IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-871-RGA
	)	
TEVA PHARMACEUTICALS DEVELOPMENT, INC., and TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendants.	)	

ANSWER TO COMPLAINT AND COUNTERCLAIMS

Defendants Teva Pharmaceuticals Development, Inc. ("Teva Development") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Teva") hereby answer the Complaint for patent infringement brought by Exelixis, Inc. ("Exelixis"). Additionally, Teva hereby asserts counterclaims for declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 9,724,342 (the "'342 Patent"); 10,039, 757 (the "'757 Patent"); and 10,034,873 (the "'873 Patent") (collectively, the "Asserted Patents").

With respect to the allegations made in the Complaint, upon knowledge with respect to Teva's own acts, and upon information and belief as to other matters, Teva responds and alleges as follows:

COMPLAINT FOR PATENT INFRINGEMENT[1]

1. Teva admits that the above-captioned action purports to be an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, Title 28 of the United States Code. Teva further admits that the action purports to relate to Teva's submission of an Abbreviated New Drug Application ("ANDA") No. 215942 to the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell Cabozantinib s-malate tablet, Eq. 20, 40, 60 mg base prior to the expiration of the Asserted Patents. Teva denies the remaining allegations in Paragraph 1 of the Complaint.

PARTIES

2. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies them.

3. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and therefore denies them.

4. Teva admits that Teva Development is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054. Teva further admits that Teva Development is an indirect, wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. Teva denies the remaining allegations contained in Paragraph 4 of the Complaint.

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint.

5. Teva admits that Teva USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054. Teva further admits that Teva USA is an indirect, wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. Teva denies the remaining allegations contained in Paragraph 5 of the Complaint.

JURISDICTION AND VENUE

6. The allegations in Paragraph 6 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201.

7. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. Teva further responds that the allegations in Paragraph 7 of the Complaint contain conclusions of law to which no response is required. To the extent that a response is required, Teva does not contest venue over Teva Development and Teva USA for purposes of this action only.

8. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. Teva further responds that the allegations in Paragraph 8 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over Teva Development and Teva USA for purposes of this action only. Teva denies the remaining allegations in Paragraph 8 of the Complaint.

9. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. Teva further responds that the allegations in Paragraph 9 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over Teva Development and Teva USA for purposes of this action only. Teva denies the remaining allegations in Paragraph 9 of the Complaint.

10. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. To the extent a response is required, Teva denies the allegations in Paragraph 10 of the Complaint.

11. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. To the extent a response is required, Teva denies the allegations in Paragraph 11 of the Complaint.

12. Teva admits that Teva USA manufactures and distributes for sale drug products through the United States, including in Delaware. Teva respectfully directs the Court to the website www.tevagenerics.com for a complete and accurate statement of its contents. Teva denies the remaining allegations in Paragraph 12 of the Complaint.

13. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. To the extent a response is required, Teva denies the allegations in Paragraph 13 of the Complaint.

14. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. To the extent a response is required, Teva denies the allegations in Paragraph 14 of the Complaint.

15. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. To the extent a response is required, Teva admits that Teva Pharmaceutical Industries Ltd. has previously filed complaints in patent litigations captioned *Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. & Torrent Pharma Inc.*, No. 07-24-JJF (D. Del.), in this District. Teva further admits that Teva Pharmaceutical Industries Ltd. has previously been named in patent litigations captioned *Takeda Pharmaceutical Company Ltd., Tap Pharmaceutical Products Inc., & Ethypharm, S.A. v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 07-331-SLR (D. Del); and *The Brigham & Women's Hospital, Inc., NPS Pharmaceuticals, Inc., & Amgen Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., & Barr Laboratories, Inc.*, No. 08-464-HB (D. Del.), in this District, and filed counterclaims in those actions. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15 of the Complaint and therefore denies them.

16. Teva admits that Teva Development has previously been named in a patent litigation captioned *Biogen Inc. et al. v. Teva Pharmaceuticals Development*, No. 21-389-LPS (D. Del.), in this District and filed counterclaims in said action. Teva does not contest that this

Court has personal jurisdiction over it for purposes of this action only. Teva denies the remaining allegations of Paragraph 16 of the Complaint.

