IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP., Defendants.	)	CA. No. 13-1461 RGA

PLAINTIFFS' ANSWER TO DEFENDANT
PAR PHARMACEUTICAL, INC.'S COUNTERCLAIMS

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") herein reply to the numbered paragraphs of the Counterclaims of Defendant Par Pharmaceutical, Inc. ("Par") as alleged in Par and IntelGenX Technologies Corp.'s ("IGX") (collectively, "Defendants") March 4, 2014 Answer To First Amended Complaint, as follows:

COUNTERCLAIMS

The Parties

1. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 1 and, therefore, deny the same.

2. RBP admits that it is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. RBP UK admits that it is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

4. MonoSol admits that it is a Delaware limited liability corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey.

Nature of the Action

5. Plaintiffs admit that Par purports to bring a counterclaim for declaratory judgment. Plaintiffs deny all other allegations in paragraph 5.

Jurisdiction

6. Paragraph 6 states a legal conclusion to which no reply is required. To the extent a reply is required, Plaintiffs admit that this Court has subject matter jurisdiction over Par's counterclaims in this action relating to U.S. Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit"), insofar as Par's Paragraph IV notice letters were timely, proper and effective. Plaintiffs aver that this action was commenced against Defendants because Par served Plaintiffs with what purport to be notice letters stating that Par's ANDA No. 20-5854 contains a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (commonly, referred to as a Paragraph IV certification) alleging that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA. Plaintiffs take no position at this time as to whether those notice letters were timely, proper or otherwise effective to trigger the 45 day period to file suit pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and fully reserve their rights in that regard.

7. Paragraph 7 states a legal conclusion to which no reply is required. To the extent a reply is required, RBP admits that this Court has personal jurisdiction over RBP in this action due to Plaintiffs' filing of a civil action in this judicial district against Defendants.

8. Par's pleading does not include a Paragraph 8. Plaintiffs deny any allegations purported and/or intended to have been made.

9. Paragraph 9 states a legal conclusion to which no reply is required. To the extent a reply is required, RBP UK admits that this Court has personal jurisdiction over RBP UK in this action due to Plaintiffs' filing of a civil action in this judicial district against Defendants.

10. Paragraph 10 states a legal conclusion to which no reply is required. To the extent a reply is required, MonoSol admits that this Court has personal jurisdiction over MonoSol in this action due to Plaintiffs' filing of a civil action in this judicial district against Defendants.

Venue

11. Paragraph 11 states a legal conclusion to which no reply is required. To the extent a reply is required, Plaintiffs admit that venue for this action is proper in this Court.

Factual Background

12. Plaintiffs admit that Defendants purport to have developed a generic drug that is administered by a "sublingual film," that is, it is administered by placing it under the tongue and allowing it to dissolve. Plaintiffs admit that the generic drug buprenorphine hydrochloride and naloxone hydrochloride sublingual film is indicated for maintenance treatment of opioid dependence; that Par submitted an ANDA for a purportedly bioequivalent product to Suboxone®; that Plaintiffs and Par discussed terms of a confidential disclosure agreement whereby Par would disclose its ANDA, but the negotiations were unsuccessful; that Plaintiffs have filed patent infringement claims against Par and IGX; that Plaintiffs filed an Amended Complaint against Defendants for infringement of the patents-in-suit; and that MonoSol has not

asserted a trade secrets claim against Par. Plaintiffs lack sufficient knowledge or information to admit or deny the remaining allegations in paragraph 12 and, therefore, deny the same.

Development of Par's ANDA Product

13. Plaintiffs admit the allegations in paragraph 13.

14. Plaintiffs admit that IGX is engaged in the business of developing oral drug delivery products. Plaintiffs lack sufficient knowledge or information to admit or deny the remaining allegations in paragraph 14 and, therefore, deny the same.

15. Plaintiffs admit that MonoSol is engaged in the business of developing pharmaceutical film products.

16. Plaintiffs admit that to the extent IGX cooperated, participated or assisted in the development and commercialization of Defendants' generic product or will actively participate in the manufacturing, marketing, and/or selling of Defendants' generic product, IGX and MonoSol are competitors. Plaintiffs deny remaining allegations contained in paragraph 16.

17. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 17 and, therefore, deny the same.

18. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 18 and, therefore, deny the same.

Par's Relationship With MonoSol

19. MonoSol admits that around June 2008, Par and MonoSol entered into a relationship to develop a pharmaceutical product, Zuplenz® (ondansetron) oral film. RBP and RBP UK lack sufficient knowledge or information to admit or deny the allegations in paragraph 19 and, therefore, deny the same.

20. MonoSol admits the allegations in paragraph 20. RBP and RBP UK lack sufficient knowledge or information to admit or deny the allegations in paragraph 20 and, therefore, deny the same.

21. MonoSol denies the allegations of paragraph 21, except that MonoSol admits that Par transferred any rights it had to the NDA for Zuplenz® to MonoSol. RBP and RBP UK lack sufficient knowledge or information to admit or deny the allegations in paragraph 21 and, therefore, deny the same.

