



April 8, 2020



LATEST NEWS



IAM Quotes Christopher Loh on What the Current Wave of Biosimilar Litigation Signals for the Future

[Christopher Loh](#)

In the Spring 2020 edition of *IAM*, [Christopher Loh](#) was quoted on what the current wave of biosimilar litigation signals for the future.

According to the article, the substantial increase in patent litigation involving biosimilar drugs over the past few years has raised important new strategic and legal questions for life sciences IP practitioners. The Biologics Price Competition and Innovation Act 2009, which created a new regulatory approval pathway for biosimilars in the United States, introduced a distinctive IP litigation framework. Centered on the multi-step exchange of information known as the ‘patent dance’, this framework also differs from that which governs generic small-molecule drug litigation.



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)

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

Spotlight On: Lantus[®] / Lantus[®] SoloSTAR[®] (insulin glargine recombinant) / Basaglar[®] (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[™]**, and **Abrilada[™]**), etanercept (**Enbrel[®]**, **Erelzi[®]**, and **Eticovo[™]**), and insulin glargine (**Lantus[®]** / **Lantus[®] SoloSTAR[®]** and **Basaglar[®]**) have been updated with activity through March 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 March 31, 2020.

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News

UPDATES

IPRs and PGRs

Neupogen[®] (filgrastim) / Neulasta[®] (pegfilgrastim):

- On March 24, 2020, in **Amgen v. Iancu** Federal Circuit Case No. 19-2171, the Federal Circuit vacated and remanded the final written decision in IPR2016-01542 consistent with the court's decision in *Arthrex*.

Herceptin[®] (trastuzumab):

- On March 26, 2020, in **Genentech v. Iancu** Federal Circuit Case Nos. 19-1263, 19-1265, 19-1267, and 19-1270, the Federal Circuit affirmed the final written decisions finding all challenged claims unpatentable in IPR2017-00731, IPR2017-00737, IPR2017-01121, and IPR2017-01122.

Ajovy[®] (fremanezumab-vfrm) / Emgality[®] (galcanezumab-gnlm):

- On March 31, 2020, the PTAB issued final written decisions in **Eli Lilly v. Teva** IPR2018-01710, IPR2018-01711, IPR2018-01712, finding no challenged claims unpatentable.

Litigations

Remicade[®] (infliximab):

- On March 5, 2020, in **Janssen v. Celltrion** Fed. Cir. Case Nos. 18-2321 and 18-2350, the Federal Circuit issued a Rule 36 affirmance of the District Court's grant of summary judgment of non-infringement in Case No. 1:17-cv-11008 (D. Mass.).

Herceptin[®] (trastuzumab):

- On March 6, 2020, in **Genentech v. Amgen** Fed. Cir. Case No. 19-2156, the Federal Circuit affirmed the District Court's denial of a Temporary Restraining Order and Preliminary Injunction in Case No. 1:18-cv-00924 (D. Del.).

Lantus® (insulin glargine recombinant):

- On March 9, 2020, the District Court issued an opinion in **Sanofi v. Mylan** Case No. 2:17-cv-09105 (D.N.J.) finding the claims at issue in U.S. Patent No. 9,526,844 were not infringed and were invalid for failure to satisfy the written description requirement.

Taltz® (ixekizumab):

- On March 16, 2020, the District Court granted **Genentech's** motion to voluntarily dismiss Case No. 3:18-cv-01518 (S.D. Cal.).

Epogen® / Procrit® (epoetin alfa):

- On March 16, 2020, the Federal Circuit denied **Hospira's** petition for en banc rehearing of its decision in Fed. Cir. Case No. 19-1067, affirming the final judgment in Case No. 1:15-cv-00839 (D. Del.).

aBLA Applications and FDA Activity

MYL-1402O (bevacizumab):

- On March 9, 2020, **Mylan** and **Biocon** announced that the FDA accepted their aBLA for **MYL-1402O (bevacizumab)**, a proposed biosimilar of **Genentech's Avastin® (bevacizumab)**.

Herzuma® (trastuzumab-pkrb):

- On March 16, 2020, **Celltrion** and **Teva** announced the launch of **Herzuma® (trastuzumab-pkrb)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, at a 10% discount.

CDER Purple Book Updates

Sarclisa® (isatuximab-irfc):

- On March 2, 2020, the FDA approved **Sanofi's Sarclisa® (isatuximab-irfc)**.

Creon® (pancrelipase (amylase; lipase; protease)):

- On March 23, 2020, the former NDA for **AbbVie's Creon® (pancrelipase)** was deemed to be a BLA.

Pancreaze® (pancrelipase (amylase; lipase; protease)):

- On March 23, 2020, the former NDA for **Vivus's Pancreaze® (pancrelipase)** was deemed to be a BLA.

