



August 10, 2020



LATEST NEWS



Patent Cases to Watch in the Second Half of 2020

[Ha Kung Wong](#) spoke with Law360 for an article about patent law Federal Circuit and Supreme Court cases to watch in 2020, including cases that will decide the fate of the Affordable Care Act and therefore the Biologics Price Competition and Innovation Act (BPCIA), whether PTAB administrative patent judges were unconstitutionally appointed, and the requirements for claiming antibody-based inventions in patents.



[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 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 July 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 July 31, 2020.

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UPDATES

IPRs and PGRs

Lantus[®] (insulin glargine recombinant):

- On July 2, 2020, the Supreme Court docketed *Sanofi v. Mylan* Case. No. 19-1451, appealing the final written decisions finding all instituted claims unpatentable in IPR2017-01526 and IPR2017-01528, which were affirmed by the Federal Circuit in Appeal Nos. 19-1368 and 19-1369.
- On July 24, 2020, **Sanofi** filed Federal Circuit Appeal Nos. 20-2029, 20-2032, 20-2033, and 20-2034, appealing the final written decisions in IPR2018-01675 (joined IPR2019-00977), IPR2018-01676 (joined IPR2019-00978), IPR2018-01678 (joined IPR2019-00980), and IPR2019-00122 (joined IPR2019-00982) respectively.
- On July 27, 2020, **Sanofi** filed Federal Circuit Appeal Nos. 20-2066, 20-2068, 20-2069, and 20-2071, appealing the final written decisions in IPR2018-01679 (joined IPR2019-00981), IPR2018-01680 (joined IPR2019-01022), IPR2018-01682 (joined IPR2019-01023), and IPR2018-01684 (joined IPR2019-00987) respectively.

Myozyme[®] / Lumizyme[®] (alglucosidase alfa):

- On July 8, 2020, the Supreme Court docketed *Duke University v. Biomarin*, Case. No. 19-1475, appealing the PTAB's decisions in IPR2013-00535, the Federal Circuit opinions in 16-1106 and 18-1696, and the application of the decision on the constitutionality of administrative patent judges in *Arthrex Inc. v. Smith & Nephew Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), reh'g denied, 953 F.3d 760 (Fed. Cir. 2020) (en banc).

Neupogen[®] (filgrastim) / Neulasta[®] (pegfilgrastim):

- On July 14, 2020, **Amgen** and **Apotex** filed a joint motion to terminate the remand proceeding in IPR2016-01542 because **Apotex** is no longer participating in the IPR.
- On July 23, 2020, a petition for writ of certiorari was filed by the US related to the *Arthrex Inc. v. Smith & Nephew Inc.* decision, asking the Supreme Court to consider whether administrative patent judges at the PTO were unconstitutionally appointed. The writ of certiorari involves Federal Circuit appeals from IPRs where the US or USPTO Director Andrei Iancu intervened, including *Amgen v. Iancu*, Fed. Cir. Appeal. No. 19-2171, appealing the final written decision in IPR2016-01542.

Eylea[®] (aflibercept):

- On July 16, 2020, **Regeneron** filed IPR2020-01317, IPR2020-01318 and IPR2020-01320 against **Novartis**.

Litigations

Enbrel® (etanercept):

- On July 1, 2020, in **Amgen v. Sandoz**, Fed. Cir. Appeal No. 20-1037, the Federal Circuit affirmed the District Court's decision finding the challenged claims were not invalid in Case No. 2:16-cv-01118 (D.N.J.). On July 31, 2020, **Sandoz** filed a request for an en banc rehearing of the Federal Circuit's opinion.

Avastin® (bevacizumab):

- On July 6, 2020, in **Genentech v. Amgen**, Fed. Cir. Appeal No. 19-2155, the Federal Circuit affirmed the District Court's denial of a temporary restraining order and motion to enforce the statutory prohibition on commercial marketing in Case No. 1:19-cv-00602 (D. Del.).
- On July 7, 2020, **Genentech** and **Amgen** submitted joint stipulations of dismissal due to settlement in Case Nos. 1:17-cv-01407 (D. Del.), 1:17-cv-01471 (D. Del.), and 1:19-cv-00602 (D. Del.), and informed the Federal Circuit in Appeal No. 19-2155 of the settlement.

Herceptin® (trastuzumab):

- On July 7, 2020, **Genentech** and **Amgen** submitted a joint stipulation of dismissal due to settlement in Case No. 1:18-cv-00924 (D. Del.).

