

MONTHLY INJECTION



February 8, 2021



LATEST NEWS



Patent Cases To Watch In 2021

[Ha Kung Wong](#) spoke with Law360 for an article analyzing the patent cases to watch in 2021, including *U.S. v. Arthrex*, which involves the constitutionality of how administrative patent law judges who preside over *inter partes* review (IPR) and post grant review (PGR) proceedings are appointed at the Patent Trial and Appeal Board (PTAB).



Spotlight On: Neulasta[®] (pegfilgrastim) / Fulphila[®] (pegfilgrastim-jmdb) / Udenyca[®] (pegfilgrastim-cbqv) / Ziextenzo[®] (pegfilgrastim-bmez) / Nyvepria[™] (pegfilgrastim-apgf)

Spotlight On: Herceptin[®] (trastuzumab) / Ogivri[™] (trastuzumab-dkst) / Herzuma[®] (trastuzumab-pkrb) /

Ontruzant[®] (trastuzumab-dttb) / Trazimera[™] (trastuzumab-qyyp) / Kanjinti[®] (trastuzumab-anns)

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) / Abrilada[™] (adalimumab-afzb) / Hulio[®] (adalimumab-fkjp)

Spotlight On: Enbrel[®] (etanercept) / Erelzi[®] (etanercept-szzs) / Eticovo[®] (etanercept-ykro)

Spotlight On: Lantus[®] / Lantus[®] SoloSTAR[®] (insulin glargine recombinant) / Basaglar[®] (insulin glargine) / Semglee[™] (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 pegfilgrastim ([Neulasta[®]](#), [Lapelga[™]](#), [Ziextenzo[®]](#), [Udenyca[®]](#), [Fulphila[®]](#), [Nyvepria[™]](#), and [MSB11455](#)), trastuzumab ([Herceptin[®]](#), [Ogivri[™]](#), [Herzuma[®]](#), [Ontruzant[®]](#), [Trazimera[™]](#), and [Kanjinti[®]](#)), rituximab ([Rituxan[®]](#), [Truxima[®]](#), and [Ruxience[®]](#)), adalimumab ([Humira[®]](#), [Amjevita[™]](#), [Cyltezo[®]](#), [Hyrimoz[™]](#), [Hadlima[™]](#), [Abrilada[™]](#), and [Hulio[®]](#)), etanercept ([Enbrel[®]](#), [Erelzi[®]](#), and [Eticovo[®]](#)), and insulin glargine ([Lantus[®]](#) / [Lantus[®] SoloSTAR[®]](#), [Basaglar[®]](#), and [Semglee[™]](#)) have been updated with activity through January 31, 2021.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through January 31, 2021.

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More
News

UPDATES

IPRs and PGRs

Keytruda[®] (pembrolizumab):

- On January 7, 2021, [Merck Sharp & Dohme](#) filed PGR2021-00036 against [Genentech](#).
- On January 20, 2021, [Merck Sharp & Dohme](#) filed PGR2021-00039 against [Genentech](#).

Eylea[®] (aflibercept):

- On January 7, 2021, [Chengdu Kanghong Biotechnology](#) filed IPR2021-00402 and PGR2021-00035 against [Regeneron](#).
- On January 15, 2021, the PTAB denied institution in [Regeneron v. Novartis](#) IPR2020-01317.

Enhertu[®] (fam-trastuzumab deruxtecan-nxki):

- On January 22, 2021, [Daiichi Sankyo](#) and [AstraZeneca](#) filed PGR2021-00042 against [Seagen](#).

