

VENABLE | Fitzpatrick



November 9, 2020

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LATEST NEWS



Legal Experts Weigh in on BPCIA Severability

Ha Kung Wong spoke with The Center for Biosimilars for an article about Amy Coney Barrett's potential appointment to the Supreme Court and what it might mean for the Affordable Care Act (ACA) and the Biologics Price Competition and Innovation Act (BPCIA). If the ACA is found unconstitutional, it could mean the end of the BPCIA and the biosimilar approval pathway.



Ha Kung Wong Elected to Board of Trustees for the Foundation for Advancement of Diversity in IP Law

Ha Kung Wong has been elected to serve on the board of trustees of the Foundation for Advancement of Diversity in IP Law (FADIPL). Comprising a diverse group of leaders dedicated to advancing diversity, equity, and inclusion, the board guides the FADIPL in its mission to support members of underrepresented racial and ethnic groups in their pursuit of careers in intellectual property law in the United States through financial support and networking, counseling, and mentoring.



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

<u>Spotlight On: Herceptin[®] (trastuzumab) / Ogivri™</u> (<u>trastuzumab-dkst) / Herzuma[®] (trastuzumab-pkrb) /</u>

Ontruzant[®] (trastuzumab-dttb) / Trazimera™ (trastuzumab-qyyp) / Kanjinti[®] (trastuzumab-anns)

Spotlight On: Biosimilar Litigations

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

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

<u>Spotlight On: Enbrel[®] (etanercept) / Erelzi[®] (etanercept-szzs) / Eticovo[®] (etanercept-ykro)</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 pegfilgrastim (Neulasta®, Lapelga™, Ziextenzo®, Udenyca®, Fulphila®, Nyvepria™, and MSB11455), 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, 2020.

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, 2020.



UPDATES

IPRs and PGRs

Lantus[®] (insulin glargine recombinant):

On October 5, 2020, the Supreme Court denied the writ of certiorari in <u>Sanofi</u> v. <u>Mylan</u>, Sup. Ct. 19-1451, appealing the Federal Circuit's decisions in Fed. Cir. Case Nos. 19-1368 and 19-1369, which affirmed the PTAB's final written decisions finding all instituted claims unpatentable in IPR2017-01526 and IPR2017-01528.

Arthrex v. Smith & Nephew:

On October 13, 2020, the Supreme Court granted certiorari in cases involving whether the appointment of PTAB administrative patent law judges were constitutionally appointed, including U.S. v. Arthrex, Sup. Ct. 19-1434, Smith & Nephew v. Arthrex, Sup. Ct. 19-1452, and Arthrex v. Smith & Nephew, Sup. Ct. 19-1458.

Dupixent® (dupilumab):

On October 13, 2020, in <u>Immunex</u> v. <u>Sanofi</u>, Fed. Cir. Appeal No. 19-1749, the Federal Circuit affirmed the PTAB's final written decision in IPR2017-01884 finding all instituted claims unpatentable. The Federal Circuit dismissed <u>Sanofi's</u> consolidated appeal of IPR2017-01879, Fed. Cir. Appeal No. 19-1777 regarding inventorship, because the same claims were affirmed to be invalid in its decision in Appeal No. 19-1749.

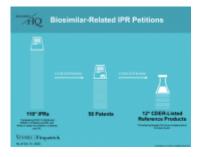
CDER Purple Book Updates

Inmazeb™ (atoltivimab; odesivimab; maftivimab):

• On October 14, 2020, the FDA approved Regeneron's Inmazeb™ (atoltivimab; odesivimab; maftivimab).

STATISTICS

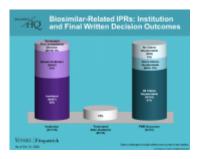
Biosimilar-Related IPR Petitions



Biosimilar-Related IPRs
by Reference
Product

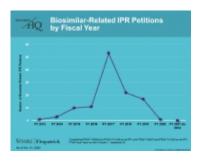


Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related
Litigations
by Year

Biosimilar-Related
IPR Petitions
by Fiscal Year



Biosimilar-Related

IPRs: Number of Patents
and Claims Challenged

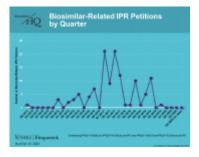


Biosimilar-Related Litigations

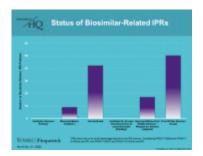


Patents Subject to Biosimilar-Related IPRs and Litigations

Biosimilar-Related
IPR Petitions
by Quarter



Status of Biosimilar-Related IPRs

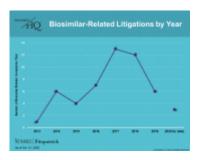


Biosimilar-Related
Litigations
by Reference
Product



Biosimilars

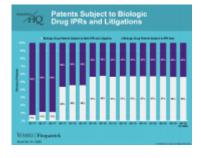
Approved in the
United States



Biosimilar Applications
Pending in the
United States

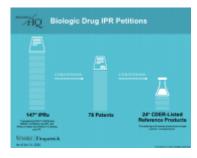


Patents Subject to Biologic Drug IPRs and Litigations





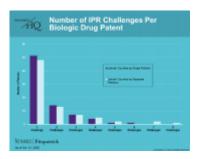
Biologic Drug IPR Petitions



Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

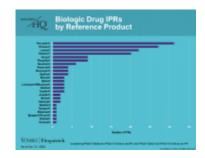


Number of IPR Challenges Per Biologic Drug Patent

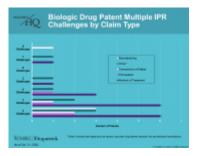


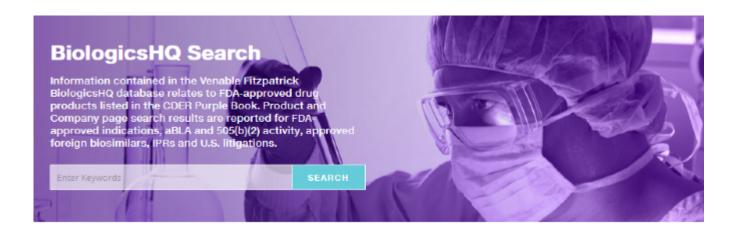


Biologic Drug IPRs by Reference Product



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



Ha Kung Wong
Partner
+1 212.218.2571
HWong@Venable.com

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

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