

BIOSIMILAR LITIGATION ACTIVITY IN 2019

I. NEW LITIGATIONS

- Jan. 24, 2019 *Coherus Biosciences, Inc. v. Amgen Inc.*, 1:19-cv-00139 (D. Del.) – Humira[®] (adalimumab) biosimilar Amgevita[™] (sold in Europe but made in US) accused of infringing Coherus biosimilar patents
 - Nov. 26, 2019 stipulated dismissal with prejudice
 - Amgen’s motion for exceptional case and attorneys’ fees pending

- Feb. 21, 2019 *Sandoz, Inc. v. Amgen Inc.*, 3:19-cv-00977 (N.D. Cal.) – Neupogen[®] (filgrastim) biosimilar Zarxio[®] and Neulasta[®] (pegfilgrastim) biosimilar Ziextenzo[®]
 - DJ action to assert later-issued patent related to those asserted in 3:14-cv-04741 and 3:16-cv- 02581
 - Amgen moved to dismiss because Sandoz failed to comply with certain patent dance procedures and was therefore prohibited from filing a DJ action
 - May 13, 2019 Sandoz filed voluntary dismissal without prejudice

- Mar. 29, 2019 *Genentech, Inc. v. Immunex Rhode Island Corp.* (and Amgen Inc.), 1:19-cv-00602 (D. Del.) – Avastin[®] (bevacizumab) biosimilar Mvasi[®]

- Apr. 5, 2019 *Genentech, Inc. v. Pfizer Inc.*, 1:19-cv-00638 (D. Del.) – Avastin[®] biosimilar Zirabev[™]
 - Sept. 20, 2019 settlement and joint dismissal without prejudice
 - Related Proceedings:
 - October 8, 2019 *Pfizer Inc. v. Hoffmann-La Roche Inc. et al.*, IPR2018-01219, terminated after settlement.
 - July 31, 2019 Federal Circuit Decision affirming Final Written Decision invalidating MOT patent. *Genentech, Inc. v. Hospira, Inc.*, Case No. 18-1959 (appeal from IPR2016-01771)
 - January 14, 2020 Federal Circuit Decision affirming FWD invalidating Process Patent. *Genentech, Inc. v. Hospira, Inc.*, Case No. 18-1933 (appeal from IPR2016-01837)

- Apr. 30, 2019 *Immunex Corp. v. Samsung Bioepis Co.*, 2:19-cv-11755 (D.N.J.) – Enbrel[®] (etanercept) biosimilar Eticovo[®]
 - Jan. 8, 2020 Consent injunction based on sealed stipulation

- Jan. 9, 2020 the parties requested an administrative stay consistent with the stipulation that allows discovery to continue
- Jul. 23, 2019 *Amgen Inc. v. Tanvex BioPharma USA, Inc.*, 3:19-cv-01374 (S.D. Cal.) – Neupogen[®] biosimilar TX-01
 - Dec. 20, 2019 Joint dismissal without prejudice

II. SETTLEMENTS (OTHER THAN ABOVE)

- May 14, 2019 *AbbVie Inc. v. Boehringer Ingelheim International GmbH*, 1:17-cv-01065 (D. Del.) – Humira[®] biosimilar Cyltezo[®]
 - Joint dismissal without prejudice
- Jul. 1, 2019 *Genentech, Inc. v. Samsung Bioepis Co.*, 1:18-cv-01363 (D. Del.) – Herceptin[®] (trastuzumab) biosimilar Ontruzant[™]
 - Joint dismissal with prejudice
 - Related proceedings:
 - July 1, 2019 Samsung withdrew as party to appeal in *Genentech, Inc. v. Iancu*, Case No. 19-1265 (Fed. Cir.) (appeals from Final Written Decisions invalidating taxoid combo patents in *Pfizer Inc. and Samsung Bioepis Co. v. Genentech, Inc.*, IPR2017-00737 and IPR2017-00731).
 - August 1, 2019 PTAB intervened to defend decision on appeal.
 - July 1, 2019 Federal Circuit granted Samsung’s request to voluntarily dismiss appeal in *Samsung Bioepis Co. v. Genentech, Inc.*, Case Nos. 19-1173, 19-1174 (Fed. Cir.) (appeals from Final Written Decisions upholding patentability of 3-weekly dosing patents in IPR2017-00804 and IPR2017-00805).
- Nov. 15, 2019 *Amgen Inc. v. Accord BioPharma*, 0:18-cv-61828 (S.D. Fla.) – Neupogen[®] biosimilar Grastofil[®] and Neulasta[®] biosimilar Lapelga[™]
 - Joint dismissal without prejudice
 - Aug. 26, 2019 Accord BioPharma had been substituted for Apotex
 - Related Proceedings:
 - October 4, 2019 *Adello Biologics LLC v. Amgen Inc et al.*, PGR2019-00001 Apotex Corp. removed as a petitioner after request for adverse judgment.

- Nov. 25, 2019 *Amgen, Inc. et al. v. Adello Biologics, LLC*, 2:18-cv-03347 (D.N.J.) - Neupogen[®] biosimilar
 - Joint dismissal without prejudice
 - Related proceedings
 - December 6, 2019 *Adello Biologics LLC v. Amgen Inc et al.*, PGR2019-00001 terminated after settlement.

