



December 9, 2020



LATEST NEWS



[2020 Analysis on PTAB Contested Proceedings](#)

By: [Justin Oliver](#)

Venable Fitzpatrick released its [annual statistical report](#) on AIA trials before the USPTO's Patent Trial and Appeal Board, including stats for IPRs, PGRs, and CBMs. The in-depth study analyzes the types of arguments that succeed more often than others and the trends over time in PTAB decisions.

The analysis has again shown the advantage of obviousness challenges over anticipation challenges for IPRs, along with a corresponding downward trend in the use of anticipation challenges. Additionally, the report shows a slight uptick in IPR unpatentability findings (the chance of a claim being found unpatentable is now about 50%). For PGRs and CBMs, the analysis further confirms the dominance of patent eligibility challenges. This year's analysis also shows another increase in the success rate for motions to amend.

Venable Fitzpatrick presents this analysis to provide practitioners additional data points in order to make informed decisions throughout the AIA trial process.



[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[®] \(etanercept-szss\) / 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 November 30, 2020.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through November 30, 2020.

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News

UPDATES

IPRs and PGRs

[Myozyme[®] / Lumizyme[®] \(alglucosidase alfa\)](#):

- On November 9, 2020, the Supreme Court denied the writ of certiorari in [Duke University v. Biomarín](#), Sup. Ct. 19-1475, appealing the decisions in Fed. Cir. Case Nos. 16-1106 and 18-1696 from the PTAB's decision in IPR2013-00535.

Litigations

[Lantus[®] \(insulin glargine recombinant\)](#):

- On November 2, 2020, the District Court entered final judgment in [Sanofi v. Mylan](#) Case No. 2:17-cv-09105 (D.N.J.). On November 19, 2020, [Sanofi](#) filed Fed. Cir. Appeal No. 21-1262.

[Avastin[®] \(bevacizumab\)](#):

- On November 12, 2020, [Genentech](#) filed Case No. 2:20-cv-00361 (E.D. Tex.) against [Centus Biotherapeutics](#), [Fujifilm](#), and [Kyowa Kirin](#) relating to proposed biosimilar [FKB238 \(bevacizumab\)](#).

Enhertu® (fam-trastuzumab deruxtecan-nxki):

- On November 13, 2020, Daiichi Sankyo and AstraZeneca filed declaratory judgment Case No. 1:20-cv-01524 (D. Del.) against Seagen.

aBLA Applications and FDA Activity

FKB238 (bevacizumab):

- On November 12, 2020, Genentech listed in a district court complaint that an aBLA for Centus Biotherapeutics, Fujifilm, and Kyowa Kirin's FKB238 (bevacizumab) had been accepted by the FDA on November 18, 2019. FKB238 (bevacizumab) is a proposed biosimilar of Genentech's Avastin® (bevacizumab).

SB11 (ranibizumab):

- On November 18, 2020, Samsung Bioepis and Biogen announced the FDA had accepted for review an aBLA for SB11 (ranibizumab), a proposed biosimilar of Genentech's Lucentis® (ranibizumab).

AVT02 (adalimumab):

- On November 19, 2020, Alvotech announced the FDA had accepted for review an aBLA for AVT02 (adalimumab), a proposed biosimilar of AbbVie's Humira® (adalimumab).

CDER Purple Book Updates

Danyelza® (naxitamab-ggqk):

- On November 25, 2020, the FDA approved Y-Mabs Therapeutics' Danyelza® (naxitamab-ggqk).

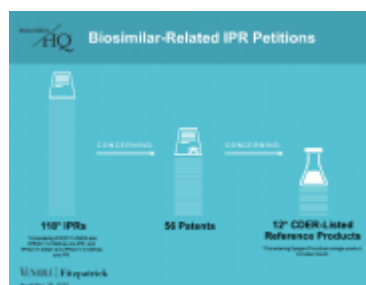
Non-U.S. Biosimilars / Follow-On Biologics

Nyvepria™ (pegfilgrastim-apgf):

- On November 23, 2020, Pfizer announced that Nyvepria™ (pegfilgrastim-apgf), a biosimilar of Amgen's Neulasta® (pegfilgrastim) was approved in the E.U.

