

VENABLE | Fitzpatrick

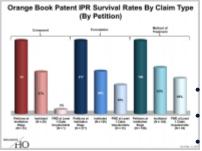
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MONTHLY INJECTION

January 7, 2020

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LATEST NEWS



Venable Fitzpatrick's 10 Most Read Articles of 2019

In case you missed them, check out Venable Fitzpatrick's most read articles of 2019:

Seven Years of Orange Book Patent IPRs: Where Are We Now?

Biosimilar Experts Give Highlights of U.S. Uptake Issues

The Most Important U.S. Patent Cases of 2019 Thus Far

- Biosimilars and the BPCIA: Past, Present, and Future
- <u>Will Authorized Biologics Disrupt the Market for Biosimilars?</u>
- <u>U.S. Patent System Crimps Drug Innovation for Toughest Diseases</u>
- More Uncertainty After DOJ Signals Approval of ACA Reversal
- Why is Biosimilar Adoption Slow in the U.S., and Can Something Be Done to Boost Uptake?
- Can Congress Speed Biosimilars to Market by Limiting Patent Litigations?
- How Can Biosimilars Make Headway in the U.S. Market?



Supreme Court Prohibits United States Patent and Trademark Office from Shifting Attorney's Fees in Certain District Court Proceedings

By: Christopher Loh

The Supreme Court on December 11, 2019 unanimously ruled in *Peter v. NantKwest, Inc.*, No. 18-801, that the United States Patent and Trademark Office (USPTO) cannot shift the fees of its attorneys and paralegals to litigants in district court proceedings brought under 35 U.S.C. §145.



Spotlight On: Biosimilar Litigations

<u>Spotlight On: Rituxan[®] (rituximab) / Truxima[®] (rituximababbs) / Ruxience[®] (rituximab-pvvr)</u>

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

<u>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)</u>

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning rituximab (<u>Rituxan[®]</u>, <u>Truxima[®]</u>, and <u>Ruxience[®]</u>), adalimumab (<u>Humira[®]</u>, <u>AmjevitaTM</u>, <u>Cyltezo[®]</u>, <u>HyrimozTM</u>, <u>HadlimaTM</u>, and <u>AbriladaTM</u>), etanercept (<u>Enbrel[®]</u>, <u>Erelzi[®]</u>, and <u>EticovoTM</u>), and insulin glargine (<u>Lantus[®] / Lantus[®] SoloSTAR[®]</u> and <u>Basaglar[®]</u>) have been updated with activity through December 31, 2019.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through December 31, 2019.



UPDATES

IPRs and PGRs

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

- On December 6, 2019, the PTAB granted <u>Kashiv BioSciences</u> and <u>Amgen's</u> joint motions to dismiss IPR2019-00791 and IPR2019-00797 due to settlement.
- On December 6, 2019, the PTAB granted <u>Kashiv BioSciences</u> and <u>Amgen's</u> joint motion to dismiss PGR2019-00001 due to settlement.
- On December 10, 2019, the PTAB instituted IPR2019-01183 filed by Fresenius Kabi.

<u>Myozyme[®] / Lumizyme[®] (alglucosidase alfa)</u>:

 On December 11, 2019, Duke University filed a petition for en banc rehearing of the Federal Circuit's decision in Appeal No. 18-1696, appealing the final written decision in Duke v. <u>BioMarin</u>, IPR2013-00535.

Lantus[®] (insulin glargine recombinant):

On December 19, 2019, <u>Mylan</u> and <u>Sanofi</u> filed petitions for panel rehearings in Fed. Cir. Appeal No. 19-1368 and consolidated appeal 19-1369, where the Federal Circuit affirmed the PTAB's determinations that all challenged claims were unpatentable in IPR2017-01526 and IPR2017-01528. <u>Sanofi</u> also filed petitions for en banc rehearing.

<u>Neulasta[®] (pegfilgrastim)</u>:

• On December 20, 2019, Fresenius Kabi filed IPR2020-00314.

Litigations

<u>Epogen[®] / Procrit[®] (epoetin alfa)</u>:

On December 16, 2019, the Federal Circuit affirmed the jury verdict and denial of JMOL or new trial in <u>Amgen</u> v. <u>Hospira</u>, Fed. Cir. Appeal Nos. 19-1067 and 19-1102, appealing Case No. 1:15-cv-00839 (D. Del.).

