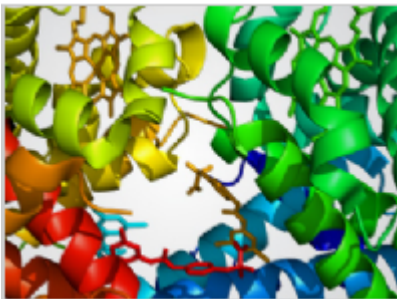




September 9, 2020

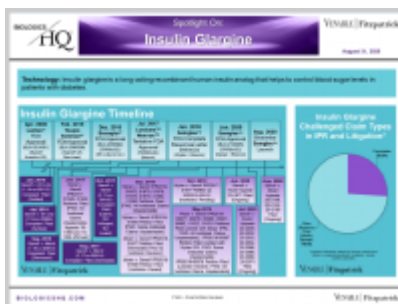


LATEST NEWS



[Pharma Giants Tee Up Biologics Innovation Fight At Fed. Circ.](#)

[Ha Kung Wong](#) spoke with Law360 for an article about [Amgen v. Sanofi](#), a case currently pending at the Federal Circuit involving patents related to the biologic drugs [Praluent](#) and [Repatha](#). At issue in this case is whether patents claiming a genus of antibodies meet the enablement requirement. Numerous companies, including [Bristol-Myers Squibb](#), [Merck](#), [Eli Lilly](#), and [Pfizer](#) have filed amicus briefs.



[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® \(etanercept-szsz\) / 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 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 August 31, 2020.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through August 31, 2020.

Read
More
News

UPDATES

IPRs and PGRs

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

- On August 6, 2020, [Mylan](#) and [Pfizer](#) filed Federal Circuit cross Appeal No. 20-2139 against [Sanofi](#), appealing the final written decision in IPR2018-01684 (IPR2019-00987 joined). On August 10, 2020, [Mylan](#) and [Pfizer](#) filed a second cross appeal, Federal Circuit Appeal No. 20-2144.
- On August 11, 2020, the PTAB issued a final written decision in [Mylan v. Sanofi](#) IPR2019-00979 finding all challenged claims unpatentable. On August 17, 2020, [Sanofi](#) filed Federal Circuit Appeal No. 20-2159 appealing this final written decision.

Litigations

[Hemlibra[®] \(emicizumab-kxwh\):](#)

- On August 27, 2020, in [Baxalta v. Genentech](#), Fed. Cir. Appeal No. 19-1527, the Federal Circuit vacated and remanded the District Court's decision in 1:17-cv-00509 (D. Del.) that found the patent-at-issue was not infringed.

aBLA Applications and FDA Activity

[Semglee[™] \(insulin glargine\):](#)

- On August 31, 2020, [Mylan](#) and [Biocon](#) announced the launch of [Semglee[™] \(insulin garginine\)](#), a follow-on product of [Sanofi's Lantus[®] \(insulin glargine recombinant\)](#), at a 77% discount for individual vials.

CDER Purple Book Updates

[Blenrep[®] \(belantamab mafodotin-blmf\):](#)

- On August 5, 2020, the FDA approved GlaxoSmithKline's **Blenrep[®]** (belantamab mafodotin-blmf).

Enspryng[™] (satralizumab):

- On August 14, 2020, the FDA approved Genentech's **Enspryng[™]** (satralizumab).

Kesimpta[®] (ofatumumab):

- On August 20, 2020, the FDA approved Novartis's **Kesimpta[®]** (ofatumumab).

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

Herzuma[®] (trastuzumab-pkrb):

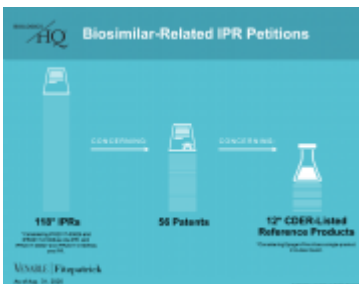
- On August 3, 2020, Celltrion announced that the World Health Organization (WHO) had awarded Herzuma[®] (trastuzumab-pkrb), a biosimilar of Genentech's **Herceptin[®]** (trastuzumab), prequalification certification.

Aybintio[™] (bevacizumab):

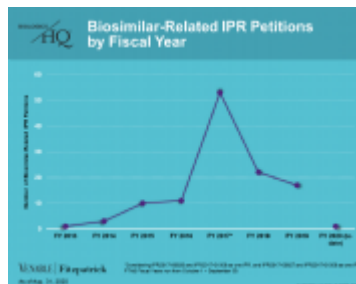
- On August 20, 2020, Samsung Bioepis announced that Aybintio[™] (bevacizumab), a biosimilar of Genentech's **Avastin[®]** (bevacizumab), was approved in the E.U.

