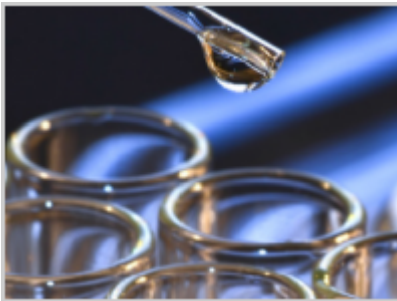


MONTHLY
INJECTION

January 12, 2021



LATEST NEWS



CfB Board Members Reflect on Year in Biosimilars

[Ha Kung Wong](#) spoke with The Center for Biosimilars for an article reflecting on the biosimilar market in 2020 and what to expect in 2021, particularly with respect to the BPCIA, which is under review at the Supreme Court.



Opinion: The Year Ahead in Biosimilar Potential

[Ha Kung Wong](#) spoke with The Center for Biosimilars for an article discussing what to expect for biosimilars in 2021, including the potential for the first authorized biologics, and the *Arthrex v. Smith & Nephew* case pending at the Supreme Court, which has the potential to impact *inter partes* review (IPR) and post grant review (PGR) proceedings at the USPTO by determining whether Patent Trial and Appeal Board (PTAB) judges were constitutionally appointed.



The Leading “Not So Different” Podcast Episodes of 2020

The Center for Biosimilars’ “Not So Different” podcast “Biosimilar Law Experts Discuss Potential Bills and Chances for Passage” featuring Venable Fitzpatrick’s [Ha Kung Wong](#) and [April Breyer Menon](#), was one of the series’ most-listened-to 2020 podcasts. In the podcast, [Wong](#) and [Breyer Menon](#) discuss potential bills to improve biosimilar uptake and their chances for passage.

Read
More
News

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On December 7, 2020, the PTAB granted Petitioner **Regeneron's** request to terminate IPR2020-01318 against **Novartis** prior to an institution decision.

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

- On December 15, 2020, **Lupin** filed IPR2021-00326 against **Amgen**.

Rituxan® (rituximab):

- On December 16, 2020, in Fed. Cir. Appeal No. 19-1364, the Federal Circuit affirmed the PTAB's final written decision finding all instituted claims unpatentable in **Biogen v. Pfizer** IPR2017-01168.

Dysport® (abobotulinumtoxinA) / Botox® (onabotulinumtoxinA):

- On December 23, 2020, the PTAB *sua sponte* extended the pendency of **Galderma v. Medy-Tox**, PGR2019-00062, after determining good cause existed due to travel restrictions caused by the COVID-19 pandemic.

Enhertu® (fam-trastuzumab deruxtecan-nxki):

- On December 23, 2020, **Daiichi Sankyo** and **AstraZeneca** filed PGR2021-00030 against **Seagen**.

Litigations

Avonex® (interferon beta-1a) / Betaseron® (interferon beta-1b) / Extavia® (interferon beta-1b) / Rebif® (interferon beta-1a):

- On December 18, 2020, in **Biogen v. EMD Serono**, Fed. Cir. Case No. 19-1133, appealing Case No. 2:10-cv-02734 (D.N.J.), the Federal Circuit denied **Biogen's** petition for panel rehearing and en banc rehearing.

aBLA Applications and FDA Activity

Riabni™ (rituximab-arrx):

- On December 17, 2020, the FDA approved **Amgen** and **Allergan's Riabni™ (rituximab-arrx)**, a biosimilar of **Genentech's Rituxan® (rituximab)**.

MYL-1402O (bevacizumab):

- On December 25, 2020, **Mylan** and **Biocon** announced that the FDA deferred action on the aBLA for **MYL-1402O (bevacizumab)**, a proposed biosimilar of **Genentech's Avastin® (bevacizumab)**, due to restrictions on travel to inspect the manufacturing facility because of the COVID-19 pandemic. The anticipated FDA decision date was previously December 27, 2020.

CDER Purple Book Updates

Margenza™ (margetuximab-cmkb):

- On December 16, 2020, the FDA approved **Macrogenics' Margenza™ (margetuximab-cmkb)**.