22. MonoSol admits the allegations in paragraph 22. RBP and RBP UK lack sufficient knowledge or information to admit or deny the allegations in paragraph 22 and, therefore, deny the same.

23. MonoSol admits the allegations in paragraph 23. RBP and RBP UK lack sufficient knowledge or information to admit or deny the allegations in paragraph 23 and, therefore, deny the same.

24. Plaintiffs admit that MonoSol filed patent applications with the U.S. Patent and Trademark Office directed to the formulation and manufacture of pharmaceutical films and that certain of these applications were made public through publication of the applications and/or issuance of patents. Plaintiffs lack sufficient knowledge or information to admit or deny the remaining allegations in paragraph 24 and, therefore, deny the same.

Filing of Par's ANDA

25. Plaintiffs admit the allegations in paragraph 25.

26. Plaintiffs admit the allegations in paragraph 26.

27. Plaintiffs admit the allegations in paragraph 27.

28. Plaintiffs admit that MonoSol is the lawful owner of the ’150 patent and the ’514 patent. Plaintiffs deny all other allegations in paragraph 28.

29. Plaintiffs admit that RBK UK is the lawful owner of the ’832 patent. Plaintiffs deny all other allegations in paragraph 29.

30. Plaintiffs admit the allegations in paragraph 30.

31. Plaintiffs admit the allegations of the first and third sentences of paragraph 31. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in the second sentence of paragraph 31 and, therefore, deny the same.

32. Plaintiffs admit the allegations of the first and second sentences of paragraph 32. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in the second sentence of paragraph 32 and, therefore, deny the same.

33. Plaintiffs state that to the extent Par’s allegation characterizes the letter dated July 29, 2013, the letter speaks for itself. Plaintiffs deny the allegations of paragraph 33, except admit that Plaintiffs objected to the terms of the Offer.

34. Plaintiffs state that to the extent Par’s allegation characterizes the letter dated July 31, 2013, the letter speaks for itself. Plaintiffs deny the allegations of paragraph 34, except admit that Par and Plaintiffs exchanged correspondence relating to the terms of the Offer but failed to arrive at an agreement.

35. Plaintiffs state that to the extent Par’s allegation characterizes the letter dated August 2, 2013, the letter speaks for itself. Plaintiffs deny the allegations of paragraph 35, except admit that no agreement was reached.

36. Plaintiffs state that to the extent Par's allegation characterizes the letter dated August 13, 2013, the letter speaks for itself. Plaintiffs deny the allegations of paragraph 36, except admit that no agreement was reached.

37. Plaintiffs state that to the extent Par's allegation characterizes the letter dated August 16, 2013, the letter speaks for itself. Plaintiffs deny any remaining allegations in paragraph 37, except admit that no agreement was reached.

38. Plaintiffs state that to the extent Par's allegation characterizes the letter dated August 19, 2013, the letter speaks for itself. Plaintiffs deny any remaining allegations in paragraph 38, except admit that no agreement was reached.

39. Plaintiffs admit the allegations in paragraph 39.

40. Plaintiffs admit that the Complaint did not include an allegation of trade secrets misappropriation.

41. Plaintiffs admit that Plaintiffs and Par did not successfully negotiate an agreement and that Plaintiffs, therefore, did not obtain or review a copy of Defendants' ANDA before filing this action.

COUNT ONE

(Declaratory Judgment that Par Has Not Misappropriated Any Trade Secret of MonoSol)

42. Plaintiffs repeat the responses contained in paragraphs 1-41 of their Answer as if fully set forth herein.

43. MonoSol admits the allegations in paragraph 43.

44. Plaintiffs state that to the extent Par's allegation characterizes the letter dated August 2, 2013, the letter speaks for itself. Plaintiffs deny any remaining allegations in paragraph 44.

45. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 45 and, therefore, deny the same.

46. The allegations of paragraph 46 contain a legal conclusion to which no response is required. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 46 in that the allegations are a characterization of an unidentified "governing trade secret law," and, therefore, deny the same. Plaintiffs deny any remaining allegations in paragraph 46.

47. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 47 and, therefore, deny the same.

48. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 48 and, therefore, deny the same.

49. Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 49 and, therefore, deny the same.

50. Plaintiffs deny making any allegation that Par has misappropriated trade secrets. Plaintiffs lack sufficient information to admit or deny the remaining allegations in paragraph 50 and, therefore, deny the same.

51. Plaintiffs deny making any allegation that Par has misappropriated trade secrets. Plaintiffs lack sufficient knowledge or information to admit or deny the remaining allegations in paragraph 51 and, therefore, deny the same.

52. Plaintiffs lack sufficient information to admit or deny the allegations in paragraph 52 and, therefore, deny the same; except admit that Plaintiffs' suit seeks to enjoin approval and sales of Par's ANDA product until the latest expiration of any infringed asserted patent.