Eylea® (aflibercept):

- On July 30, 2020, the Court granted **Novartis** and **Regeneron's** request to stay Case No. 1:20-cv-00690 (N.D.N.Y.) pending ITC proceeding 337-TA-1207.

aBLA Applications and FDA Activity

Hulio® (adalimumab-fkjp):

- On July 6, 2020, the FDA approved **Mylan's Hulio® (adalimumab-fkjp)**, a biosimilar of **AbbVie's Humira® (adalimumab)**.

CDER Purple Book Updates

Qwo™ (collagenase clostridium histolyticum-aaes):

- On July 6, 2020, the FDA approved **Endo Global Aesthetics' Qwo™ (collagenase clostridium histolyticum-aaes)**.

Monjuvi® (tafasitamab-cxix):

- On July 31, 2020, the FDA approved **Morphosys's Monjuvi® (tafasitamab-cxix)**.

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

Insulin Aspart Sanofi (insulin aspart):

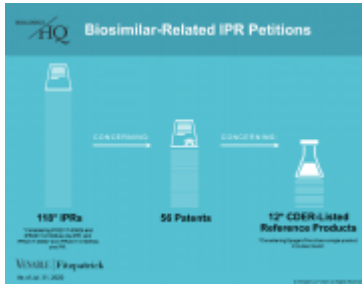
- On July 3, 2020, **Sanofi** announced that **Insulin Aspart Sanofi (insulin aspart)**, a biosimilar of **Novo Nordisk's Novolog® (insulin aspart)**, was approved in the E.U.

Zercepac (trastuzumab):

- On July 29, 2020, **Shanghai Henlius Biotech** and **Accord Healthcare** announced that **Zercepac (trastuzumab)**, a biosimilar of **Genentech's Herceptin® (trastuzumab)**, was approved in the E.U.

STATISTICS

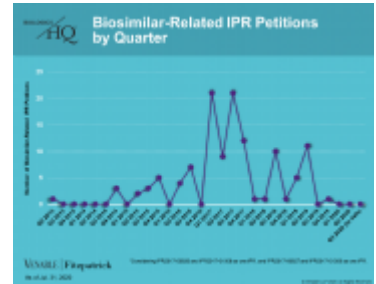
Biosimilar-Related IPR Petitions



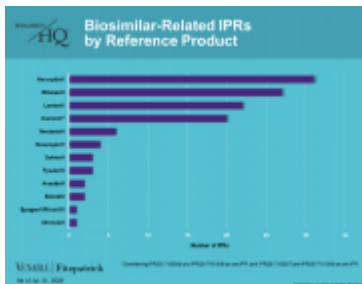
Biosimilar-Related IPR Petitions by Fiscal Year



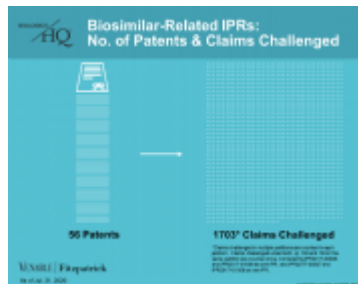
Biosimilar-Related IPR Petitions by Quarter



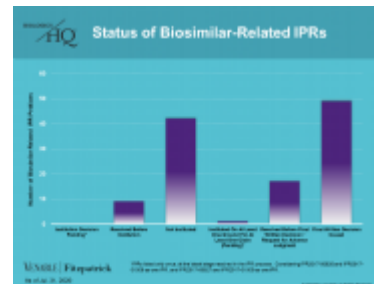
Biosimilar-Related IPRs by Reference Product



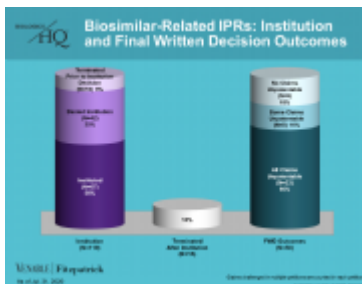
Biosimilar-Related IPRs: Number of Patents and Claims Challenged



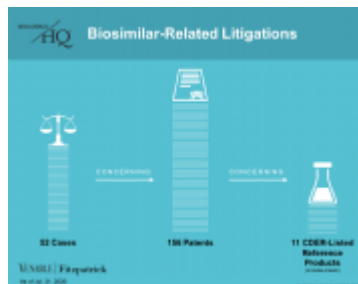
Status of Biosimilar-Related IPRs



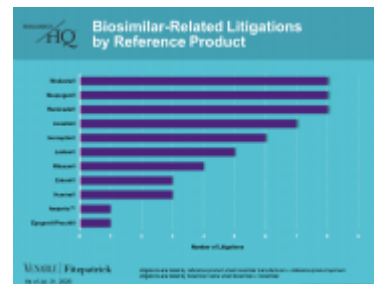
Biosimilar-Related IPRs: Institution and Final Written Decision Outcomes



