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Webinar Series: Biosimilars

Biosimilars: 2019 A Year in Review

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TODAY'S AGENDA

- U.S. Market for Biosimilars
- FDA Biosimilar Guidance
- Biosimilar Legislation
- Biosimilar Litigation
- Antitrust Developments
- Post Grant Activity
- Looking Forward to 2020

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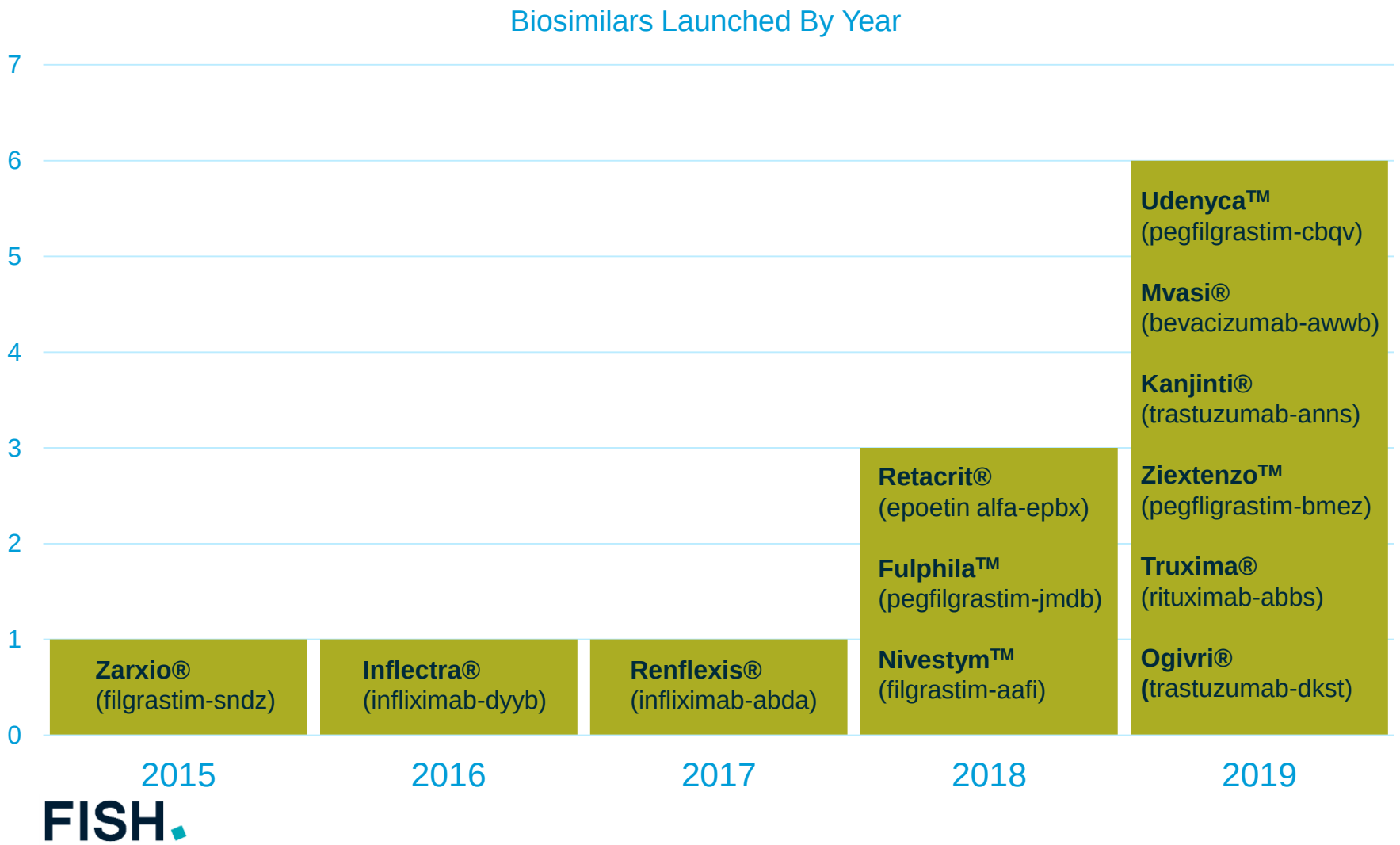
FDA Approved 26 Biosimilars by End of 2019

	Biosimilar	Biologic Reference Product	FDA Approval Date	Biosimilar Code
1	Zarxio (Sandoz)	Neupogen (Amgen)	March 2015	Filgrastim-sndz
2	Inflectra (Pfizer/Celltrion)	Remicade (J&J)	April 2016	Infliximab-dyyb
3	Erelzi (Sandoz)	Enbrel (Amgen)	August 2016	Etanercept-szzs
4	Amjevita (Amgen)	Humira (AbbVie)	September 2016	Adalimumab-atto
5	Renflexis (Samsung Bioepis/Merck)	Remicade (J&J)	April 2017	Infliximab-abda
6	Cyltezo / BI-695501 (BI)	Humira (AbbVie)	August 2017	Adalimumab-adbm
7	Mvasi (Amgen)	Avastin (Roche)	September 2017	Bevacizumab-awwb
8	Ogivri (Mylan)	Herceptin (Genentech/Roche)	December 2017	Trastuzumab-dkst
9	Ixifi (Pfizer)	Remicade (J&J)	December 2017	Infliximab-qbtx
10	Retacrit (Pfizer/Hospira)	Epogen/Procrit (Amgen/J&J)	May 2018	Epoetin alfa-epbx
11	Fulphila (Mylan/Biocon)	Neulasta (Amgen)	June 2018	Pegfilgrastim-jmdb
12	Nivestym (Pfizer)	Neupogen (Amgen)	July 2018	Filgrastim-aafi
13	Hyrimoz (Sandoz)	Humira (AbbVie)	November 2018	Adalimumab-adaz
14	Udencya / CHS-1701 (Coherus)	Neulasta (Amgen)	November 2018	Pegfilgrastim-cbqv
15	Truxima (Celltrion/Teva)	Rituxan (Roche/Genentech)	November 2018	Rituximab-abbs
16	Herzuma (Celltrion)	Herceptin (Genentech)	December 2018	Trastuzumab-pkrb
17	Ontruzant (Samsung Bioepis/Merck)	Herceptin (Genentech)	January 2019	Trastuzumab-dttb
18	Trazimera (Pfizer)	Herceptin (Genentech)	March 2019	Trastuzumab-qyyp
19	Eticovo (Samsung Bioepis)	Enbrel (Amgen)	April 2019	Etanercept-ykro
20	Kanjinti (Amgen)	Herceptin (Genentech)	June 2019	Trastuzumab-anns
21	Zirabev (Pfizer)	Avastin (Roche)	June 2019	Bevacizumab-bvzr
22	Hadlima (Samsung Bioepis)	Humira (AbbVie)	July 2019	Adalimumab-bwwd
23	Ruxience (Pfizer)	Rituxan (Roche/Genentech)	July 2019	Rituximab-pvvr
24	Ziextenzo (Sandoz)	Neulasta (Amgen)	November 2019	Pegfligrastim-bmez
25	Abrilada (Pfizer)	Humira (AbbVie)	December 2019	Adalimumab-afzb
26	Avsola (Amgen)	Remicade (J&J)	December 2019	Infliximab-axxq

