BIOLOGICS HQ

VENABLE LLP

April 10, 2025

LATEST NEWS

Potential Impact of the Affordable Prescriptions for Patients Act Patent Limit on BPCIA Litigations

By: Robert S. Schwartz, Ph.D.

On March 17, 2025, Senators Chuck Grassley (R-IA), John Cornyn (R-TX), Richard Blumenthal (D-CT), and Richard Durbin (D-IL) re-introduced the "Affordable Prescriptions for Patients Act" ("APPA"), which previously passed the U.S. Senate as S.150 in the 2024 Congressional session, but was not passed by the House. On April 3, 2025, the Committee on the Judiciary ordered the bill to be reported favorably without amendment. The APPA limits the number of patents that can be asserted by a reference product sponsor ("RPS") against a biosimilar manufacturer in Biologics Price Competition and Innovation Act ("BPCIA") litigations under 35 U.S.C. § 271(e).

We sought to determine the potential impact the APPA could have on streamlining biosimilar litigations. To do this, we reviewed the impact the APPA would have had on the BPCIA litigations that have been filed as of March 17, 2025.

Prolia® / Xgeva® (denosumab) Biosimilar Updates: Celltrion Biosimilar Approval, Amneal aBLA Filing, and Fresenius Kabi Litigation Settlement

By: Robert S. Schwartz, Ph.D.

On March 3, 2025, Amneal and mAbxience announced the FDA accepted for review its aBLA for two denosumab biosimilars of Prolia® / Xgeva®.

On March 7, 2025, Amgen and Fresenius Kabi dismissed their BPCIA litigation, Case No. 1:25-cv-01080 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.), which was recently transferred from the Northern District of Illinois and consolidated into a Multidistrict Litigation (*see* Biosimilar Cases to Watch: Prolia/Xgeva and Denosumab Competitors). The settlement came only five months after the case was filed.

Federal Circuit Affirms Preliminary Injunction Decisions for EYLEA® Biosimilars

By: Robert S. Schwartz, Ph.D.

On March 5, 2025, the Federal Circuit affirmed the grant of a preliminary injunction against the launch of Celltrion's proposed EYLEA® (aflibercept) biosimilar CT-P42 in CAFC Case Nos. 24-2058 and 24-2147 (appealing from 1:23-cv-00089 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.)). Robert Schwartz summarizes the Federal Circuit's opinion.

FDA Approves First Interchangeable Biosimilar of Xolair®: Celltrion's Omlyclo® (omalizumab-igec)

By: Robert S. Schwartz, Ph.D.

On March 7, 2025, the FDA approved Celltrion's Omlyclo® (omalizumab-igec), the first interchangeable biosimilar of Genentech's Xolair® (omalizumab). Omlyclo® was approved for all of Xolair®'s approved indications, including for certain patients with asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), IgE-mediated food allergy, and chronic idiopathic urticaria (CSU).

Biosimilar Cases to Watch: Prolia/Xgeva and Denosumab Competitors with The Center for Biosimilars

By: Ha Kung Wong and April Breyer Menon

In an article for The Center for Biosimilars, Ha Kung Wong and April Breyer Menon discuss Prolia® / Xgeva® (denosumab) cases to watch, including cases against Samsung Bioepis (1:24-cv-08417 (D.N.J.)), Fresenius Kabi (1:25-cv-01080 (D.N.J.)), and Accord (1:25-cv-01305 (D.N.J.)) that were recently consolidated in MDL 1:25-md-03138 (D.N.J.), as well as settlement agreements and whether there may be any at-risk launches.

March Stelara® Biosimilar Launches: Fresenius Kabi's Otulfi® and Celltrion's Steqeyma™

By: Robert S. Schwartz, Ph.D.

On March 3, 2025, Fresenius Kabi and Formycon announced the launch of Otulfi™ (ustekinumab-aauz), a provisionally interchangeable biosimilar of Janssen / Johnson & Johnson's Stelara® (ustekinumab), subject to the interchangeable exclusivity of Amgen's Wezlana™ (ustekinumab-auub).