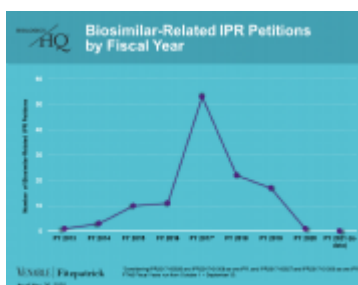
STATISTICS

Biosimilar-Related IPR Petitions



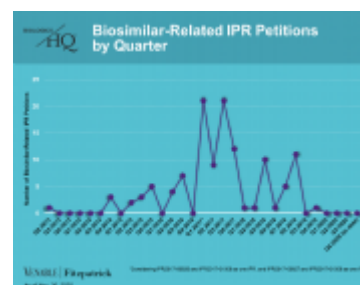
Biosimilar-Related IPRs by Reference

Biosimilar-Related IPR Petitions by Fiscal Year



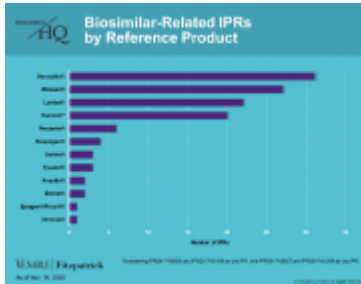
Biosimilar-Related IPRs: Number of Patents

Biosimilar-Related IPR Petitions by Quarter

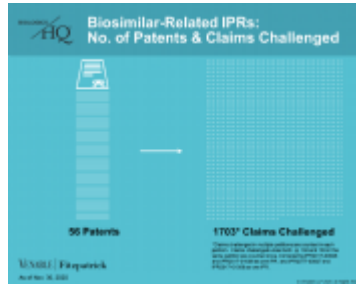


Status of Biosimilar-

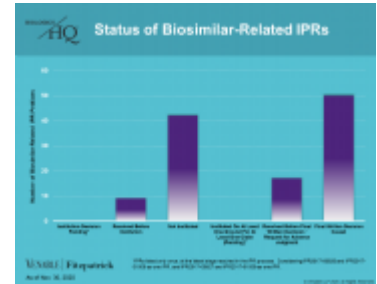
Product



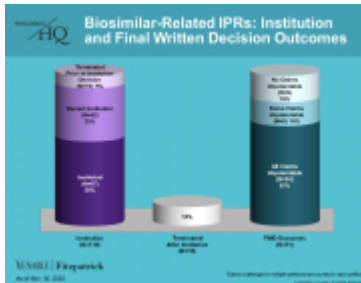
and Claims Challenged



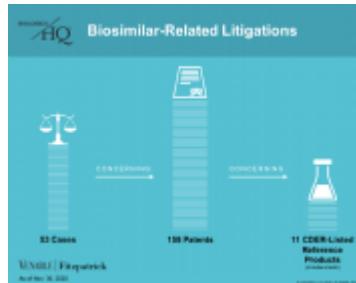
Related IPRs



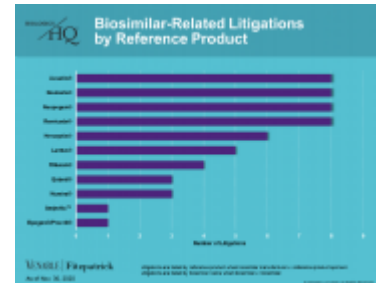
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



