BIOLOGICS HQ

VENABLE LLP

July 14, 2025

LATEST NEWS

Sandoz Launches Jubbonti® / Wyost® (denosumab-bbdz) as First Prolia® / Xgeva® Interchangeable Biosimilars

By: Robert S. Schwartz, Ph.D.

On June 2, 2025, Sandoz announced the launch of Jubbonti® / Wyost® (denosumab-bbdz), the first Prolia® / Xgeva® (denosumab) interchangeable biosimilars to launch in the U.S. Jubbonti® , interchangeable with Prolia®, is indicated for increasing bone mass in patients with osteoporosis, prostate cancer, and breast cancer. Wyost®, interchangeable with Xgeva®, is indicated for prevention and treatment of skeletal-related events in patients with various cancers, including multiple myeloma, solid tumors, and giant cell tumor of bone.

Samsung Bioepis and Formycon's EYLEA® IPRs Discretionarily Denied Institution Among Wave of Fintiv Denials; Regeneron Files Second BPCIA Lawsuit Against Amgen's Pavblu™

By: Robert S. Schwartz, Ph.D.

On June 2, 2025, the Patent Trial and Appeal Board issued decisions denying institution of Samsung Bioepis's IPR2025-00176 and Formycon's IPR2025-00233 against claims 1–12, 14–17, 19, 20, 22–36, 39–42, 44, 45, and 47–55 of Regeneron's U.S. Patent No. 11,084,865. It also denied Formycon's request for joinder with IPR2025-00176 given the institution denial.

These denials come as part of a wave of IPR discretionary denials over the last few months after Acting Director Coke Morgan Stewart became head of the PTAB and rescinded a previous guidance memorandum ("Interim Procedure") from Director Vidal concerning the discretionary denial standard under *Fintiv*.

On June 17, 2025, Regeneron filed a second BPCIA lawsuit (2:25-cv-05499 (C.D. Cal.)) against Amgen's EYLEA® (aflibercept) biosimilar Pavblu™ (aflibercept-ayyh). This lawsuit alleges infringement of Regeneron's newly issued U.S. Patent No. 12,331,099 claiming ophthalmic formulations of a glycosylated VEGF antagonist fusion protein.

Pembrolizumab Patent IPR Final Written Decision Issued and Director Review Requested

By: Robert S. Schwartz, Ph.D.

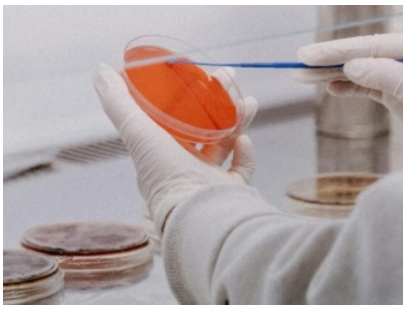
On June 9, 2025, the Patent Trial and Appeal Board issued a Final Written Decision ("FWD") in Merck's IPR2024-00240 against The Johns Hopkins University's ("JHU") U.S. Patent No. 11,591,393 ("the '393 patent"), finding method of treatment claims 1-2, 4-7, 11-12, 14-15, 17-20, 24-25, 27-42 unpatentable as anticipated, and claims 1-42 unpatentable as obvious. The '393 patent is directed to anti-cancer therapies that block immune system checkpoints, including the PD-1 receptor, in colorectal cancer patients. Merck sells anti-PD-1 antibody Keytruda® (pembrolizumab), which is FDA-approved for patients with microsatellite instability-high and mismatch repair deficient colorectal cancer.

On June 26, 2025, JHU requested Director Review of the FWD issued in IPR2024-00240 asserting that the conduct of the case presents an important policy issue.

Amgen Files Three New Prolia® / Xgeva® BPCIA Litigations Against Hikma, Shanghai Henlius Biotech, and Biocon's Proposed Biosimilars

By: Robert S. Schwartz, Ph.D.

