

MONTHLY
INJECTION

June 8, 2020



LATEST NEWS

[Commentary: A Competitive Marketplace for Biosimilars](#)By: [April Breyer Menon](#) and [Ha Kung Wong](#)

On March 9, 2020, FDA and the US Federal Trade Commission (FTC) held a public workshop to discuss issues related to biosimilars in the United States. According to FDA and FTC, the workshop's purpose was to discuss the "FDA and FTC's collaborative efforts to support appropriate adoption of biosimilars, discourage false or misleading statements about biosimilars, and deter anticompetitive behaviors in the biologic marketplace." The workshop included speakers from the FDA, FTC, the pharmaceutical industry, biosimilar organizations, and patient advocacy groups. A public comment session allowed stakeholders to inform FDA and FTC of issues relevant to their businesses and organizations.

In BioPharm International, Venable Fitzpatrick's [April Breyer Menon](#) and [Ha Kung Wong](#) discuss important topics at the FDA/FTC Workshop, including:

- FDA's recent draft guidance "Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers"
- Exclusionary contracting, discounts, rebates, reimbursement, formulary placement
- Interchangeability
- Uncertainty
- Market Shares
- Product-specific FDA guidances
- Savings sharing programs

[April Breyer Menon Discusses 2 Potential Bills to Aid Biosimilar Uptake](#)

It's no secret that the US biosimilar industry has had a slow start in terms of uptake. Although the Hatch-Waxman Act and the Biologic Price Competition and Innovation Act (BPCIA) established pathways to



approval for both generic drugs and biosimilars, there is still much legislative work to be done in order to truly reap the benefits of biosimilars.

The Center for Biosimilars sat down with [April Breyer Menon](#) to discuss potential legislation such as The Hatch-Waxman Integrity Act and the Stop Stalling Act that would address barriers to biosimilar market entry.



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

Read
More
News

UPDATES

IPRs and PGRs

Taltz® (ixekizumab):

- On May 26, 2020, the PTAB granted Patent Owner **Genentech's** request for adverse judgment after institution in PGR2019-00043 filed by **Eli Lilly** and PGR2019-00044, filed by **UCB** on the same patent.

Lantus® (insulin glargine recombinant):

- On May 29, 2020, the PTAB issued final written decisions in **Mylan v. Sanofi** and joined **Pfizer v. Sanofi** IPRs.
 - The PTAB found all instituted claims unpatentable in IPR2018-01675 (and joined IPR2019-00977), IPR2018-01676 (and joined IPR2019-00978), IPR2018-01678 (and joined IPR2019-00980), IPR2018-01679 (and joined IPR2019-00981), IPR2018-01680 (and joined IPR2019-01022), IPR2018-01682 (and joined IPR2019-01023), and IPR2019-00122 (and joined IPR2019-00982)
 - The PTAB found some instituted claims unpatentable in IPR2018-01684 (and joined IPR2019-00987)
 - The PTAB also denied **Sanofi's** motion to amend in IPR2018-01679 / IPR2019-00981, IPR2018-01680 / IPR2019-01022, and IPR2018-01682 / IPR2019-01023.
- On May 29, 2020, **Sanofi** filed a notice of appeal from the final written decision finding all instituted claims unpatentable in IPR2018-01670.

Soliris® (eculizumab):

- On May 29, 2020, **Alexion** and **Amgen** filed joint motions to terminate due to settlement after institution in IPR2019-00739, IPR2019-00740 and IPR2019-00741.

Litigations

Remicade® (infliximab):

- On May 13, 2020, a stipulated motion to dismiss was granted in **Janssen v. Hyclone**, Case No. 1:16-cv-00071 (N.D. Utah).

Cimzia® (certolizumab pegol):

- On May 15, 2020, **Celltech** and **UCB** filed a declaratory judgment action, Case No. 1:20-cv-00650 (D. Del.), against **Nektar Therapeutics** related to patents allegedly covering **UCB's Cimzia® (certolizumab pegol)**.

aBLA Applications and FDA Activity

MSB11455 (pegfilgrastim):

- On May 27, 2020, **Fresenius Kabi** announced that the FDA accepted for review its aBLA for **MSB11455 (pegfilgrastim)**, a proposed biosimilar of **Amgen's Neulasta® (pegfilgrastim)**.