STATISTICS

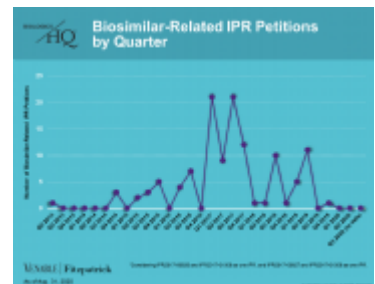
Biosimilar-Related IPR Petitions



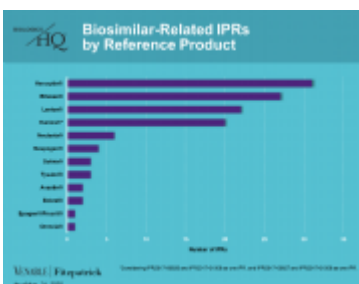
Biosimilar-Related IPR Petitions by Fiscal Year



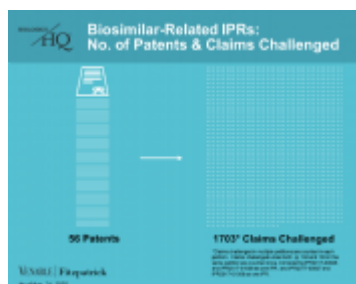
Biosimilar-Related IPR Petitions by Quarter



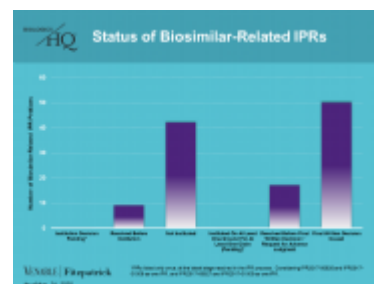
Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs: Number of Patents and Claims Challenged



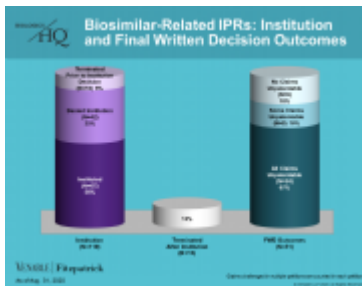
Status of Biosimilar-Related IPRs



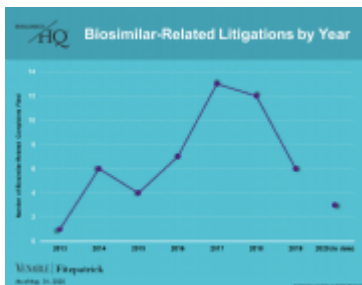
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes

Biosimilar-Related Litigations

Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year

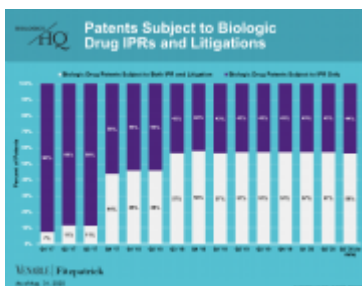


Biosimilar Applications Pending in the United States

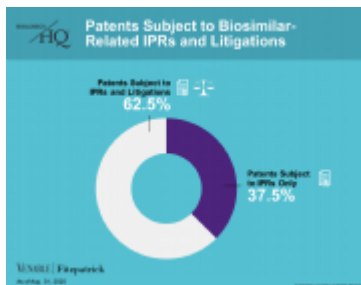
Biosimilar Applications Pending in the United States*

Reference Drug	Generic Name	IPR/USDA	Reference Product	Reference Product Approval	IPR Status
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA
AMGEN	Enbrel	USDA	Enbrel	Approved Dec 2010	USDA

Patents Subject to Biologic Drug IPRs and Litigations



Patents Subject to Biosimilar-Related IPRs and Litigations



Biologic Drug IPR Petitions

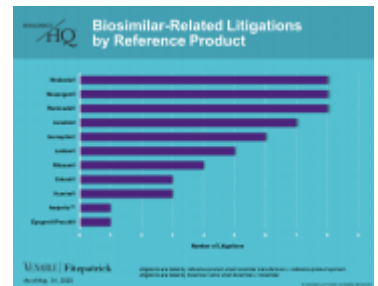


Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Number of IPR Challenges Per Biologic Drug Patent

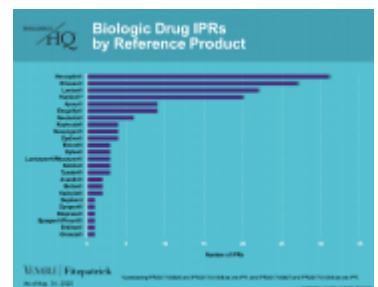
Biosimilars Approved in the United States



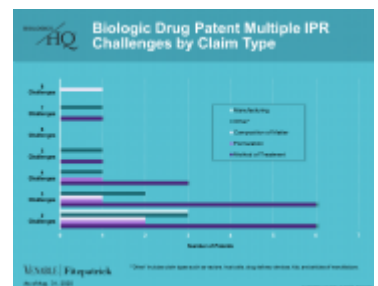
Biosimilars Approved in the United States

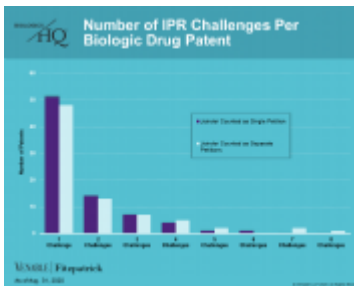
ANDA No.	Reference Drug	Generic Name	Reference Product	Reference Product Approval	IPR Status	USDA Status
ANDA 141021	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141022	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141023	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141024	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141025	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141026	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141027	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141028	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141029	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA
ANDA 141030	Enbrel	Enbrel	Enbrel	Approved Dec 2010	USDA	USDA

Biologic Drug IPRs by Reference Product



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.

Enter Keywords

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