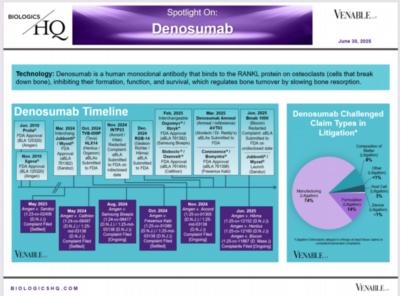
On June 25, 2025, Amgen filed its sixth and seventh BPCIA lawsuits against proposed biosimilars of Prolia® / Xgeva® (denosumab), Case No. 1:25-cv-12152 (D.N.J.) against Hikma and Gedeon Richter's RGB-14 and Case No. 1:25-cv-12160 (D.N.J.) against Shanghai Henlius Biotech and Organon's HLX14. On June 30, 2025, Amgen filed an additional BPCIA lawsuit against Biocon Biologics' Bmab 1000, Case No. 1:25-cv-11867 (D. Mass.). The Complaint against Biocon was the first public announcement that Biocon has filed an aBLA for a Prolia® / Xgeva® biosimilar.



Sarepta Files Two IPRs Against Genzyme's Patents Gene Therapy Elevidys® Allegedly Infringes

By: Robert S. Schwartz, Ph.D.

On June 26, 2025, Sarepta Therapeutics filed IPR2025-01194, challenging as obvious claims 3-6 of Genzyme's U.S. Patent No. 9,051,542 ("the '542 patent), and IPR2025-01195 challenging claims 1-4, 6-7 and 11 of U.S. Patent No. 7,704,721 ("the '721 patent") as obvious. The '542 patent claims a composition for the storage of purified, recombinant adeno-associated virus (rAAV) vector particles, and the '721 patent claims manufacturing methods of preventing aggregation of rAAV virions. In July 2024, Genzyme accused Sarepta's Elevidys® (delandistrogene moxeparvovec-rokl) of infringing these patents in Case No. 1:24-cv-00882 (D. Del.), which is ongoing.



Spotlight On: Prolia® / Xgeva® (denosumab) / Jubbonti® / Wyost® (denosumab-bbdz) / Ospomyv™ / Xbryk™ (denosumab-dssb) / Stoboclo® / Osenvelt® (denosumab-bmwo) / Conexxence™ / Bomyntra™ (denosumab-bnht)

Spotlight On: Actemra® (tocilizumab) / Tofidence™ (tocilizumab-bavi) / Tyenne® (tocilizumab-aazg)

Spotlight On: Neulasta® (pegfilgrastim) / Fulphila® (pegfilgrastim-jmdb) / Udenyca® (pegfilgrastim-cbqv) / Ziextenzo® (pegfilgrastim-bmez) / Nyvepria®(pegfilgrastim-apgf) / Fylnetra™ (pegfilgrastim-apgf) / Stimufend® (pegfilgrastim-fpgk)

Spotlight On: Herceptin® (trastuzumab) / Ogivri® (trastuzumab-dkst) / Herzuma® (trastuzumab-pkrb) / Ontruzant® (trastuzumab-dttb) / Trazimera® (trastuzumab-qyyp) / Kanjinti® (trastuzumab-anns) / Hercessi™ (trastuzumab-strf)

Spotlight On: Biosimilar Litigations

Spotlight On: Rituxan® (rituximab) / Truxima® (rituximab-abbs) / Ruxience® (rituximab-pvvr) / Riabni™ (rituximab-arrx)

Spotlight On: Humira® (adalimumab) / Amjevita™ (adalimumab-atto) / Cyltezo® (adalimumab-adbm) / Hyrimoz® (adalimumab-adaz) / Hadlima™ (adalimumab-bwwd) / Abrilada™ (adalimumab-afzb) / Hulio® (adalimumab-fkjp) / Yusimry™ (adalimumab-aqvh) / Idacio® (adalimumab-aacf) / Yuflyma® (adalimumab-aaty) / Simlandi® (adalimumab-ryvk)

Spotlight On: Enbrel® (etanercept) / Erelzi® (etanercept-szzs) / Eticovo® (etanercept-ykro)

Spotlight On: Lantus® / Lantus® SoloSTAR® (insulin glargine recombinant) / Basaglar® (insulin glargine) / Semglee® (insulin glargine-yfgn) / Rezvoglar™ (insulin glargine-aglr)

