



May 7, 2019



LATEST NEWS



More Uncertainty After DOJ Signals Approval of ACA Reversal

Ha Kung Wong comments on what could happen if the Trump administration is successful in persuading the Fifth Circuit Court of Appeals to affirm a lower court ruling that the Affordable Care Act is invalid for the Center for Biosimilars.



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

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

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" 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®**, **Erelzi®**, and **Eticovo™**), and insulin glargine (**Lantus®** / **Lantus® SoloSTAR®** and **Basaglar®**) have been updated with activity through April 30, 2019.

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UPDATES

IPRs and PGRs

Lantus® (insulin glargine recombinant):

- On April 2, 2019, IPR2018-01675 and IPR2018-01676 filed by **Mylan** and **Biocon** were instituted.
- On April 3, 2019, IPR2018-01670, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, and IPR2019-00122 filed by **Mylan** and **Biocon** were instituted.
- On April 3, 2019, IPR2018-01696 filed by **Mylan** and **Biocon** was denied institution.

Rituxan® (rituximab):

- On April 2, 2019, **Pfizer** and **Genentech's** joint request to terminate IPR2017-01923 due to settlement after institution was granted.

Taltz® (ixekizumab):

- On April 2, 2019, **Eli Lilly** filed PGR2019-00043.

Ajovy® (fremanezumab-vfrm) / Emgality® (galcanezumab-gnlm):

- On April 3, 2019, IPR2018-01710, IPR2018-01711 and IPR2018-01712 filed by **Eli Lilly** were instituted.

Dupixent® (dupilumab):

- On April 10, 2019, **Immunex** filed Federal Circuit Appeal No. 19-1749, appealing the final written decision finding all challenged claims unpatentable in IPR2017-01884.
- On April 17, 2019, **Sanofi** filed Federal Circuit Appeal No. 19-1777, appealing the final written decision finding no challenged claim unpatentable in IPR2017-01879.

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

- On April 14, 2019, **Fresenius Kabi** and Dr. Reddy's filed IPR2019-00971.
- On April 19, 2019, PGR2019-00001 filed by **Apotex** and **Kashiv BioSciences** was instituted.

Litigations

Eylea® (aflibercept) / Lucentis® (ranibizumab) / Zaltrap® (ziv-aflibercept):

- On April 1, 2019, partial judgment/stipulation of non-infringement was entered for claims 1, 2, 4-6, 8, 9, 13, and 14 of U.S. Patent No. 5,688,688 in Case No. 7:18-cv-02434 (S.D.N.Y) between **Novartis** and **Regeneron**. The case remains pending for claim 17.

Avastin® (bevacizumab):

- On April 3, 2019, **Genentech** filed Case No. 1:19-cv-00638 (D. Del.) against **Pfizer**.

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

- On April 4, 2019, **Apotex's** motion to dismiss Case No. 0:18-cv-61828 (S.D. Fla.) filed by **Amgen** was denied.

Enbrel® (etanercept):

- On April 30, 2019, **Amgen**, **Hoffmann-La Roche**, and **Immunex** filed Case No. 2:19-cv-11755 (D.N.J.) against **Samsung Bioepis**.

aBLA Applications and FDA Activity

LA-EP2006 (pegfilgrastim):

- On April 3, 2019, **Sandoz** resubmitted its aBLA for **LA-EP2006**, a proposed biosimilar of **Amgen's Neulasta® (pegfilgrastim)**.

Eticovo™ (etanercept-ykro):

- On April 25, 2019, **Samsung Bioepis's Eticovo™ (etanercept-ykro)**, a biosimilar of **Immunex's Enbrel® (etanercept)** was approved.

CDER Purple Book Updates

Evenity® (romosozumab-aqqg):

- On April 9, 2019, the FDA approved **Amgen's Evenity® (romosozumab-aqqg)**.

Skyrizi™ (risankizumab-rzaa):

- On April 23, 2019, the FDA approved **AbbVie's Skyrizi™ (risankizumab-rzaa)**.

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

Idacio® (adalimumab):

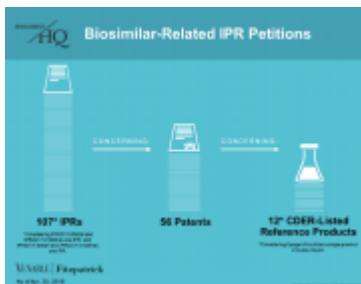
- On April 3, 2019, **Fresenius Kabi's Idacio® (adalimumab)**, a biosimilar of **AbbVie's Humira® (adalimumab)** was approved in the E.U.

Truxima® (rituximab-abbs):

- On April 10, 2019, **Teva** announced that **Truxima® (rituximab-abbs)**, a biosimilar of **Genentech's Rituxan® (rituximab)** was approved in Canada.

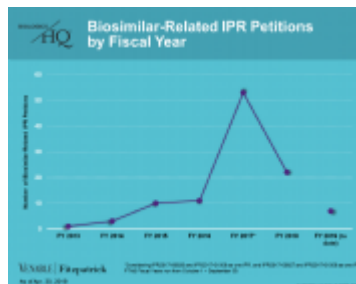
STATISTICS

Biosimilar-Related IPR Petitions



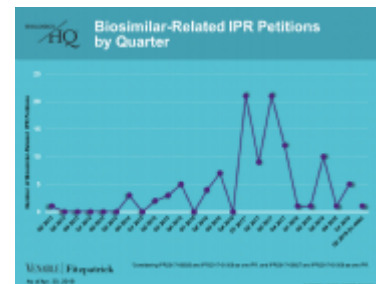
Biosimilar-Related IPRs by Reference Product