On March 13, 2025, Celltrion announced the launch of its Stelara® biosimilar Steqeyma™ (ustekinumab-stba), at an 85% discount to Stelara®'s wholesale acquisition cost. Celltrion has secured a listing agreement

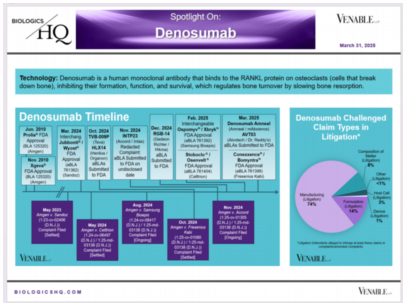
with Costco Health Solutions for Steqeyma™ to be designated as a preferred drug on its formulary.

Prolia® / Xgeva® Biosimilar Updates: Alvotech / Dr. Reddy's AVT03 aBLA Acceptance, Fresenius Kabi's Conexxence™ / Bomyntra™ FDA-Approval

By: Robert S. Schwartz, Ph.D.

On March 18, 2025, Alvotech and Dr. Reddy's announced the FDA acceptance of an aBLA for AVT03 (denosumab), a proposed biosimilar of Amgen's Prolia® / Xgeva® (denosumab). Under their agreement, Alvotech is responsible for the development and manufacture of AVT03, and Dr. Reddy's is responsible for its registration and commercialization.

On March 25, 2025, the FDA approved Fresenius Kabi's Conexxence™ / Bomyntra™ (denosumab-bnht) as the fourth biosimilars of Prolia® / Xgeva®. Earlier in March, Fresenius Kabi settled its BPCIA litigation with Amgen, Case No. 1:25-cv-01080 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.), allowing a launch in June 2025.



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, and AVT03), 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 March 31, 2025.

BiologicsHQ's "Spotlight On Biosimilar Litigations" dashboard provides, at a glance, an overview of the status of U.S. biosimilar patent litigations through March 31, 2025.

Read More News

UPDATES

Litigations

Herceptin® (trastuzumab) / Herceptin Hylecta® (trastuzumab; hyaluronidase-oysk) / Perjeta® (pertuzumab) / Phesgo® (pertuzumab; trastuzumab; hyaluronidase-zzxf):

- On March 3, 2025, the Court granted partial summary judgment of invalidity of the Trustees of the University of Pennsylvania's U.S. Patent No. 7,625,558 in Case No. 1:22-cv-00145 (D. Del.). On March 14, 2025, The Court granted the Trustees of the University of Pennsylvania and **Genentech's** joint stipulation of dismissal due to settlement.

Eylea® (aflibercept):

- On March 5, 2025, in CAFC Case Nos. 24-2058 and 24-2147, the Federal Circuit affirmed the grant of a preliminary injunction against **Celltrion's** proposed **Eylea® (aflibercept)** biosimilar **CT-P42** granted in Case No. 1:23-cv-00089 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) brought by **Regeneron**.
- On March 14, 2025, in CAFC Case No. 24-2351, the Federal Circuit affirmed the denial of a preliminary injunction against **Amgen's Eylea® (aflibercept)** biosimilar **Pavblu™ (aflibercept-ayyh)**, appealed from Case No. 1:24-cv-

00039 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.) brought by **Regeneron**.

Prolia® / Xgeva® (denosumab):

- On March 7, 2025, **Amgen** and **Fresenius Kabi** dismissed Case No. 1:25-cv-01080 (D.N.J.) / MDL 1:25-md-03138 (D.N.J.) due to settlement. Under the settlement agreement, **Conexxence™ / Bomynetra™ (denosumab-bnht)** will be permitted to launch as early as June 2025.

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aBLA Applications and FDA Activity

Otulfi™ (ustekinumab-aauz):

- On March 3, 2025, **Fresenius Kabi** and **Formycon** announced the launch of **Otulfi™ (ustekinumab-aauz)**, a provisionally interchangeable biosimilar of **Janssen** / **Johnson & Johnson's** **Stelara® (ustekinumab)**.

Denosumab Amneal (denosumab):

- On March 3, 2025, **Amneal** and **mAbxience** announced the FDA acceptance of aBLAs for two proposed **denosumab** biosimilars referencing **Amgen's** **Prolia®** / **Xgeva® (denosumab)**.

Stoboclo® / Osenvelt® (denosumab-bmwo):

- On March 4, 2025, **Celltrion** announced the FDA approval of **Stoboclo® / Osenvelt® (denosumab-bmwo)**, biosimilars of **Amgen's** **Prolia®** / **Xgeva® (denosumab)**.