Pertzye® (pancrelipase (amylase; lipase; protease)):

- On March 23, 2020, the former NDA for **Digestive Care's Pertzye® (pancrelipase)** was deemed to be a BLA.

Viokace® (pancrelipase (amylase; lipase; protease)):

- On March 23, 2020, the former NDA for **Viokace** and **Allergan's Viokace® (pancrelipase)** was deemed to be a BLA.

Zenpep® (pancrelipase (amylase; lipase; protease)):

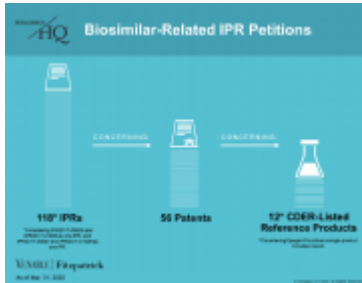
- On March 23, 2020, the former NDA for **Allergan's Zenpep® (pancrelipase)** was deemed to be a BLA.

Pulmotech™ MAA (technetium Tc 99m albumin aggregated):

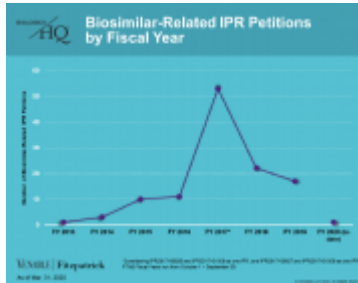
- On March 23, 2020, the former NDA for **Cis Bio's Pulmotech™ MAA (technetium Tc 99m albumin aggregated)** was deemed to be a BLA.

STATISTICS

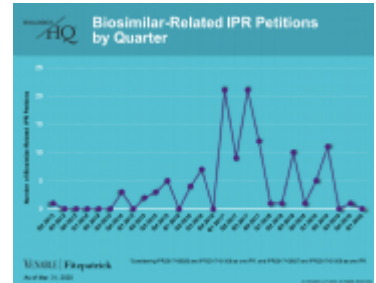
Biosimilar-Related IPR Petitions



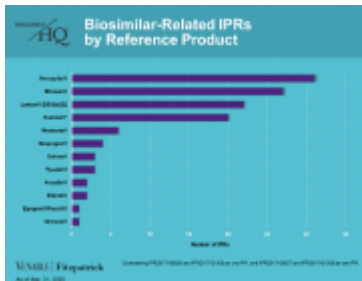
Biosimilar-Related IPR Petitions by Fiscal Year



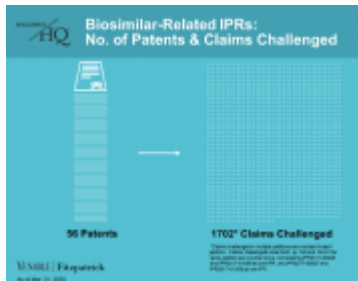
Biosimilar-Related IPR Petitions by Quarter



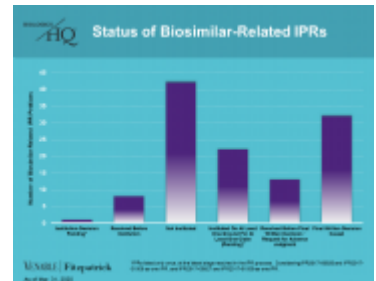
Biosimilar-Related IPRs by Reference Product



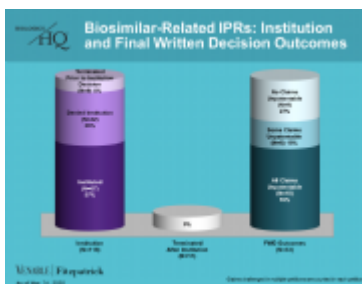
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



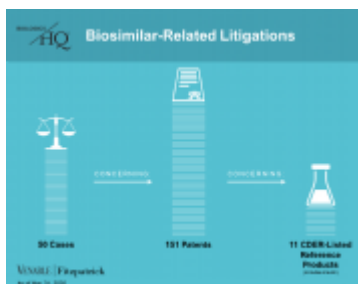
Status of Biosimilar-Related IPRs



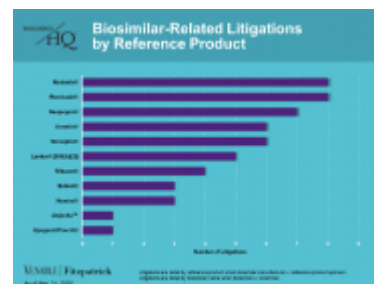
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations



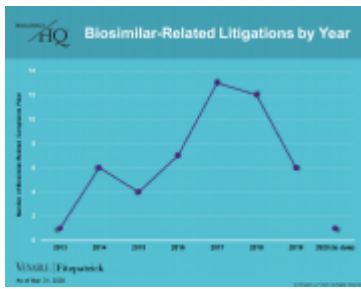
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year