17. Teva admits that Teva USA has filed claims for patent litigation in this District, including in *Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. & Torrent Pharma Inc.*, No. 07-24-JJF (D. Del.); *Takeda Pharmaceutical Company Ltd., Tap Pharmaceutical Products Inc., & Ethypharm, S.A. v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 07-331-SLR (D. Del); and *The Brigham & Women's Hospital, Inc., NPS Pharmaceuticals, Inc., & Amgen Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., & Barr Laboratories, Inc.*, No. 08-464-HB (D. Del.). Teva does not contest that this Court has personal jurisdiction over it for purposes of this action only. Teva denies the remaining allegations of Paragraph 17 of the Complaint.

18. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18 of the Complaint and therefore denies them.

19. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19 of the Complaint and therefore denies them.

20. The allegations in Paragraph 20 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that

this Court has personal jurisdiction over Teva Development for purposes of this action only. Teva denies the remaining allegations in Paragraph 20 of the Complaint.

21. The allegations in Paragraph 21 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over Teva Development for purposes of this action only.

22. The allegations in Paragraph 22 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over Teva USA for purposes of this action only. Teva denies the remaining allegations in Paragraph 22 of the Complaint.

23. The allegations in Paragraph 23 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over Teva USA for purposes of this action only.

24. The allegations in Paragraph 24 of the Complaint contain conclusions of law to which no response is required. To the extent that a response is required, Teva does not contest venue as to Teva Development for purposes of this action only.

25. The allegations in Paragraph 25 of the Complaint contain conclusions of law to which no response is required. To the extent that a response is required, Teva does not contest venue as to Teva USA for purposes of this action only.

26. Teva responds that in accordance with D.I. 12, Teva Pharmaceutical Industries Limited is no longer a party to this action, and therefore no further answer is required as to allegations pertaining to Teva Pharmaceutical Industries Limited. To the extent a response is required, Teva further responds that the allegations in Paragraph 26 of the Complaint contain conclusions of law to which no response is required.

BACKGROUND

27. Teva admits that the face of the '342 Patent bears the title "C-met Modulator Pharmaceutical Compositions." Teva further admits that the face of the '342 Patent states that it was issued on August 8, 2017. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegation concerning the expiration date of the '342 Patent and on that basis denies the allegation. Teva denies the remaining allegations of Paragraph 27 of the Complaint.

28. Teva admits that the face of the '757 Patent bears the title "C-met Modulator Pharmaceutical Compositions." Teva further admits that the face of the '757 Patent states that it was issued on August 8, 2017. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegation concerning the expiration date of the '757 Patent and on that basis denies the allegation. Teva denies the remaining allegations of Paragraph 28 of the Complaint.

29. Teva admits that the face of the '873 Patent bears the title "C-met Modulator Pharmaceutical Compositions." Teva further admits that the face of the '873 Patent states that it was issued on July 31, 2018. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegation concerning the expiration date of the '873 Patent and on that basis denies the allegation. Teva denies the remaining allegations of Paragraph 29 of the Complaint.

30. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 of the Complaint pertaining to the ownership and assignment related to the '342, '757, and '873 Patents. Teva denies the remaining allegations of Paragraph 30 of the Complaint.

31. Teva admits that the FDA-approved Prescribing Information for CABOMETYX (cabozantinib) states that it is a tyrosine kinase inhibitor, for oral administration, and is indicated for the treatment of "patients with advanced renal cell carcinoma [and] patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib." Teva further

admits that the New Drug Application No. 208692 associated with CABOMETYX was approved by the FDA in 2016. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 31 of the Complaint and therefore denies them.

32. Teva admits that the Asserted Patents are listed in the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 208692. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 32 of the Complaint and therefore denies them.