12 Biosimilars Launched by End of 2019



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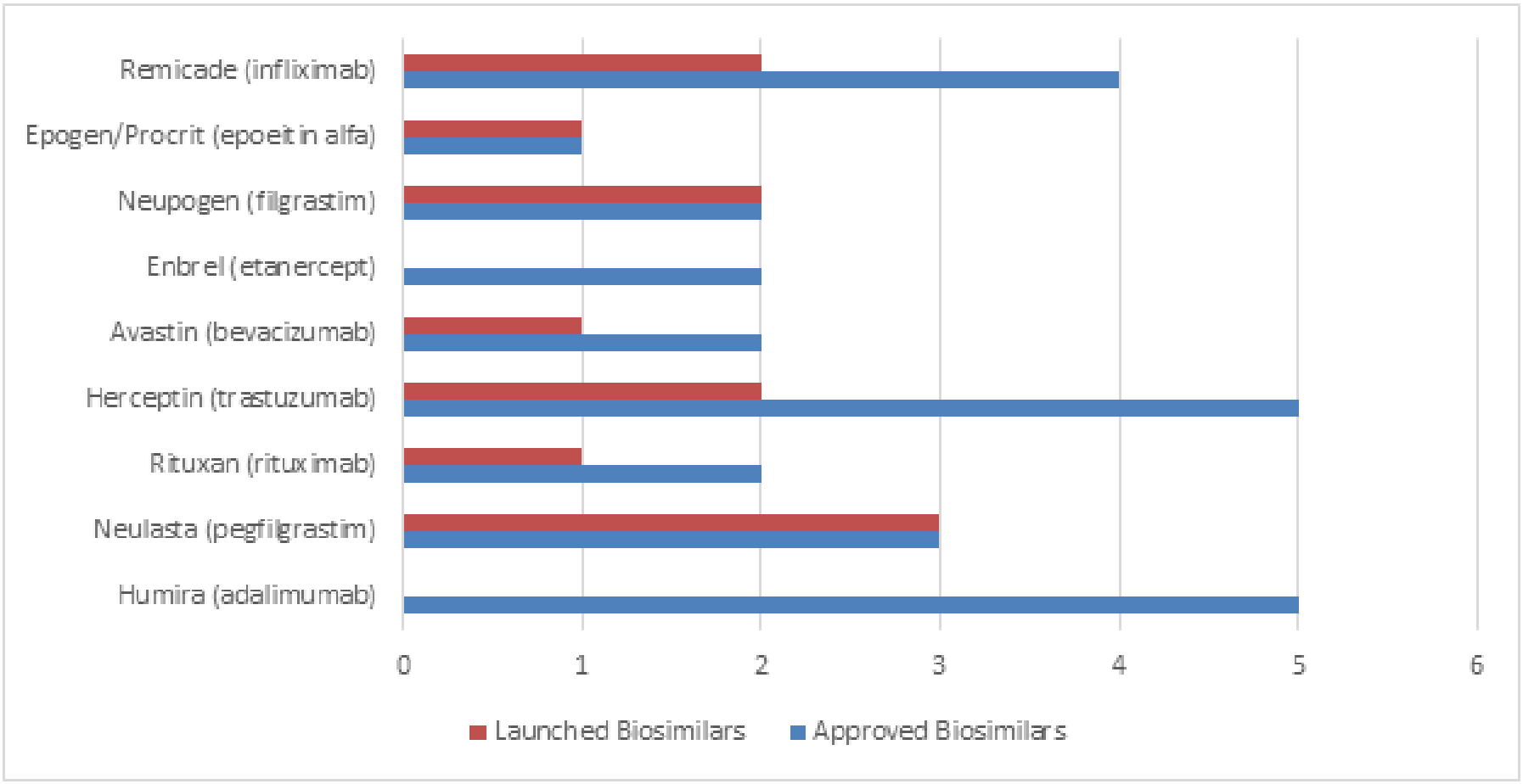
Biosimilar Approvals Versus Launches through 2019



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FDA Updates

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“Biosimilars Action Plan” Deliverables

2. Maximizing scientific and regulatory clarity for the biosimilar product development community.

The FDA is increasing stakeholder communications related to biosimilars, including timely guidance for sponsors in order to provide scientific and regulatory predictability, as well as more efficient structures to support the development and review of biosimilar and interchangeable products. This includes efforts to harmonize international regulation of biosimilars and the acceptance of non-U.S. comparator products, as well as greater use of real-world data supporting regulatory decision making related to biosimilars.

FDA Guidance in 2019

- **March 2019**
  - "Nonproprietary Naming of Biological Products: Update" (draft)
    - **FDA proposes to remove transition biological products from the scope of the naming convention**
    - **FDA no longer intends to retroactively modify the names of approved biologics to include 4-letter suffixes devoid of meaning**
- **May 2019**
  - "Considerations in Demonstrating Interchangeability With a Reference Product" (final)
    - **Focuses on the evidence required to establish interchangeability with a reference biologic product**
    - **FDA will consider the totality of the evidence provided by the sponsor, typically requiring a switching study**
  - "Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations"
    - **Recommendations on design and evaluation of comparative analytical studies that aim to demonstrate that a proposed therapeutic protein product is biosimilar to a RPS**

FDA Guidance in 2019

- **September 2019**
  - "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act" (final)
    - **Seeks to lessen the impact that FDA review of certain citizen petitions may have on any pending BLA approval actions**
    - **Provides some of the factors the agency will consider in determining whether a petition is submitted with the primary purpose of delaying the approval of a drug application**
- **November 2019**
  - "Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products" (draft)
    - **The guidance is part of FDA's efforts to facilitate the upcoming March 23, 2020 transition of approved marketing applications for biological products regulated under the Federal Food, Drug, and Cosmetic Act to be approved biologic license applications under the PHS Act**

Legislation

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Exemplary Federal Legislation

- **Make patent information for biologic products available**
  - The Purple Book Continuity Act of 2019 (H.R. 1520)
  - The Biologic Patent Transparency Act (BPTA) (S. 659)
- **Curb anticompetitive conduct by biologic drug manufacturers, such as "product hopping," "pay-for-delay" agreements, abusive or sham citizen petitions, and patent "evergreening"**
  - The Affordable Prescriptions for Patients Act of 2019 (S. 1416)
  - The Protecting Consumer Access to Generics Act of 2019 (H.R. 1499)
  - The Preserve Access to Affordable Generics and Biosimilars Act (H.R. 2375)
  - The Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (STALLING) Act (S. 1224/H.R. 2374)
  - The Stop the Overuse of Petitions and Get Affordable Medicines to Enter Soon (STOP GAMES) Act of 2019 (H.R. 2387)
  - The Terminating the Extension of Rights Misappropriated (TERM) Act (H.R. 3199)
  - The Second Look at Drug Patents Act of 2019 (S. 1617)

State Biosimilar Substitution Laws

- **State legislatures regulate biosimilar substitution at the pharmacy**
- **At least 4 more states enacted substitution laws in 2019: Alabama, Arkansas, Maine, and Mississippi**
- **Now, at least 49 states and Puerto Rico have substitution laws**
- **State laws vary in a number of ways, for example:**
  - Notification or communication to patient and prescriber
  - Permissive versus mandatory substitution
  - Cost savings requirements
  - Recordkeeping
  - Immunity for pharmacists

