

VENABLE | Fitzpatrick

MONTHLY INJECTION

July 9, 2020

in y f 🌶

LATEST NEWS



Biosimilar Law Experts Discuss Potential Bills and Chances for Passage

Ha Kung Wong and April Breyer Menon Discuss Promising and Not-so-Promising Biosimilar Legislation

By: Ha Kung Wong and April Breyer Menon

Despite the United States having had a biosimilar pathway for a decade now, the industry has launched just 17 biosimilars, well behind the pace in Europe and India. Several pieces of legislation have been introduced in Congress to help boost uptake, generate savings for payers and patients, and increase biosimilar access. However, not every bill is likely to become a law, as politics and money can often get in the way.

In interviews with the Center for Biosimilars, <u>Ha Kung Wong</u> and <u>April Breyer Menon</u> discuss potential bills to improve biosimilar uptake, including the Hatch-Waxman Integrity Act, Stop STALLING Act, Biologic Patent Transparency Act, Affordable and Safe Prescription Drug Importation Act, Biosim Act, and their chances for passage. They also discuss additional issues that may affect biosimilar legislation such as COVID-19, upcoming elections, and biosimilar uptake in the US.



It's a New Set of Rules for Insulin Products Under 351(k)

By: <u>Ha Kung Wong</u>

Based on a June 2020 announcement, the longtime generics manufacturer Lannett would become among the first to file for insulin glargine product approval under the 351(k) Biologics License Application pathway.

<u>Ha Kung Wong</u> discusses previous and future approval processes for insulin biosimilars, including clinical testing and the possibility of receiving an interchangeability designation.



<u>Spotlight On: Herceptin[®] (trastuzumab) / Ogivri™</u> (trastuzumab-dkst) / Herzuma[®] (trastuzumab-pkrb) / Ontruzant[®] (trastuzumab-dttb) / Trazimera™ (trastuzumabqyyp) / Kanjinti™ (trastuzumab-anns)

Spotlight On: Biosimilar Litigations

Spotlight On: Rituxan[®] (rituximab) / Truxima[®] (rituximab-

<u>abbs) / Ruxience[®] (rituximab-pvvr)</u>

<u>Spotlight On: Humira[®] (adalimumab) / Amjevita™ (adalimumab-atto) / Cyltezo[®] (adalimumab-adbm) / Hyrimoz™ (adalimumab-adaz) / Hadlima™ (adalimumab-bwwd) / Abrilada™ (adalimumab-afzb)</u>

<u>Spotlight On: Enbrel[®] (etanercept) / Erelzi[®] (etanercept-szzs) / Eticovo™ (etanerceptykro)</u>

<u>Spotlight On: Lantus[®] / Lantus[®] SoloSTAR[®] (insulin glargine recombinant) / Basaglar[®] (insulin glargine) / Semglee™ (insulin glargine)</u>

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning trastuzumab (<u>Herceptin[®]</u>, <u>Ogivri[™]</u>, <u>Herzuma[®]</u>, <u>Ontruzant[®]</u>, <u>Trazimera[™]</u>, and <u>Kanjinti[™]</u>), rituximab (<u>Rituxan[®]</u>, <u>Truxima[®]</u>, and <u>Ruxience[®]</u>), adalimumab (<u>Humira[®]</u>, <u>Amjevita[™]</u>, <u>Cyltezo[®]</u>, <u>Hyrimoz[™]</u>, <u>Hadlima[™]</u>, and <u>Abrilada[™]</u>), etanercept (<u>Enbrel[®]</u>, <u>Erelzi[®]</u>, and <u>Eticovo[™]</u>), and insulin glargine (<u>Lantus[®] / Lantus[®] SoloSTAR[®], <u>Basaglar[®]</u>, and <u>Semglee[™]</u>) have been updated with activity through June 30, 2020.</u>

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through June 30, 2020.

Read	
More	
News	5

UPDATES

IPRs and PGRs

<u>Soliris[®] (eculizumab)</u>:

 On June 1, 2020, the PTAB granted <u>Alexion</u> and <u>Amgen's</u> joint motions to terminate due to settlement after institution in IPR2019-00739, IPR2019-00740 and IPR2019-00741.

Lantus[®] (insulin glargine recombinant):

 On June 10, 2020, <u>Sanofi</u> filed Federal Circuit Appeal No. 20-1871, appealing the final written decision in IPR2018-01670 finding the 1 challenged claim unpatentable.

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

On June 11, 2020, <u>Eli Lilly</u> filed Federal Circuit Appeal Nos. 20-1876, 20-1877, and 20-1878, appealing the final written decisions finding no instituted claim unpatentable in IPR2018-01710, IPR2018-01711, and IPR2018-01712 respectively.

<u>Neulasta[®] (pegfilgrastim)</u>:

On June 19, 2020, the PTAB granted <u>Amgen</u> and <u>Fresenius Kabi's</u> joint request to terminate IPR2020-00314 prior to an institution decision due to settlement.

