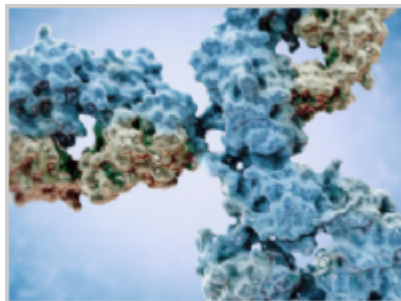




October 8, 2019



LATEST NEWS



Can Congress Speed Biosimilars to Market by Limiting Patent Litigations?

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

Biosimilar uptake has been low in the United States so far, with market shares for most biosimilars under 10%. Given the cost savings potential, trying to increase biosimilar uptake has been high on Congress’ agenda. There are many bills pending in Congress dealing with issues from a

variety of angles, such as changes to the FDA Purple Book listing of biologic drugs, limits on patent litigation, changes to patent office proceedings, and ways to combat anticompetitive behavior, such as innovator product sponsors inappropriately withholding samples. But will they actually help bring biosimilars to market more quickly?

Using data compiled for [BiologicsHQ.com](#), we analyzed 2 bills, the Affordable Prescriptions for Patients Act of 2019 (S.1416) and the Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act (HR.3991), that propose changes to patent litigation by limiting the number of patents a reference product sponsor can assert in a patent litigation to see how many biosimilar cases they would have impacted so far and whether they would really help bring biosimilars to market sooner.

Reference Product	Biosimilar	Litigation Case	Status
Humira® (adalimumab)	Amjevita™ (adalimumab-atto)	Humira® (adalimumab) v. Amjevita™ (adalimumab-atto) (2018-10-15)	Settlement
Humira® (adalimumab)	Amjevita™ (adalimumab-atto)	Humira® (adalimumab) v. Amjevita™ (adalimumab-atto) (2018-10-15)	Settlement
Humira® (adalimumab)	Amjevita™ (adalimumab-atto)	Humira® (adalimumab) v. Amjevita™ (adalimumab-atto) (2018-10-15)	Settlement
Humira® (adalimumab)	Amjevita™ (adalimumab-atto)	Humira® (adalimumab) v. Amjevita™ (adalimumab-atto) (2018-10-15)	Settlement
Humira® (adalimumab)	Amjevita™ (adalimumab-atto)	Humira® (adalimumab) v. Amjevita™ (adalimumab-atto) (2018-10-15)	Settlement

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[®] \(etanercept-szszs\) / 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 September 30, 2019.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through September 30, 2019.

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UPDATES

IPRs and PGRs

[Neupogen[®] \(filgrastim\) / Neulasta[®] \(pegfilgrastim\):](#)

- On September 11, 2019, IPR2019-00791 and IPR2019-00797 filed by [Kashiv BioSciences](#) and [Amneal](#) were instituted.

Litigations

[Neupogen[®] \(filgrastim\):](#)

- On September 3, 2019, in Fed. Cir. Case No. 18-1551 (appealing 3:14-cv-04741 (N.D. Cal.)), and consolidated Fed. Cir. Case No. 18-1552 (appealing 3:16-cv-02581 (N.D. Cal.)), [Amgen's](#) petition for rehearing *en banc* was granted-in-part, removing the sentence from the Court's opinion stating that the doctrine of equivalents "applies only in exceptional cases."

[Herceptin[®] \(trastuzumab\):](#)

- On September 4, 2019, in [Genentech v. Amgen](#), Case No. 1:18-cv-00924 (D. Del.), [Genentech](#) added U.S. Patent No. 9,868,760 to its complaint.

[Eylea[®] \(aflibercept\) / Lucentis[®] \(ranibizumab\) / Zaltrap[®] \(ziv-aflibercept\):](#)

- On September 5, 2019, in [Novartis Vaccines and Diagnostics v. Regeneron](#), Case No. 1:18-cv-02434 (S.D.N.Y.), the Court issued a judgment of non-infringement and order of dismissal after the parties stipulated to non-infringement and requested dismissal of the case.

[Kadcyla[®] \(ado-trastuzumab emtansine\):](#)

- On September 5, 2019, in [Phigenix v. Genentech](#), Fed. Cir. Case No. 17-2617, the Federal Circuit affirmed the District Court's summary judgment of non-infringement in Case No. 5:15-cv-01238 (N.D. Cal.). Because the

opinion was affirmed, the conditional cross appeal, Fed. Cir. 18-1042, was not decided.