53. Plaintiffs admit the allegations in paragraph 53.

54. The allegations of paragraph 54 contain a legal conclusion to which no response is required. In addition, Plaintiffs lack sufficient knowledge or information to admit or deny the allegations in paragraph 54 and, therefore, deny the same.

55. The allegations of paragraph 55 contain a legal conclusion to which no response is required. To the extent a reply is required, Plaintiffs aver that this action was commenced against Defendants because Par served Plaintiffs with what purport to be notice letters stating that Par's ANDA No. 20-5854 contains a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (commonly, referred to as a Paragraph IV certification) alleging that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA. Plaintiffs take no position at this time as to whether those notice letters were timely, proper or otherwise effective to trigger the 45 day period to file suit pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and fully reserve their rights in that regard. Plaintiffs deny that Par is entitled to a declaratory judgment that Par did not and does not use any MonoSol proprietary information for the formulation of Par's ANDA product or the manufacture thereof. Plaintiffs lack sufficient knowledge or information to admit or deny any remaining allegations in paragraph 55 and, therefore, deny the same.

COUNT TWO

(Declaratory Judgment regarding U.S. Patent No. 8,017,150)

56. Plaintiffs repeat the responses contained in paragraphs 1-55 of their Answer as if fully set forth herein.

57. Plaintiffs deny the allegations of paragraph 57.

58. Plaintiffs deny the allegations of paragraph 58.

59. Plaintiffs deny the allegations of paragraph 59.

60. The allegations of paragraph 60 contain a legal conclusion to which no response is required. To the extent a reply is required, Plaintiffs aver that this action was commenced against Defendants because Par served Plaintiffs with what purport to be notice letters stating that Par's ANDA No. 20-5854 contains a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (commonly, referred to as a Paragraph IV certification) alleging that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA. Plaintiffs take no position at this time as to whether those notice letters were timely, proper or otherwise effective to trigger the 45 day period to file suit pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and fully reserve their rights in that regard. Plaintiffs deny all other allegations of paragraph 60.

61. Plaintiffs deny the allegations of paragraph 61.

COUNT THREE

(Declaratory Judgment regarding U.S. Patent No. 8,475,832)

62. Plaintiffs repeat the responses contained in paragraphs 1-61 of their Answer as if fully set forth herein.

63. Plaintiffs deny the allegations of paragraph 63.

64. Plaintiffs deny the allegations of paragraph 64.

65. Plaintiffs deny the allegations of paragraph 65.

66. The allegations of paragraph 66 contain a legal conclusion to which no response is required. To the extent a reply is required, Plaintiffs aver that this action was commenced against Defendants because Par served Plaintiffs with what purport to be notice letters stating that Par's ANDA No. 20-5854 contains a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (commonly, referred to as a Paragraph IV certification) alleging that the

patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA. Plaintiffs take no position at this time as to whether those notice letters were timely, proper or otherwise effective to trigger the 45 day period to file suit pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and fully reserve their rights in that regard. Plaintiffs deny all other allegations of paragraph 66.

67. Plaintiffs deny the allegations of paragraph 67.

COUNT FOUR

68. Plaintiffs repeat the responses contained in paragraphs 1-67 of their Answer as if fully set forth herein.

69. Plaintiffs deny the allegations of paragraph 69.

70. Plaintiffs deny the allegations of paragraph 70.

71. Plaintiffs deny the allegations of paragraph 71.

72. The allegations of paragraph 72 contain a legal conclusion to which no response is required. To the extent a reply is required, Plaintiffs aver that this action was commenced against Defendants because Par served Plaintiffs with what purport to be notice letters stating that Par's ANDA No. 20-5854 contains a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (commonly, referred to as a Paragraph IV certification) alleging that the '832, '150 and '514 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA. Plaintiffs take no position at this time as to whether those notice letters were timely, proper or otherwise effective to trigger the 45 day period to file suit pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and fully reserve their rights in that regard. Plaintiffs deny all other allegations of paragraph 72.

73. Plaintiffs deny the allegations of paragraph 73.

PRAYER FOR RELIEF

The "WHEREFORE" paragraph following paragraph 73 of the Counterclaims and the nine lettered paragraphs A-I that follow it purport to state Par's prayer for relief, to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations set forth in the "WHEREFORE" paragraph following paragraph 73 of the Counterclaims and the nine lettered paragraphs A-I that follow it and deny that Par is entitled to any of the relief described therein, or to any relief whatsoever.

Plaintiffs deny any and all allegations of the Counterclaims not expressly admitted herein.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) An order dismissing Par's Counterclaims with prejudice, and a judgment that Par is not entitled to the relief sought, or to any other relief on its Counterclaims;

(b) An order granting each and every Prayer for Relief sought by Plaintiffs in their First Amended Complaint; and

(c) An award of costs and expenses of Plaintiffs in defending the Counterclaims.

Dated: March 28, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on March 28, 2014, upon the following individuals via electronic mail:

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