



November 11, 2019



LATEST NEWS



**U.S. Patent System Crimps Drug Innovation for Toughest Diseases**

In an article for Bloomberg Law, [Ha Kung Wong](#) discusses how the U.S. patent system and *inter partes* review (IPR) proceedings affect pharmaceutical innovation.



**Why is Biosimilar Adoption Slow in the U.S., and Can Something Be Done to Boost Uptake?**

In an article for MedCity News, [Ha Kung Wong](#) discusses reasons for the slow uptake of biosimilars in the U.S.

Plaintiff	Defendant	Case No.	Filing Date	Settlement Type	Status
Amgen Inc. (U.S. Patent No. 7,912,100)	Amgen Inc. (U.S. Patent No. 7,912,100)	1:19-cv-00001	1/15/19	Settlement	Settled
Amgen Inc. (U.S. Patent No. 7,912,100)	Amgen Inc. (U.S. Patent No. 7,912,100)	1:19-cv-00001	1/15/19	Settlement	Settled
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**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)**

## [Spotlight On: Enbrel<sup>®</sup> \(etanercept\) / Erelzi<sup>®</sup> \(etanercept-szszs\) / 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>](#), and [Hadlima<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 October 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 October 31, 2019.

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## UPDATES

### IPRs and PGRs

#### [Taltz<sup>®</sup> \(ixekizumab\)](#):

- On October 7, 2019, PGR2019-00043 filed by [Eli Lilly](#) was instituted. PGR2019-00044 on the same patent, filed by [UCB](#), was also instituted on October 7, 2019.

#### [Myozyme<sup>®</sup> / Lumizyme<sup>®</sup> \(alglucosidase alfa\)](#):

- On October 11, 2019, in Fed. Cir. Appeal No. 18-1696, the Federal Circuit issued a Rule 36 affirmation of the PTAB's decision on remand in [Duke University v. BioMarin](#), IPR2013-00535.

#### [Neulasta<sup>®</sup> \(pegfilgrastim\)](#):

- On October 16, 2019, IPR2019-00971 filed by [Fresenius Kabi](#) was denied institution.

## Litigations

#### [Enbrel<sup>®</sup> \(etanercept\)](#):

- On October 8, 2019, in [Amgen v. Sandoz](#), Case No. 2:16-cv-01118 (D.N.J.), the District Court entered final judgment in favor of [Amgen](#) and issued a permanent injunction. [Sandoz](#) filed Federal Circuit Appeal No. 20-1037 on October 15, 2019.

#### [Praluent<sup>®</sup> \(alirocumab\) / Repatha<sup>®</sup> \(evolocumab\)](#):

- On October 24, 2019, [Amgen](#) filed Fed. Cir. Appeal No. 20-1074, appealing the final judgment in [Amgen v. Sanofi](#), Case No. 1:14-cv-01317 (D. Del.) and related cases 1:14-cv-01349 (D. Del.), 1:14-cv-01393 (D. Del.), and 1:14-cv-01414 (D. Del.).

## aBLA Applications and FDA Activity

### **Bonsity™ (teriparatide injection):**

- On October 4, 2019, the FDA approved **Pfenex's Bonsity™ (teriparatide injection)**, a follow-on of **Eli Lilly's Fortec® (teriparatide)**, under the 505(b)(2) pathway.

### **Zirabev™ (bevacizumab-bvzr) / Ruxience® (rituximab-pvvr) / Trazimera™ (trastuzumab-qyyp):**

- On October 29, 2019, **Pfizer** announced its plans for launching three biosimilars in the coming months:
  - Zirabev™ (bevacizumab-bvzr)**, a biosimilar of **Genentech's Avastin® (bevacizumab)**, on December 31, 2019
  - Ruxience® (rituximab-pvvr)**, a biosimilar of **Genentech's Rituxan® (rituximab)**, in January 2020
  - Trazimera™ (trastuzumab-qyyp)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, on Feb 15, 2020

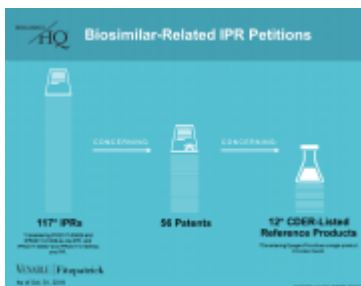
## CDER Purple Book Updates

### **Beovu® (brolocizumab-dbll):**

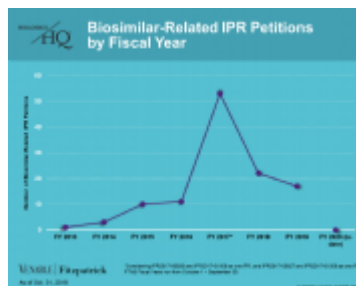
- On October 7, 2019, the FDA approved **Novartis's Beovu® (brolocizumab-dbll)**.