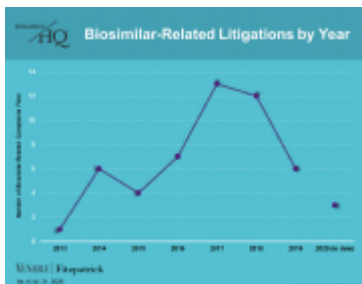
Biosimilar-Related Litigations



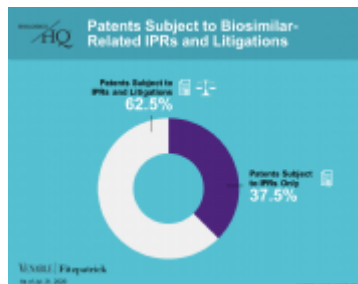
Biosimilar-Related Litigations by Reference Product



Biosimilar-Related Litigations by Year



Patents Subject to Biosimilar-Related IPRs and Litigations



Biosimilars Approved in the United States

Biosimilars Approved in the United States

NDA No.	Reference Product	Biosimilar Name	FDA Date	Approval Status	Reference Product Name	US Approval Date
ANDA 761223	Humalog	Humalog-B	May 22, 2013	Approved	Humalog	May 2013
ANDA 761224	Humalog	Humalog-B	May 24, 2013	Approved	Humalog	May 2013
ANDA 761225	Humalog	Humalog-B	May 28, 2013	Approved	Humalog	May 2013
ANDA 761226	Humalog	Humalog-B	May 29, 2013	Approved	Humalog	May 2013
ANDA 761227	Humalog	Humalog-B	May 30, 2013	Approved	Humalog	May 2013
ANDA 761228	Humalog	Humalog-B	May 31, 2013	Approved	Humalog	May 2013
ANDA 761229	Humalog	Humalog-B	Jun 3, 2013	Approved	Humalog	May 2013
ANDA 761230	Humalog	Humalog-B	Jun 4, 2013	Approved	Humalog	May 2013
ANDA 761231	Humalog	Humalog-B	Jun 5, 2013	Approved	Humalog	May 2013
ANDA 761232	Humalog	Humalog-B	Jun 6, 2013	Approved	Humalog	May 2013
ANDA 761233	Humalog	Humalog-B	Jun 7, 2013	Approved	Humalog	May 2013
ANDA 761234	Humalog	Humalog-B	Jun 10, 2013	Approved	Humalog	May 2013
ANDA 761235	Humalog	Humalog-B	Jun 11, 2013	Approved	Humalog	May 2013
ANDA 761236	Humalog	Humalog-B	Jun 12, 2013	Approved	Humalog	May 2013
ANDA 761237	Humalog	Humalog-B	Jun 13, 2013	Approved	Humalog	May 2013
ANDA 761238	Humalog	Humalog-B	Jun 14, 2013	Approved	Humalog	May 2013
ANDA 761239	Humalog	Humalog-B	Jun 17, 2013	Approved	Humalog	May 2013
ANDA 761240	Humalog	Humalog-B	Jun 18, 2013	Approved	Humalog	May 2013
ANDA 761241	Humalog	Humalog-B	Jun 19, 2013	Approved	Humalog	May 2013
ANDA 761242	Humalog	Humalog-B	Jun 20, 2013	Approved	Humalog	May 2013
ANDA 761243	Humalog	Humalog-B	Jun 21, 2013	Approved	Humalog	May 2013
ANDA 761244	Humalog	Humalog-B	Jun 24, 2013	Approved	Humalog	May 2013
ANDA 761245	Humalog	Humalog-B	Jun 25, 2013	Approved	Humalog	May 2013
ANDA 761246	Humalog	Humalog-B	Jun 26, 2013	Approved	Humalog	May 2013
ANDA 761247	Humalog	Humalog-B	Jun 27, 2013	Approved	Humalog	May 2013
ANDA 761248	Humalog	Humalog-B	Jun 28, 2013	Approved	Humalog	May 2013
ANDA 761249	Humalog	Humalog-B	Jun 29, 2013	Approved	Humalog	May 2013
ANDA 761250	Humalog	Humalog-B	Jun 30, 2013	Approved	Humalog	May 2013

USMRL / Fitzpatrick
USPTO's Intellectual Property Rights (IPR) Petitions (IPRs) for Biologics (IPRs) for Biologics (IPRs) for Biologics



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