BiologicsHQ's "Spotlight On" product dashboards provide, at a glance, an overview of the status of U.S. patent proceedings. The dashboards concerning denosumab (Prolia® / Xgeva®, Jubbonti® / Wyost®, Ospomyv™ / Xbryk™, Stoboclo® / Osenvelt®, Conexxence™ / Bomyntra™, TVB-009P, HLX14, INTP23, RGB-14, Denosumab Amneal, AVT03, and Bmab 1000), tocilizumab (Actemra®, Tofidence™, Tyenne®, and CT-P47), pegfilgrastim (Neulasta®, Fulphila®, Udenyca®, Ziextenzo®, Nyvepria®, Fylnetra™, Stimufend®, Lapelga™, and Pegfilgrastim (Lupin)), trastuzumab (Herceptin®, Ogivri®, Herzuma®, Ontruzant®, Trazimera®,

Kanjinti®, Hercessi™, TX-05, and EG12014), rituximab (Rituxan®, Truxima®, Ruxience®, Riabni™ and DRL_RI), adalimumab (Humira®, Amjevita™, Cyltezo®, Hyrimoz®, Hadlima™, Abrilada™, Hulio®, Yusimry™, Idacio®, Yuflyma®, and Simlandi®), etanercept (Enbrel®, Erelzi®, and Eticovo®), and insulin glargine (Lantus® / Lantus® SoloSTAR®, Basaglar®, Semglee®, and Rezvoglar™) have been updated with activity through June 30, 2025.

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, 2025.

Read More News

UPDATES

IPRs and PGRs

Eylea® (aflibercept):

- On June 2, 2025, the PTAB denied institution in **Samsung Bioepis's** IPR2025-00176 and **Formycon's** IPR2025-00233 and **Formycon's** request for joinder with IPR2025-00176 against **Regeneron's** U.S. Patent No. 11,084,865. The PTAB exercised its discretion to deny the IPRs under *FIntiv,* particularly due to the parallel district court litigations.
- On June 25, 2025, the PTAB denied institution in **Celltrion's** IPR2025-00456 against **Regeneron's** U.S. Patent No. 11,084,865. The PTAB exercised its discretion to deny the IPR, particularly due to the parallel district court litigations.

Keytruda® (pembrolizumab):

- On June 9, 2025, the PTAB issued a Final Written Decision in **Merck's** IPR2024-00240 against The Johns Hopkins University's U.S. Patent No. 11,591,393 finding all challenged claims unpatentable as anticipated and obvious. On June 26, 2025, Johns Hopkins requested Director Review of the Final Written Decision.

Elevidys® (delandistrogene moxeparvovec-rokl):

- On June 26, 2025, **Sarepta** filed IPR2025-01194 against **Genzyme's** U.S. Patent No. 9,051,542, and IPR2025-01195 against U.S. Patent No. 7,704,721.

Litigations

Eylea® (aflibercept):

- On June 17, 2025, **Regeneron** filed BPCIA Case No. 2:25-cv-05499 (C.D. Cal.) against **Amgen** alleging infringement of U.S. Patent No. 12,331,099 by **Amgen's Eylea® (aflibercept)** biosimilar **Pavblu™ (aflibercept-ayyh)**.

Prolia® / Xgeva® (denosumab):

- On June 25, 2025, **Amgen** filed BPCIA Case No. 1:25-cv-12152 (D.N.J.) against **Hikma** and **Gedeon Richter** alleging infringement of 32 patents by their proposed **Prolia® / Xgeva® (denosumab)** biosimilar **RGB-14**, and Case No. 1:25-cv-12160 (D.N.J.) against **Shanghai Henlius Biotech** and **Organon** alleging infringement of 26 patents by their proposed **Prolia® / Xgeva®** biosimilar **HLX14**.

- On June 30, 2025, **Amgen** filed BPCIA Case No. 1:25-cv-11867 (D. Mass.) against **Biocon Biologics** alleging infringement of 34 patents by its proposed **Prolia® / Xgeva®** biosimilar **Bmab 1000**.

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aBLA Applications and FDA Activity

Jubbonti® / Wyost® (denosumab-bbdz):

- On June 2, 2025, **Sandoz** announced the launch of **Jubbonti® / Wyost® (denosumab-bbdz)** as the first interchangeable biosimilars of **Amgen's Prolia® / Xgeva® (denosumab)**.

Bmab 1000 (denosumab):

- According to a June 30, 2025 Complaint (Case No. 1:25-cv-11867 (D. Mass.)), **Biocon Biologics** submitted an aBLA to the FDA for **Bmab 1000 (denosumab)**, a proposed biosimilar of **Amgen's Prolia® / Xgeva® (denosumab)**, on an undisclosed date.

