UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant.	Consolidated Civil Action No. 14-07869(MAS)(LHG) Civil Action No. 14-8082(MAS)(LHG) Civil Action No. 15-2631(MAS)(LHG) **FINAL JUDGMENT**
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACCORD HEALTHCARE, INC., Defendant.	Civil Action No. 14-08079(MAS)(LHG) Civil Action No. 15-02520(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. BPI LABS, LLC AND BELCHER PHARMACEUTICALS, LLC, Defendants.	Civil Action No. 14-08081(MAS)(LHG) Civil Action No. 15-02521(MAS)(LHG)

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. APOTEX CORP. AND APOTEX INC., Defendants.	Civil Action No. 15-00287(MAS)(LHG) Civil Action No. 15-01835(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	Civil Action No. 15-00289(MAS)(LHG) Civil Action No. 15-01836(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. MYLAN LABORATORIES LTD., Defendant.	Civil Action No. 15-00290(MAS)(LHG) Civil Action No. 15-03392(MAS)(LHG)

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACTAVIS LLC AND ACTAVIS ELIZABETH LLC, Defendants.	Civil Action No. 15-00776(MAS)(LHG) Civil Action No. 15-03107(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. 15-02522(MAS)(LHG) Civil Action No. 16-02259(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA AND GLENMARK PHARMACEUTICALS LTD., Defendants.	Civil Action No. 15-02523(MAS)(LHG)

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. 16-05678(MAS)(LHG)

This consolidated patent infringement action was brought by Plaintiffs Sanofi Aventis U.S. LLC, Aventis Pharma S.A., and Sanofi ("Plaintiffs") against Defendants Fresenius Kabi USA, LLC ("Fresenius"), Accord Healthcare, Inc. ("Accord"), BPI Labs and Belcher Pharmaceuticals, LLC (collectively, "BPI"), Apotex Corp. and Apotex Inc. (collectively, Apotex"), Breckenridge Pharmaceutical, Inc. ("Breckenridge"), Mylan Laboratories Ltd. ("Mylan"), Actavis LLC and Actavis Elizabeth LLC (collectively, "Actavis"), Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's"), Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals Ltd. (collectively, "Glenmark"), and Sandoz Inc. ("Sandoz") (all collectively, "Defendants"), alleging infringement of U.S. Patent Nos. 5,847,170 ("the '170 patent") and/or 8,927,592 ("the '592 patent").

On September 15, 2017, the Court consolidated for trial the above-captioned suits pending against Fresenius, Accord, Apotex, Mylan, and Actavis in *Sanofi-Aventis U.S. LLC et al. v. Fresenius Kabi USA, LLC, et al.*, No. 3:14-cv-7869-MAS-LHG (D.N.J.) (hereinafter, "Consolidated Lead Case"). Civil Action No. 14-7869, D.I. 232, ¶ 2. On or before September 15, 2017, the Court entered stipulations between Plaintiffs and each of BPI, Glenmark, Dr. Reddy's, Breckenridge, and Sandoz, under which the parties to these other actions agreed, *inter alia*, to be bound by particular aspects of any final judgment in the Consolidated Lead Case.

More specifically, BPI, Dr. Reddy's, Breckenridge, and Sandoz agreed to be bound by any judgment as to the infringement and validity of the '170 and '592 patents entered in the Consolidated Lead Case. *Sanofi-Aventis U.S. LLC et al. v. BPI Labs, LLC, et al.*, Nos. 3:14-cv-8081 (D.N.J.), D.I. 58, Stipulation ¶ 2, 3:15-cv-2521 (D.N.J.), D.I. 48, Stipulation ¶ 2; *Sanofi-Aventis U.S. LLC et al. v. Dr. Reddy's Labs., Inc. et al.*, No. 3:15-cv-2522 (D.N.J.), D.I. 48, Stipulation ¶ 2, 3:16-cv-2259 (D.N.J.), D.I. 24, Stipulation ¶ 2; *Sanofi-Aventis U.S. LLC et al. v. Breckenridge Pharmaceutical, Inc.*, Nos. 15-cv-289 (D.N.J.), D.I. 79, Stipulation ¶ 2, 15-cv-1836 (D.N.J.), D.I. 56, Stipulation ¶ 2; *Sanofi-Aventis U.S. LLC et al. v. Sandoz Inc.*, No. 16-cv-5678 (D.N.J.), D.I. 32, Stipulation ¶ 2. Glenmark agreed to be bound by any judgment as to the infringement and validity of the '592 patent entered in the Consolidated Lead Case. *Sanofi-Aventis U.S. LLC et al. v. Glenmark Pharmaceuticals, Inc., USA et al.*, No. 15-cv-2523 (D.N.J.), D.I. 56, Stipulation ¶ 1. Prior to trial, Plaintiffs notified Defendants that Claims 1-6, 8-10, 12-13, 17-20, 22-25, and 27-29 of the '592 patent were not asserted.