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Litigation Update

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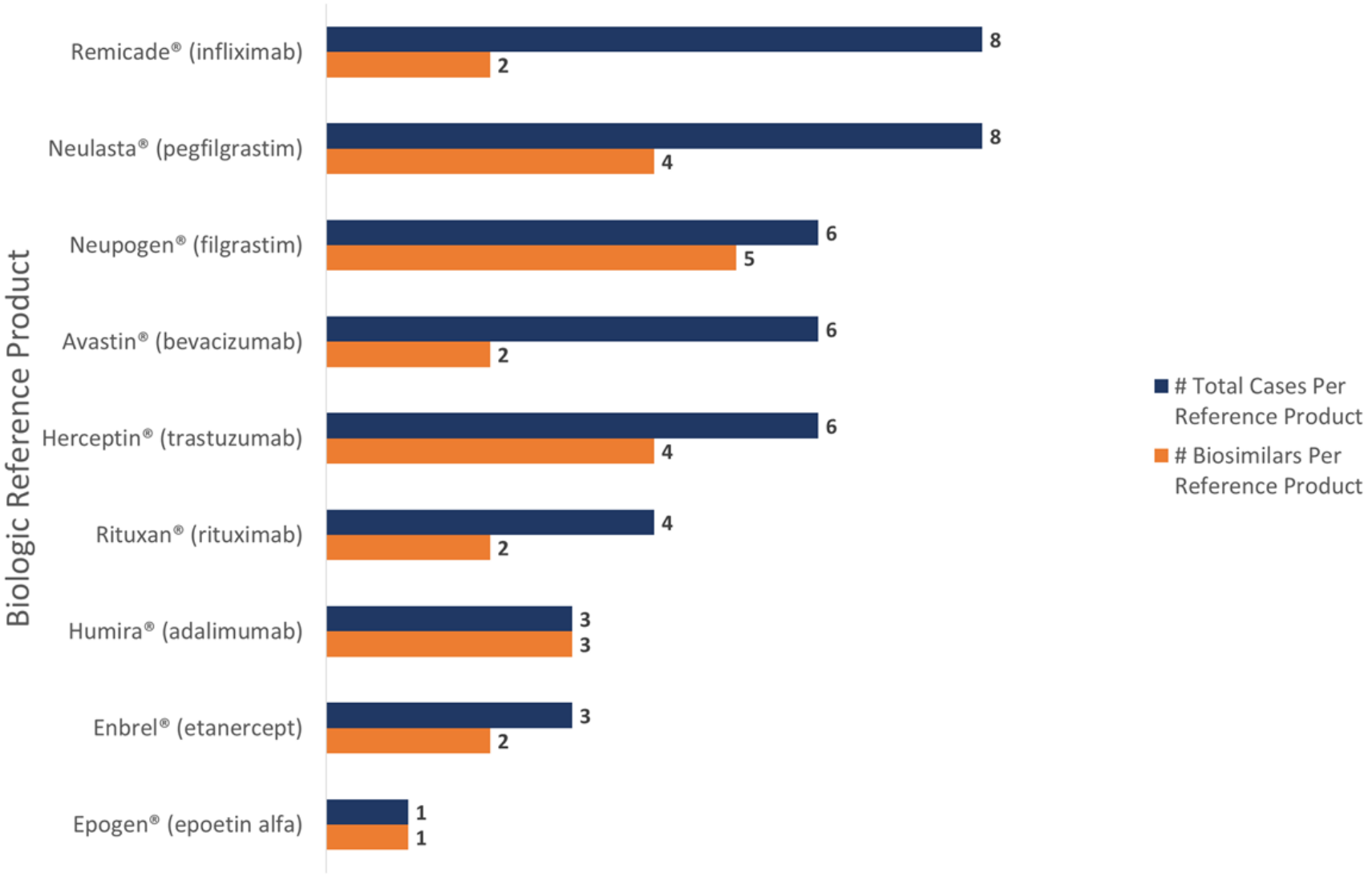
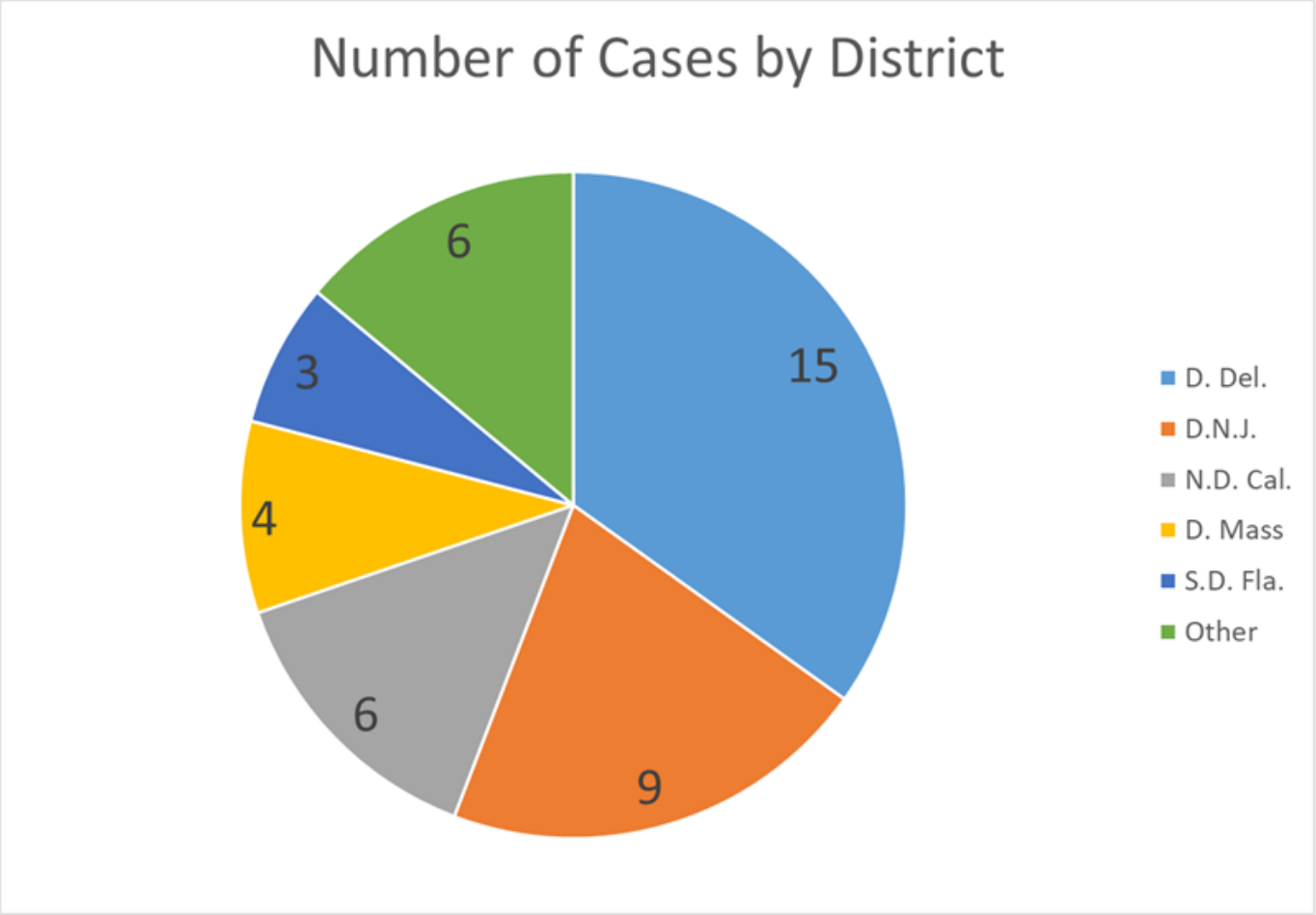
BPCIA Cases by Reference Product