CDER Purple Book Updates

Enflonsia™ (clesrovimab-cfor):

- On June 9, 2025, the FDA approved **Merck's Enflonsia™ (clesrovimab-cfor)**.

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

Qoyvolma™ (ustekinumab-stba):

- On June 9, 2025, **Celltrion** announced the approval of **Qoyvolma™ (ustekinumab-stba)**, its second biosimilar of **Janssen** / **Johnson & Johnson's Stelara® (ustekinumab)**, in the E.U. **Celltrion's SteQeyma™ (ustekinumab-stba)** was approved in the E.U. in August 2024. **Qoyvolma™** is specialized for the European market and adds an additional ulcerative colitis indication to **SteQeyma™'s** indications.

Dyrupeg™ (pegfilgrastim):

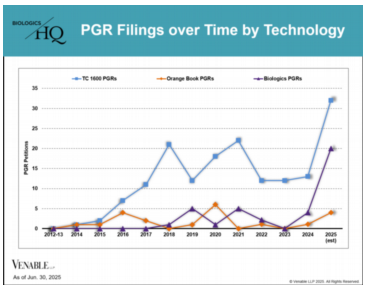
- On June 24, 2025, **Aurobindo** / **CuraTeQ** announced the approval of **Dyrupeg™ (pegfilgrastim)**, a biosimilar of **Amgen's Neulasta® (pegfilgrastim)**, in the U.K.

Yesafili® (aflibercept-jbvf):

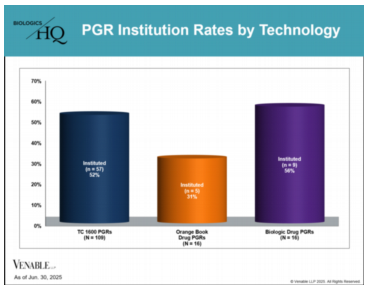
- On June 27. 2025, **Biocon** announced the approval of **Yesafili® (aflibercept-jbvf)**, a biosimilar of **Regeneron's Eylea® (aflibercept)**, in Canada.

STATISTICS

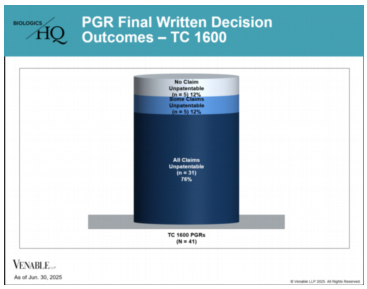
PGR Filings Over Time by Technology	PGR Institution Rates by Technology	PGR Final Written Decision Outcomes – TC 1600



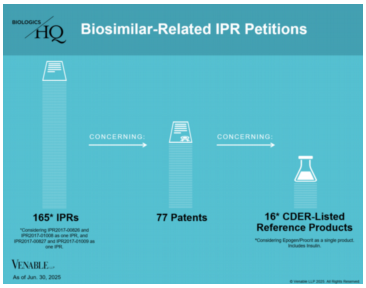
Biosimilar-Related IPR Petitions



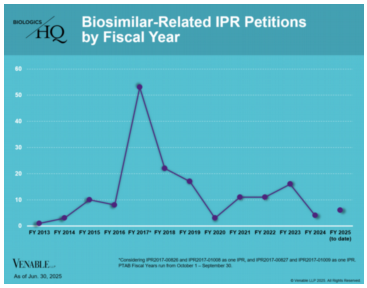
Biosimilar-Related IPR Petitions by Fiscal Year



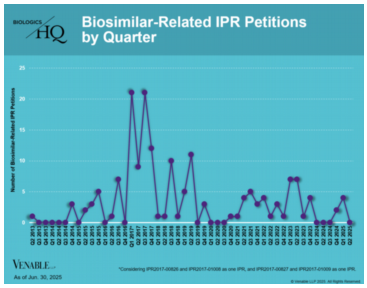
Biosimilar-Related IPR Petitions by Quarter



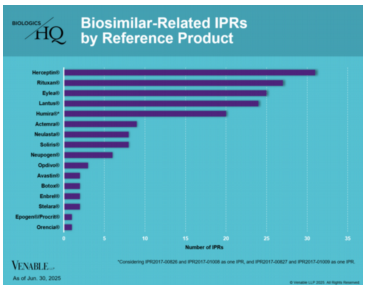
Biosimilar-Related IPRs by Reference Product