<u>Neupogen[®] (filgrastim) / Neulasta[®] (pegfilgrastim):</u>

 On June 23, 2020, the PTAB granted <u>Amgen</u> and <u>Fresenius Kabi's</u> joint request to terminate IPR2019-01183 after institution due to settlement.

Litigations

<u>Eylea[®] (aflibercept)</u>:

 On June 19, 2020, <u>Novartis</u> filed Case No. 1:20-cv-00690 (N.D.N.Y.) against <u>Regeneron</u> related to <u>Regeneron's Eylea[®] (aflibercept)</u>.

<u>Avastin[®] (bevacizumab)</u>:

 On June 28, 2020, <u>Genentech</u> filed Case No. 1:20-cv-00859 (D. Del.) against <u>Samsung Bioepis's</u> related to <u>Samsung Bioepis's</u> proposed biosimilar <u>SB8 (bevacizumab)</u>.

aBLA Applications and FDA Activity

Nyvepria™ (pegfilgrastim-apgf):

On June 10, 2020, the FDA approved <u>Pfizer</u> and <u>Hospira's Nyvepria™ (pegfilgrastim-apgf)</u>, a biosimilar of <u>Amgen's Neulasta[®] (pegfilgrastim)</u>.

<u>Semglee™ (insulin glargine)</u>:

On June 11, 2020, the FDA approved <u>Mylan's Semglee™ (insulin gargine)</u>, a biosimilar of <u>Sanofi's Lantus[®]</u> (insulin glargine recombinant).

CDER Purple Book Updates

<u>Uplinza™ (inebilizumab)</u>:

• On June 11, 2020, the FDA approved <u>Viela Bio's Uplinza™ (inebilizumab)</u>.

Lyumjev™ (insulin lispro-aabc):

• On June 15, 2020, the FDA approved <u>Eli Lilly's Lyumjev™ (insulin lispro-aabc)</u>.

<u>Phesgo™ (pertuzumab; trastuzumab; hyaluronidase-zzxf)</u>:

• On June 29, 2020, the FDA approved <u>Genentech's Phesgo™ (pertuzumab; trastuzumab; hyaluronidase-</u><u>zzxf)</u>.

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

Nepexto[™] (etanercept):

On June 4, 2020, <u>Mylan</u> and <u>Lupin</u> announced that <u>Nepexto[™] (etanercept)</u>, a biosimilar of <u>Amgen's Enbrel[®]</u> (<u>etanercept</u>), was approved in the E.U.

<u>Truxima[®] (rituximab-abbs)</u>:

On June 5, 2020, the World Health Organization (WHO) preqalified <u>Celltrion's Truxima[®] (rituximab-abbs)</u>, a biosimilar of <u>Genentech's Rituxan[®] (rituximab)</u>.

Ziextenzo[®] (pegfilgrastim-bmez):

 On June 9, 2020, <u>Sandoz</u> announced that <u>Ziextenzo[®] (pegfilgrastim-bmez)</u>, a biosimilar of <u>Amgen's</u> <u>Neulasta[®] (pegfilgrastim)</u>, was approved for marketing in Canada.

Riximyo[®] (rituximab):

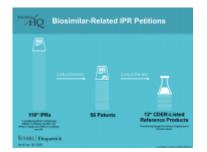
On June 9, 2020, <u>Sandoz</u> announced that <u>Riximyo[®] (rituximab)</u>, a biosimilar of <u>Genentech's Rituxan[®]</u> (<u>rituximab</u>), was approved for marketing in Canada.

Hulio[®] (adalimumab):

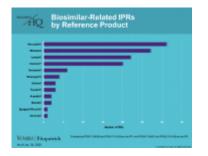
On June 29, 2020, <u>Fujifilm Kyowa Kirin Biologics</u> announced that <u>Hulio[®] (adalimumab)</u>, a biosimilar of <u>AbbVie's Humira[®] (adalimumab)</u>, was approved in Japan.

STATISTICS

Biosimilar-Related IPR Petitions

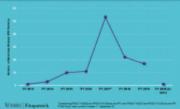


Biosimilar-Related IPRs by Reference Product



Biosimilar-Related IPRs:

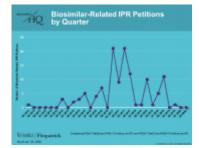
Biosimilar-Related IPR Petitions by Fiscal Year



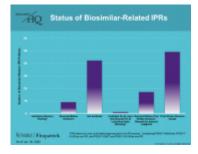
Biosimilar-Related IPRs: Number of Patents and Claims Challenged

	Related IPRs: its & Claims Challenged
a _	
55 Patents	1703' Claims Challenged
VENULE Fitopatrick	These index to available of the second station are approximately used to available of the second station and approximately used to available of the second state of the second state of the second state of the second state of the second state of the second state of the second state of the second state of the second state of th