BPCIA Cases Filed by District



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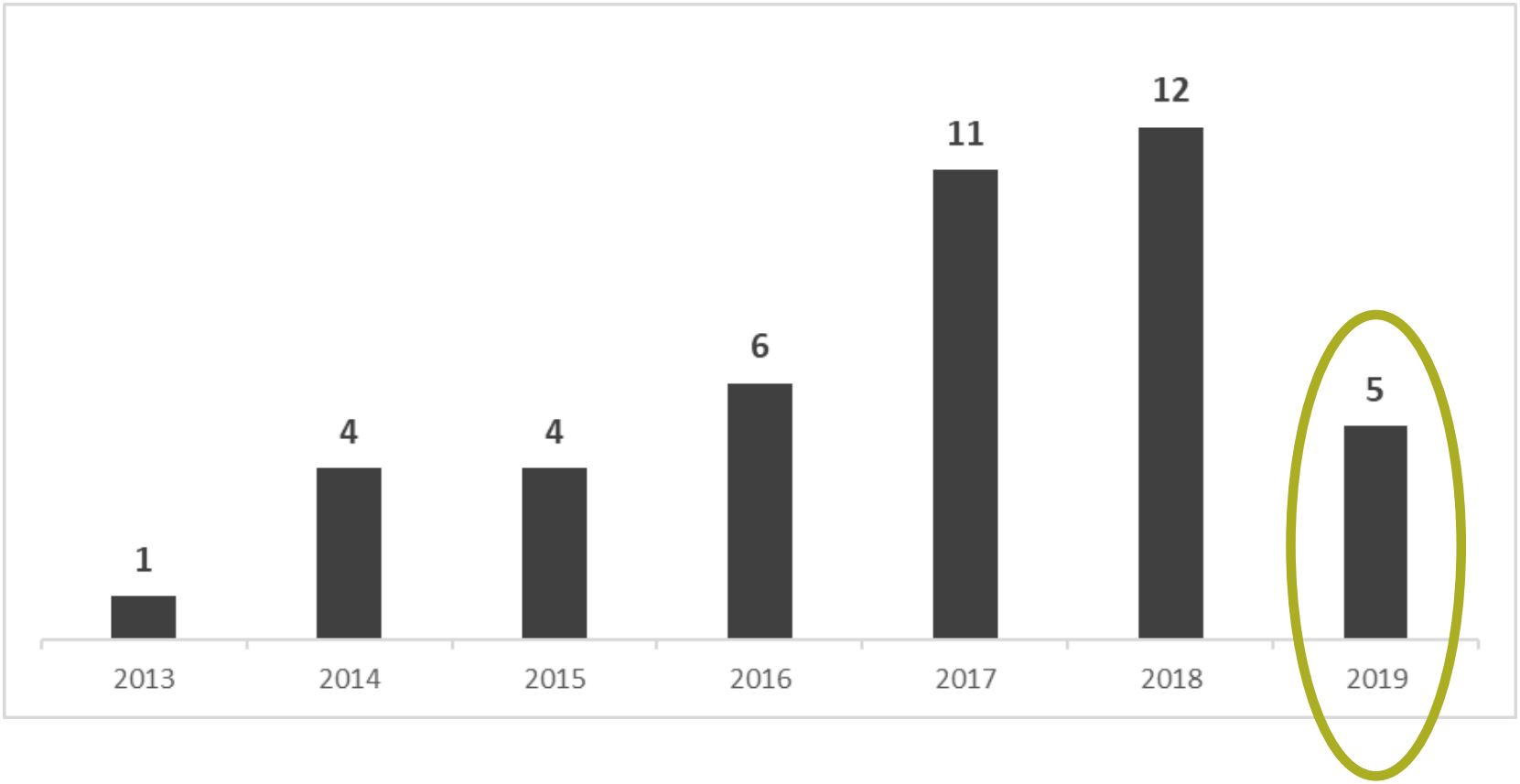
BPCIA Cases Filed by Year



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New Biosimilar-Related Cases Filed in 2019

Parties	Case No.	Reference
Sandoz v. Amgen	19-cv-977 (N.D. Cal.)	Neupogen® Neulasta®
Genentech v. Immunex	19-cv-602 (D. Del.)	Avastin®
Genentech v. Pfizer	19-cv-638 (D. Del.)	Avastin®
Immunex v. Samsung Bioepis	19-cv-11755 (D.N.J.)	Enbrel®
Amgen v. Tanvex	19-cv-01374 (S.D. Cal.)	Neupogen®
Coherus v. Amgen	19-cv-139 (D. Del.)	Humira®

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Sandoz v. Amgen – Declaratory Judgment

- ***Sandoz v. Amgen* (19-cv-977, N.D. Cal. – filed Feb. 21, 2019)**
  - Related to Sandoz's biosimilars of Amgen's Neupogen® and Neulasta®
    - Sandoz's Zarxio® (filgrastim) has been on the market since 2015
    - Sandoz's Ziextenzo™ (pegfilgrastim) was not FDA-approved at time of filing, but was approved and launched in November 2019
  - Sandoz sought DJ of non-infringement and invalidity of U.S. Patent 9,643,997, issued May 9, 2017
    - Amgen had notified Sandoz of the patent when it issued and said it could be reasonably asserted
    - But Amgen did not amend its claim in the previous litigations to include the '997 patent
  - Sandoz argued "[t]he same parties litigated patent infringement claims in this District regarding the same patent family, the same products and the same accused purification processes…."
  - Final judgment in favor of Sandoz was entered in the prior suits in Jan. 2018
  - Sandoz sought "to ensure that any issues … are resolved promptly, efficiently, and well in advance of the launch of Sandoz's pegfilgrastim product."