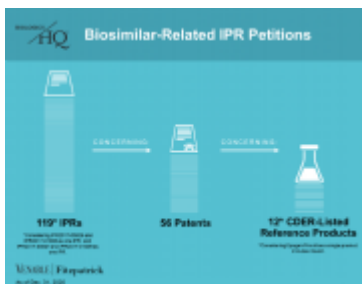
Non-U.S. Biosimilars / Follow-On Biologics

Hyrimoz® (adalimumab-adaz):

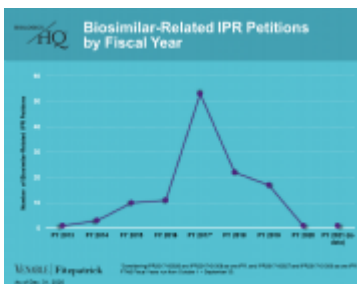
- On December 17, 2020, **Sandoz** announced **Hyrimoz® (adalimumab-adaz)**, a biosimilar of **AbbVie's Humira® (adalimumab)**, had been approved in Canada in November 2020.

STATISTICS

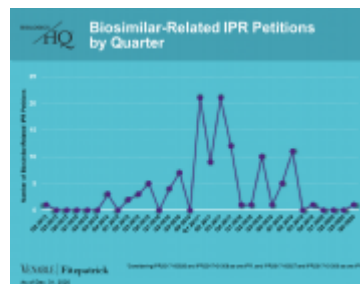
Biosimilar-Related IPR Petitions



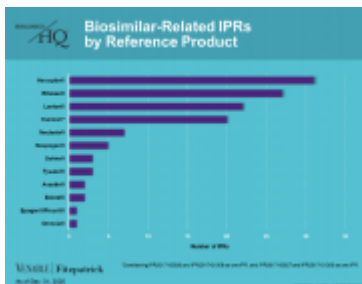
Biosimilar-Related IPR Petitions by Fiscal Year



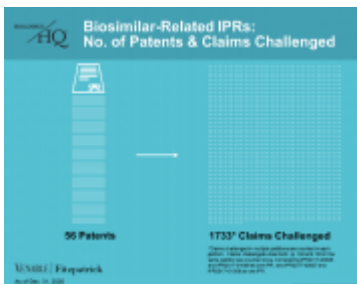
Biosimilar-Related IPR Petitions by Quarter



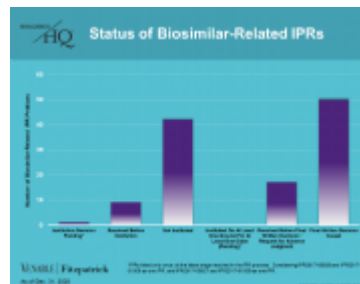
Biosimilar-Related IPRs by Reference Product



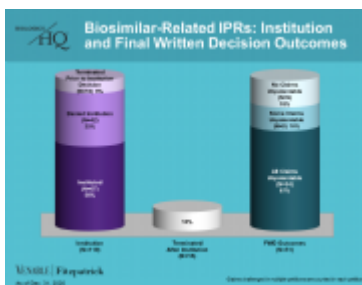
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



Status of Biosimilar-Related IPRs



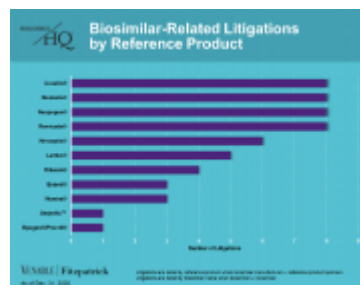
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations



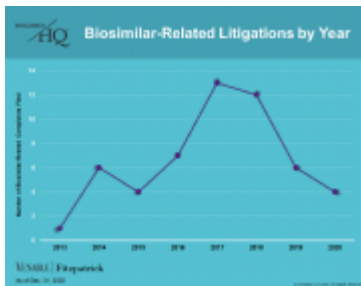
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year

Patents Subject to Biosimilar-Related IPRs and Litigations

Biosimilars Approved in the United States



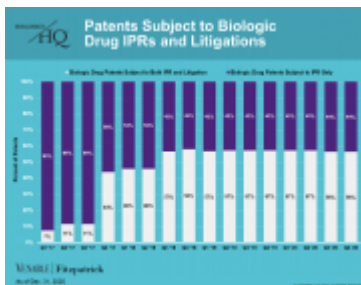
Biosimilar Applications Pending in the United States