Lantus[®] (insulin glargine recombinant):

- On January 27, 2021, [Pfizer](#) withdrew Fed. Cir. Cross Appeal No. 20-2144, appealing the final written decision in IPR2018-01684 finding some instituted claims unpatentable.

aBLA Applications and FDA Activity

Nyvepria[™] (pegfilgrastim-apgf):

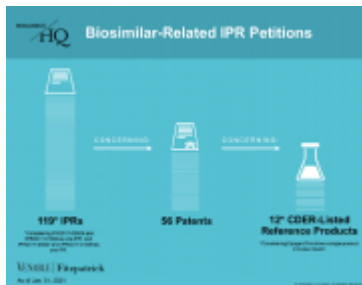
- On January 22, 2021, it was announced that [Pfizer](#) and [Hospira](#) launched [Nyvepria[™] \(pegfilgrastim-apgf\)](#), a biosimilar of [Amgen's Neulasta[®] \(pegfilgrastim\)](#), in the U.S.

BAT1706 (bevacizumab):

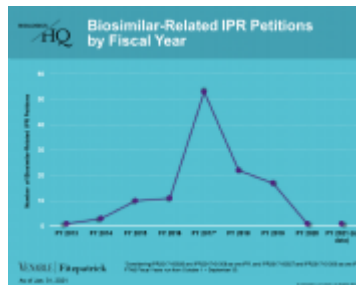
- On January 28, 2021, **Bio-Thera Solutions** announced that the FDA had accepted an aBLA for **BAT1706 (bevacizumab)**, a proposed biosimilar of **Genentech's Avastin® (bevacizumab)**.

STATISTICS

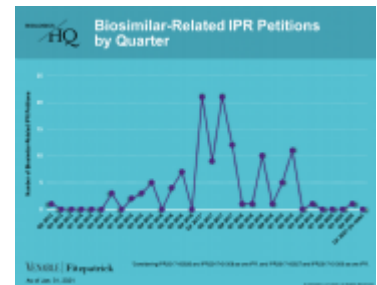
Biosimilar-Related IPR Petitions



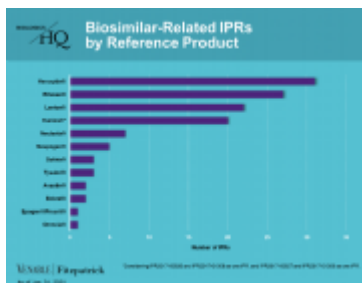
Biosimilar-Related IPR Petitions by Fiscal Year



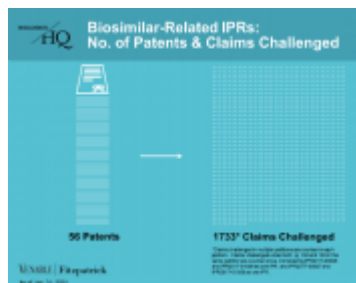
Biosimilar-Related IPR Petitions by Quarter



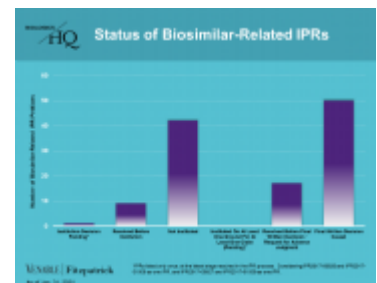
Biosimilar-Related IPRs by Reference Product



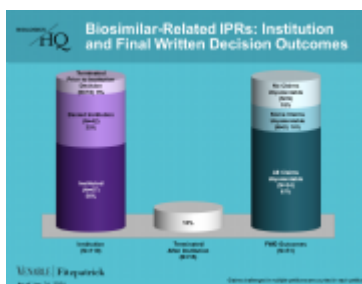
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



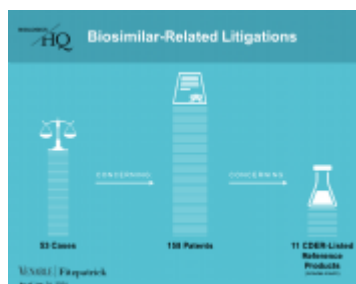
Status of Biosimilar-Related IPRs



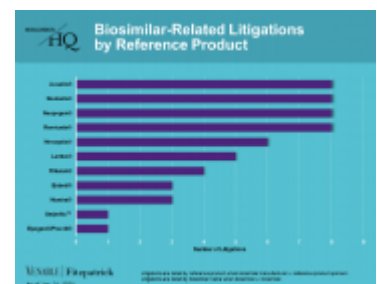
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations



