

MONTHLY INJECTION



July 9, 2019



LATEST NEWS



New Bill Would Reshape Drug Patent Cases in Uncertain Ways

Ha Kung Wong commented on the Terminating the Extension of Rights Misappropriated Act, or TERM Act, H.R. 3199, as part of the Law360 article "New Bill Would Reshape Drug Patent Cases in Uncertain Ways."

The TERM Act was introduced in the House of Representatives on June 12, 2019 by Rep. Hakeem Jeffries, D-N.Y., to address drug companies obtaining multiple patents on the same drug to prevent generic

competition, referred to as "evergreening."



Comparing the Economics of Biosimilars and Generics

Ha Kung Wong spoke at the ACI 10th Summit on Biosimilars as part of a panel that reviewed the economics of biosimilars and generic drugs. Highlights from his presentation comparing biosimilar markets in Europe and the United States and his take-home points for stakeholders were included in the article "Comparing the Economics of Biosimilars and Generics" by the Center for Biosimilars.

Spotlight On: Biosimilar Litigations					
Plaintiff	Defendant	Case Name	Filing Date	Case Status	Notes
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018
AbbVie Inc. (Plaintiff)	Amgen Inc. (Defendant)	Amgen Inc. v. AbbVie Inc.	8/1/2018	Settlement	Settled 12/1/2018

Spotlight On: Biosimilar Litigations

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" product 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 June 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 June 30, 2019.

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News

UPDATES

IPRs and PGRs

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

- On June 6, 2019, [Fresenius Kabi](#) and Dr. Reddy's filed IPR2019-01183.

Herceptin[®] (trastuzumab):

- On June 28, 2019, [Samsung Bioepis](#) and [Genentech](#) filed a motion to dismiss Fed. Cir. Case No. 19-1173, appealing the final written decision in IPR2017-01959, due to settlement.

Litigations

Neupogen[®] (filgrastim):

- On June 7, 2019, [Amgen](#) filed a petition for an *en banc* rehearing of the Federal Circuit's decision in Case No. 18-1551, which affirmed the District Court's decision in Case No. 3:14-cv-04741 (N.D. Cal.).

Opdivo[®] (nivolumab):

- On June 13, 2019, the court ordered [Bristol-Myers Squibb](#) and [Genentech's](#) stipulated dismissal in Case No. 1:17-cv-01027 (D. Del.).
- On June 13, 2019, the court ordered [Bristol-Myers Squibb](#) and [AstraZeneca's](#) stipulated dismissal in Case No. 1:17-cv-01028 (D. Del.).

Herceptin[®] (trastuzumab):

- On June 28, 2019, [Samsung Bioepis](#) and [Genentech](#) filed a stipulation of dismissal due to settlement in Case No. 1:18-cv-01363 (D. Del.).

aBLA Applications and FDA Activity

Kanjinti™ (trastuzumab-anns):

- On June 13, 2019, Amgen and Allergan's Kanjinti™ (trastuzumab-anns), a biosimilar of Genentech's Herceptin® (trastuzumab) was approved.

Zirabev™ (bevacizumab-bvzr):

- On June 27, 2019, Pfizer's Zirabev™ (bevacizumab-bvzr), a biosimilar of Genentech's Avastin® (bevacizumab) was approved.

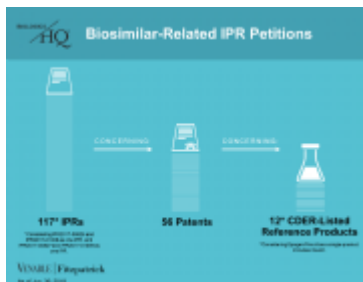
CDER Purple Book Updates

Polivy™ (polatuzumab vedotin-piiq):

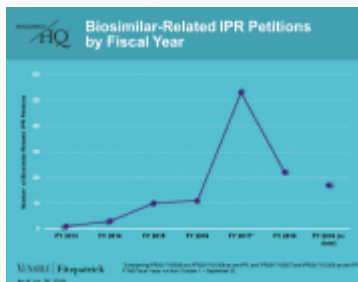
- On June 10, 2019, the FDA approved Genentech's Polivy™ (polatuzumab vedotin-piiq).