Neulasta® (pegfilgrastim):

- On September 16, 2019, **Amgen** and **Mylan** stipulated to non-infringement of U.S. Patent No. 9,643,997 in Case No. 2:17-cv-01235 (W.D. Pa.). The case is now terminated as the parties previously stipulated to non-infringement of U.S. Patent No. 8,273,707.

Avastin® (bevacizumab):

- On September 20, 2019, **Genentech** and **Pfizer's** stipulated dismissal due to settlement in Case No. 1:19-cv-00638 (D. Del.) was ordered.

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

Herzuma® (trastuzumab-pkrb):

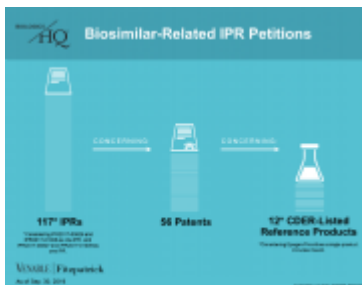
- On September 11, 2019, **Teva** and **Celltrion** announced that **Herzuma® (trastuzumab-pkrb)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, was approved in Canada.

Aranesp® (darbepoetin alfa):

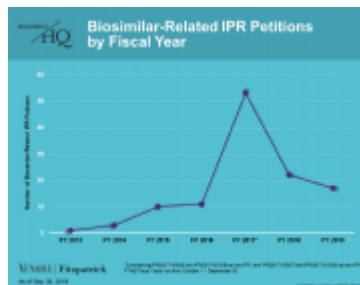
- On September 23, 2019, Dong-A ST and Sanwa Kagaku Kenkyusho (SKK) announced that DA-3880, a biosimilar of **Amgen's Aranesp® (darbepoetin alfa)** was approved in Japan.
- On September 24, 2019, Chong Kun Dang Pharmaceutical announced that CKD-11101, a biosimilar of **Amgen's Aranesp® (darbepoetin alfa)** was approved in Japan.

STATISTICS

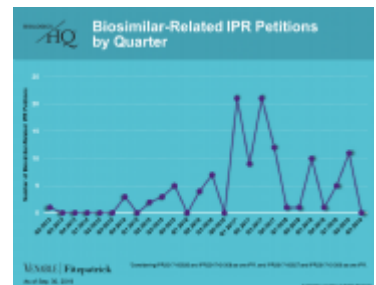
Biosimilar-Related IPR Petitions



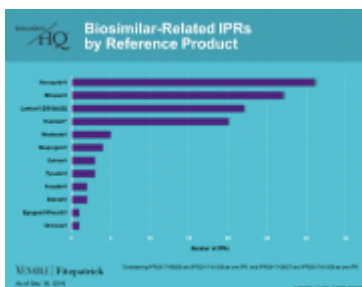
Biosimilar-Related IPR Petitions by Fiscal Year



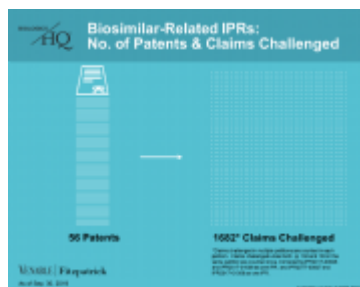
Biosimilar-Related IPR Petitions by Quarter



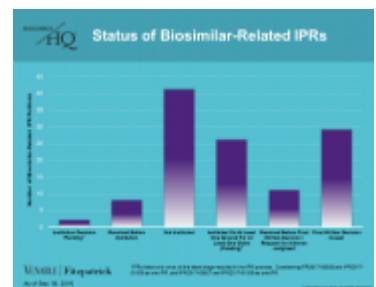
Biosimilar-Related IPRs by Reference Product



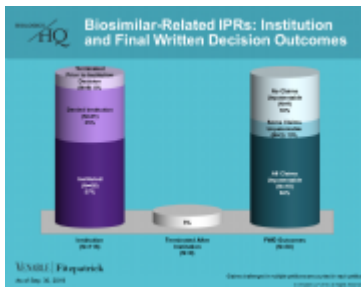
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



