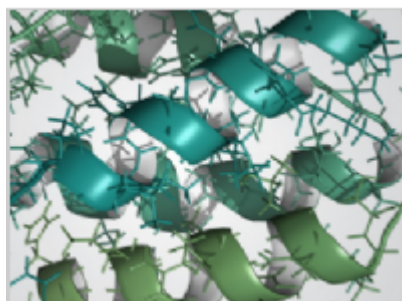


MONTHLY
INJECTION

November 8, 2021



LATEST NEWS

**FDA Approves Boehringer Ingelheim's Cyltezo® as Interchangeable with Humira®**By: [April Breyer Menon](#)

On October 15, 2021, the FDA approved [Boehringer Ingelheim's Cyltezo® \(adalimumab-adbm\)](#) as interchangeable with [AbbVie's Humira® \(adalimumab\)](#) for many of [Humira's](#) approved indications. As an interchangeable, [Cyltezo](#) can be automatically substituted for [Humira](#) at the pharmacy, subject to individual state laws. Grant of interchangeability status was based on the phase III VOLTAIRE-X study, which evaluated switching patients with moderate-to-severe chronic plaque psoriasis between [Cyltezo](#) and [Humira](#) and back again, and found that those who switched had similar clinical outcomes in terms of safety, efficacy, pharmacokinetics, and immunogenicity to those who did not switch.

**U.S. Patent Legal Landscape Outlook**By: [Ha Kung Wong](#)

[Ha Kung Wong](#), Wei Campbell, and Christine Cochran gave a LSPN Live presentation titled "[US Patent Legal Landscape Outlook: What are the Main Challenges Facing the US Patent System and how do we Prepare for them?](#)" where they discussed recent Supreme Court cases and the current IP system in the U.S.

2021 Patent Caselaw Roundup – Lawline CLEBy: [Christopher Loh](#)

[Christopher Loh](#) taught a Lawline CLE updating in-house and outside counsel on the latest developments in patent case law. The CLE includes a review of the Supreme Court's *Arthrex* decision and its effects on the



logistics of *inter partes* review proceedings, the Supreme Court's *Minerva* decision and its effects on the assignor estoppel doctrine, a roundup of key Federal Circuit decisions, and recent developments in the Western District of Texas concerning jurisdiction and venue disputes.



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

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 pegfilgrastim ([Neulasta[®]](#), [Lapelga[™]](#), [Ziextenzo[®]](#), [Udenyca[®]](#), [Fulphila[®]](#), [Nyvepria[™]](#), [MSB11455](#), and [Pegfilgrastim \(Lupin\)](#)), 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 October 31, 2021.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through October 31, 2021.

**Read
More
News**

UPDATES

IPRs and PGRs

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

- On October 4, 2021, Amgen filed a request for Director review of the final written decision in IPR2016-01542.

Eylea® (aflibercept) / Lucentis® (ranibizumab):

- On October 26, 2021, the PTAB instituted IPR2021-00816 filed by Regeneron against Novartis.
-

Litigations

Botox® (onabotulinumtoxinA):

- On October 1, 2021, Allergan filed Case No. 1:21-cv-01411 (D. Del.) against Revance Therapeutics related to Revance's daxibotulinumtoxinA (not yet FDA approved).

Forteo® (teriparatide):

- On October 1, 2021, consent judgment of noninfringement was entered in Amphastar Pharmaceuticals v. Eli Lilly, Case No. 1:21-cv-01922 (S.D. Ind.).

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

- On October 4, 2021, the Supreme Court denied Biogen's writ of certiorari in Supreme Court Case No. 20-1604, appealing from Fed. Cir. Case No. 19-1133 and District Court Case No. 2:10-cv-02734 (D.N.J.).

Cimzia® (certolizumab pegol):

- On October 19, 2021, the Court ordered UCB Pharma and Nektar Therapeutics' stipulation of dismissal of Case No. 1:20-cv-00650 (D. Del.).
-

aBLA Applications and FDA Activity

CT-P16 (bevacizumab):

- On October 1, 2021, Celltrion announced submission of an aBLA for CT-P16 (bevacizumab), a proposed biosimilar of Genentech's Avastin® (bevacizumab).

Cyltezo® (adalimumab-adbm):

- On October 15, 2021, the FDA approved Boehringer Ingelheim's Cyltezo® (adalimumab-adbm) as interchangeable with AbbVie's Humira® (adalimumab). Cyltezo® (adalimumab-adbm) is the second biosimilar to be granted interchangeable status in the U.S.
-

CDER Purple Book Updates

Susvimo™ (ranibizumab):

- On October 22, 2021, the FDA approved **Genentech's Susvimo™ (ranobizumab)**.