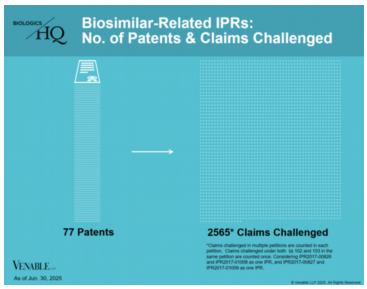
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



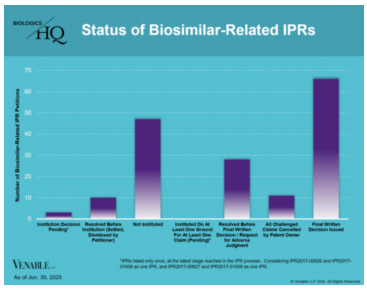
Status of Biosimilar-Related IPRs



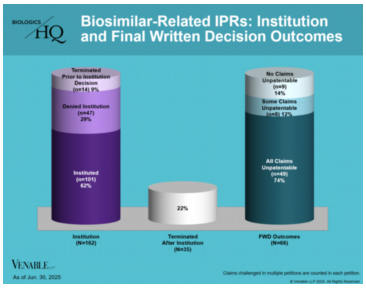
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



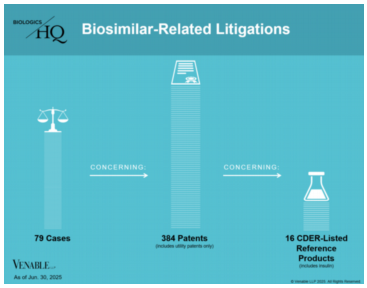
Biosimilar-Related Litigations



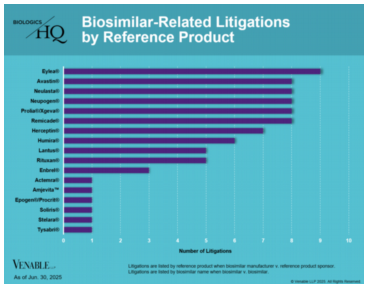
Biosimilar-Related Litigations by Reference Product



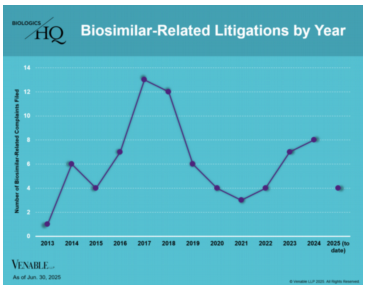
Biosimilar-Related Litigations by Year

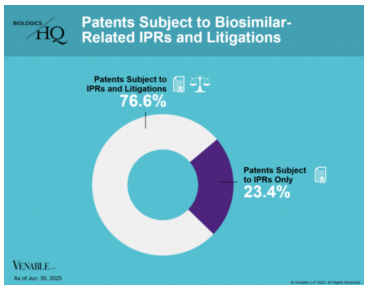


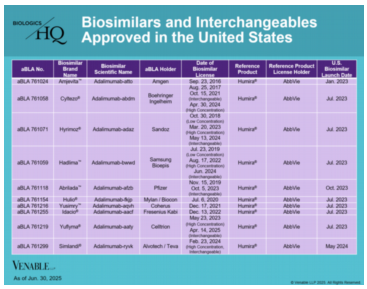
Patents Subject to Biosimilar-Related IPRs and Litigations



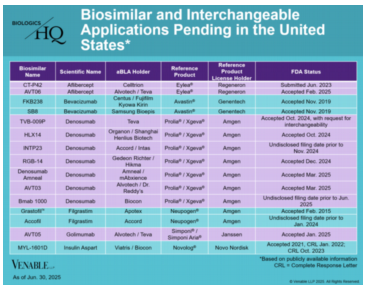
Biosimilars and Interchangeables Approved in the United States