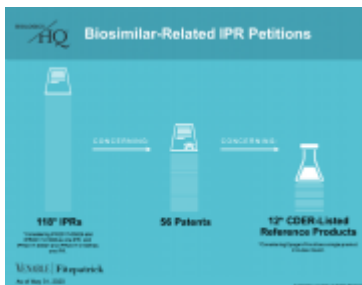
CDER Purple Book Updates

Darzalex Faspro™ (daratumumab; hyaluronidase-fihj):

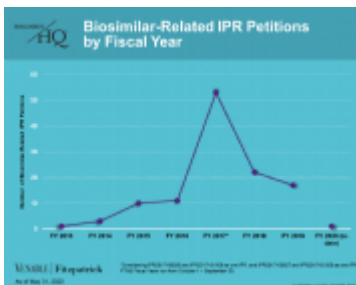
- On May 1, 2020, the FDA approved **Janssen Biotech's Darzalex Faspro™ (daratumumab; hyaluronidase-fihj)**.

STATISTICS

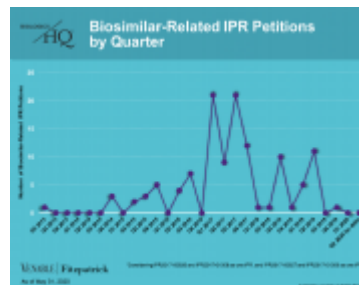
Biosimilar-Related IPR Petitions



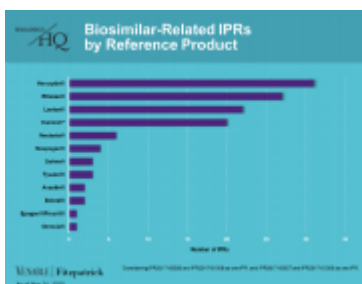
Biosimilar-Related IPR Petitions by Fiscal Year



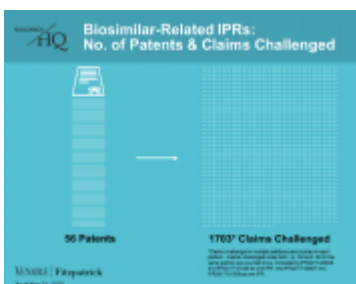
Biosimilar-Related IPR Petitions by Quarter



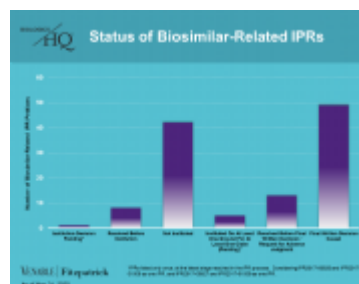
Biosimilar-Related IPRs by Reference Product



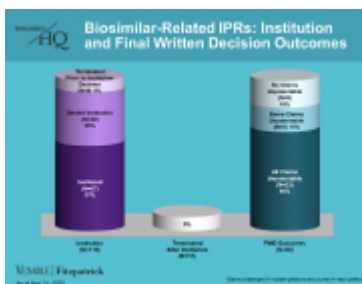
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



Status of Biosimilar-Related IPRs



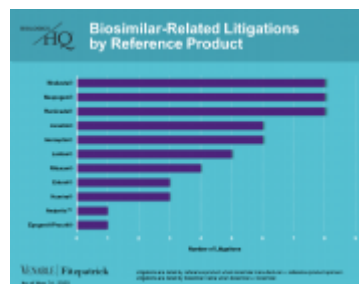
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



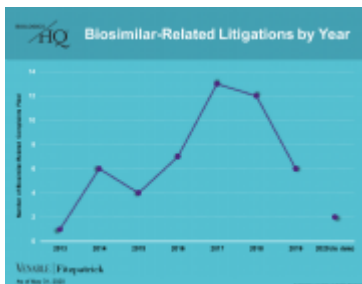
Biosimilar-Related Litigations



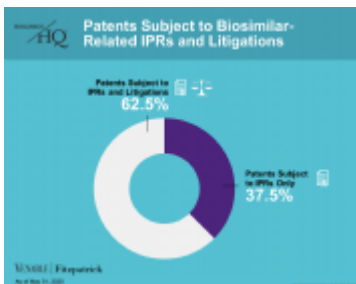
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



Biosimilars Approved in the United States

Biosimilars Approved in the United States (cont'd)