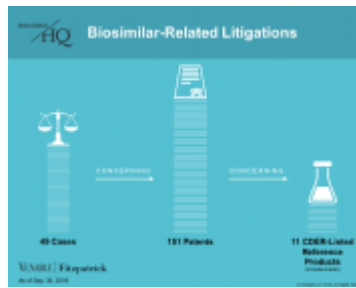
Status of Biosimilar-Related IPRs



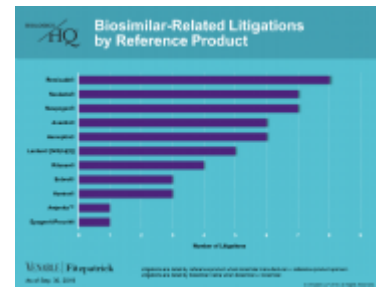
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



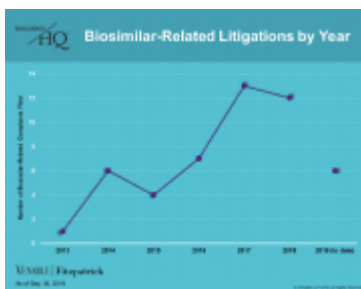
Biosimilar-Related Litigations



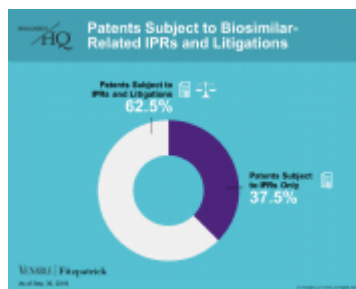
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



Biosimilars Approved in the United States

U.S. Brand Name	Reference Product	Manufacturer	Approval Date	Approval Type	U.S. Marketing Status
Humira	Adalimumab	AbbVie Inc.	Aug 30, 2013	Standard	U.S. Brand
Avastin	Pegfilgrastin	Roche	Jul 25, 2013	Standard	U.S. Brand
Enbrel	Etanercept	Amgen Inc.	Jul 25, 2013	Standard	U.S. Brand
Other biosimilars	Various	Various	2013-2018	Standard	U.S. Brand

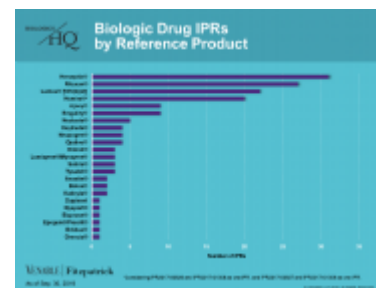
Biosimilar Applications Pending in the United States

Reference Product	Manufacturer	U.S. Brand Name	Approval Date	U.S. Marketing Status
Humira	AbbVie Inc.	Humira	Aug 30, 2013	U.S. Brand
Avastin	Roche	Avastin	Jul 25, 2013	U.S. Brand
Enbrel	Amgen Inc.	Enbrel	Jul 25, 2013	U.S. Brand
Other biosimilars	Various	Various	2013-2018	U.S. Brand

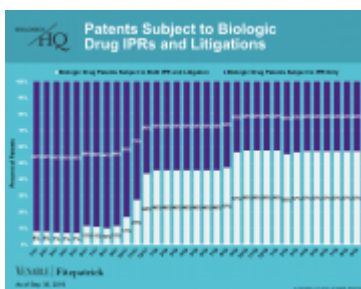
Biologic Drug IPR Petitions



Biologic Drug IPRs by Reference Product



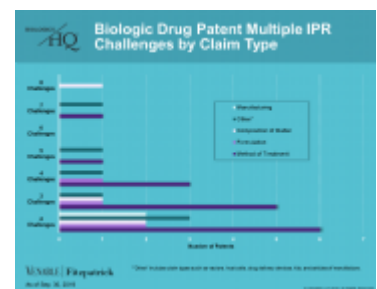
Patents Subject to Biologic Drug IPRs and Litigations



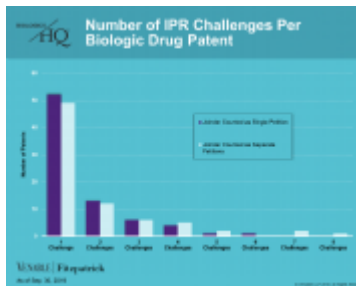
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



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.

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