Sandoz v. Amgen - Declaratory Judgment

- April 24, 2019 - Amgen moved to dismiss under 12(b)(6)
  - **Argued Sandoz was barred under the BPCIA section (*l*)(9) from bringing a DJ action, and neither notice of commercial marketing, *nor actual marketing,* lifts the statutory bar to DJ**
  - **Argued court should decline to exercise its discretion to entertain the DJ action**
- May 8, 2019
  - **Court granted parties' joint request to extend MTD briefing schedule to account for the newly issued CAFC affirmance of non-infringement in related cases**
- May 13, 2019
  - **Sandoz voluntarily dismissed the case**

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Genentech v. Immunex – New Patent Dances

- ***Genentech v. Immunex* (19-cv-602, D. Del. – filed Mar. 29, 2019)**
  - Related to Immunex/Amgen's Mvasi® biosimilar of Genentech's Avastin®
    - **Redacted complaint asserts numerous patents at issue in another pending case between the parties, but adds two additional patents**
  - May 13, 2019: Immunex filed a motion to dismiss the entire complaint
    - **Immunex argues, *inter alia*, that the two new patents should have been added to the already-pending case, and this new suit is just an attempt to side-step the deadlines and good cause requirements in the previous case.**
  - June 17, 2019: Genentech opposed motion to dismiss
    - **Genentech takes the position that Immunex's supplemental BLA filing kicks off another patent dance (and lawsuit) under the statute**
    - **"This dispute raises a statutory construction question of first impression: does an 'application' in 42 U.S.C. § 262(*l*), unmodified by any adjective, include the type of filing known as a supplemental biologics license application?"**

Genentech v. Immunex cont'd

- July 10, 2019
  - **Emergency motion to enforce statutory prohibition on commercial marketing and TRO from marketing Mvasi**
    - Argues Mvasi product Amgen seeks to launch under the supplement is different from the product approved by FDA in Sept. 2017 and the subject of the prior notice of commercialization letter in Oct 2017
- July 19, 2019
  - **Motions denied**
    - FDA can approve changes to Mvasi manufacturing and labeling after FDA approved original biosimilar application
    - Mvasi product of the original application is the same under the supplements
    - Mvasi has been licensed since Sept 2017
    - Amgen's Oct 2017 letter satisfied 262(l)(8)'s requirement that Amgen provide notice of commercialization
  - **Mvasi launched**
  - **Genentech appealed**

Genentech v. Pfizer – Striking Counterclaims/ Defenses

- ***Genentech v. Pfizer* (19-cv-638, D. Del. – filed April 5, 2019)**
  - Genentech asserted 22 patents against Pfizer's Avastin® biosimilar
  - May 20, 2019: Genentech moved to dismiss counterclaims and affirmative defenses
    - **Declaratory judgment counterclaims are "actions" barred by BPCIA because Pfizer failed to fully comply with Section (2)(A) of the patent dance (e.g., failed to produce entire BLA)**
    - **DJ counterclaims and affirmative defenses of invalidity and unenforceability are "facially deficient" because they allege grounds broader than those disclosed during dance (e.g., providing contentions for patents that Pfizer did not include in (3)(B) contentions)**
  - June 3, 2019: Pfizer opposition to motion to dismiss
    - **Pfizer complied with (2)(A) – and anyway the BPCIA does not preclude counterclaims for declaratory relief**
    - **"[T]he BPCIA does not limit Pfizer to only the legal theories in its detailed statement pursuant to § 262(*l*)(3)(B)"**
  - September 2019
    - **Parties stipulated to dismissal due to settlement**

Immunex v. Samsung Bioepis

- ***Immunex v. Samsung Bioepis* (19-cv-11755 D.N.J. – filed April 30, 2019)**
  - Immunex/Amgen asserted 5 patents against Samsung Bioepis related to an Enbrel® biosimilar
  - Patents overlap with those asserted against Sandoz
  - Pending motion from Sandoz to intervene
  - Recent scheduling order set close of fact discovery for December 2020; close of expert discovery for April 2021
  - January 6, 2020: Stipulation and Order entered under seal
  - January 9, 2020: Parties requested administrative stay pursuant to their confidential stipulation and consent injunction

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Amgen v. Tanvex

- ***Amgen v. Tanvex* (19-cv-01374 S.D. Cal. – filed July 23, 2019)**
  - Amgen accused Tanvex's TX-01, a Neupogen® biosimilar, of infringing US 9,856,287
  - The '287 Patent had been previously asserted against other parties, including Apotex and Kashiv
  - The parties jointly stipulated to dismissal on December 19, 2019

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Coherus v. Amgen - Biosimilar v. Biosimilar

- ***Coherus v. Amgen* (19-cv-139, D. Del. - filed Jan. 24, 2019)**
  - Both Coherus and Amgen are developing Humira® (adalimumab) biosimilars
    - Amgen launched Amgevita™ in Europe in October 2018
    - Per settlements with AbbVie, earliest US launch is 2023 for both parties
  - Coherus filed a complaint against Amgen asserting several adalimumab formulation patents based on Amgen "actively offering for sale and selling Amgevita™ throughout Europe" and "actively manufacturing Amgevita™ in the United States for sale in Europe."
  - November 2019: parties stipulated to dismissal
  - December 2019: Amgen moved for attorneys' fees based on "Coherus' wrongful, continued maintenance of this action…"

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BPCIA District Court Cases Resolved in 2019

Parties	Case No.	Reference
AbbVie v. Boehringer Ingelheim	17-cv-01065 D. Del.	Humira®
Amgen v. Mylan	17-cv-01235 W.D. Pa.	Neulasta®
Amgen v. Kashiv (Adello)	18-cv-03347 D.N.J.	Neupogen®
Amgen v. Apotex	18-cv-61828 S.D. Fla.	Neupogen® Neulasta®
Genentech v. Samsung Bioepis	18-cv-01363 D. Del.	Herceptin®
Sandoz v. Amgen	19-cv-00977 N.D. Cal.	Neulasta®
Genentech v. Pfizer	19-cv-00638 D. Del.	Avastin®
Amgen v. Tanvex	19-cv-01374 S.D. Cal.	Neupogen®

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Pending BPCIA District Court Litigation

Parties	Case No.	Reference	Current Status
Janssen v. HyClone Labs	16-cv-00071 D. Utah	Remicade®	Administratively closed pending Celltrion case in D.Mass., now on appeal
Genentech v. Amgen	17-cv-01407 D. Del. 17-cv-01471 D. Del.	Avastin®	Trial set for November 2020
Genentech v. Amgen	18-cv-00924 D. Del.	Herceptin®	Trial set for April 2020
Amgen v. Hospira/Pfizer	18-cv-01064 D. Del.	Neupogen ®	Trial set for June 2020
Amgen v. Coherus	17-cv-00546 D. Del.	Neulasta®	Pending motion for attorneys' fees
Genentech v. Immunex	19-cv-00602 D. Del.	Avastin®	Pending motion to dismiss; pending appeal re PI
Immunex v. Samsung Bioepis	19-cv-11755 D.N.J.	Enbrel®	Fact discovery to close December 2020; may be stayed

BPCIA Appeals at the Federal Circuit

Case	Status	Reference
Amgen v. Sandoz (18-1551, 1552)	Fed. Cir. **affirmed** (May 8, 2019; *en banc* Sept. 3, 2019)	Neupogen® Neulasta®
Amgen v. Coherus (18-1993)	Fed. Cir. **affirmed** (July 29, 2019)	Neulasta®
Janssen v. Celltrion (18-2321, 2350)	Briefing complete; no oral argument date set yet	Remicade®
Amgen v. Hospira (19-1067)	Fed. Cir. **affirmed** (Dec. 16, 2019)	Epogen®
Genentech v. Immunex (19-2155)	Appeal re PI: briefing ongoing	Avastin®
Genentech v. Amgen (19-2156)	Appeal re PI: briefing complete; no oral argument date set yet	Herceptin®
Immunex v. Sandoz (20-1037)	Briefing complete; no oral argument date set yet	Enbrel®