Biosimilar-Related IPR Petitions by Fiscal Year

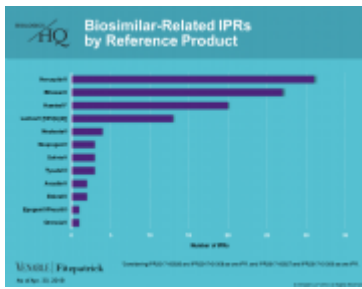


Biosimilar-Related IPRs: Number of Patents and Claims Challenged

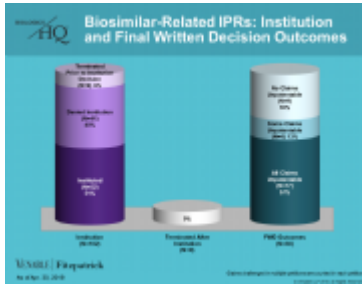
Biosimilar-Related IPR Petitions by Quarter



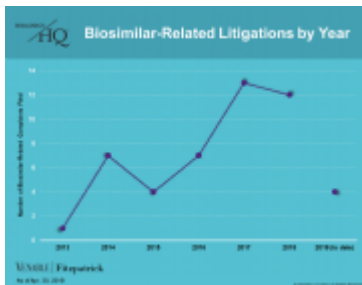
Status of Biosimilar-Related IPRs



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



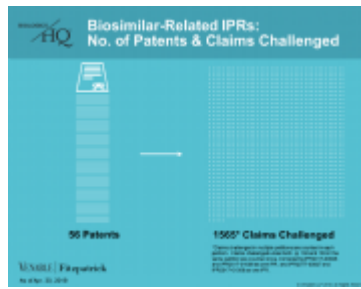
Biosimilar-Related Litigations by Year



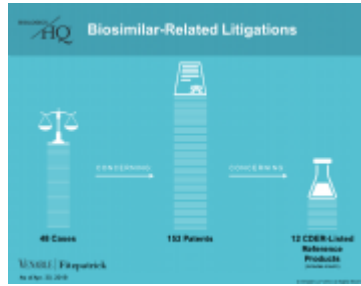
Biosimilar Applications Pending in the United States

Reference Product	Generic Name	IPR to Reference Product	Reference Product	Reference Product	Patent	Patent	Patent
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab
Amgen	Adalimumab	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab

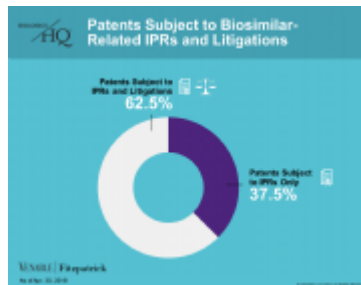
Patents Subject to Biologic Drug IPRs and Litigations



Biosimilar-Related Litigations



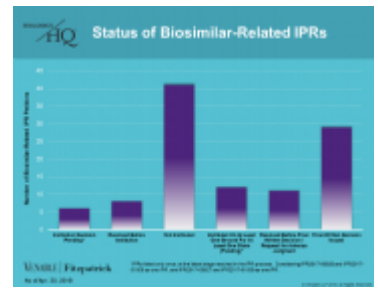
Patents Subject to Biosimilar-Related IPRs and Litigations



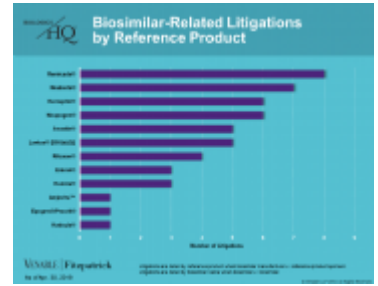
Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



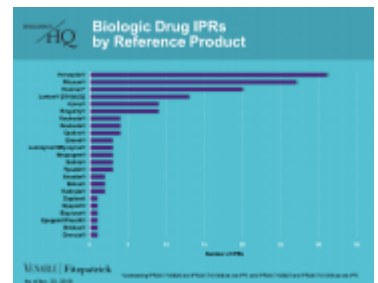
Biosimilar-Related Litigations by Reference Product



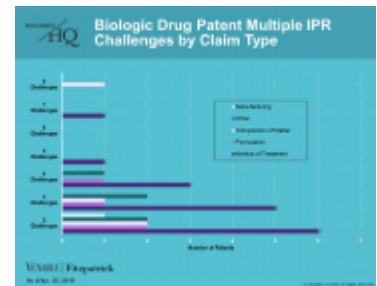
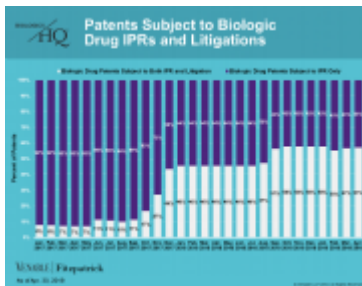
Biosimilars Approved in the United States

IPR No.	Reference Product	Generic Name	Reference Product	Reference Product	Patent	Patent	Patent	Patent	U.S. Patent
IPR 1000001	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000002	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000003	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000004	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000005	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000006	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000007	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000008	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000009	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab
IPR 1000010	Amgen	Adalimumab	Amgen	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab	Adalimumab

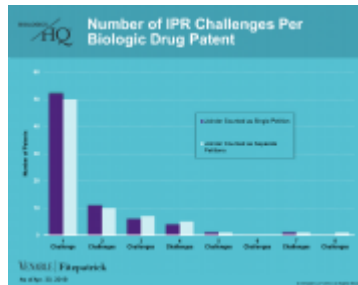
Biologic Drug IPRs by Reference Product



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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