Patents Subject to Biosimilar-Related IPRs and Litigations

Biosimilars Approved in the United States

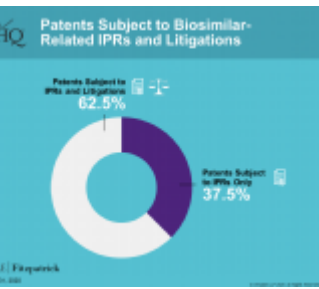
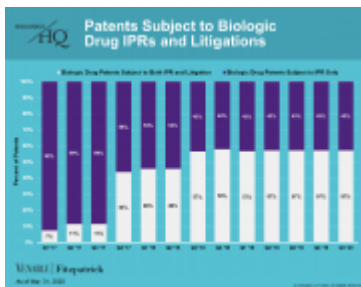


Biosimilar Applications Pending in the United States

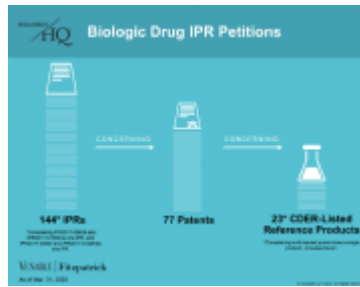
Reference Product	Generic Name	SRA	Approval Date
Amgen Inc.	Humira	Amgen	2013
Novartis	Humira	Novartis	2013
Amgen Inc.	Humira	Amgen	2014
Novartis	Humira	Novartis	2014
Amgen Inc.	Humira	Amgen	2015
Novartis	Humira	Novartis	2015
Amgen Inc.	Humira	Amgen	2016
Novartis	Humira	Novartis	2016
Amgen Inc.	Humira	Amgen	2017
Novartis	Humira	Novartis	2017
Amgen Inc.	Humira	Amgen	2018
Novartis	Humira	Novartis	2018
Amgen Inc.	Humira	Amgen	2019
Novartis	Humira	Novartis	2019
Amgen Inc.	Humira	Amgen	2020
Novartis	Humira	Novartis	2020

Source: IQVIA | Fiqarek

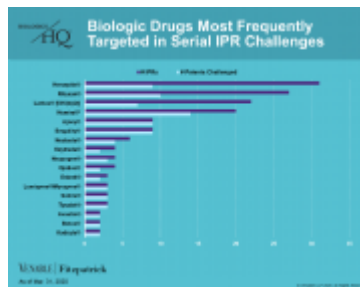
Patents Subject to Biologic Drug IPRs and Litigations



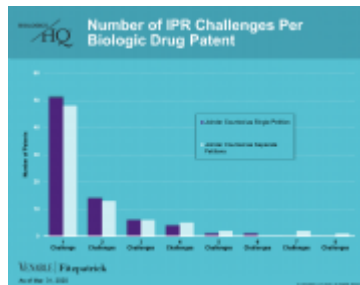
Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



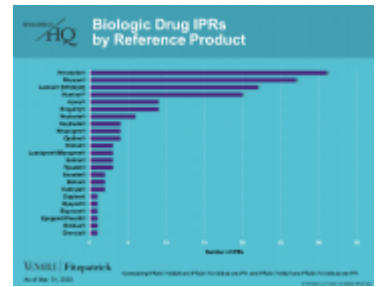
Number of IPR Challenges Per Biologic Drug Patent



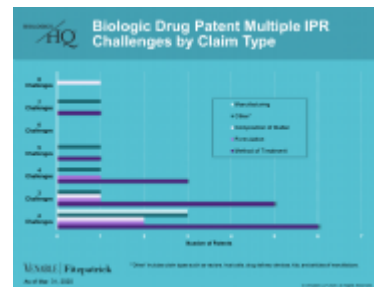
Reference Product	Generic Name	SRA	Approval Date
Amgen Inc.	Humira	Amgen	2013
Novartis	Humira	Novartis	2013
Amgen Inc.	Humira	Amgen	2014
Novartis	Humira	Novartis	2014
Amgen Inc.	Humira	Amgen	2015
Novartis	Humira	Novartis	2015
Amgen Inc.	Humira	Amgen	2016
Novartis	Humira	Novartis	2016
Amgen Inc.	Humira	Amgen	2017
Novartis	Humira	Novartis	2017
Amgen Inc.	Humira	Amgen	2018
Novartis	Humira	Novartis	2018
Amgen Inc.	Humira	Amgen	2019
Novartis	Humira	Novartis	2019
Amgen Inc.	Humira	Amgen	2020
Novartis	Humira	Novartis	2020

Source: IQVIA | Fiqarek

Biologic Drug IPRs by Reference Product



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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