

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

APICORE US LLC and
MYLAN INSTITUTIONAL LLC,

Plaintiffs,

v.

BELOTECA, INC.

Defendant.

Civil Action No.

**APICORE US LLC’S AND MYLAN INSTITUTIONAL LLC’S
COMPLAINT FOR DECLARATORY JUDGMENT OF INFRINGEMENT**

Plaintiffs Apicore US LLC (“Apicore”) and Mylan Institutional LLC (“Mylan Institutional”) (collectively, “Plaintiffs”) for its Complaint for Declaratory Judgment of Infringement against Defendant Beloteca, Inc. (“Beloteca”) herein allege as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of infringement arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, Title 35, United States Code, Sections 1 *et seq.*, involving United States Patent No. 8,969,616 (the “’616 Patent”) and United States Patent No. 9,353,050 (the “’050 Patent”) (collectively, the “Patents-in-Suit”).

2. On information and belief, Beloteca intends to manufacture, use, offer to sell, sale, and/or import into the United States an isosulfan blue for injection product that is the subject of its Abbreviated New Drug Application (“ANDA”) No. 210714 (“the Beloteca ANDA Product”) submitted to the U.S. Food and Drug Administration (“FDA”), prior to the expiration of the Patents-in-Suit.

3. Beloteca has stated in a public filing that “Based on the approval of its ANDA No. 210714, Plaintiff Beloteca intends to manufacture, market, distribute and/or sell in the United States . . . the isosulfan blue product that is the subject of ANDA No. 210714.”

4. On information and belief, the process for manufacturing the Beloteca ANDA Product would infringe at least one claim of the '616 Patent.

5. On information and belief, the Beloteca ANDA Product would infringe at least one claim of the '050 Patent.

THE PARTIES

6. Apicore is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 49 Napoleon Court, Somerset, New Jersey 08873.

7. Apicore is a pharmaceutical company that provides innovative solutions to the pharmaceutical industry in the field of active pharmaceutical ingredient manufacturing.

8. Apicore developed a process for the manufacture of a high purity isosulfan blue product that is superior to other methods of isosulfan blue synthesis and has entered into an exclusive arrangement with Mylan Institutional to commercialize this innovation.

9. Mylan Institutional is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 1718 Northrock Court, Rockford, Illinois 61103.

10. Mylan Institutional is a pharmaceutical company that develops and commercializes injectable and other pharmaceutical products.

11. On information and belief, Beloteca is a California Corporation having a place of business at 10525 Vista Sorrento Parkway, Suite 100, San Diego, California 92121.

JURISDICTION AND VENUE

12. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, Title 35, United States Code, Sections 1 *et seq.*

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States, Title 35, United States Code, Sections 1 *et seq.*

14. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this case involves an actual controversy within the Court's jurisdiction and seeks a declaratory judgment that the '616 and '050 Patents will be infringed.

15. This Court has personal jurisdiction over Beloteca by virtue of actions Beloteca has taken for the purpose of engaging in injury-causing and wrongful marketing conduct in Texas and this District. *See Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 759-60 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017).

16. Beloteca has taken the significant and costly step of requesting FDA approval to engage in the marketing of the Beloteca ANDA Product described in ANDA No. 210714 purposefully directed at Texas and this District.

17. The FDA approved Beloteca's ANDA No. 210714 on January 16, 2019.

18. Beloteca has publicly stated its intent to engage in the marketing of the Beloteca ANDA Product described in ANDA No. 210714 in the United States without any limitations.

19. Beloteca's ANDA conduct is therefore suit-related and has a substantial connection with Texas and this District because Beloteca's ANDA filing is tightly tied, in purpose and planned effect, to the deliberate making of sales in Texas and this District and the suit relates to whether that in-State activity will infringe Apicore's Patents-in-Suit.

20. On information and belief, Beloteca knows and intends that its proposed ISB product described in ANDA No. 210714 will displace sales of Plaintiffs' ISB product causing injury to Plaintiffs in Texas and in this District.

21. It is a proper exercise of judicial power in this District to prevent Beloteca's planned, non-speculative harmful conduct before it occurs.

22. Venue is proper in this District. (28 U.S.C. § 1391(b), 28 U.S.C. § 1400(b))

PATENTS-IN-SUIT

23. Apicore was formed in 2004. For several years, the entire company was devoted to the development of isosulfan blue. After years of effort and significant expense, Apicore developed a superior manufacturing process that allowed for the commercial synthesis of isosulfan blue at a purity level much greater than previously achieved by others. That superior process is the basis for the technology claimed in the Patents-in-Suit.

24. Apicore's highly pure isosulfan blue is also the Reference Standard product as designated by the FDA because the isosulfan blue Reference Listed Drug product previously sold by Covidien is no longer commercially available. *See* Exhibit C (FDA webpage showing that Apicore's isosulfan blue is the Reference Standard).

