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Celgene Corporation*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

_____)	
CELGENE CORPORATION,)	
)	
Plaintiff,)	Civil Action No. _____
)	
v.)	COMPLAINT FOR PATENT
)	INFRINGEMENT
)	
NATCO PHARMA LIMITED,)	(Filed Electronically)
ARROW INTERNATIONAL LIMITED,)	
WATSON PHARMACEUTICALS, INC.)	
and WATSON LABORATORIES, INC.,)	
)	
Defendants.)	
_____)	

Plaintiff Celgene Corporation (“Celgene”), by its undersigned attorneys, for its Complaint against defendants Natco Pharma Limited (“Natco”), Arrow International Limited (“Arrow”), Watson Pharmaceuticals, Inc. (“Watson Pharma”), and Watson Laboratories, Inc. (“Watson Labs”) (collectively, “Defendants”), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Natco’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market a generic version of Celgene’s REVLIMID® drug product prior

to the expiration of United States Patent Nos. 5,635,517 (the “517 patent”), 6,045,501 (the “501 patent”), 6,281,230 (the “230 patent”), 6,315,720 (the “720 patent”), 6,555,554 (the “554 patent”), 6,561,976 (the “976 patent”), 6,561,977 (the “977 patent”), 6,755,784 (the “784 patent”), 7,119,106 (the “106 patent”), 7,465,800 (the “800 patent”), 7,189,740 (the “740 patent”), 7,968,569 (the “569 patent”), 7,977,357 (the “357 patent”), and 8,193,219 (the “219 patent”) all owned by Celgene.

The Parties

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. Defendant Natco is a corporation organized and existing under the laws of India, having a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad 500 033 India.

4. On information and belief, Natco is registered to do business in the State of New Jersey. On information and belief, Natco also regularly transacts business within this judicial district. Further, on information and belief, Natco develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. On information and belief, Natco also prepares and/or aids in the preparation and submission of ANDAs to the FDA. Additionally, on information and belief, Natco has partnered with Arrow and Watson Pharma and/or Watson Labs to market and distribute Natco’s generic drug products complained of herein, including in this district.

5. Defendant Arrow is a corporation organized and existing under the laws of Malta, having a principal place of business at 57 St. Christopher St., Valletta VLT 08 Malta.

6. On information and belief, Arrow is registered to do business in the State of New Jersey. Further, on information and belief, Arrow also regularly transacts business within this judicial district. Further, on information and belief, Arrow develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. On information and belief, Arrow also prepares and/or aids in the preparation and submission of ANDAs to the FDA. Additionally, on information and belief, Arrow has partnered with Natco and Watson Pharma and/or Watson Labs to market and distribute Natco's generic drug products complained of herein, including in this district. Arrow is a wholly owned subsidiary of Watson Pharma.

7. On information and belief, Defendant Watson Pharma is a corporation organized and existing under the laws of Nevada, having a principal place of business in this judicial district at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Watson Pharma regularly conducts business in this judicial district, including marketing and selling pharmaceutical products. Watson Labs is a wholly subsidiary of Watson Pharma.

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Natco by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Natco has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. On information and belief, Natco also has purchased retail pharmacies in the State of New Jersey. Further, Natco has customers in the State of New Jersey. Natco also failed to contest jurisdiction and

has availed itself of this forum by filing counterclaims in a related litigation in this jurisdiction. *See Celgene Corp. v. Natco Pharma Limited, et al.*, No. 10-5197 (D.N.J.).

10. This Court has personal jurisdiction over Arrow by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Arrow has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. On information and belief, Arrow has customers in the State of New Jersey. Further, on information and belief, Arrow is a wholly owned subsidiary of Watson Pharma, which has substantial contacts with the State of New Jersey. Arrow also failed to contest jurisdiction, and has availed itself of this forum by filing counterclaims, in a related litigation in this jurisdiction. *See Celgene Corp. v. Natco Pharma Ltd, et al.*, No. 10-5197 (D.N.J.).

11. This Court has personal jurisdiction over Watson Pharma and Watson Labs by virtue of those parties maintaining “Corporate Headquarters” in this judicial district. Additionally, on information and belief, Watson Pharma and Watson Labs, make, ship, use, offer to sell or sell, or cause others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and derive revenue from such activities. On information and belief, Watson Pharma and Watson Labs also have customers in the State of New Jersey. Watson Pharma and Watson Labs also failed to contest jurisdiction, and have availed themselves of this forum by filing counterclaims, in a related litigation in this jurisdiction. *See Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 10-5197 (D.N.J.).

12. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents-in-Suit

13. On June 3, 1997, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’517 patent, entitled “Method of Reducing TNF α Levels with Amino Substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisindolines” to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. On June 29, 1999, the USPTO duly and lawfully issued a reexamination certificate for the ’517 patent. On March 27, 2008, the USPTO extended the term of the ’517 patent under 35 U.S.C. § 156 for a period of 1,167 days. A copy of the ’517 patent and its reexamination certificate are attached hereto as Exhibit A.

14. On August 28, 2001, the USPTO duly and lawfully issued the ’230 patent, entitled “Isoindolines, Method of Use, and Pharmaceutical Compositions” to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. A copy of the ’230 patent is attached hereto as Exhibit B.

15. On March 13, 2007, the USPTO duly and lawfully issued the ’740 patent, entitled “Methods of Using 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione for the Treatment and Management of Myelodysplastic Syndromes” to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the ’740 patent is attached hereto as Exhibit C.

16. On June 28, 2011, the USPTO duly and lawfully issued the ’569 patent, entitled “Methods for Treatment of Multiple Myeloma Using 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione” to Celgene as assignee of the inventor Jerome B. Zeldis. On August 9, 2011, the USPTO issued a certificate of correction amending the claims of the ’569 patent. A copy of the ’569 patent and its certificate of correction are attached hereto as Exhibit D.

17. On July 12, 2011, the USPTO duly and lawfully issued the '357 patent, entitled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione" to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '357 patent is attached hereto as Exhibit E.

18. On June 5, 2012, the USPTO duly and lawfully issued the '219 patent, entitled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione" to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '219 patent is attached hereto as Exhibit F.

The REVLIMID[®] Drug Product

19. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for lenalidomide capsules (NDA No. 21-880), which it sells under the trade name REVLIMID[®]. The claims of the patents-in-suit cover, inter alia, lenalidomide, solid forms of lenalidomide, pharmaceutical compositions containing lenalidomide, and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

20. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to REVLIMID[®].

Acts Giving Rise to this Suit

21. Pursuant to Section 505 of the FFDCA, Natco filed ANDA No. 201-452 ("Natco's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale, or importation into the United States of lenalidomide capsules 5 mg, 10 mg, 15 mg and 25 mg ("Natco's Proposed Products"), before the patents-in-suit expire. Arrow assisted

Natco in preparing and filing that ANDA. On information and belief, Watson Labs is now prosecuting ANDA 201-452 before the FDA.

22. In connection with the filing of its ANDA as described in the preceding paragraph, Natco has provided written certifications to the FDA, as called for by Section 505 of the FDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Natco's ANDA.

23. No earlier than August 30, 2010, Natco sent a first written notice of its ANDA certifications to Celgene ("Natco's First Notice Letter"). Natco's First Notice Letter alleged, inter alia, that some or all of the claims of the '517, '501, '720, '554, '976, '977, '784, '106 and '800 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Natco's ANDA. Natco's First Notice Letter also informed Celgene that Natco seeks approval to market Natco's Proposed Products before the '517, '501, '720, '554, '976, '977, '784, '106 and '800 patents expire.

24. On October 8, 2010, Celgene brought suit against Defendants in the District of New Jersey. *See Celgene Corp. v. Natco Pharma Limited, et al.*, No. 10-5197 (D.N.J.). That action is currently pending before the Hon. Susan D. Wigenton, U.S.D.J. and the Hon. Madeline C. Arleo, U.S.M.J.

25. No earlier than June 12, 2012, Natco sent a written notice of additional ANDA certifications to Celgene ("Natco's Second Notice Letter"). Natco's Second Notice Letter alleged, inter alia, that some or all claims of the '517, '230, '740, and '569 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Natco's ANDA. On information and belief, Natco had not previously certified against the '230, '740, or '569

patents. Natco's Second Notice Letter also informed Celgene that Natco seeks approval to market Natco's Proposed Products before the '517, '230, '740, and '569 patents expire.

26. Natco entered into an agreement with Arrow in November of 2009, under which Arrow, among other things, will market and distribute Natco's Proposed Products upon FDA approval of Natco's ANDA throughout the United States, including within the State of New Jersey. Certain portions of that agreement were subsequently amended by the parties in December of 2009.

27. On information and belief, Watson Pharma subsequently acquired Arrow. On information and belief, on or before the date of that acquisition, Watson Pharma and/or Watson Labs took over prosecution of Natco's ANDA at the FDA, and presently manages prosecution of that application. Further, on information and belief, Watson Pharma and/or Watson Labs will, among other things, market and distribute Natco's Proposed Products upon FDA approval of Natco's ANDA throughout the United States, including within the State of New Jersey. On information and belief, neither Watson Pharma nor Watson Labs have signed any written agreement with Natco detailing the precise relationship between the parties with respect to Natco's ANDA and Natco's Proposed Products.

