



August 6, 2019



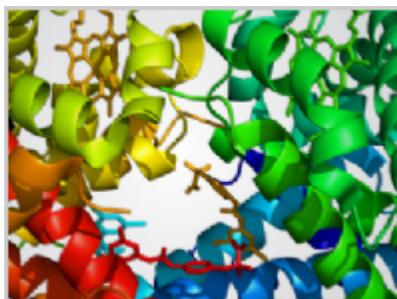
LATEST NEWS



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.

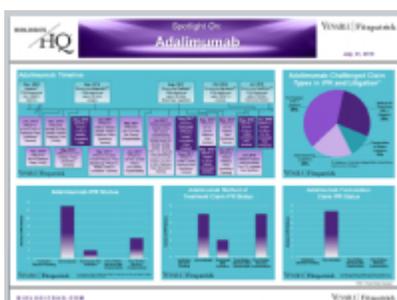


How Can Biosimilars Make Headway in the U.S. Market?

[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® \(etanercept-szsz\) / 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):

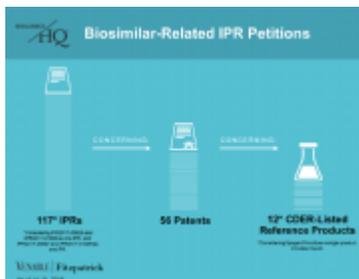
- On July 23, 2019, **Samsung Bioepis's Hadlima™ (adalimumab-bwwd)**, a biosimilar of **AbbVie's Humira® (adalimumab)**, was approved.

Ruxience® (rituximab-pvvr):

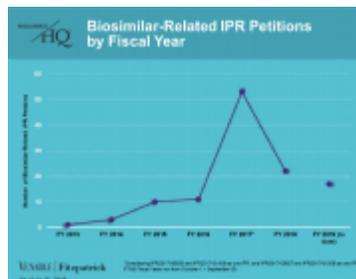
- On July 23, 2019, **Pfizer's Ruxience® (rituximab-pvvr)**, a biosimilar of **Genentech's Rituxan® (rituximab)**, was approved.

STATISTICS

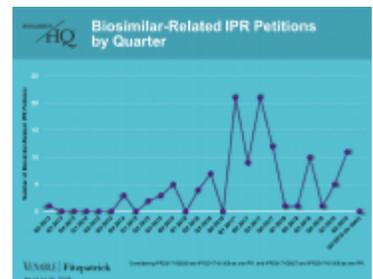
Biosimilar-Related IPR Petitions



Biosimilar-Related IPR Petitions by Fiscal Year



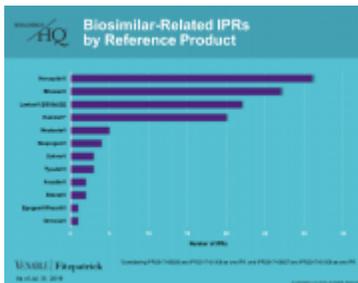
Biosimilar-Related IPR Petitions by Quarter



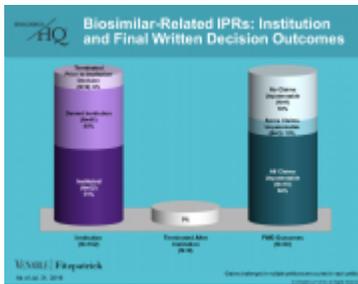
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPRs: Number of Patents and Claims Challenged

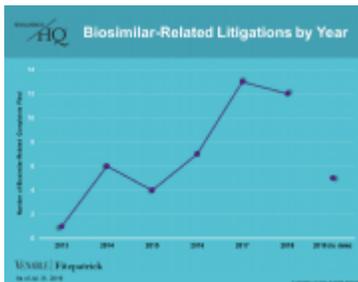
Status of Biosimilar-Related IPRs



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations by Year

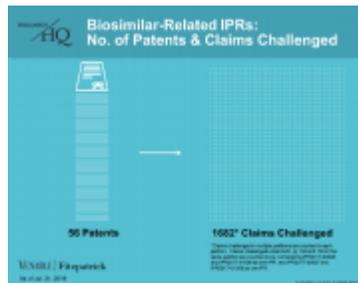


Biosimilar Applications Pending in the United States

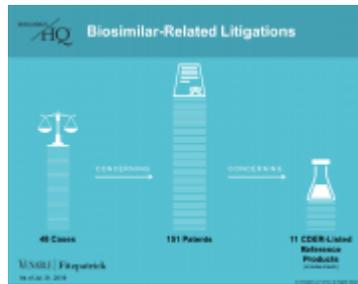
Biosimilar Applications Pending in the United States*