33. Teva admits that on May 4, 2021, Teva USA sent a letter titled "Notice of ANDA No. 215942 Cabozantinib s-malate Tablet, Eq. 20, 40, 60 mg Base, With Paragraph IV Certification Concerning U.S. Patent Nos. 9,724,342, 10,039,757 and 10,034,873" (the "First Notice Letter"). Teva further admits that the First Notice Letter notified Exelixis that the "FDA has received an Abbreviated New Drug Application ('ANDA') from Teva for cabozantinib s-malate tablet, Eq. 20, 40, and 60 mg base." Teva lacks knowledge or information sufficient to form a belief as to the date that Exelixis received the First Notice Letter and on that basis denies that allegation. Teva denies the remaining allegations in Paragraph 33 of the Complaint.

34. Teva admits that on May 17, 2021, Teva Development sent a letter titled "Notice of ANDA No. 215942 Cabozantinib s-malate Tablet, Eq. 20, 40, 60 mg Base, With Paragraph IV Certification Concerning U.S. Patent Nos. 9,724,342, 10,039,757 and 10,034,873" (the "Second Notice Letter"). Teva further admits that the Second Notice Letter states "[a] typographical error with regards to the name of the entity that submitted ANDA 215942." Teva admits that the Second Notice Letter notified Exelixis that Teva Development and not Teva USA had submitted ANDA No. 215942 for Cabozantinib s-malate Tablet, Eq. 20, 40, 60 mg. Teva lacks knowledge

or information sufficient to form a belief as to the date that Exelixis received the Second Notice Letter and on that basis denies that allegation. Teva denies the remaining allegations in Paragraph 34 of the Complaint.

35. Teva admits that the parties negotiated terms pursuant to which Teva would produce ANDA No. 215942 to Exelixis. Teva further admits that it produced ANDA No. 215942 to Exelixis counsel.

36. Teva admits that in ANDA No. 215942, Teva Development represented to the FDA that the active ingredient in Teva's ANDA Products is cabozantinib s-malate, Eq. 20, 40, and 60 mg base and that Teva's ANDA Product is bioequivalent to CABOMETYX. Teva denies the remaining allegations of Paragraph 36 of the Complaint.

37. Admitted.

38. Admitted.

39. The allegations of Paragraph 39 of the Complaint relate to future conduct to which no final decision has been made and Teva therefore denies those allegations.

40. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 40 of the Complaint and therefore denies them.

CLAIM FOR RELIEF

COUNT 1: INFRINGEMENT OF US PATENT NO. 9,724,342

41. Teva incorporates by reference each and every response to Paragraphs 1-40 as though fully set forth herein.

42. Denied.

43. Denied.

44. Denied.

45. Admitted.

46. Denied.

47. Denied.

48. Denied.

COUNT II: INFRINGEMENT OF US PATENT NO. 10,039,757

49. Teva incorporates by reference each and every response to Paragraphs 1-48 as though fully set forth herein.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

54. Admitted.

55. Denied.

56. Denied.

57. Denied.

COUNT III: INFRINGEMENT OF US PATENT NO. 10,034,873

58. Teva incorporates by reference each and every response to Paragraphs 1-57 as though fully set forth herein.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Admitted.

64. Denied.

65. Denied.

66. Denied.

PRAYER FOR RELIEF

This section of Exelixis' Complaint constitutes Prayers for Relief that do not require a response. Teva denies that Exelixis is entitled to any of the requested relief or any other relief. Each averment and/or allegation contained in Exelixis' Complaint that is not specifically admitted herein is hereby denied.

AFFIRMATIVE AND OTHER DEFENSES

FIRST DEFENSE: NON-INFRINGEMENT OF US PATENT NO. 9,724,342

Teva does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '342 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND DEFENSE: INVALIDITY OF US PATENT NO. 9,724,342

Each claim of the '342 Patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation.

THIRD DEFENSE: NON-INFRINGEMENT OF US PATENT NO. 10,039,757

Teva does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '757 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE: INVALIDITY OF US PATENT NO. 10,039,757

Each claim of the '757 Patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*,

including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and any judicially created bases for invalidation.

FIFTH DEFENSE: NON-INFRINGEMENT OF US PATENT NO. 10,034,873

Teva does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '873 Patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SIXTH DEFENSE: INVALIDITY OF US PATENT NO. 10,034,873

Each claim of the '873 Patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and any judicially created bases for invalidation.

