

MONTHLY
INJECTION



February 11, 2019



LATEST NEWS

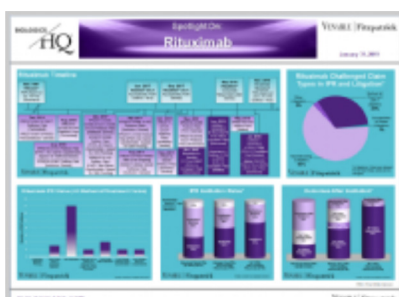


Featured Video: Upcoming Changes to Biologics Regulation

Ha Kung Wong discusses how upcoming changes to the regulation of biologics are generating industry uncertainty with his answer to the question, "By 2020, some products that are currently regulated as drugs, like insulin, will be regulated as biologics. Does this fact pose any challenges—or opportunities—from the patent litigation standpoint?" as part of a video series for the Center for Biosimilars.

View Additional Commentary on Biosimilars from Ha Kung Wong:

- **The Center for Biosimilars Most Watched Biosimilars Interview of 2018: FDA and FTC Cooperation to Address Anticompetitive Behavior**
- **Noteworthy Ongoing Biosimilar Litigation**
- **Changes to IPRs and PGRs for Biologics**
- **The BPCIA One Year After Sandoz v. Amgen**
- **Biosimilar Manufacturer's Approach to the Patent Dance**
- **The Importation of Biologics and Biosimilars**
- **The FDA's Biosimilar Action Plan**



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

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

Spotlight On: Enbrel[®] (etanercept) / Erelzi[®]

(etanercept-szszs)

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[®]** and **Erelzi[®]**), and insulin glargine (**Lantus[®] / Lantus[®] SoloSTAR[®]** and **Basaglar[®]**) have been updated with activity through January 31, 2019.

Read More
News

UPDATES

IPRs and PGRs

Rituxan[®] (rituximab):

- On January 3, 2019, **Biogen** filed Federal Circuit Appeal No. 19-1364 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-01168.
- On January 16, 2019, the PTAB granted **Pfizer's** request to withdraw its request for rehearing of the decision not to institute in IPR2017-01166.

Herceptin[®] (trastuzumab):

- On January 10, 2019, **Hospira** was dismissed from Federal Circuit Appeal No. 19-1265 appealing the Final Written Decision finding all instituted claims unpatentable in IPR2017-00737, due to settlement. The appeal remains ongoing for **Samsung Bioepis**.

Humira[®] (adalimumab):

- On January 31, 2019, **Coherus** was dismissed after settlement from consolidated Federal Circuit Appeal Nos. 17-2304, 17-2305, and 17-2306 appealing the Final Written Decisions finding all instituted claims unpatentable in IPR2016-00172, IPR2016-00188, and IPR2016-00189. The appeals remain ongoing between **AbbVie** and the U.S. as Intervenor.

Litigations

Praluent[®] (alirocumab) / Repatha[®] (evolocumab):

- On January 7, 2019, the Supreme Court denied the writ of certiorari in **Amgen v. Sanofi**, Case No. 18-127.

Herceptin[®] (trastuzumab):

- On January 17, 2019, **Genentech** added U.S. Patent No. 10,160,811 to **Genentech v. Amgen**, Case No. 1:18-cv-00924 (D. Del.).

Amjevita[™] (adalimumab):

- On January 24, 2019, **Coherus** filed Case No. 1:19-cv-00139 (D. Del.) against **Amgen**.

Hemlibra[®] (emicizumab-kxwh):

- On January 25, 2019, final judgment of non-infringement was entered and invalidity counterclaims were dismissed in **Baxalta v. Genentech**, Case No. 1:17-cv-00509 (D. Del.).

Darzalex® (daratumumab):

- On January 31, 2019, stipulated dismissal was entered in *MorphoSys v. Janssen*, Case No. 1:16-cv-00221 (D. Del.).

aBLA Applications and FDA Activity

Udenyca™ (pegfilgrastim-cbqv):

- On January 3, 2019, **Coherus** confirmed it had launched **Udenyca™ (pegfilgrastim-cbqv)**, its biosimilar of **Neulasta® (pegfilgrastim)**.