Amgen v. Sandoz

- **District Court case (N.D. Cal. 14-cv-04741, 16-cv-2581)**
  - Amgen asserted U.S. Patent Nos. 8,940,878 and 6,162,427 were infringed by Sandoz's biosimilars of Neupogen® (filgrastim) and Neulasta® (pegfilgrastim)
  - After claim construction, Amgen and Sandoz stipulated to non-infringement of the '427 Patent
  - In December 2017, the Northern District of California granted summary judgment of non-infringement regarding the '878 Patent because the asserted protein purification method required separate washing and eluting steps, but Sandoz's process involved a single, simultaneous washing and eluting step
  - The court also denied Amgen's Rule 56(d) motion to deny or continue the motion for summary judgment until Sandoz submitted its intended new purification method to FDA, since the revised method would not materially change the infringement analysis

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Amgen v. Sandoz (CAFC 2018-1551, 1552)

- **May 8, 2019: Federal Circuit affirmed lower court ruling**
  - Affirmed claim construction and non-infringement (literal and under DOE)
  - With respect to 56(d), court analogized to Hatch-Waxman setting –
    - **Court needs to determine whether "what is likely to be sold" will infringe**
    - **"[W]hile a district court cannot ignore amendments to an ANDA or aBLA … it also has a broad mandate to render a 'just, speedy, and inexpensive decision.'"**
  - Here, denying Amgen's Rule 56(d) motion was proper
    - **For the anticipated pegfilgrastim product, "Amgen has conceded that, under the claim construction we have affirmed, there is no genuine dispute that the process Sandoz will likely use … will not infringe…"**
    - **For Zarxio, the analysis is for the product actually sold**
  - "[I]f the facts change" then Amgen can plead infringement in the future

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Amgen v. Sandoz (CAFC 2018-1551, 1552)

- **June 7, 2019: Amgen petitioned for rehearing en banc**
  - "Amgen respectfully submits that *en banc* review is warranted because a panel of this Court has established a bright-line rule that 'the doctrine of equivalents applies only in exceptional cases,' which it then applied to 'accordingly' find that the district court was correct to grant summary judgment of no infringement under the doctrine of equivalents."
  - Panel did not define "exceptional"
  - Such a rule is contrary to Supreme Court precedent and its retroactive application "in many cases may destroy the value of existing patent claims."
  - "Under the correct standard for proving infringement under the doctrine of equivalents, the district court's grant of summary judgment should be reversed."
- **Sept. 3, 2019: *En Banc* clarification**
  - Federal Circuit grants Amgen's petition for rehearing *en banc* to remove the few words that said DOE only applies in exceptional cases
  - Otherwise denied, and Sandoz's Neupogen® and Neulasta® biosimilars do not infringe

Amgen v. Coherus (CAFC 18-1993)

- **District Court (17-cv-546, D.Del.)**
  - Amgen accused Coherus's Neulasta® (pegfilgrastim) biosimilar of infringing one patent related to methods of purifying proteins
  - In March 2018, D. Del. granted Coherus's motion to dismiss
    - **It was undisputed that Coherus's protein purification process differed from the process claimed in Amgen's asserted patent**
    - **Amgen was barred by prosecution history estoppel from asserting infringement under the doctrine of equivalents.**
    - **Amgen was also barred by the dedication-disclosure doctrine**
- **July 29, 2019: Federal circuit affirmed dismissal**
  - Amgen had "clearly and unmistakably surrendered unclaimed salt combinations during prosecution" when it successfully distinguished a prior art reference by arguing that the reference did not disclose or suggest the "*particular* combinations" of salts recited in the claims.
  - Federal Circuit did not reach the dedication-disclosure doctrine

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Amgen v. Hospira

- **District Court (15-cv-839, D. Del.)**
  - In September 2017, a jury awarded Amgen $70 million in reasonable royalty damages based on Hospira's infringement of U.S. Patent No. 5,856,298 (the "'298 Patent") in relation to a biosimilar of Amgen's Epogen® (epoetin alfa)
    - **First BPCIA Damages award**
    - **Patent was expired by time of trial**
    - **The biosimilar was neither approved nor launched at time of award**
    - **Damages awarded for "stockpiling" batches not covered by safe harbor of 35 U.S.C. § 271(e)**
  - The jury also found that Hospira did not infringe U.S. Patent No. 5,756,349 (the "'349 Patent")
  - In ruling on post-trial motions, Judge Andrews of the District of Delaware upheld the jury verdict

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Amgen v. Hospira (CAFC 19-1067, 1102)

- **Hospira's appeal**
  - Whether the court/jury were correct on claim construction, infringement, and validity of the '298 patent
  - Whether the court incorrectly instructed the jury on Hospira's subjective intent for purposes of the safe harbor rather than objectively reasonable uses of the batches
  - Whether a reasonable jury correctly determined the batches were not covered by the safe harbor
  - Whether the court erred in allowing the jury to consider a damages position from Plaintiffs' damages expert that "goes well beyond what was adequate to compensate for infringement … and was not tied to any damages suffered by Amgen, but sought $170 million in damages for two expired patents, although Hospira made no sales"
- **Amgen's cross-appeal**
  - Whether JMOL of non-infringement of the '349 patent was proper
  - Whether the court properly denied a new trial motion on the '349 patent

Amgen v. Hospira (CAFC 19-1067, 1102)

- **December 16, 2019: Federal Circuit Affirmed on Each Issue**
  - As to the safe harbor defense:
    - **The jury instructions were not legally erroneous**
      - "[T]he patented inventions are Amgen's claimed methods of manufacture" and the "accused activity is Hospira's use of Amgen's claimed methods of manufacture," so "[t]he relevant inquiry, therefore, is not *how* Hospira used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to FDA."
    - **Substantial evidence supported the jury's finding that certain batches were not protected**
      - For example, evidence was submitted that Hospira was not required by FDA to manufacture additional batches after 2012
      - It was relevant (but not dispositive) that Hospira planned for some of the batches to "serve as commercial inventory," even though Hospira later changed the designation of some of its batches after it received a Complete Response Letter from FDA

Janssen v. Celltrion

- **District Court (17-cv-11008, D. Mass.)**
  - Janssen alleged that the cell culture media used by Celltrion to produce its Remicade® biosimilar infringes U.S. Patent No. 7,598,083 (the "'083 Patent") under the doctrine of equivalents
    - DOE theory accounted for "at least twelve differences in concentration" in the claimed cell media component ranges
  - In July 2018, Judge Wolf of the District of Massachusetts granted Celltrion's motion for summary judgment of non-infringement
    - 104-page opinion on ensnarement

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Janssen v. Celltrion (CAFC 18-2321, 2350)