Omlyclo® (omalizumab-igec):

- On March 7, 2025, the FDA approved **Celltrion's** **Omlyclo® (omalizumab-igec)** as the first interchangeable biosimilar of **Genentech's** **Xolair® (omalizumab**).

Steqeyma™ (ustekinumab-stba):

- On March 13, 2025, **Celltrion** announced the launch of **Steqeyma™ (ustekinumab-stba)**, a biosimilar of **Janssen** / **Johnson & Johnson's** **Stelara® (ustekinumab)** at an 85% discount to **Stelara®'s** wholesale acquisition cost.

AVT03 (denosumab):

- On March 18, 2025, **Alvotech** and **Dr. Reddy's** announced the FDA acceptance of an aBLA for **AVT03 (denosumab)**, a proposed biosimilar of **Amgen's** **Prolia®** / **Xgeva® (denosumab)**.

Conexxence™ / Bomyntra™ (denosumab-bnht):

- On March 25, 2025, the FDA approved **Fresenius Kabi's** **Conexxence™ / Bomyntra™ (denosumab-bnht)** as biosimilars of **Amgen's** **Prolia® / Xgeva® (denosumab)**.

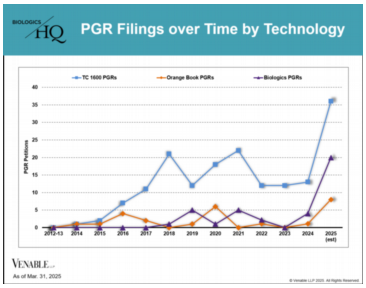
CDER Purple Book Updates

Encelto™ (revakinagene taroretcel-lwey):

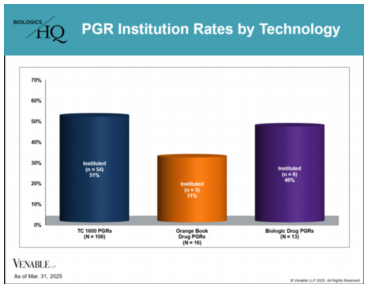
- On March 5, 2025, the FDA approved **Neurotech Pharmaceuticals'** **Encelto™ (revakinagene taroretcel-lwey)**.

STATISTICS

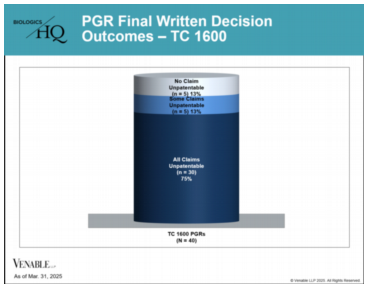
PGR Filings Over Time by Technology



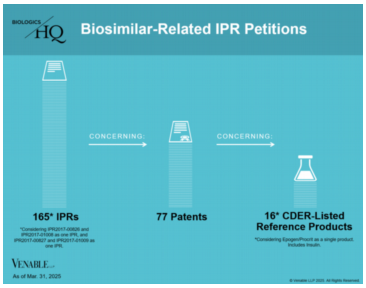
PGR Institution Rates by Technology



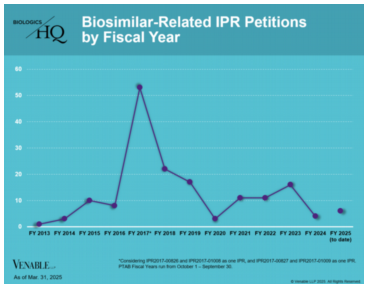
PGR Final Written Decision Outcomes – TC 1600



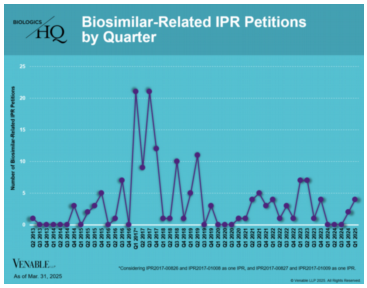
Biosimilar-Related IPR Petitions



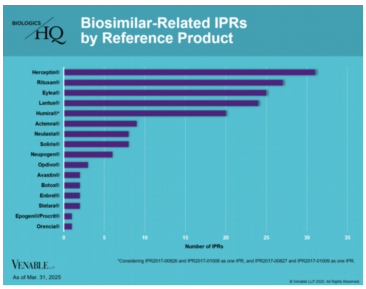
Biosimilar-Related IPR Petitions by Fiscal Year