Ontruzant® (trastuzumab-dttb):

- On January 18, 2019, the FDA approved **Samsung Bioepis's Ontruzant® (trastuzumab-dttb)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**.

Kanjinti™ (ABP 980) (trastuzumab):

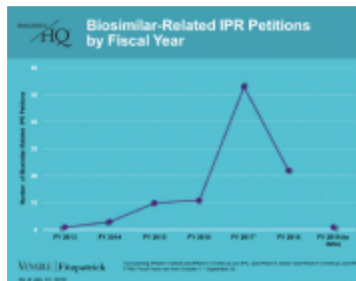
- On January 29, 2019, **Amgen** announced that it resubmitted its aBLA for **Kanjinti™ (ABP 980) (trastuzumab)**, it's proposed biosimilar of **Genentech's Herceptin® (trastuzumab)**, to the FDA in December 2018.

STATISTICS

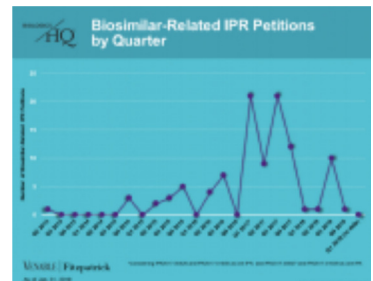
Biosimilar-Related IPR Petitions



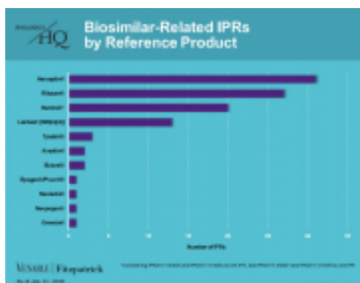
Biosimilar-Related IPR Petitions by Fiscal Year



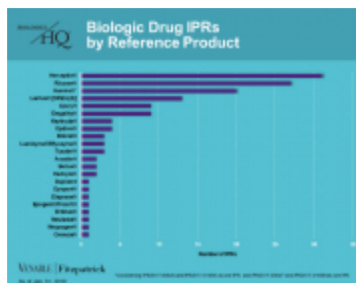
Biosimilar-Related IPR Petitions by Quarter



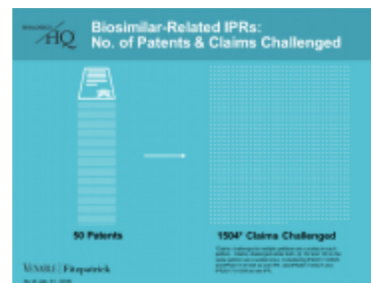
Biosimilar-Related IPRs by Reference Product



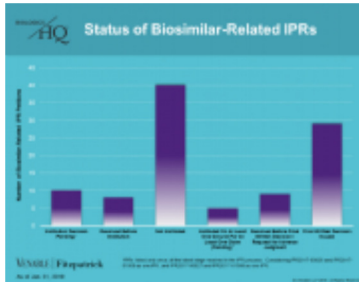
Biologic Drug IPRs by Reference Product



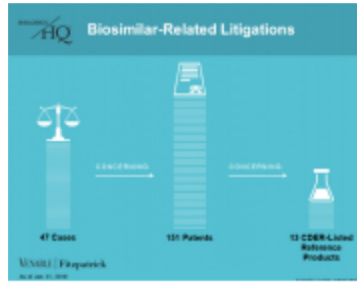
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



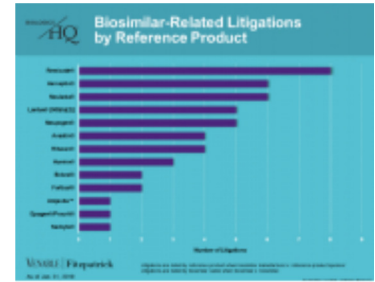
Status of Biosimilar-Related IPRs



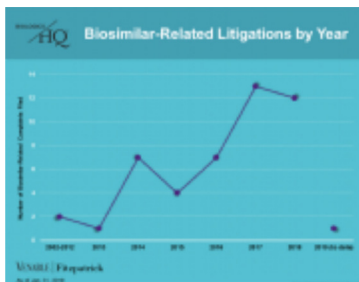
Biosimilar-Related Litigations



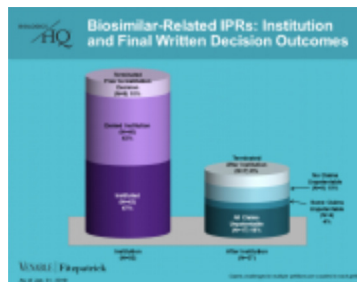
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