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

Nypozi™ (filgrastim):

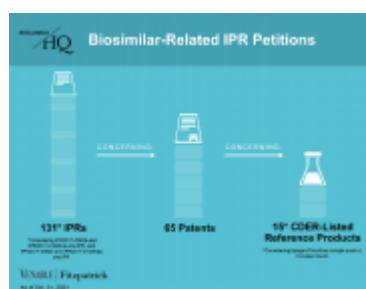
- On October 4, 2021, **Tanvex Biopharma's Nypozi™ (filgrastim)**, a biosimilar of **Amgen's Neupogen® (filgrastim)**, was approved in Canada.

Kirsty (insulin aspart):

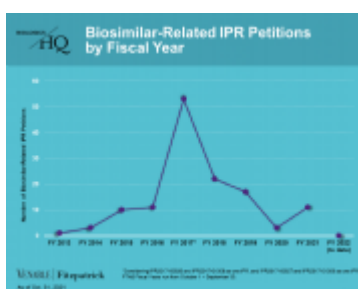
- On October 12, 2021, **BGP Pharma's (part of Viatris) Kirsty (insulin aspart)**, a biosimilar of **Novo Nordisk's Novolog® (insulin aspart)**, was approved in Canada.

STATISTICS

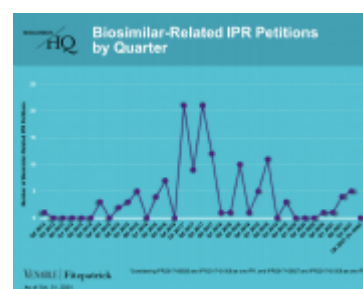
Biosimilar-Related IPR Petitions



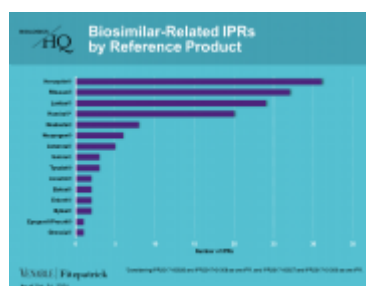
Biosimilar-Related IPR Petitions by Fiscal Year



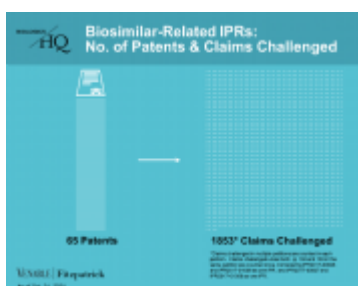
Biosimilar-Related IPR Petitions by Quarter



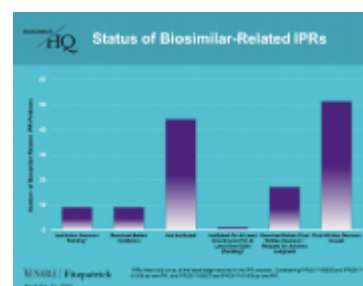
Biosimilar-Related IPRs by Reference Product



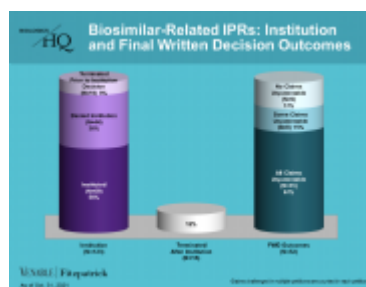
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



Status of Biosimilar-Related IPRs



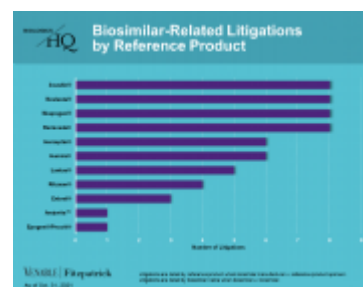
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations



Biosimilar-Related Litigations by Reference Product



Year	Number of Biosimilar-Related Litigations Filed
2011	1
2012	4
2013	3
2014	5
2015	7
2016	12
2017	11
2018	5
2019	3
2020	2
2021	2
2022 (preliminary)	1

Patents Subject to Biosimilar-Related IPRs and Litigations

Category	Percentage
Patents Subject to IPRs and Litigations	64.6%
Patents Subject to IPRs Only	35.4%

Source: USPTO, *US Patent and Trademark Office*

[illegible][illegible]

Biologic Drug IPR Petitions

162¹ IPRs
162 IPRs were filed from January 2012 to July 2013. Of these, 108 IPRs were granted and 54 IPRs were denied.