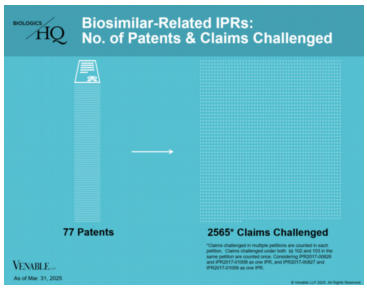
Biosimilar-Related IPR Petitions by Quarter



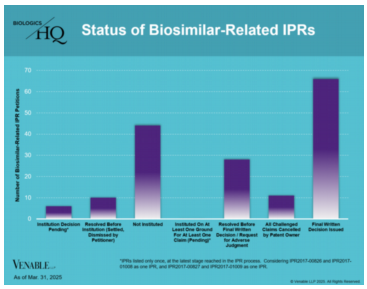
Biosimilar-Related IPRs by Reference Product



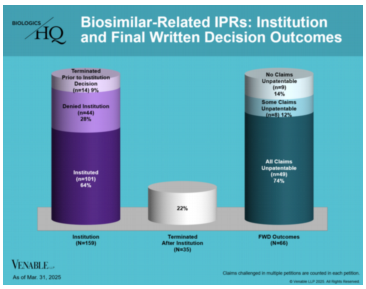
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



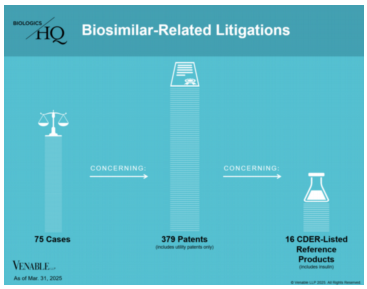
Status of Biosimilar-Related IPRs



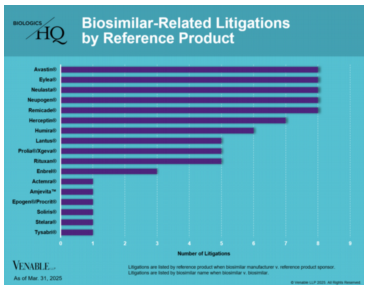
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



Biosimilar-Related Litigations



Biosimilar-Related Litigations by Reference Product

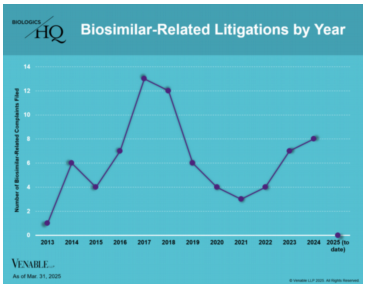


Biosimilar-Related Litigations

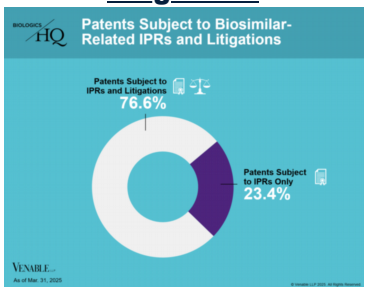
Patents Subject to Biosimilar-Related

Biosimilars and Interchangeables

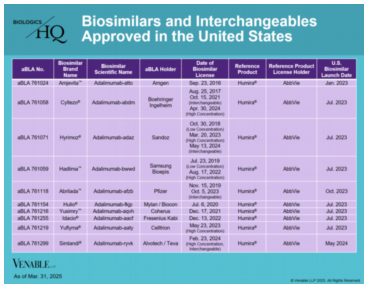
by Year



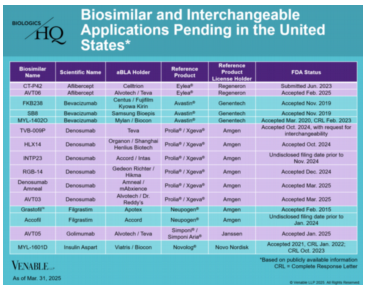
IPRs and Litigations



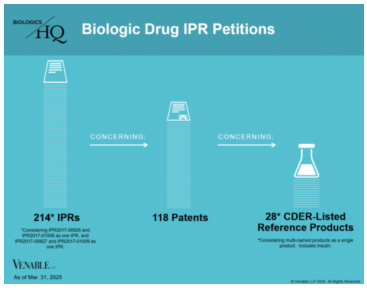
Approved in the United States



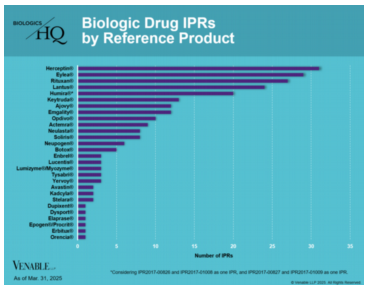
Biosimilar and Interchangeable Applications Pending in the United States