## STATISTICS

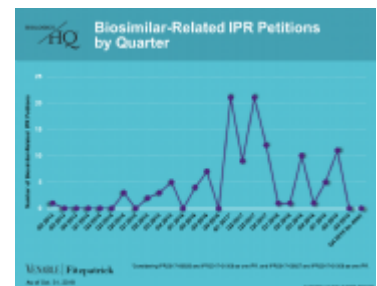
### **Biosimilar-Related IPR Petitions**



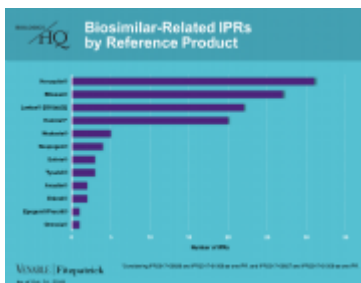
### **Biosimilar-Related IPR Petitions by Fiscal Year**



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

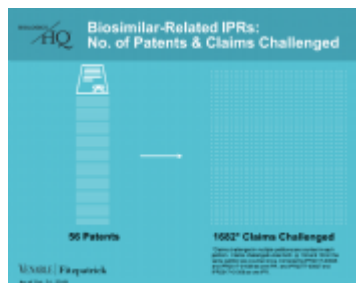


### **Biosimilar-Related IPRs by Reference Product**



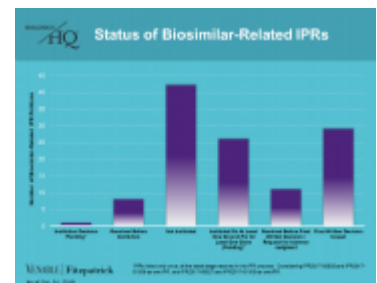
### **Biosimilar-Related IPRs:**

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



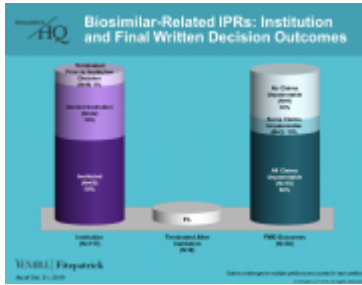
### **Biosimilar-**

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

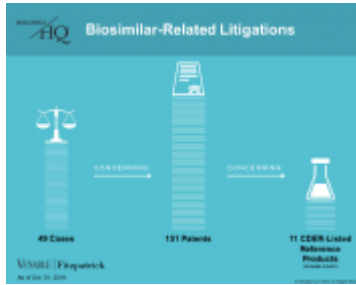


### **Biosimilar-Related**

## Institution and Final Written Decision Outcomes



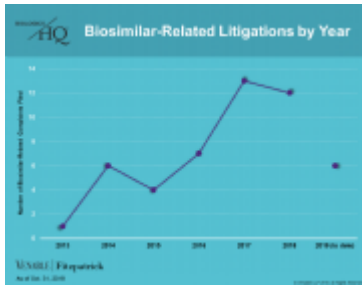
## Related Litigations



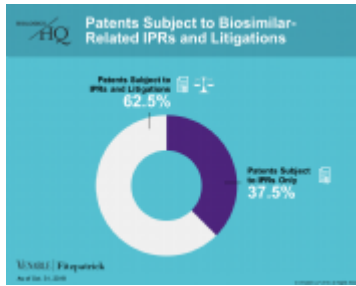
## Litigations by Reference Product



## Biosimilar-Related Litigations by Year



## Patents Subject to Biosimilar-Related IPRs and Litigations



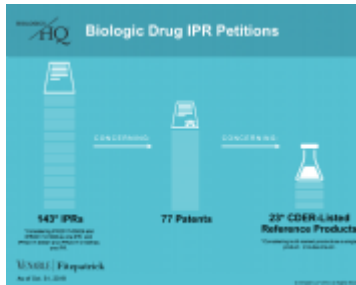
## Biosimilars Approved in the United States

U.S. Brand Name	Reference Product	Manufacturer	Approval Date	Approval Type	U.S. Marketing Start Date
U.S. Brand Name	Reference Product	Manufacturer	Approval Date	Approval Type	U.S. Marketing Start Date
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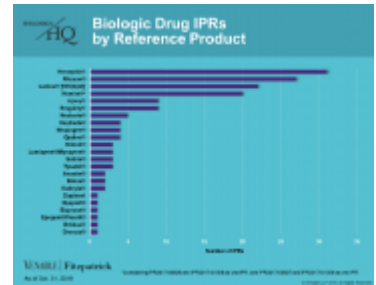
## Biosimilar Applications Pending in the United States

U.S. Brand Name	Reference Product	Manufacturer	Approval Date	Approval Type	U.S. Marketing Start Date
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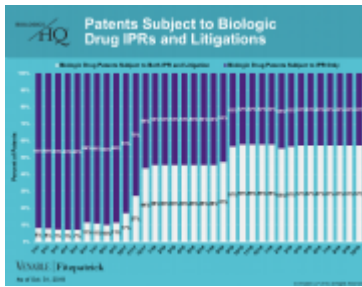
## Biologic Drug IPR Petitions



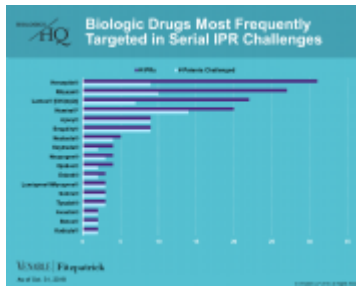
## Biologic Drug IPRs by Reference Product



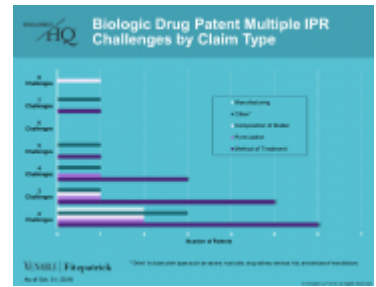
## Patents Subject to Biologic Drug IPRs and Litigations



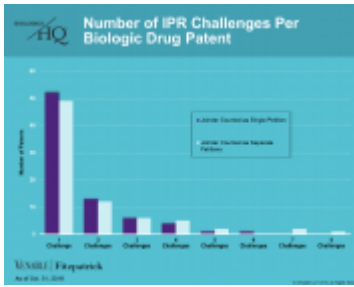
## Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



## Biologic Drug Patent Multiple IPR Challenges by Claim Type



## Number of IPR Challenges Per Biologic Drug Patent



## 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.

Enter Keywords

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