



November 9, 2020



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)

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[®] \(etanercept-szsz\) / 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[™]](#), 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.

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UPDATES

IPRs and PGRs

[Lantus[®] \(insulin glargine recombinant\):](#)

- On October 5, 2020, the Supreme Court denied the writ of certiorari in [Sanofi v. Mylan](#), 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 [Immunex v. Sanofi](#), 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 [Sanofi's](#) 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.

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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