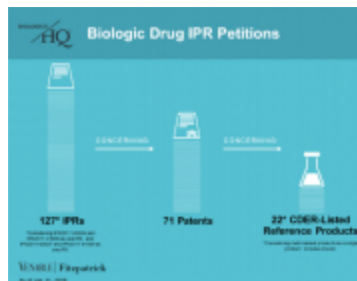
Biosimilars Approved in the United States

ANDA #	Reference Product	Generic Product	Approval Date	Approval Type	Manufacturer	US Approval
ANDA 141024	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141025	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141026	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141027	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141028	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141029	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141030	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141031	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141032	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141033	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141034	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141035	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141036	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141037	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141038	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141039	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes
ANDA 141040	Humira	Humira	Aug 14, 2013	ANDA	Amgen	Yes

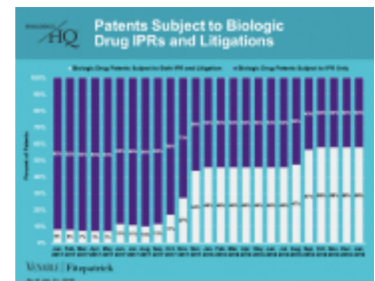
Biosimilar Applications Pending in the United States

Reference Product	Generic Name	ANDA Status	Reference Product	Reference Product Status	ICR Status
Humira	Adalimumab	Approved	Humira	Approved	Adopted Nov 2013
Avastin	Bevacizumab	Approved	Avastin	Approved	Adopted Nov 2013
Enbrel	Etanercept	Approved	Enbrel	Approved	Adopted Nov 2013
Humira	Adalimumab	Approved	Humira	Approved	Adopted Nov 2013
Avastin	Bevacizumab	Approved	Avastin	Approved	Adopted Nov 2013
Enbrel	Etanercept	Approved	Enbrel	Approved	Adopted Nov 2013
Humira	Adalimumab	Approved	Humira	Approved	Adopted Nov 2013
Avastin	Bevacizumab	Approved	Avastin	Approved	Adopted Nov 2013
Enbrel	Etanercept	Approved	Enbrel	Approved	Adopted Nov 2013
Humira	Adalimumab	Approved	Humira	Approved	Adopted Nov 2013
Avastin	Bevacizumab	Approved	Avastin	Approved	Adopted Nov 2013
Enbrel	Etanercept	Approved	Enbrel	Approved	Adopted Nov 2013
Humira	Adalimumab	Approved	Humira	Approved	Adopted Nov 2013
Avastin	Bevacizumab	Approved	Avastin	Approved	Adopted Nov 2013
Enbrel	Etanercept	Approved	Enbrel	Approved	Adopted Nov 2013

Biologic Drug IPR Petitions



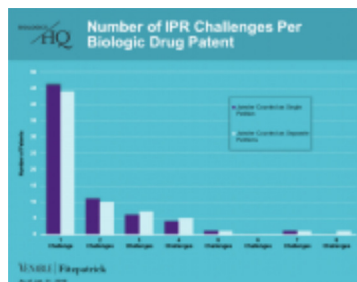
Patents Subject to Biologic Drug IPRs and Litigations



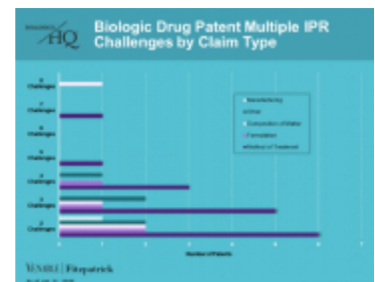
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Number of IPR Challenges Per Biologic Drug Patent



Biologic Drug Patent Multiple IPR Challenges by Claim Type



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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