RESERVATION OF DEFENSES

Teva reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs Teva Pharmaceuticals Development, Inc. ("Teva Development") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Teva" or "Counterclaim-Plaintiffs") assert the following counterclaims against Plaintiff and Counterclaim-Defendant Exelixis, Inc. ("Exelixis").

NATURE OF THE COUNTERCLAIMS

1. These counterclaims include claims for declaratory judgment that Teva has not infringed U.S. Patent Nos. 9,724,342 (the "'342 Patent"), 10,039,757 (the "'757 Patent"), and 10,034,873 (the "'873 Patent") (collectively, the "Asserted Patents") and that the Asserted Patents are invalid.

THE PARTIES

2. Teva Development is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054.

3. Teva USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054.

4. On information and belief and as alleged in Plaintiff's Complaint, Exelixis is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1851 Harbor Bay Parkway, Alameda, California 94502.

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

6. This Court has subject-matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

7. Exelixis has availed itself of this forum in this action and is therefore subject to personal jurisdiction in this District for purposes of these counterclaims.

8. To the extent that venue is proper in connection with Exelixis' Complaint, it is equally proper for these counterclaims under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

9. The '342 Patent is titled "C-met Modulator Pharmaceutical Compositions" and issued on August 8, 2017.

10. The '757 Patent is titled "C-met Modulator Pharmaceutical Compositions" and issued on August 8, 2017.

11. The '873 Patent is titled "C-met Modulator Pharmaceutical Compositions" and issued on July 31, 2018.

12. Upon information and belief and as alleged in Exelixis' Complaint, Exelixis owns rights, title, and interests in and to the Asserted Patents.

13. The Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists Exelixis as the holder of the New Drug Application ("NDA") No. 208692 for CABOMETYX. The active ingredient in CABOMETYX is Cabozantinib S-malate.

14. Teva Development submitted ANDA No. 215942 under 21 U.S.C. § 355(j) seeking FDA approval to manufacture and sell Cabozantinib S-malate tablet, Eq. 20, 40, and 60 mg base ("Teva's ANDA Products") prior to the expiration of the Asserted Patents.

15. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Teva Development submitted a certification in ANDA No. 215942 stating that the claims of the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Teva's ANDA Products.

16. In accordance with 21 U.S.C. § 355(j)(2)(B), Teva Development notified Exelixis in writing that Teva's ANDA was filed with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by Teva's ANDA Products ("Teva's Notice Letters"). In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(ii), Teva's Notice Letters included a detailed statement of the factual and legal basis for the certification that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by Teva's ANDA Products.

17. On June 17, 2021, Exelixis sued Teva in the District of Delaware, alleging infringement of the Asserted Patents.

COUNT I: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '342, PATENT

18. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 17 of the counterclaims.

19. There is an actual, substantial, continuing, and justiciable controversy between Teva and Exelixis regarding whether Teva's submission of ANDA No. 215942 and/or Teva's manufacture, use, offer to sell, or sale of the Teva ANDA Products, has infringed or will infringe any valid or enforceable claim of the '342 Patent either directly or indirectly, and either literally or under the doctrine of equivalents. Exelixis' suit has restrained the free exploitation of Teva's non-infringing goods by excluding Teva from entering the market with Teva's ANDA Products.

20. Teva has not infringed any valid and enforceable claim of the '342 Patent either literally or under the doctrine of equivalents.

21. Teva is entitled to a declaration by the Court that it does not infringe any valid and enforceable claim of the '342 Patent.

22. Teva is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT II: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '757 PATENT

23. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 22 of the counterclaims.

24. There is an actual, substantial, continuing, and justiciable controversy between Teva and Exelixis regarding whether Teva's submission of ANDA No. 215942 and/or Teva's manufacture, use, offer to sell, or sale of the Teva ANDA Products, has infringed or will infringe any valid or enforceable claim of the '757 Patent either directly or indirectly, and either literally

or under the doctrine of equivalents. Exelixis' suit has restrained the free exploitation of Teva's non-infringing goods by excluding Teva from entering the market with Teva's ANDA Products.

25. Teva has not infringed any valid and enforceable claim of the '757 Patent either literally or under the doctrine of equivalents.