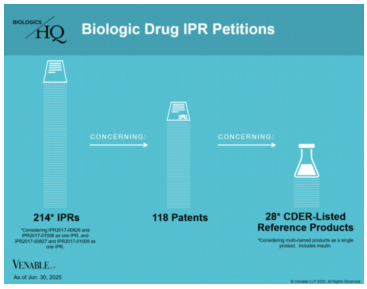




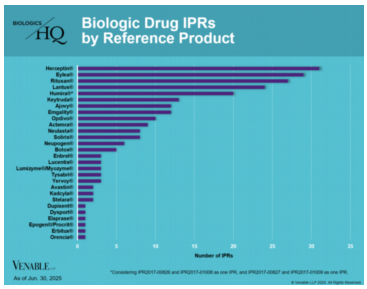
Biosimilar and Interchangeable Applications Pending in the United States



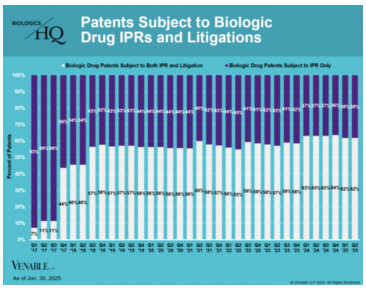
Biologic Drug IPR Petitions



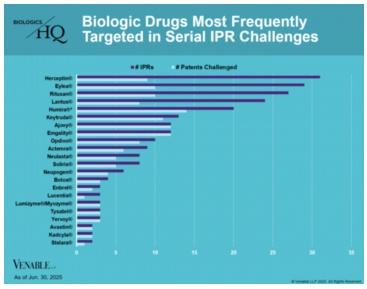
Biologic Drug IPRs by Reference Product



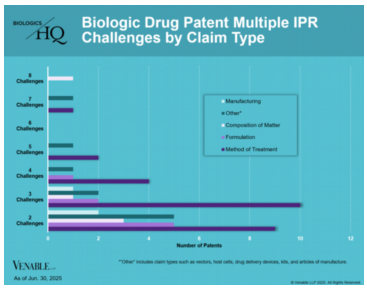
Patents Subject to Biologic Drug IPRs and Litigations



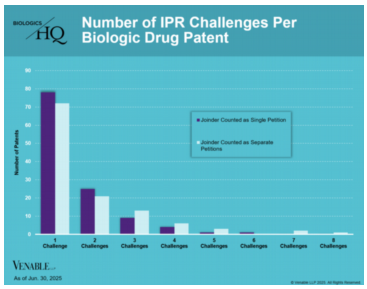
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

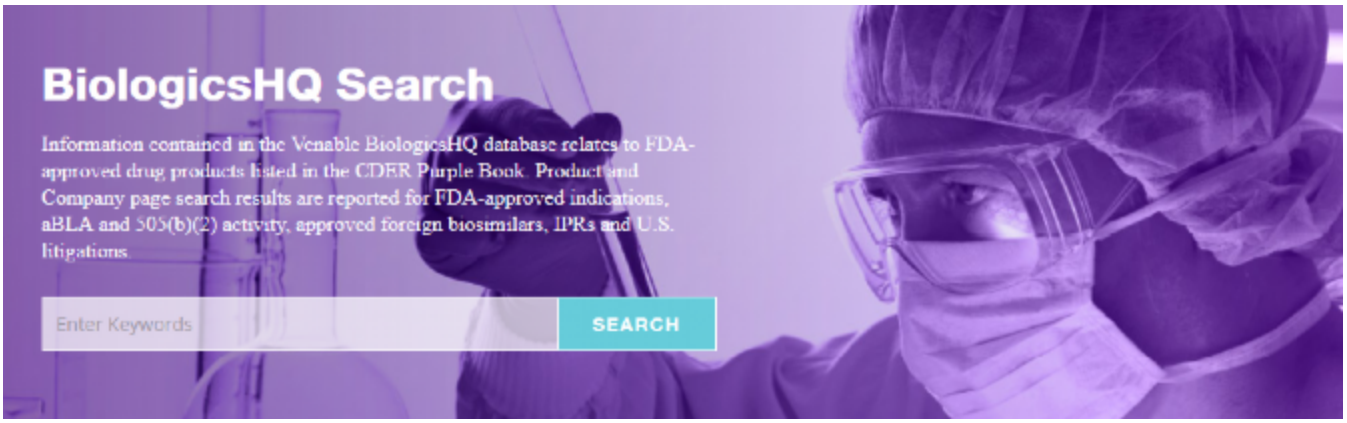


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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 | COLORADO | DELAWARE | FLORIDA | ILLINOIS | MARYLAND | NEW YORK | VIRGINIA | WASHINGTON, DC