Biosimilar Applications Pending in the United States*

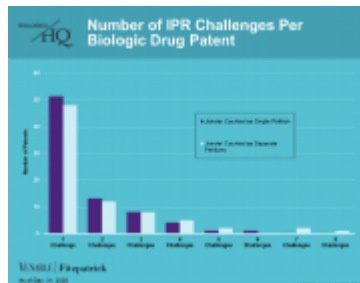
Application No.	Generic Name	ATC/ANDA	Reference Product	Patent/ Patent Expires	FDA Status
142172	Abiraterone	ANDA 75042	Levamisole	Patent	Approved Mar. 2018
142173	Abiraterone	ANDA 75043	Levamisole	Patent	Approved Mar. 2018
142174	Abiraterone	ANDA 75044	Levamisole	Patent	Approved Mar. 2018
142175	Abiraterone	ANDA 75045	Levamisole	Patent	Approved Mar. 2018
142176	Abiraterone	ANDA 75046	Levamisole	Patent	Approved Mar. 2018
142177	Abiraterone	ANDA 75047	Levamisole	Patent	Approved Mar. 2018
142178	Abiraterone	ANDA 75048	Levamisole	Patent	Approved Mar. 2018
142179	Abiraterone	ANDA 75049	Levamisole	Patent	Approved Mar. 2018
142180	Abiraterone	ANDA 75050	Levamisole	Patent	Approved Mar. 2018
142181	Abiraterone	ANDA 75051	Levamisole	Patent	Approved Mar. 2018
142182	Abiraterone	ANDA 75052	Levamisole	Patent	Approved Mar. 2018
142183	Abiraterone	ANDA 75053	Levamisole	Patent	Approved Mar. 2018
142184	Abiraterone	ANDA 75054	Levamisole	Patent	Approved Mar. 2018
142185	Abiraterone	ANDA 75055	Levamisole	Patent	Approved Mar. 2018
142186	Abiraterone	ANDA 75056	Levamisole	Patent	Approved Mar. 2018
142187	Abiraterone	ANDA 75057	Levamisole	Patent	Approved Mar. 2018
142188	Abiraterone	ANDA 75058	Levamisole	Patent	Approved Mar. 2018
142189	Abiraterone	ANDA 75059	Levamisole	Patent	Approved Mar. 2018
142190	Abiraterone	ANDA 75060	Levamisole	Patent	Approved Mar. 2018

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Source: UN. Data

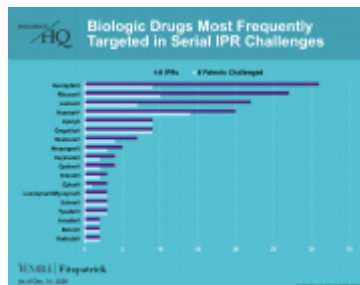
Patents Subject to Biologic Drug IPRs and Litigations



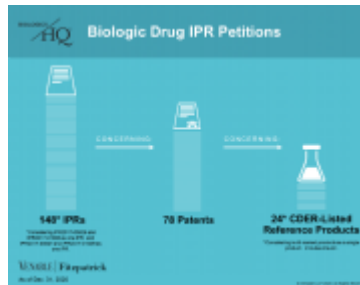
Number of IPR Challenges Per Biologic Drug Patent



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



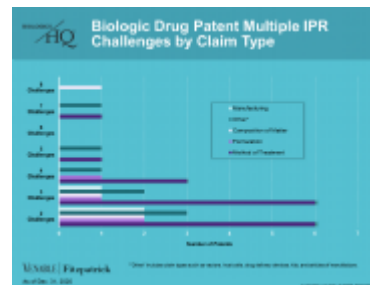
Biologic Drug IPR Petitions



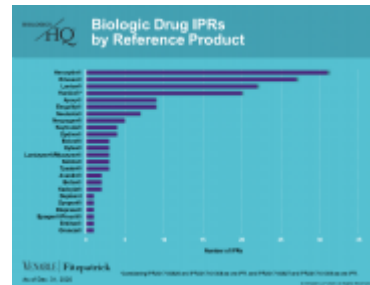
Biologic Drug Patent Multiple IPR Challenges by Claim Type



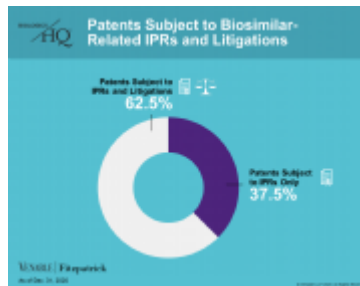
Biologic Drug Patent Multiple IPR Challenges



Biologic Drug IPRs by Reference Product



Patents Subject to Biosimilar-Related IPRs and Litigations



Biologic Drug IPRs by Reference Product

Biosimilars Approved in the United States

ANDA No.	Reference Product	Generic Name	ATC Code	Approval Date	Patent Status	Patent Expires	Patent Litigation	US Patents
142172	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142173	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142174	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142175	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142176	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142177	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142178	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142179	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142180	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142181	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142182	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142183	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142184	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142185	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142186	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142187	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142188	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142189	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2
142190	Abiraterone	Abiraterone	N02BA01	Mar. 28, 2018	Approved	Patent		2

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Source: UN. Data

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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