- **Dec. 2018: Janssen filed its opening brief, arguing the district court erred by:**
  (1) impermissibly using hindsight to find that a hypothetical claim covering Celltrion's cell culture medium would have been obvious;
  (2) failing to find Celltrion's arguments regarding ensnarement legally baseless where Celltrion failed to offer any motivation to choose and modify the prior art references; and
  (3) failing to draw reasonable inferences in Janssen's favor (e.g., teaching away from using ferric ammonium citrate and evidence of copying) in its summary judgment analysis.
- **Feb. 2019: Celltrion responded and cross-appealed, arguing:**
  - Janssen does not have standing because not all co-owners of the '083 patent were joined as plaintiffs – assignments for many of the inventors assigned to more than just Janssen.
- **Briefing completed, no oral argument date set**

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Genentech v. Immunex, Amgen (CAFC 19-2155, 2156)

- Appeals related to the district court's denial of preliminary relief
- Federal Circuit denied motions for injunctions pending appeal
- Biosimilars in both cases launched in July 2019 (Mvasi and Kanjinti)
- ***Genentech v. Immunex* (CAFC 19-2155)**
  - Related to Immunex's biosimilar of Avastin®
  - Issue is whether Immunex was required to provide new notice of commercial marketing given its supplemental BLAs for Mvasi
  - Briefing ongoing
- ***Genentech v. Amgen* (CAFC 19-2156)**
  - Related to Amgen's biosimilar of Herceptin®
  - Genentech asserts district court erred by
    - "inferring that Genentech will not suffer irreparable harm because it waited to seek preliminary injunctive relief until Amgen affirmatively decided to launch [Kanjinti]"
    - "adopting a categorical rule that licensing of *future* activity negates irreparable harm from *present* infringement"
  - Briefing complete; oral argument has not yet been scheduled

Immunex v. Sandoz (CAFC 20-1037)

- **District Court (2-16-cv-01118, D.N.J.)**
  - Involved two patents originally prosecuted in 1995, expiring in 2028 and 2029, related to Sandoz's Enbrel® biosimilar
  - Sandoz did not contest infringement
  - Sandoz challenged validity of patents
    - **Written Description**
    - **Enablement**
    - **Obviousness**
    - **Obviousness-type double patenting (ODP)**
  - August 9, 2019: **District court held the patents not invalid**
- **On October 15, 2019, Sandoz appealed**
  - Sandoz challenged the district court's ODP, written description, and obviousness analyses
  - Samsung Bioepis submitted an amicus brief re obviousness
  - Briefing proceeded on expedited schedule and is complete
  - Oral argument has not been scheduled

Antitrust Update

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Biosimilar Antitrust Litigation - Infliximab

- **Cases filed in 2017-2018 in E.D. Pa alleged J&J/Janssen maintained market share and pricing for Remicade® through exclusionary contracts, anticompetitive bundling, and coercive rebates**
- ***Pfizer v. J&J and Janssen* (No. 17-cv-04180)**
  - Fact discovery ongoing
- ***In re Remicade (Indirect Purchaser) Antitrust Litigation* (No. 17-cv-04326)**
  - Fact discovery ongoing
- ***In re Remicade (Direct Purchaser) Antitrust Litigation* (No. 18-cv-00303)**
  - In September 2019, Third Circuit held that these antitrust claims must be arbitrated pursuant to a 2015 distribution contract
- ***Walgreen Co. and The Kroger Co. v. J&J, et al.* (No. 18-cv-02357)**
  - District Court dismissed for lack of standing to assert federal antitrust claims under assignment agreements
  - Appeal pending at Third Circuit (oral arguments held in November 2019)

Biosimilar Antitrust Litigation - Adalimumab

- ***In re: Humira (Adalimumab) Antitrust Litigation* (1:19-cv-1873, N.D. Ill.)**
  - First case filed March 18, 2019
  - Since then, the court has consolidated for pretrial purposes more than 10 different class action suits filed on behalf of end-payers against AbbVie and parties that settled with AbbVie re Humira®
  - Numerous theories:
    - **Patent thickets**
    - **Pay-for-delay settlements**
  - Numerous counts – federal and state claims
  - October 15, 2019: AbbVie moved to dismiss

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AbbVie's Humira® Biosimilar Settlements

Manufacturer	Date of Settlement	Date of U.S. Entry	Date of European Union Entry	Associated U.S. BPCIA Litigation
Amgen (Amjevita™)	September 2017	01/31/2023	10/16/2018	(16-cv-666, D. Del.)
Samsung Bioepis (Imraldi™)	April 2018	06/30/2023	10/16/2018	
Mylan (Hulio™)	July 2018	07/31/2023	N/A	
Sandoz (Hyrimoz™)	October 2018	09/30/2023	10/16/2018	(18-cv-12668, D.N.J)
Fresenius Kabi (MSB11022)	October 2018	09/30/2023	Date of approval from European Medicines Agency	
Momenta (M923)	November 2018	11/20/2023	Date of approval from European Medicines Agency	
Pfizer (PF-06410293)	November 2018	11/20/2023	Date of approval from European Medicines Agency	
Coherus (CHS-1420)	March 2019	12/15/2023	N/A	
BI (Cyltezo™)	May 2019	7/1/2023	N/A	(17-cv-1065, D. Del.)

Post Grant Update

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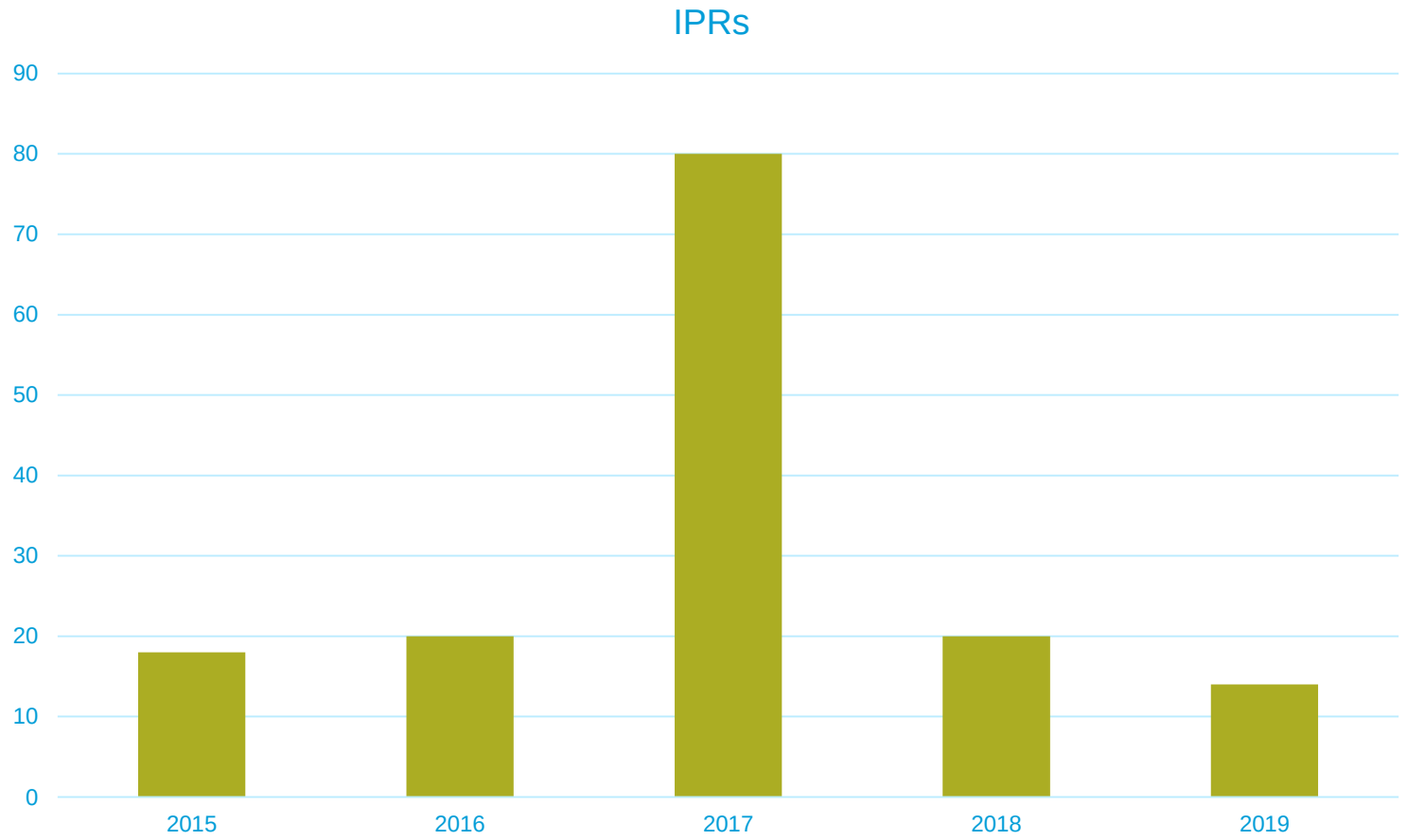
Inter-Partes Review of Biologic-Related Patents