25. A "[r]eference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval." 21 CFR 314.3; *see also* <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>, Section 1.4 (defining "Reference Standard").

26. The '616 Patent, entitled "Process for Preparation of Isosulfan Blue," was duly and legally issued by the USPTO on March 3, 2015. The named inventors of the '616 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Apicore is the assignee of the '616 Patent. A true and correct copy of the '616 Patent is attached hereto as Exhibit A.

27. The '050 Patent, entitled "Process for Preparation of Isosulfan Blue," was duly and legally issued by the USPTO on May 31, 2016. The named inventors of the '050 Patent are

Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Apicore is the assignee of the '050 Patent. A true and correct copy of the '050 Patent is attached hereto as Exhibit B.

28. Apicore is the lawful owner of the Patents-in-Suit and has all right, title and interest in and to the Patents-in-Suit.

29. Mylan Institutional is an exclusive licensee of each of the Patents-in-Suit.

ACTS GIVING RISE TO THIS ACTION

30. Neither Apicore nor Mylan Institutional has authorized or licensed Beloteca to make, use, sell, or offer for sale and/or import into the United States any of the inventions claimed in the Patents-in-Suit.

31. Beloteca was aware of the '616 Patent and the '050 Patent prior to the commencement of this action.

32. On information and belief, Beloteca submitted ANDA No. 210714 to the FDA seeking approval to engage in the commercial manufacture, use, marketing, offer for sale, and sale of an isosulfan blue product.

33. Beloteca received approval of its ANDA No. 210714 on January 16, 2019. The day after, Beloteca filed a declaratory judgment action against Apicore and Mylan Institutional asserting non-infringement and invalidity of the Patents-in-Suit in the Northern District of Illinois. *Beloteca Inc. v. Apicore US LLC and Mylan Institutional*, Case No. 1:19-cv-00360 (N.D. Ill.).

34. The Eastern District of Texas is the most proper forum for this action to be heard and is clearly more convenient. Because Plaintiffs previously asserted the Patents-in-Suit in this District, Beloteca could have sued Plaintiffs here. Further, this Court has familiarity with Plaintiffs and the Patents-in-Suit because the previous case in this District progressed through preliminary injunction proceedings.

COUNT I

Declaratory Judgment of Infringement of the '616 Patent

35. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

36. On information and belief, Beloteca will infringe (literally and/or under the doctrine of equivalents) the '616 Patent, including at least Claim 1 by making, using, offering to sell and/or selling within the United States and/or importing into the United States the Beloteca ANDA Product.

37. On information and belief, the process for manufacturing the Beloteca ANDA Product is described and/or claimed in Beloteca's PCT Patent Application No. PCT/US2017/037660, which published as WO2017218764A1 ("the '764 Publication")

38. The process described in the '764 Publication for manufacturing isosulfan blue API would infringe one or more claims of Apicore's '616 Patent, including at least Claim 1.

39. Like the '616 Patent's disclosure, the '764 Publication discloses a process of making isosulfan blue that includes combining isoleuco acid with silver oxide and a polar reagent and recovering isosulfan blue acid.

40. Like the '616 Patent's disclosure, the '764 Publication discloses treating the isosulfan blue acid with a sodium solution to obtain isosulfan blue.

41. The '764 Publication discloses the treatment of the recovered isosulfan blue acid with a sodium ion exchange resin in water.

42. Placing the sodium ion exchange resin in water as described in the '764 Publication will form a sodium solution as claimed in the '616 Patent.

43. Beloteca had knowledge of Apicore's '616 Patent as early as March 3, 2015 and no later than June 15, 2017.

44. Beloteca has had constructive notice of Apicore's '616 Patent as of its date of issuance on March 3, 2015.

45. On information and belief, Beloteca copied portions of the '616 Patent when drafting its '764 Publication.

46. On information and belief, Beloteca copied portions of the shared specification of Apicore's '616 and '050 Patents when drafting its '764 Publication.

47. Plaintiffs will be substantially and irreparably damaged and harmed if Beloteca's infringement of the '616 Patent is not enjoined by this Court.

48. Beloteca's infringement of the '616 Patent will cause Plaintiffs substantial harm.

COUNT II

Declaratory Judgment of Infringement of the '050 Patent

49. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

50. On information and belief, Beloteca will infringe (literally and/or under the doctrine of equivalents) the '050 Patent, including at least Claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States the Beloteca ANDA Product.

51. On information and belief, the Beloteca ANDA Product is described and/or claimed in the '764 Publication.

52. The '764 Publication in Example 1 of the specification specifically discloses that the final purity of its isosulfan blue product is about 99% pure.