The Court conducted an eight-day bench trial on September 18-20 and September 25-29, 2017 in the Consolidated Lead Case. The parties in the Consolidated Lead Case submitted post-trial briefs on October 31, 2017, and the Court heard closing arguments on November 8, 2017. The parties filed supplemental correspondence on November 17, 2017, December 4, 2017, and December 11, 2017. Pursuant to Court order, the parties filed supplemental legal briefs on December 13, 2017. The Court issued an Order in the Consolidated Lead Case on December 17, 2017 (D.I. 306).

In the Consolidated Lead Case, the Court has set forth its Findings of Fact and Conclusions of Law in an accompanying Opinion. Having considered the documentary evidence

and testimony, and having reviewed the parties' post-trial briefs and supplemental legal briefs, for the reasons set forth in the Court's Opinion dated December 19, 2017 (D.I. 308),

IT IS HEREBY ORDERED AND ADJUDGED that:

1. Final judgment is entered in favor of Plaintiffs and against Defendants (except for Glenmark, which did not challenge the '170 patent) that Claims 1 and 2 of the '170 patent are not invalid due to obviousness and obviousness-type double patenting.

2. Final judgment is entered in favor of Plaintiffs and against Fresenius Kabi USA, LLC that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Injection, 60 mg/1.5 mL solution that is the subject of Abbreviated New Drug Application ("ANDA") No. 207591 would infringe Claims 1 and 2 of the '170 patent.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of ANDA No. 207591 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Fresenius Kabi USA, LLC and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of ANDA No. 207591 until the expiration date of the '170 patent, which is currently March 26, 2021.

5. Final judgment is entered in favor of Plaintiffs and against Fresenius Kabi USA, LLC that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Injection, 60 mg/3 mL (20 mg/mL) solution that is the subject of New Drug Application ("NDA") No. 207937 would infringe Claims 1 and 2 of the '170 patent.

6. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of NDA No. 207937 under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

7. Pursuant to 35 U.S.C. § 271(e)(4)(B), Fresenius Kabi USA, LLC and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of NDA No. 207937 until the expiration date of the '170 patent, which is currently March 26, 2021.

8. Final judgment is entered in favor of Plaintiffs and against Accord Healthcare, Inc. that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Injection, 60 mg/1.5 mL product that is the subject of ANDA No. 207693 would infringe Claims 1 and 2 of the '170 patent.

9. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of ANDA No. 207693 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not

earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

10. Pursuant to 35 U.S.C. § 271(e)(4)(B), Accord Healthcare, Inc. and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of ANDA No. 207693 until the expiration date of the '170 patent, which is currently March 26, 2021.

11. Final judgment is entered in favor of Plaintiffs and against Accord Healthcare, Inc. that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Injection, 20 mg/mL, 3mL product that is the subject of NDA No. 207949 would infringe Claims 1 and 2 of the '170 patent.

12. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of NDA No. 207949 under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

13. Pursuant to 35 U.S.C. § 271(e)(4)(B), Accord Healthcare, Inc. and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of NDA No. 207949 until the expiration date of the '170 patent, which is currently March 26, 2021.

14. Final judgment is entered in favor of Plaintiffs and against BPI Labs, LLC and Belcher Pharmaceuticals, LLC that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel 60 mg/1.5 mL solution for intravenous infusion that is the subject of ANDA No. 207735 would infringe Claims 1 and 2 of the '170 patent.

15. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of ANDA No. 207735 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

16. Pursuant to 35 U.S.C. § 271(e)(4)(B), BPI Labs, LLC and Belcher Pharmaceuticals, LLC and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of ANDA No. 207735 until the expiration date of the '170 patent, which is currently March 26, 2021.

17. Final judgment is entered in favor of Plaintiffs and against Apotex Corp. and Apotex Inc. that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Injection, 60 mg/1.5 mL product that is the subject of ANDA No. 207736 would infringe Claims 1 and 2 of the '170 patent.

18. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of ANDA No. 207736 under

§ 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

19. Pursuant to 35 U.S.C. § 271(e)(4)(B), Apotex Corp. and Apotex, Inc. and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of ANDA No. 207736 until the expiration date of the '170 patent, which is currently March 26, 2021.

20. Final judgment is entered in favor of Plaintiffs and against Breckenridge Pharmaceutical, Inc. that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Solution, IV, 60 mg/1.5 mL (40 mg/mL) product that is the subject of ANDA No. 207619 would infringe Claims 1 and 2 of the '170 patent.

21. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of ANDA No. 207619 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

22. Pursuant to 35 U.S.C. § 271(e)(4)(B), Breckenridge Pharmaceutical, Inc. and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within

the United States or importation into the United States of the product that is the subject of ANDA No. 207619 until the expiration date of the '170 patent, which is currently March 26, 2021.

23. Final judgment is entered in favor of Plaintiffs and against Mylan Laboratories Ltd. that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Injection [60 mg/1.5 mL] [40 mg/mL] product that is the subject of ANDA No. 207381 would infringe Claims 1 and 2 of the '170 patent.

24. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of ANDA No. 207381 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

25. Pursuant to 35 U.S.C. § 271(e)(4)(B), Mylan Laboratories Ltd. and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of ANDA No. 207381 until the expiration date of the '170 patent, which is currently March 26, 2021.

26. Final judgment is entered in favor of Plaintiffs and against Actavis LLC and Actavis Elizabeth LLC that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Injection, 10 mg/mL product that is the subject of NDA No. 207970 would infringe Claims 1 and 2 of the '170 patent.

27. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of NDA No. 207970 under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

28. Pursuant to 35 U.S.C. § 271(e)(4)(B), Actavis LLC and Actavis Elizabeth LLC and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of NDA No. 207970 until the expiration date of the '170 patent, which is currently March 26, 2021.

29. Final judgment is entered in favor of Plaintiffs and against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel, 60 mg/1.5 mL product that is the subject of ANDA No. 207718 would infringe Claims 1 and 2 of the '170 patent.

30. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of ANDA No. 207718 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

31. Pursuant to 35 U.S.C. § 271(e)(4)(B), Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of ANDA No. 207718 until the expiration date of the '170 patent, which is currently March 26, 2021.

32. Final judgment is entered in favor of Plaintiffs and against Sandoz Inc. that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the Cabazitaxel Injection (10 mg/mL), 45 mg/4.5 mL and 60 mg/6 mL product that is the subject of NDA No. 208715 would infringe Claims 1 and 2 of the '170 patent.

33. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of NDA No. 208715 under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)) shall be a date not earlier than the date of expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs. Currently the '170 patent together with the period of Pediatric Exclusivity expires on September 26, 2021.

34. Pursuant to 35 U.S.C. § 271(e)(4)(B), Sandoz Inc. and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of NDA No. 208715 until the expiration date of the '170 patent, which is currently March 26, 2021.

35. Final judgment is entered in favor of Defendants and against Plaintiffs that claims 7, 11, 14, 15, 16, 21, 26, and 30 of the '592 patent are invalid due to obviousness.

36. In the event that any portion of this Final Judgment is appealed, any motion for attorneys' fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.2, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within thirty (30) days after final disposition of any such appeal.

37. In the event that no portion of this Final Judgment is appealed, any motion for attorneys' fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.2, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within thirty (30) days after the expiration of the time for filing a notice of appeal under Fed. R. App. P. 3 and 4.

38. This Judgment is final and appealable, as all other claims, counterclaims, and defenses have been finally adjudicated.

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Hon. Michael A. Shipp
United States District Judge

Dated: 3/5/18