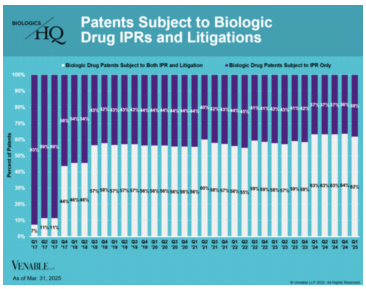
Biologic Drug IPR Petitions



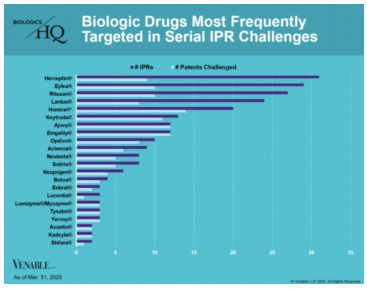
Biologic Drug IPRs by Reference Product



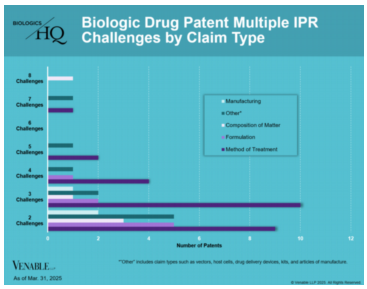
Patents Subject to Biologic Drug IPRs and Litigations



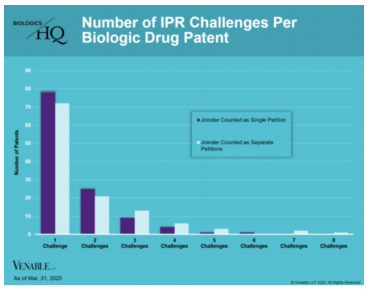
Biologic Drugs Most Frequently Targeted in Serial IPR Challenges

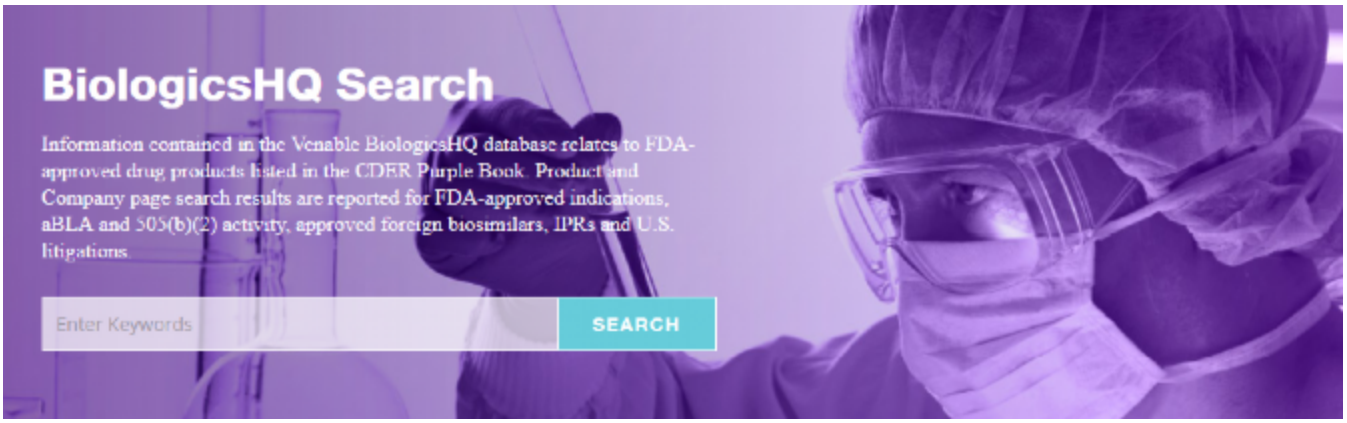


Biologic Drug Patent Multiple IPR Challenges by Claim Type



Number of IPR Challenges Per Biologic Drug Patent





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