Count I: Infringement of the '517 Patent

28. Plaintiff repeats and realleges the allegations of the preceding paragraphs as though fully set forth herein.

29. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '517 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. There is a justiciable controversy between the parties hereto as to the infringement of the '517 patent.

31. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '517 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

32. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '517 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '517 patent and knowledge that their acts are encouraging infringement.

33. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '517 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '517 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

34. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '517 patent is not enjoined.

35. Celgene does not have an adequate remedy at law.

36. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '230 Patent

37. Plaintiff repeats and realleges the allegations of the preceding paragraphs as though fully set forth herein.

38. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '230 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

39. There is a justiciable controversy between the parties hereto as to the infringement of the '230 patent.

40. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '230 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

41. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '230 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '230 patent and knowledge that their acts are encouraging infringement.

42. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '230 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed

Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '230 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

43. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '230 patent is not enjoined.

44. Celgene does not have an adequate remedy at law.

45. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '740 Patent

46. Plaintiff repeats and realleges the allegations of the preceding paragraphs as though fully set forth herein.

47. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '740 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

48. There is a justiciable controversy between the parties hereto as to the infringement of the '740 patent.

49. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '740 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

50. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '740 patent under 35 U.S.C. § 271(b) by making,

using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '740 patent and knowledge that their acts are encouraging infringement.

51. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '740 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '740 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

52. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '740 patent is not enjoined.

53. Celgene does not have an adequate remedy at law.

54. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '569 Patent

55. Plaintiff repeats and realleges the allegations of the preceding paragraphs as though fully set forth herein.

56. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '569 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. There is a justiciable controversy between the parties hereto as to the infringement of the '569 patent.

58. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '569 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

59. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '569 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '569 patent and knowledge that their acts are encouraging infringement.

60. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '569 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '569 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

61. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '569 patent is not enjoined.

62. Celgene does not have an adequate remedy at law.

63. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '357 Patent

64. Plaintiff repeats and realleges the allegations of the preceding paragraphs as though fully set forth herein.

65. Natco, by its submission of its ANDA certification to the FDA, has indicated that it seeks approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '357 patent.

66. Natco's ANDA has been pending before the FDA since at least August 30, 2010, the date of Natco's First Notice Letter.

67. There is a justiciable controversy between the parties hereto as to the infringement of the '357 patent.

68. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '357 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

69. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '357 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '357 patent and knowledge that their acts are encouraging infringement.

70. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '357 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '357 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

71. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '357 patent is not enjoined.

72. Celgene does not have an adequate remedy at law.

73. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '219 Patent

74. Plaintiff repeats and realleges the allegations of the preceding paragraphs as though fully set forth herein.

75. Natco, by its submission of its ANDA certification to the FDA, has indicated that it seeks approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '219 patent.

76. Natco's ANDA has been pending before the FDA since at least August 30, 2010, the date of Natco's First Notice Letter.

77. There is a justiciable controversy between the parties hereto as to the infringement of the '219 patent.

78. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '219 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

79. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '219 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '219 patent and knowledge that their acts are encouraging infringement.

80. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '219 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '219 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

81. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '219 patent is not enjoined.

82. Celgene does not have an adequate remedy at law.

83. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

- (A) A Judgment be entered that Defendants have infringed the '517, '230, '740, and '569 patents by submitting ANDA No. 201-452;
- (B) A Judgment be entered that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing Natco's Proposed Products into the United States will infringe one or more claims of the '517, '230, '740, '569, '357, and '219 patents;
- (C) An Order that the effective date of FDA approval of ANDA No. 201-452 be a date which is not earlier than the later of the expiration of the '517, '230, '740, '569, '357, and '219 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;
- (D) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Natco's Proposed Products into the United States until after the expiration of the '517, '230, '740, '569, '357, and '219 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;
- (E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any compounds, methods or compositions as claimed in the '517, '230, '740, and '569 patents, or from actively inducing or contributing to the infringement of any claim of any of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;
- (F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Natco's Proposed Products will directly infringe, induce and/or contribute to infringement of the '517, '230, '740, '569, '357, and '219 patents;

(G) To the extent that Defendants have committed any acts with respect to the compounds, methods, or compositions claimed in the '517, '230, '740, '569, '357, and '219 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff be awarded damages for such acts;

(H) If Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Natco's Proposed Products prior to the expiration of the '517, '230, '740, '569, '357, and '219 patents, a Judgment awarding damages to Plaintiff resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: July 20, 2012

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

I hereby certify that the matter in controversy involves the same plaintiff, two of the same patents (United States Patent Nos. 5,635,517 and 6,281,230), three of the same defendants, and the same Abbreviated New Drug Application that are at issue in the matter captioned *Celgene Corporation v. Natco Pharma Limited, et al.*, Civil Action No. 10-5197 (SDW)(MCA), which is currently pending in this judicial district.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: July 20, 2012

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