

MONTHLY INJECTION



October 8, 2020



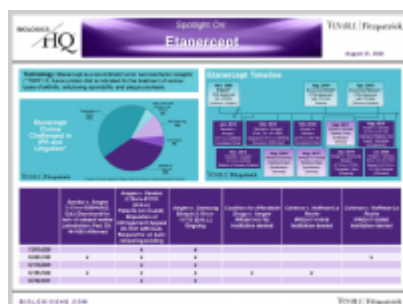
LATEST NEWS



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

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. A new dashboard concerning pegfilgrastim (Neulasta[®], Lapelga[™], Ziextenzo[®], Udenyca[®],

Fulphila[®], Nyvepria[™], and MSB11455) is now available, with activity through September 30, 2020.



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 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 September 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 September 30, 2020.

Read
More
News

UPDATES

Litigations

[Avonex[®] \(interferon beta-1a\) / Betaseron[®] \(interferon beta-1b\) / Extavia[®] \(interferon beta-1b\) / Rebif[®] \(interferon beta-1a\):](#)

- On September 28, 2020, in [Biogen v. EMD Serono](#), Fed. Cir. Case No. 19-1133, the Federal Circuit reversed and remanded the District Court's grant of judgment as a matter of law (JMOL) and conditional grant of a new trial on that ground, reinstating the jury's verdict of invalidity due to anticipation in Case No. 2:10-cv-02734 (D.N.J.) and consolidated Case No. 2:10-cv-02760 (D.N.J.).

[Enbrel[®] \(etanercept\):](#)

- On September 29, 2020, [Sandoz's](#) petition for panel rehearing and rehearing en banc was denied in Fed. Cir. Case No. 20-1037, appealing the decision in [Amgen v. Sandoz](#), Case No. 2:16-cv-01118 (D.N.J.).

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

[Equidacent \(bevacizumab\):](#)

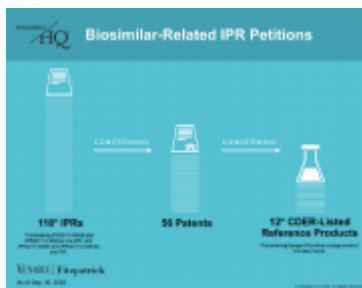
- On September 30, 2020, Centus Biotherapeutics announced that [Equidacent \(bevacizumab\)](#), a biosimilar of [Genentech's Avastin[®] \(bevacizumab\)](#), was approved in the E.U.

STATISTICS

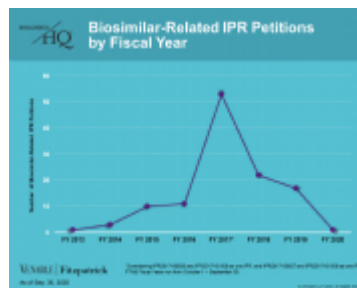
[Biosimilar-Related IPR Petitions](#)

[Biosimilar-Related IPR Petitions by Fiscal Year](#)

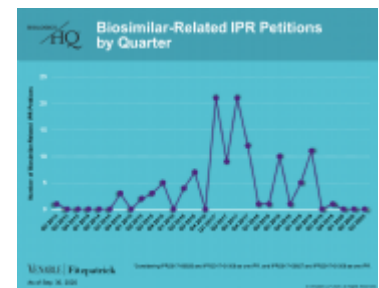
[Biosimilar-Related IPR Petitions by Quarter](#)



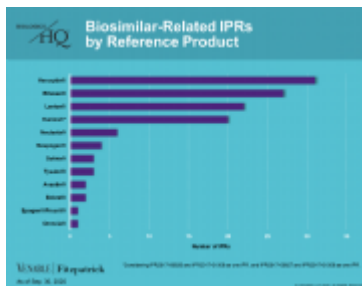
Biosimilar-Related IPRs by Reference Product