Biosimilar-Related IPR Petitions by Quarter



Status of Biosimilar-Related IPRs



Biosimilar-

Biosimilar-Related

Institution and Final Written Decision Outcomes



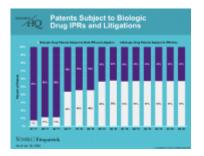
Biosimilar-Related Litigations by Year



Biosimilar Applications Pending in the United States

HQ Biosimilar Applications Pending in the United States*					
	tion the Same	40.1108	Reference Analise	Party and a second	F(1.546)
MIL-14ED	Burnersy had	Inter Sugar	Lastr.	Conservation in the	Accepted No. 1978
18 6 (8	Tay and to	Tanto Belication (Second), March Delayer:		1000	August No. 214 August No. 217
1940	Taxaba	Taxes Inflame	inequal.	Anser	Copper No. 2010
Cashing The	Partyana	Apples	Tenterio"	1000	standard Day 1914
1.070	Puppane	family.	Name*	Anger	Research Str. 2011
MORE WELL	Partynia	Personal Public	Same -	Argen	Accession/Infer 2020
PARTY	Testing and	Dataset (Base)	Laurant	Consectants.	Manufact Con. 21-8
Taxabar*	Name -		Read.	Selected.	Longitat ben 2017. 100, fors 2010. Samta en traje preving 113. Apresenta el fan 2014.
	-	Anger Literape	Read.	(second and	NAMES OF BRIDE
Value -	Institution	Name.	Lation	Next Area	Terration Supress Ad 2017
WARDER N.	- Repairiek				There is a place would be also also

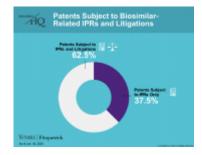
Patents Subject to Biologic Drug IPRs and Litigations



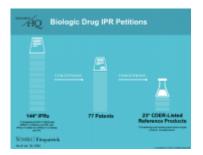
Related Litigations



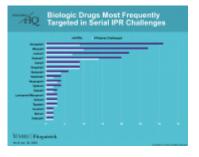
Patents Subject to Biosimilar-Related IPRs and Litigations



Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



Number of IPR Challenges Per Biologic Drug Patent

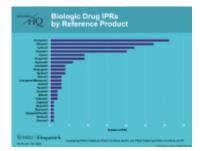
Litigations by Reference Product



Biosimilars Approved in the United States

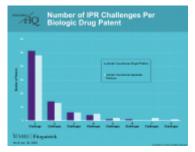
***	-	Reader South Series	-	340+1 1-1-1-1	No.	Reference Realized (concer-	
10.1 11.01	input-	Addressed and	impe	10125-018	mean ²	LINIA	
10.4.1010	Colorest.	Maryan.	that in some	No. 18, 217	iness?	1007	
10.1 10.011	Area"	International labor	Name	the states.	man!	1005	
10.479-001	"rated"	Marking.	Real Property lies	M-31209	Acres 1	1007	
10.4.10110	ioner.		TOP:	10.10.000	many.	1005	
10.1710	100	Bearing-	ingen	10.0.07	Amor	(Internet)	10.00
10.1.11	Date?	Bernard Inc.	The state	ALC: UNK	Annal	Ownerhol-	Dec 10
48.4 10.8.8	No.	Treasu Managine	Income of the other	44.00.000	Respont.	integral.	100.00
41.1910	Tast.	Francisco and	handra	100 IN 101	Filler#	Internation (Second	
10.4.1910	diam'	Descent des	Arrest	At 11,124	Land.	Interaction (Interaction)	
101.1 101.011	And a	Taxan and	Taking .	101.0.000	Income?	integral.	Taylor and
10.17100	Name of T	Destination	Nav	34.31.201	No. of Concession, Name	ingen.	Ges 20
MACHINE.	interest.	Menal-lak	Deliver 1 March	No.5.2181	Terminal P	Lower Date:	Res 20
49.4.19.004	Techoo?	Characteria.	Dents.	10121-002	Termine?	- second the sec	
10.17110	107	Information of the	Har.	10.10.007	formal?	Arrest Bratt	
-	1000	The second second	anger (-	The same	And Person	

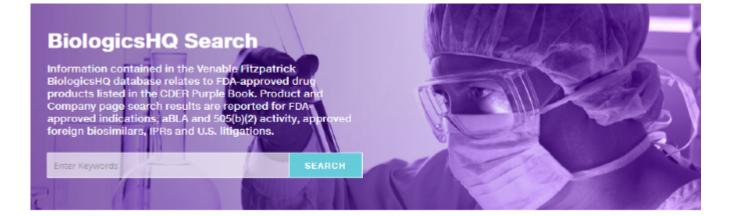
Biologic Drug IPRs by Reference Product



Biologic Drug Patent Multiple IPR Challenges by Claim Type







Contact the BiologicsHQ Team



Robert S. Schwartz, Ph.D. Chair +1 212.218.2298 RSchwartz@Venable.com



<u>Ha Kung Wong</u> Partner +1 212.218.2571 <u>HWong@Venable.com</u>

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.