53. The FDA currently lists Mylan Institutional's ISB product as the Reference Standard for isosulfan blue.

54. The Beloteca ANDA product was approved while Mylan Institutional's ISB product was listed as the Reference Standard for isosulfan blue.

55. Because Mylan Institutional's ISB product is listed as the Reference Standard for isosulfan blue, any new ANDA for ISB, including the Beloteca ANDA, would be compared to Mylan Institutional's ISB product in any required *in vivo* bioequivalence studies.

56. Apicore's isosulfan blue API and Mylan Institutional's ISB product, which incorporates Apicore's isosulfan blue API, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

57. On information and belief, because comparison to Mylan Institutional's ISB product as the Reference Standard product would be required, the isosulfan blue API used in the Beloteca ANDA for ISB is likely to have the same purity as Apicore's 99% pure product.

58. On information and belief, the Beloteca ANDA Product likely has the same or similar purity by HPLC as Mylan Institutional's ISB product for Beloteca's ANDA Product to have been approved by the FDA.

59. On information and belief, Beloteca infringes at least claim 1 of the '050 Patent because the isosulfan blue API used in the Beloteca ANDA Product has a purity of at least 99.0% by HPLC.

60. Beloteca's only allegation that the '050 Patent is invalid in Beloteca's N.D. Ill. Complaint relies on the reasons stated in the Petition for *Inter Partes* Review of U.S. Patent No. 9,353,050, in the matter captioned *Luitpold Pharmaceuticals, Inc. v. Apicore US LLC*, Case No. IPR2018-01640, currently pending before the USPTO, Patent Trial and Appeal Board. Because Beloteca does not provide any supporting allegations as to why it does not infringe the '050 Patent, this reliance necessarily implies that absent invalidation, Beloteca will infringe the '050 Patent.

61. On information and belief, Beloteca had knowledge of the '050 Patent as least as early as May 31, 2016 and no later than June 15, 2017.

62. Beloteca has had constructive notice of the '050 Patent as of its date of issuance on May 31, 2016.

63. Plaintiffs will be substantially and irreparably damaged and harmed if Beloteca's infringement of the '050 Patent is not enjoined by this Court.

64. Beloteca's infringement of the '050 Patent will cause Plaintiffs substantial harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court enter judgment in its favor and against Defendant Beloteca as follows:

- (a) A judgment that Beloteca will infringe the '616 Patent under 35 U.S.C. §§ 271(a), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States the Beloteca ANDA Product;
- (b) A judgment that Beloteca will infringe the '050 Patent under 35 U.S.C. §§ 271(a), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States the Beloteca ANDA Product;
- (c) A judgment that the '616 Patent is valid and enforceable;
- (d) A judgment that the '050 Patent is valid and enforceable;
- (e) An order preliminarily and/or permanently enjoining Beloteca, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting or attempting to act in concert or privity with them, their successors, and assigns, or acting on their behalf, from infringing, contributorily infringing, or inducing others to infringe the Patents-in-Suit, including engaging in the manufacture, use, offer to sell, and selling in the United States, and/or importation into the United States, of the Beloteca ANDA Product until the expiration of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity to which Plaintiffs are or may become entitled;
- (f) A judgment awarding Plaintiffs damages or other monetary relief under 35 U.S.C. § 281 as appropriate;
- (g) A judgment ordering Beloteca to pay damages to Plaintiffs to compensate for its infringement of each of the Patents-in-Suit, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with pre-judgment and post-judgment interest on the damages awarded,

with all of these damages to be enhanced in an amount up to treble the amount of the calculated compensatory damages as justified under 35 U.S.C. § 284 as appropriate;

- (h) A judgment declaring that infringement of the Patents-in-Suit was willful, and awarding treble damages under 35 U.S.C. § 284 as appropriate;
- (i) A judgment that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and
- (j) Such further and other relief as this Court may deem just and proper.

Dated: March 4, 2019

By: /s/ Melissa R. Smith

Melissa R. Smith
GILLAM & SMITH LLP
303 South Washington Avenue
Marshall, TX 75670
Phone: 903-934-8450
Fax: 903-934-9257
Email: melissa@gillamsmithlaw.com

Of Counsel:

Nicole Stafford
Bobby Delafield
Aden Allen
Diyang Liu
WILSON SONSINI GOODRICH & ROSATI
PROFESSIONAL CORPORATION
900 South Capital of Texas Highway
Las Cimas IV, Fifth Floor
Tel: (512) 338-5400
nstafford@wsgr.com
bdelafield@wsgr.com
aallen@wsgr.com
dliu@wsgr.com

David S. Steuer
WILSON SONSINI GOODRICH & ROSATI
PROFESSIONAL CORPORATION
650 Page Mill Rd.
Palo Alto, CA
Tel: (650) 320-4855
dsteuer@wsgr.com

*Attorneys for Apicore US LLC and Mylan
Institutional LLC*