CONCENTRATED

88 Patents
Of the 108 granted IPRs, 88 patents were identified.

CONCENTRATED

26² CDER-Listed Reference Products
Of the 88 patents, 26 patents were identified as CDER-Listed Reference Products.

UNABLE / FREQUENT

Biologic Drug IPRs by Reference Product

Reference Product	Number of IPRs
Humira	28
Enbrel	24
Avastin	22
Rituximab	18
Herceptin	16
Humalog	14
Humalog Mix 50/50	13
Humalog Mix 25/75	12
Humalog Mix 100/100	11
Humalog Mix 100/50	10
Humalog Mix 100/25	9
Humalog Mix 100/10	8
Humalog Mix 100/5	7
Humalog Mix 100/2	6
Humalog Mix 100/1	5
Humalog Mix 100/0.5	4
Humalog Mix 100/0.25	3
Humalog Mix 100/0.1	2
Humalog Mix 100/0.05	1
Humalog Mix 100/0.025	1
Humalog Mix 100/0.01	1
Humalog Mix 100/0.005	1
Humalog Mix 100/0.0025	1
Humalog Mix 100/0.001	1
Humalog Mix 100/0.0005	1
Humalog Mix 100/0.00025	1
Humalog Mix 100/0.0001	1
Humalog Mix 100/0.00005	1
Humalog Mix 100/0.000025	1
Humalog Mix 100/0.00001	1

Source: Humira, Enbrel, Avastin, Rituximab, Herceptin, Humalog, Humalog Mix 50/50, Humalog Mix 25/75, Humalog Mix 100/100, Humalog Mix 100/50, Humalog Mix 100/25, Humalog Mix 100/10, Humalog Mix 100/5, Humalog Mix 100/2, Humalog Mix 100/1, Humalog Mix 100/0.5, Humalog Mix 100/0.25, Humalog Mix 100/0.1, Humalog Mix 100/0.05, Humalog Mix 100/0.025, Humalog Mix 100/0.01, Humalog Mix 100/0.005, Humalog Mix 100/0.0025, Humalog Mix 100/0.001, Humalog Mix 100/0.0005, Humalog Mix 100/0.00025, Humalog Mix 100/0.0001, Humalog Mix 100/0.00005, Humalog Mix 100/0.000025, Humalog Mix 100/0.00001.

Year	Biologic Drug Patents Subject to IPR and Litigation	All Biologic Drug Patents
2007	100	150
2008	120	180
2009	150	220
2010	180	250
2011	200	280
2012	220	300
2013	240	320
2014	260	340

Source: Freepatent Analytics

Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

Drug	All IPRs	All Patents Challenged
Humira	34	34
Enbrel	28	28
Avastin	27	27
Actemra	26	26
Humalog	25	25
Humalog	24	24
Humalog	23	23
Humalog	22	22
Humalog	21	21
Humalog	20	20
Humalog	19	19
Humalog	18	18
Humalog	17	17
Humalog	16	16
Humalog	15	15
Humalog	14	14
Humalog	13	13
Humalog	12	12
Humalog	11	11
Humalog	10	10
Humalog	9	9
Humalog	8	8
Humalog	7	7
Humalog	6	6
Humalog	5	5
Humalog	4	4
Humalog	3	3
Humalog	2	2
Humalog	1	1

Source: IPR Watch

Drug Class	Non-infringement or Invalid	Unpatentable under 35 USC 101	Unpatentable under 35 USC 102	Unpatentable under 35 USC 103
Monoclonal Antibody	1	0	0	0
Polyclonal Antibody	1	0	0	0
Fusion Protein	1	0	0	0
Recombinant Protein	1	0	0	0
Small Molecule	1	0	0	0

Source: WIPAC, Inc. (2014)

Number of IPR Challenges Per Biologic Drug Patent

Company	Number of IPR Challenges per Biologic Patent	Number of IPR Challenges per Biologic Patent
Amgen	9.5	9.0
AbbVie	4.0	3.5
Novartis	2.0	1.5
Merck	1.5	1.0
Bristol-Myers Squibb	0.5	0.5
Pfizer	0.5	0.5
Eli Lilly	0.5	0.5
AstraZeneca	0.5	0.5
Sanofi	0.5	0.5

Legend: Number of IPR Challenges per Biologic Patent (dark blue), Number of IPR Challenges per Biologic Patent (light blue)

Source: USPTO, IPR Challenges, 2013-2017

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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