US Approval Date	Reference Product	Generic Name	Trade Name	US Approval Date	Reference Product	Generic Name	Trade Name	US Approval Date
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014
Jul 1, 2014	Humira	Adalimumab	Humira	Apr 1, 2015	Humira	Adalimumab	Humira	Jul 1, 2014

UNSWR | Fitzpatrick
As of May 31, 2020

Biosimilar Applications Pending in the United States

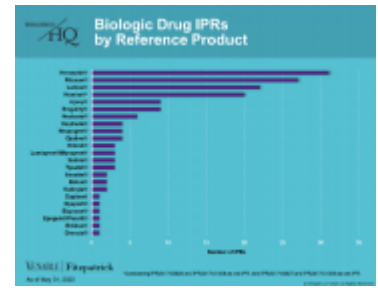
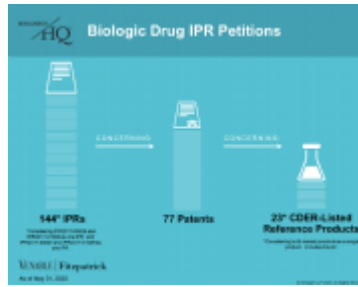
Biologic Drug IPR Petitions

Biologic Drug IPRs by Reference Product

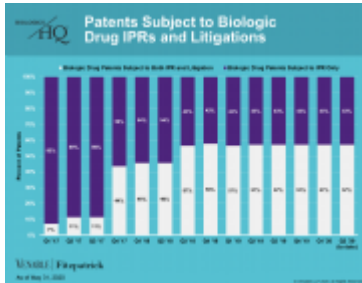
Biosimilar Applications Pending in the United States*

Reference Product	Generic Name	AbbVie (Reference Product)	Reference Product	Reference Product	Reference Product	Reference Product
Humira®	Adalimumab	AbbVie	Amgen	Amgen	Amgen	Amgen
Enbrel®	Etanercept	Amgen	Amgen	Amgen	Amgen	Amgen
Actemra®	Tocilizumab	Novartis	Novartis	Novartis	Novartis	Novartis
Avastin®	Bevacizumab	Roche	Roche	Roche	Roche	Roche
Keytruda®	Pembrolizumab	Merck	Merck	Merck	Merck	Merck
Opdivo®	Nivolumab	Ono	Ono	Ono	Ono	Ono
Imbruvica®	Venclextar	Novartis	Novartis	Novartis	Novartis	Novartis
TruSight®	Canakinumab	Novartis	Novartis	Novartis	Novartis	Novartis
Stempegi®	Stempegi	Novartis	Novartis	Novartis	Novartis	Novartis
... (many more rows)

*There is public available information on U.S. generic biosimilars.



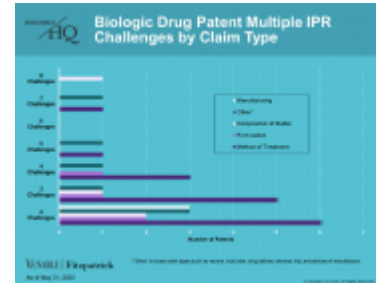
Patents Subject to Biologic Drug IPRs and Litigations



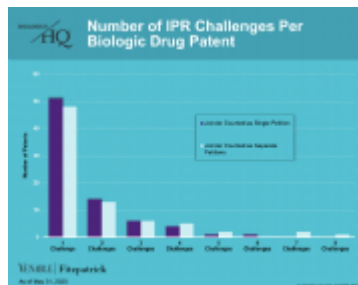
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



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.

Enter Keywords

Contact the BiologicsHQ Team



[Robert S. Schwartz, Ph.D.](#)
Chair
+1 212.218.2298
RSchwartz@Venable.com



[Ha Kung Wong](#)
Partner
+1 212.218.2571
HWong@Venable.com

CALIFORNIA | DELAWARE | MARYLAND | NEW YORK | VIRGINIA | WASHINGTON, DC

© 2020 Venable LLP. This email is published by the law firm Venable LLP. It is not intended to provide legal advice or opinion. Such advice may only be given when related to specific fact situations that Venable has accepted an engagement as counsel to address. ATTORNEY ADVERTISING.

Venable.com | Manage Preferences | Unsubscribe | If you are having trouble viewing this email, click here to view it in the browser or contact us by mail at Venable LLP, 600 Massachusetts Avenue, NW, Washington, DC 20001.