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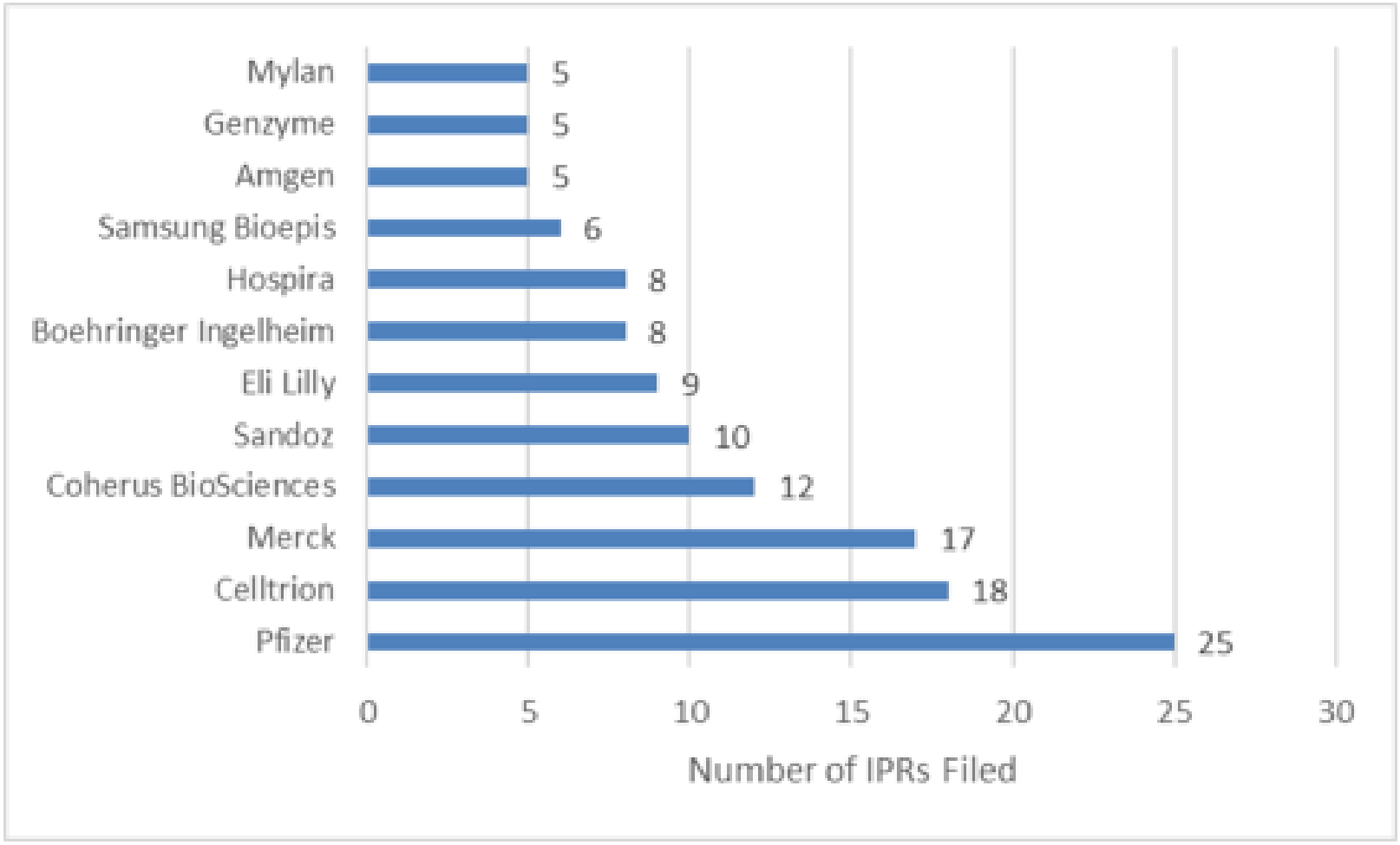
Most Active IPR Petitioners Through 2019



Constitutionality of IPRs

- ***Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019)**
  - Held that the use of IPR proceedings for patents issued prior to the AIA was not an unconstitutional taking under the Fifth Amendment
- ***Genentech, Inc. v. Hospira, Inc.*, 774 Fed. Appx. 677 (Fed. Cir. July 31, 2019)**
  - Affirmed without opinion a PTAB decision invalidating a patent relating to Avastin®
  - Implicitly rejected Genentech's Fifth Amendment challenge to the use of IPR proceedings for pre-AIA patents
- ***AbbVie v. U.S.* (Lead case: CAFC 17-2304)**
  - PTAB invalidated three AbbVie Patents re Humira® in five IPRs
  - AbbVie appealed, raising constitutional challenges under Article III and Seventh Amendment in particular for pre-AIA patents
  - The U.S. intervened to address AbbVie's constitutionality challenges
  - January 7, 2020: Rule 36 affirmance without addressing constitutional issues

Looking Forward to 2020

- **U.S. Market Development**
  - Data on market penetration from biosimilars launched in 2019 and before
  - New product launches
- **More from FDA**
  - Additional approvals – any maybe the first interchangeable?
  - Additional guidance documents
- **Biosimilar Legislation**
- **Input from the Courts**
  - Three trials scheduled for 2020
  - Four pending BPCIA appeals likely to be decided in 2020
- **Post-Grant Activity**

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Thank you!

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SPECIAL THANK YOU TO PHILIP CHEN AND FELIX EYZAGUIRRE

Please send your NY CLE forms or questions about the webinar to marketing at lundberg@fr.com.

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A replay of the webinar will be available for viewing at www.fr.com.

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