. 1:19-cv-00139 (D. Del.) against **Amgen** adding U.S. Patent No. 10,207,000 to the proceeding.

## aBLA Applications and FDA Activity

### **Trazimera™ (trastuzumab-qyyp):**

- On March 11, 2019, **Pfizer's Trazimera™ (trastuzumab-qyyp)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)** was approved by the FDA.

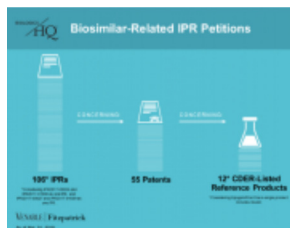
## Non-U.S. Biosimilars / Follow-On Biologics

### **YLB133 (etanercept):**

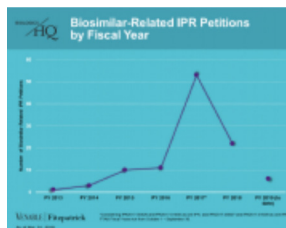
- On March 26, 2019, Lupin and YL Biologics announced that **YLB133 (etanercept)**, a biosimilar of **Immunex's Enbrel® (etanercept)** was approved in Japan.

## STATISTICS

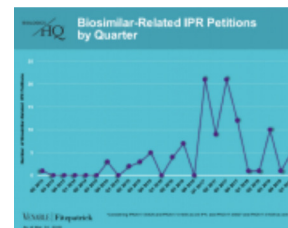
### **Biosimilar-Related IPR Petitions**



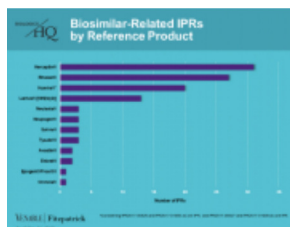
### **Biosimilar-Related IPR Petitions by Fiscal Year**



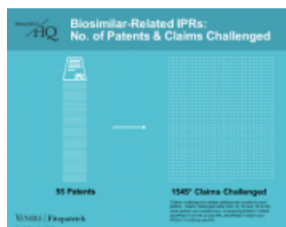
### **Biosimilar-Related IPR Petitions by Quarter**



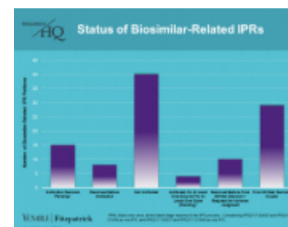
### **Biosimilar-Related IPRs by Reference Product**



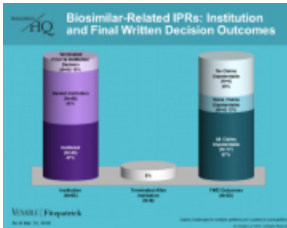
### **Biosimilar-Related IPRs: Number of Patents and Claims Challenged**



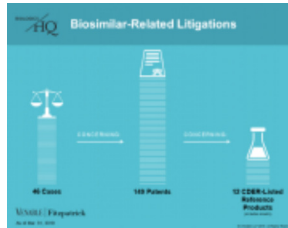
### **Status of Biosimilar-Related IPRs**



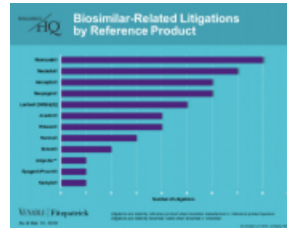
**Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes**



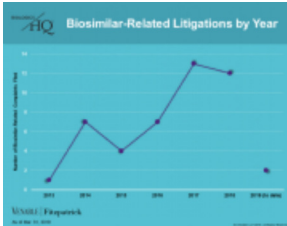
**Biosimilar-Related Litigations**



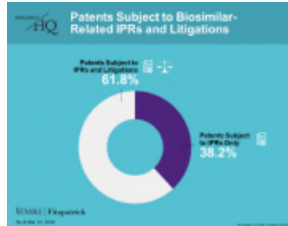
**Biosimilar-Related Litigations by Reference Product**



**Biosimilar-Related Litigations by Year**



**Patents Subject to Biosimilar-Related IPRs and Litigations**



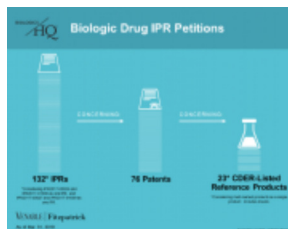
**Biosimilars Approved in the United States**

Drug Name	Sponsor	Approval Date	Reference Product	Reference Product Approval Date
Amgen	Amgen	2015-01-13	Humira	2006-12-09
Astrazenca	Astrazenca	2015-01-13	Avastin	2006-07-19
Novartis	Novartis	2015-01-13	Enbrel	2002-09-24
Lundbeck	Lundbeck	2015-01-13	Humalog	1985-09-01
Abbott	Abbott	2015-01-13	Actemra	2007-11-29

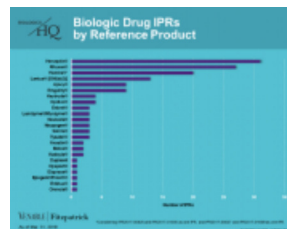
**Biosimilar Applications Pending in the United States**

Reference Product	Biosimilar Name	IPR Institution	Final Decision	Final Decision Date
Amgen	Amgen	Amgen	Amgen	2018-03-01
Astrazenca	Astrazenca	Astrazenca	Astrazenca	2018-03-01
Novartis	Novartis	Novartis	Novartis	2018-03-01

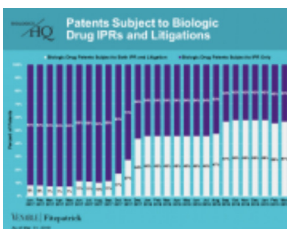
**Biologic Drug IPR Petitions**



**Biologic Drug IPRs by Reference Product**



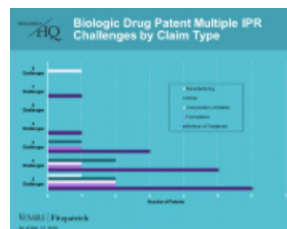
**Patents Subject to Biologic Drug IPRs and Litigations**



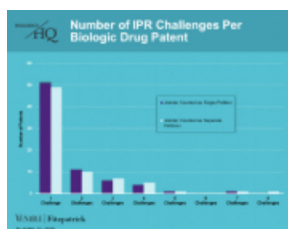
**Biologic Drugs Most Frequently Targeted in Serial IPR Challenges**



**Biologic Drug Patent Multiple IPR Challenges by Claim Type**



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



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.

Enter Keywords:

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