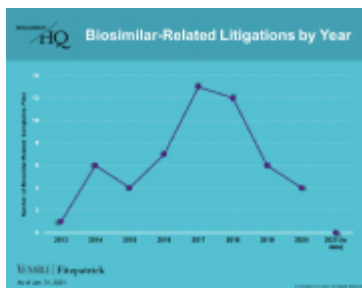
Biosimilar-Related Litigations by Reference Product



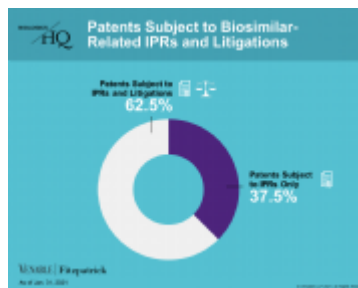
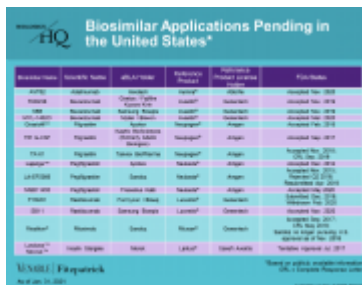
Biosimilar-Related Litigations by Year

Patents Subject to Biosimilar-Related IPRs and Litigations

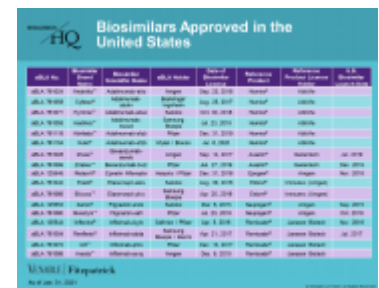
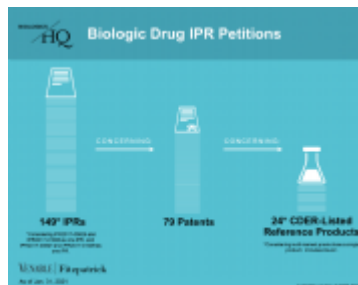
Biosimilars Approved in the United States



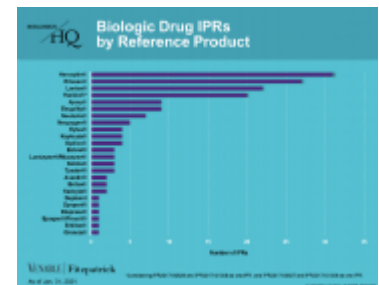
Biosimilar Applications Pending in the United States



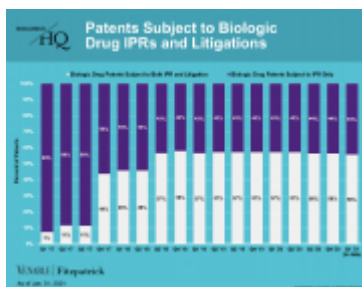
Biologic Drug
IPR
Petitions



Biologic Drug IPRs by Reference Product



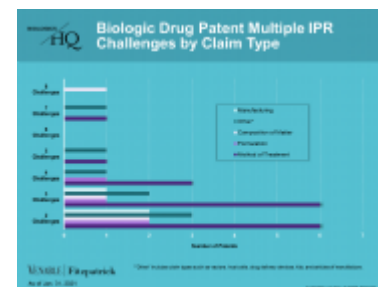
Patents Subject to Biologic Drug IPRs and Litigations



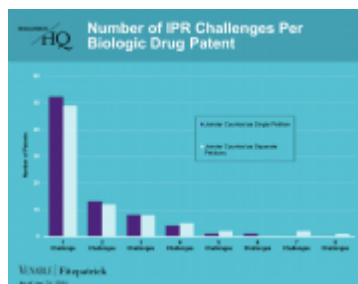
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



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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