26. Teva is entitled to a declaration by the Court that it does not infringe any valid and enforceable claim of the '757 Patent.

27. Teva is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT III: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '873 PATENT

28. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 27 of the counterclaims.

29. There is an actual, substantial, continuing, and justiciable controversy between Teva and Exelixis regarding whether Teva's submission of ANDA No. 215942 and/or Teva's manufacture, use, offer to sell, or sale of the Teva ANDA Products, has infringed or will infringe any valid or enforceable claim of the '873 Patent either directly or indirectly, and either literally or under the doctrine of equivalents. Exelixis' suit has restrained the free exploitation of Teva's non-infringing goods by excluding Teva from entering the market with Teva's ANDA Products.

30. Teva has not infringed any valid and enforceable claim of the '873 Patent either literally or under the doctrine of equivalents.

31. Teva is entitled to a declaration by the Court that it does not infringe any valid and enforceable claim of the '873 Patent.

32. Teva is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '342 PATENT

33. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 32 of the counterclaims.

34. Exelixis has alleged in this action that Teva infringed the '342 Patent by filing ANDA No. 215942 and that Teva's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed drug product described in ANDA No. 215942 would infringe the '342 Patent.

35. The '342 Patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created basis for invalidation.

36. Accordingly, a present, genuine, and justiciable controversy exists between Teva and Exelixis regarding the validity of the claims of the '342 Patent.

37. Teva is entitled to a declaration by the Court that one or more of the claims of the '342 Patent are invalid.

38. Teva is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT V: DECLARATORY JUDGMENT OF INVALIDITY OF THE '757 PATENT

39. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 38 of the counterclaims.

40. Exelixis has alleged in this action that Teva infringed the '757 Patent by filing ANDA No. 215942 and that Teva's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed drug product described in ANDA No. 215942 would infringe the '757 Patent.

41. The '757 Patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created basis for invalidation.

42. Accordingly, a present, genuine, and justiciable controversy exists between Teva and Exelixis regarding the validity of the claims of the '757 Patent.

43. Teva is entitled to a declaration by the Court that one or more of the claims of the '757 Patent are invalid.

44. Teva is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '873 PATENT

45. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 44 of the counterclaims.

46. Exelixis has alleged in this action that Teva infringed the '873 Patent by filing ANDA No. 215942 and that Teva's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed drug product described in ANDA No. 215942 would infringe the '873 Patent.

47. The '873 Patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created basis for invalidation.

48. Accordingly, a present, genuine, and justiciable controversy exists between Teva and Exelixis regarding the validity of the claims of the '873 Patent.

49. Teva is entitled to a declaration by the Court that one or more of the claims of the '873 Patent are invalid.

50. Teva is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

PRAYER FOR RELIEF

WHEREFORE, Teva requests that the Court enter judgment in its favor against Plaintiff/Counterclaim-Defendant Exelixis as follows:

(a) Declaring that the filing of Teva's ANDA No. 215942 has not infringed, does not infringe, and will not infringe, either directly, or indirectly, any valid and enforceable claim of the '342 patent;

(b) Declaring that the filing of Teva's ANDA No. 215942 has not infringed, does not infringe, and will not infringe, either directly, or indirectly, any valid and enforceable claim of the '757 patent;

(c) Declaring that the filing of Teva's ANDA No. 215942 has not infringed, does not infringe, and will not infringe, either directly, or indirectly, any valid and enforceable claim of the '873 patent;

(d) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '342 Patent;

(e) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '757 Patent;

(f) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's ANDA Products does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '873 Patent;

(g) Declaring that the claims of the '342 Patent are invalid and/or unenforceable;

(h) Declaring that the claims of the '757 Patent are invalid and/or unenforceable;

(i) Declaring that the claims of the '873 Patent are invalid and/or

unenforceable;

(j) If the facts demonstrate that the case is exceptional within the meaning of 35 U.S.C. § 285, awarding Teva reasonable attorneys' fees and costs reasonably incurred in prosecuting this action; and

(k) Granting Teva such other and further relief as the Court deems just and appropriate.

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