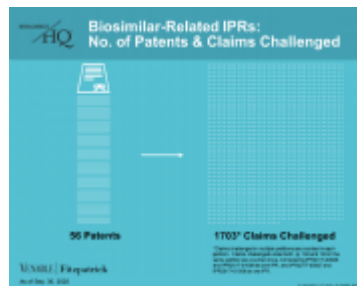
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



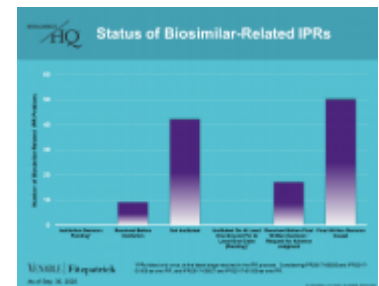
Status of Biosimilar- Related IPRs



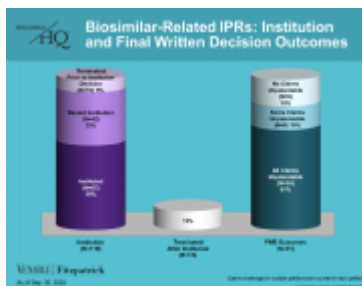
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



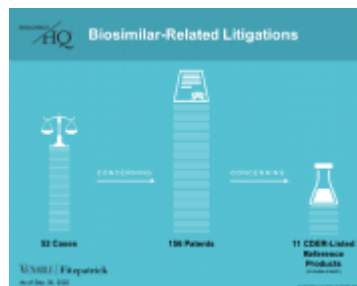
Biosimilar-Related Litigations



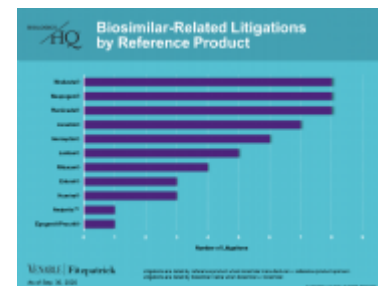
Biosimilar-Related Litigations by Reference Product



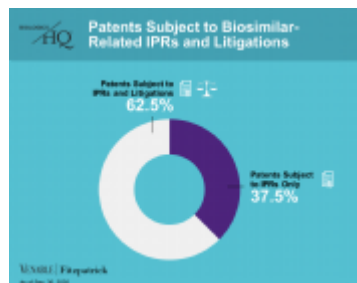
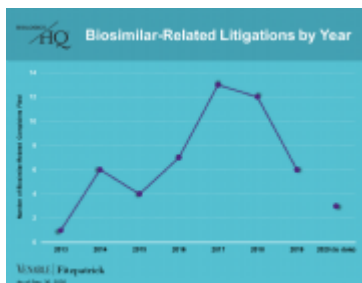
Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



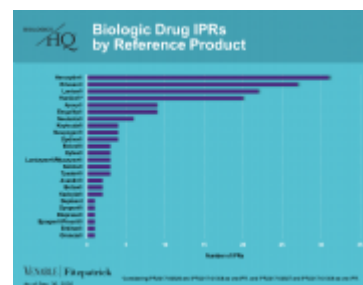
Biosimilars Approved in the United States

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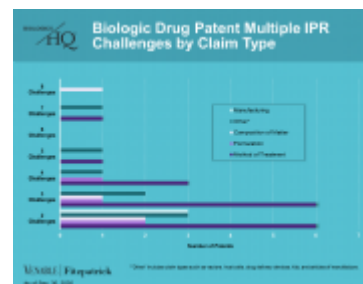
Biosimilar Applications Pending in the United States

Biologic Drug IPR Petitions

Biologic Drug IPRs by Reference Product



Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent

Category	Alliance Combination Drug/Patents	Alliance Combination Biotech Patents
All Biologics	10	9
All Biologics	4	3
All Biologics	2	2
All Biologics	1	1
All Biologics	1	0
All Biologics	0	0
All Biologics	0	0
All Biologics	0	0
All Biologics	0	0
All Biologics	0	0

Source: www.fda.gov/oc/ohrt/biologics

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