<u>Neupogen[®] (filgrastim):</u>

 On December 20, 2019, the Court granted <u>Amgen</u> and <u>Tanvex's</u> joint motion to dismiss Case No. 3:19-cv-01374 (S.D. Cal.).

aBLA Applications and FDA Activity

<u>Ogivri™ (trastuzumab-dkst)</u>:

On December 3, 2019, <u>Mylan</u> and <u>Biocon</u> announced the launch of <u>Ogivri™ (trastuzumab-dkst)</u>, a biosimilar of <u>Genentech's Herceptin[®] (trastuzumab)</u>.

<u>Avsola™ (infliximab-axxq)</u>:

 On December 6, 2019, the FDA approved <u>Amgen's Avsola™ (infliximab-axxq)</u>, a biosimilar of <u>Janssen's</u> <u>Remicade[®] (infliximab)</u>.

ABP 798 (rituximab):

 On December 19, 2019, <u>Amgen</u> and <u>Allergan</u> announced the submission of an aBLA for <u>ABP 798 (rituximab)</u>, a proposed biosimilar of <u>Genentech's Rituxan[®] (rituximab)</u>.

CDER Purple Book Updates

Padcev™ (enfortumab vedotin-ejfv):

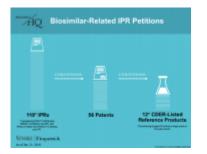
• On December 18, 2019, the FDA approved <u>Astellas's Padcev™ (enfortumab vedotin-ejfv)</u>.

Enhertu[®] (fam-trastuzumab deruxtecan-nxki):

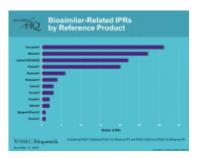
• On December 20, 2019, the FDA approved Daiichi's Enhertu® (fam-trastuzumab deruxtecan-nxki).

STATISTICS

Biosimilar-Related IPR Petitions Biosimilar-Related IPR Petitions by Fiscal Year Biosimilar-Related IPR Petitions by Quarter



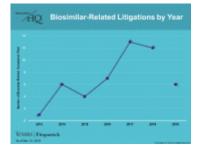
Biosimilar-Related IPRs by Reference Product



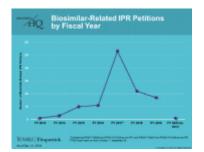
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations by Year



Biosimilar Applications Pending in the United States



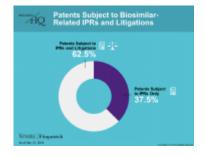
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



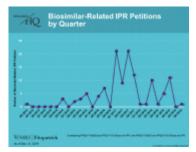
<u>Biosimilar-</u> <u>Related</u> <u>Litigations</u>



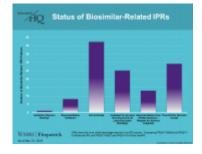
Patents Subject to Biosimilar-Related IPRs and Litigations



Biologic Drug IPR Petitions



<u>Status of</u> <u>Biosimilar-</u> <u>Related IPRs</u>



Biosimilar-Related Litigations by Reference Product



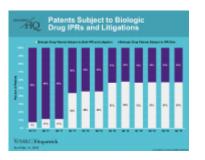
Biosimilars Approved in the United States

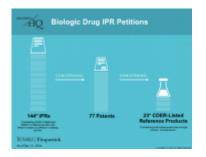
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Biologic Drug IPRs by Reference Product

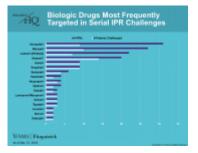
HQ Biosimilar Applications Pending in the United States*						
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Patents Subject to Biologic Drug IPRs and Litigations

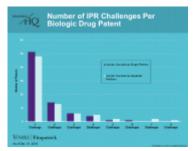


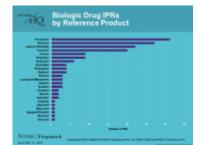


Biologic Drugs Most Frequently Targeted in Serial IPR Challenges



<u>Number of IPR</u> <u>Challenges Per</u> <u>Biologic Drug Patent</u>





Biologic Drug Patent Multiple IPR Challenges by Claim Type

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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, approve foreign biosimilars, IPRs and U.S. litigations.

SEARCH



Contact the BiologicsHQ Team

Enter Keywords







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