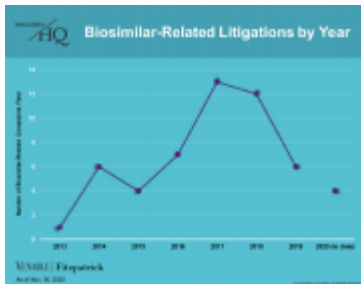
Biosimilar-Related Litigations



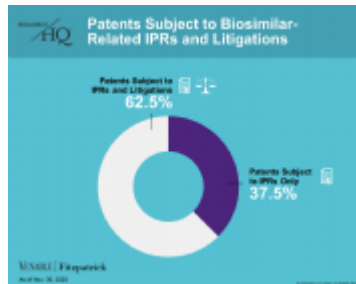
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



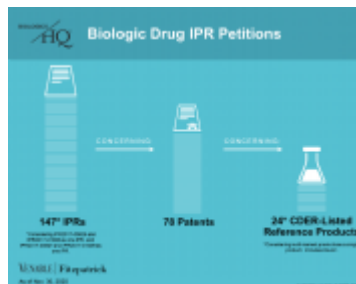
Biosimilars Approved in the United States

ANDA No.	Generic Name	Reference Product	USDA Name	Approval Date	Manufacturer	Reference Product Manufacturer	USDA Status
ANDA 101001	Humira	Adalimumab	Humira	Mar 23, 2013	Amgen	Amgen	Approved
ANDA 101002	Enbrel	Etanercept	Enbrel	May 28, 2013	Amgen	Amgen	Approved
ANDA 101003	Avastin	Pegfilgrastim	Avastin	May 28, 2013	Amgen	Amgen	Approved
ANDA 101004	Herceptin	Trastuzumab	Herceptin	May 28, 2013	Amgen	Amgen	Approved
ANDA 101005	Rituximab	Rituximab	Rituximab	May 28, 2013	Amgen	Amgen	Approved
ANDA 101006	Humira	Adalimumab	Humira	May 28, 2013	Amgen	Amgen	Approved
ANDA 101007	Enbrel	Etanercept	Enbrel	May 28, 2013	Amgen	Amgen	Approved
ANDA 101008	Avastin	Pegfilgrastim	Avastin	May 28, 2013	Amgen	Amgen	Approved
ANDA 101009	Herceptin	Trastuzumab	Herceptin	May 28, 2013	Amgen	Amgen	Approved
ANDA 101010	Rituximab	Rituximab	Rituximab	May 28, 2013	Amgen	Amgen	Approved
ANDA 101011	Humira	Adalimumab	Humira	May 28, 2013	Amgen	Amgen	Approved
ANDA 101012	Enbrel	Etanercept	Enbrel	May 28, 2013	Amgen	Amgen	Approved
ANDA 101013	Avastin	Pegfilgrastim	Avastin	May 28, 2013	Amgen	Amgen	Approved
ANDA 101014	Herceptin	Trastuzumab	Herceptin	May 28, 2013	Amgen	Amgen	Approved
ANDA 101015	Rituximab	Rituximab	Rituximab	May 28, 2013	Amgen	Amgen	Approved

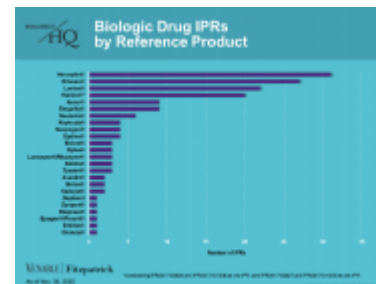
Biosimilar Applications Pending in the United States

ANDA No.	Generic Name	Reference Product	USDA Name	Approval Date	Manufacturer	Reference Product Manufacturer
ANDA 101016	Humira	Adalimumab	Humira	May 28, 2013	Amgen	Amgen
ANDA 101017	Enbrel	Etanercept	Enbrel	May 28, 2013	Amgen	Amgen
ANDA 101018	Avastin	Pegfilgrastim	Avastin	May 28, 2013	Amgen	Amgen
ANDA 101019	Herceptin	Trastuzumab	Herceptin	May 28, 2013	Amgen	Amgen
ANDA 101020	Rituximab	Rituximab	Rituximab	May 28, 2013	Amgen	Amgen

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

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