- Nov. 25, 2019 *Amgen Inc. v. Kashiv Biosciences, LLC*, 2:18-cv-03347 (D.N.J.) – Neupogen[®] biosimilar
 - Joint dismissal without prejudice
 - Related Proceedings:
 - December 6, 2019 *Kashiv Biosciences, LLC et al. v. Amgen Inc. et al.*, IPR2019-00791 and IPR2019-00797 terminated after settlement

III. OTHER DEVELOPMENTS

- *Genentech, Inc. v. Immunex Rhode Island Corp.*, 1:19-cv-00602 (D. Del.) and Federal Circuit Appeal 19-2155– Avastin[®] biosimilar Mvasi[®]
 - Dispute about whether Amgen’s supplemental BLA modifying label and adding manufacturing site after initial notice of commercial marketing required another notice and 180-day waiting period
 - Jul. 18-19, 2019 District court said no and denied Genentech’s motion for an order preventing launch and for injunction pending appeal. Amgen launched.
 - Aug. 16, 2019 Federal Circuit denied motion for an injunction pending appeal
 - Appeal in progress – Amgen’s brief filed December 2019
 - Still pending before district court is Amgen’s motion to dismiss for claim splitting
 - Genentech brought suit after supplemental BLA that included two new patents not asserted in prior pending litigation
 - Jury trial in *Genentech, Inc. v. Amgen, Inc.*, 1:17-cv-1407 (D. Del.) (Avastin[®] biosimilar Mvasi[®]) scheduled for November 30, 2020.

- *Amgen Inc. v. Hospira, Inc.*, 1:15-cv-00839 (D. Del) and Federal Circuit Appeals 19-1067, 19-1102 – Epopgen[®] (epoetin alfa) biosimilar Retacrit[®]
 - Hospira appealed denial of post-trial motions challenging jury verdict of infringement, validity, and that batches of biosimilar were not covered by the Safe Harbor

- Amgen appealed denial of post-trial motions challenging jury verdict of noninfringement of another patent
- Dec. 16, 2019 Federal Circuit affirmed the district court in full
 - The Court addressed infringement, anticipation, Safe Harbor, and denial of a Daubert motion to exclude Amgen’s damages expert
 - Safe Harbor may be of interest. The Court found the jury verdict, which led to damages award, supported by substantial evidence: Amgen’s regulatory expert testimony testified that later batches were not required for approval, and documents indicated that some of the batches would serve as commercial product supporting launch
- *Immunex Corp. v. Sandoz Inc.*, 2:16-cv-01118 (D.N.J.) and Federal Circuit Appeal 20-1027 – Enbrel® biosimilar Erelzi®
 - Oct. 8, 2019 final judgment after bench trial in favor of Immunex finding infringement (stipulated) and validity of two patents and issuing permanent injunction
 - Sandoz appealed on expedited schedule; briefing is complete; oral argument scheduled for March 4, 2020
- *Amgen Inc. v. Sandoz*, Federal Circuit Appeal 18-1551 (from 3:14-cv-04741 (N.D. Cal.)) and consolidated Appeal 18-1552 (from 3:16-cv-02581 (N.D. Cal.)) – Neupogen® biosimilar Zarxio® and Neulasta® biosimilar Ziextenzo®
 - May 8, 2019 Federal Circuit affirmed claim construction of patent on which Amgen had stipulated to noninfringement and summary judgment of non-infringement of another patent
 - Federal Circuit also affirmed denial of motion for a continuance for summary judgment: the district court was not required to postpone summary judgment to wait for amended BLA from Sandoz
 - Motion for panel rehearing granted in part only to remove statement that doctrine of equivalents “applies only exceptional cases”
- *Amgen Inc. v. Mylan Inc.*, 2:17-cv-01235 (W.D. Pa.) – Neulasta® biosimilar Fulphila®
 - Sept. 17, 2019 Stipulated judgment of noninfringement in view of Federal Circuit decision in *Amgen v. Sandoz*, 18-1551 addressing construction of claim terms
- *Amgen Inc. v. Hospira Inc.*, 1:18-cv-01064 (D. Del.) - Neupogen® biosimilar Nivestym®
 - Nivestym® has already lost and is commercially available
 - May 15, 2019 Markman Hearing held
 - Jury Trial set for June 15, 2020.

- *Amgen Inc. v. Coherus Biosciences, Inc.*, Federal Circuit Appeal 18-1993 (from 1:17-cv-00546 (D. Del.)) – Neulasta[®] biosimilar Udenyca[®]
 - Jul. 29, 2019 Federal Circuit affirmed dismissal for failure to state a claim based on noninfringement in view of prosecution history estoppel
 - Coherus motion for attorneys’ fees pending before district court

- *Genentech, Inc. v. Amgen Inc.*, 1:18-cv-00924 (D. Del.) and Federal Circuit Appeal 19-2156 – Herceptin[®] biosimilar Kanjinti[®]
 - Jul. 18, 2019 Genentech’s motion for temporary restraining order and preliminary injunction denied by the district court
 - Aug. 7, 2019 Federal Circuit denied motion for a preliminary injunction pending appeal
 - Sept. 26, 2019 case switched to a jury trial, which is scheduled for Apr. 2020
 - Oral Argument on appeal scheduled for March 3, 2020

- *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, Federal Circuit Appeal 18-2321 (from 1:17-cv-11008 (D. Mass.)) - Remicade[®] biosimilar Inflectra[®]
 - July 30, 2018 District Court granted Celltrion’s motion for summary judgment of non-infringement and Janssen appealed to the Federal Circuit
 - Oral argument on appeal scheduled for March 4, 2020.