STATISTICS

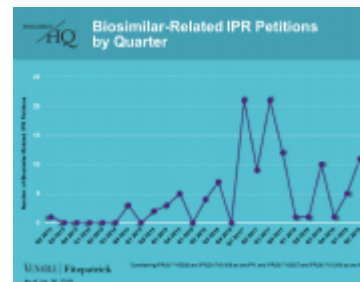
Biosimilar-Related IPR Petitions



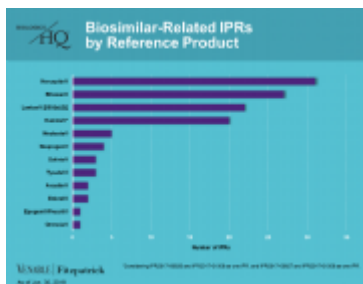
Biosimilar-Related IPR Petitions by Fiscal Year



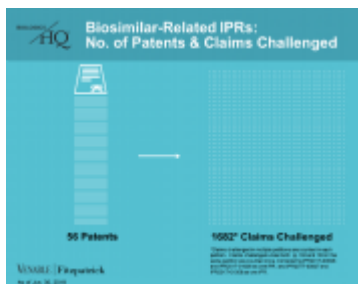
Biosimilar-Related IPR Petitions by Quarter



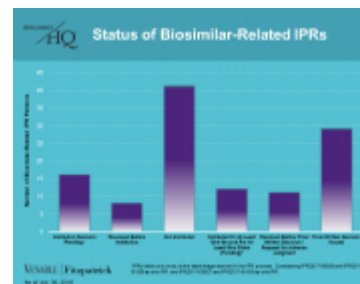
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



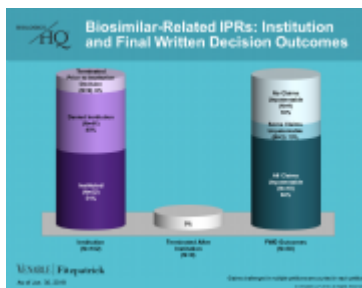
Status of Biosimilar-Related IPRs



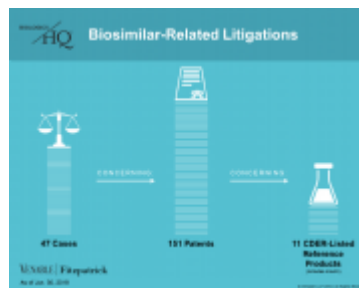
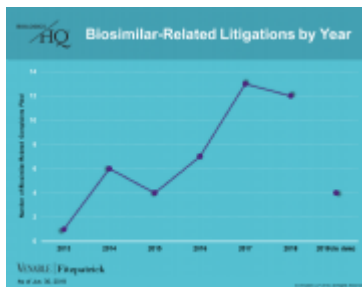
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

Biosimilar-Related Litigations

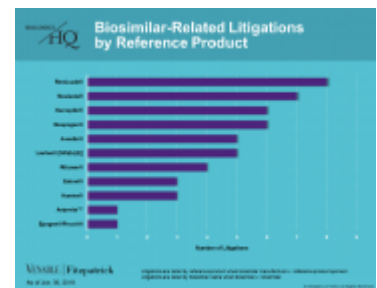
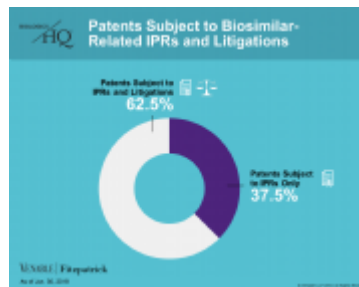
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



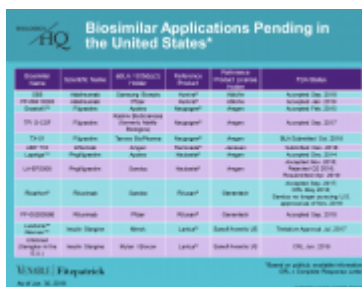
Patents Subject to Biosimilar-Related IPRs and Litigations



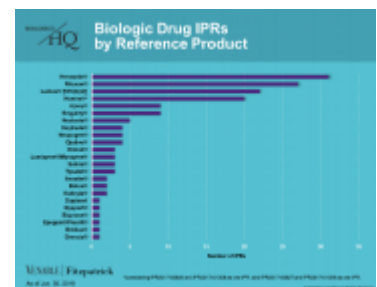
Biosimilars Approved in the United States



Biosimilar Applications Pending in the United States



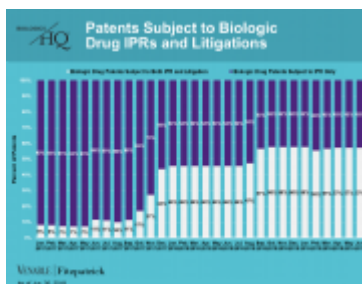
Biologic Drug
IPR
Petitions



Biologic Drug Patent Multiple IPR Challenges by Claim Type



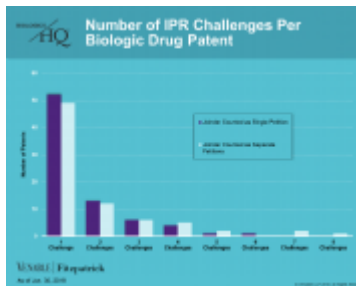
Patents Subject to Biologic Drug IPRs and Litigations



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



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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