Reference Product	Generic Name	IPR Status	Priority Review	Reference Product (US)	Approval Date
IPR 1000	Humira	Final	Standard	Humira	Accepted Jan 2018
IPR 1001	Humira	Final	Standard	Humira	Accepted Feb 2018
IP 1002	Humira	Final	Standard	Humira	Accepted Sep 2017
7437	Humira	Final	Standard	Humira	Accepted Sep 2017
IPR 754	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 755	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 756	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 757	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 758	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 759	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 760	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 761	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 762	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 763	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 764	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 765	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 766	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 767	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 768	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 769	Humira	Final	Standard	Humira	Submitted Dec 2018
IPR 770	Humira	Final	Standard	Humira	Submitted Dec 2018

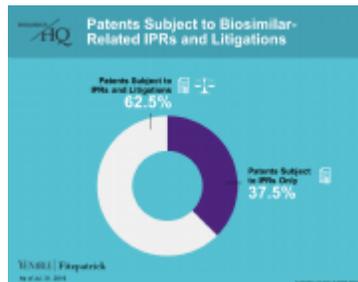
Patents Subject to Biologic Drug IPRs and Litigations



Biosimilar-Related Litigations



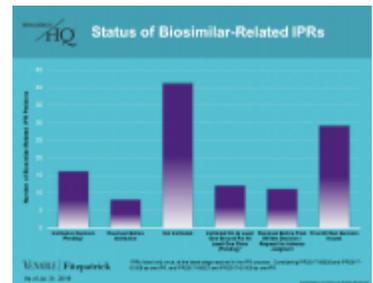
Patents Subject to Biosimilar-Related IPRs and Litigations



Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Biosimilar-Related Litigations by Reference Product

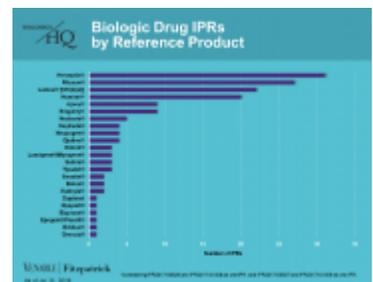


Biosimilars Approved in the United States

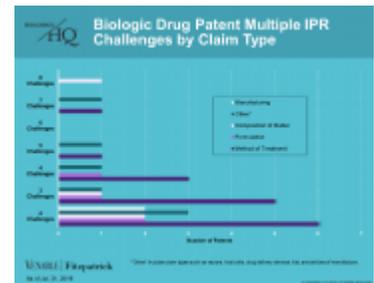
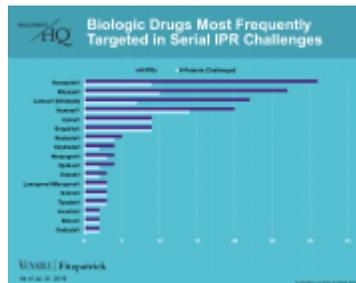
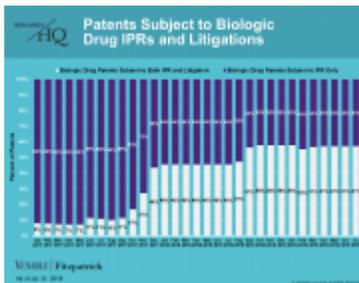
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IPR 1000	Humira	Humira	Final	Standard	Humira	Accepted Jan 2018
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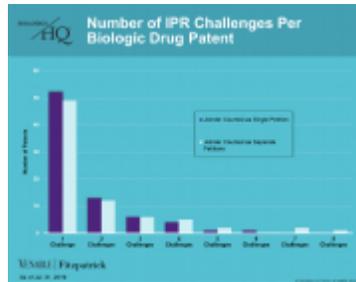
Biologic Drug IPRs by Reference Product



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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