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Shire Pharmaceutical Development Inc.,  
Cosmo Technologies Limited, and  
Nogra Pharma Limited*

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

**SHIRE DEVELOPMENT LLC, SHIRE  
PHARMACEUTICAL DEVELOPMENT  
INC., COSMO TECHNOLOGIES  
LIMITED, and NOGRA PHARMA  
LIMITED,**

**Plaintiffs,**

**v.**

**AMNEAL PHARMACEUTICALS LLC,  
AMNEAL PHARMACEUTICALS OF  
NEW YORK, LLC, AMNEAL  
PHARMACEUTICALS CO. (I) PVT. LTD.,  
and AMNEAL LIFE SCIENCES PVT.  
LTD.,**

**Defendants.**

**Civil Action No. \_\_\_\_\_**

**COMPLAINT FOR PATENT  
INFRINGEMENT**

**(Filed Electronically)**

**COMPLAINT**

Plaintiffs Shire Development LLC, Shire Pharmaceutical Development Inc. (collectively, “Shire”), Cosmo Technologies Limited (“Cosmo”), and Nogra Pharma Limited (“Nogra”) (collectively, “Plaintiffs”) by their undersigned attorneys, for their Complaint against defendants

Amneal Pharmaceuticals, LLC (“Amneal Pharmaceuticals”), Amneal Pharmaceuticals of New York, LLC (“Amneal New York”), Amneal Pharmaceuticals Co. (I) Pvt. Ltd. (“Amneal India”), and Amneal Life Sciences Pvt. Ltd. (“Amneal Life Sciences”) (collectively “Amneal” or “Defendants”) herein, allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 6,773,720 (“the ’720 patent” or “the patent-in-suit”), attached hereto as Exhibit A.

**THE PARTIES**

2. Plaintiff Shire Development LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

3. Plaintiff Shire Pharmaceutical Development Inc. is a corporation organized and existing under the laws of the State of Maryland, having its principal place of business at 1801 Research Boulevard, Rockville, Maryland 20850.

4. Plaintiff Cosmo is a company organized and existing under the laws of Ireland, having its principal place of business at The Connolly Building, 42-43 Amiens Street, Dublin 1, Ireland.

5. Plaintiff Nogra is a company organized and existing under the laws of Ireland, having its principal place of business at 33 Sir John Rogerson’s Quay, Dublin 2, Ireland.

6. Upon information and belief, Amneal Pharmaceuticals is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

Amneal Pharmaceuticals is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under registration number 5002991.

7. Upon information and belief, Amneal Pharmaceuticals is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the state of New Jersey—through its various subsidiaries, including Amneal New York.

8. Upon information and belief, Amneal New York is a wholly owned subsidiary of Amneal Pharmaceuticals. Upon information and belief, Amneal New York acts at the direction of, under the control of, and for the direct benefit of Amneal Pharmaceuticals and is controlled and/or dominated by Amneal Pharmaceuticals.

9. Upon information and belief, Amneal India is a private limited company organized and existing under the laws of India, having a principal place of business at 882/1-871, Nr. Hotel Kankavati, Village Rajoda, Bavla Taluka, Ahmedabad-382220, Gujarat, India.

10. Upon information and belief, Amneal India is engaged in the business of, *inter alia*, the development and manufacture of generic pharmaceutical products for sale and distribution throughout the United States, including throughout the State of New Jersey.

11. Amneal Pharmaceuticals' website states that the Amneal India Research and Development Centre "is one of the two key drivers . . . behind [its] organic growth and achieving [its] goal of 30+ ANDA approvals per year."<sup>1</sup> Amneal Pharmaceuticals' website further states that "[t]his state-of-the-art R&D Centre boasts 75,000 square-feet of pure R&D. Amneal

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<sup>1</sup> Amneal Pharmaceuticals - Our Operation - Amneal India, <http://amneal.in/operation/amnindia.php> (last visited April 22, 2015).

develops over a dozen FDA ANDAs from this Centre annually across all dosage forms—all of which are to be filed from our US facilities.”<sup>2</sup>

12. Upon information and belief, Amneal India manufactures generic pharmaceutical products that are imported throughout the United States and thus avail themselves of the privileges and benefits of the laws and commerce of the United States and New Jersey.

13. Upon information and belief, Amneal India manufactures generic pharmaceutical products for which Amneal Pharmaceuticals is the ANDA applicant and distributor, including Warfarin Sodium Tablets (1 mg, 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg, and 10 mg) (reference brand Coumadin<sup>®</sup>), Metaxalone Tablets (800 mg) (reference brand Skelaxin<sup>®</sup>), and Tramadol/APAP Tablets (37.5/325 mg) (reference brand Ultracet<sup>®</sup>). Upon information and belief, Defendants derive substantial revenue from the sale of such generic pharmaceutical products.

14. Upon information and belief, Amneal Life Sciences is a private limited company organized and existing under the laws of India, having its principal place of business at Plot Nos. 15, 16, 17, Pharmez (Special Economic Zone - SEZ), Sarkhej Bavla Highway, Matoda, Sanand, Ahmedabad - 382213, Gujarat, India. Upon information and belief, Amneal Life Sciences is a subsidiary of Amneal Pharmaceuticals.

15. Upon information and belief, Amneal Life Sciences is engaged in the business of, *inter alia*, the development and manufacture of generic pharmaceutical products for sale and distribution throughout the United States, including throughout the State of New Jersey.

16. Amneal Pharmaceuticals’ website states that its generic product pipeline is “[d]riven through five proprietary research and development facilities located in New York, New

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<sup>2</sup> Amneal Pharmaceuticals - Our Operation - Research & Development, <http://amneal.in/operation/research.php> (last visited April 22, 2015).

Jersey and India . . . .”<sup>3</sup> Amneal Pharmaceuticals’ website identifies, *inter alia*, the following locations in the United States and India: (1) Primary Packaging Facility in East Hanover, New Jersey; (2) Oral Solids Manufacturing in Paterson, New Jersey; (3) Transdermal, Topicals, & Complex Oral Solids Manufacturing and R&D in Piscataway, New Jersey; (4) Oral Solids, Softgels, High Potency, Hormonal, Controlled Substances Manufacturing and R&D in Brookhaven, New York; (5) Administrative Offices - Oral Solids & Controlled Substances Manufacturing in Hauppauge, New York;<sup>4</sup> (6) Oral Solids Manufacturing and R&D in Ahmedabad, Gujarat, India; (7) Oral Solid Dosage Unit in Ahmedabad, Gujarat, India; and (8) a Parenteral Unit in Ahmedabad, Gujarat, India.<sup>5</sup>

17. Upon information and belief, Amneal Pharmaceuticals LLC operates in India as Amneal Life Sciences and Amneal Pharmaceuticals for R&D, manufacturing, and API production as well as oral solids and injectable formulations.

18. Upon information and belief, Amneal New York is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 85 Adams Avenue, Hauppauge, New York 11788. Amneal New York is registered as a drug manufacturer in the State of New Jersey under the registration number 5003663.

19. Upon information and belief, Amneal New York is in the business of, *inter alia*, the development, manufacture, and distribution of generic pharmaceutical products throughout the United States, including throughout the State of New Jersey.

20. Upon information and belief, Amneal New York manufactures generic pharmaceutical products for which Amneal Pharmaceuticals is the ANDA applicant and distributor, including Guanfacine Hydrochloride Tablets (1 mg and 2 mg) (reference brand

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<sup>3</sup> Pipeline | Amneal, <http://amneal.com/products/pipeline> (last visited April 22, 2015).

<sup>4</sup> United States | Amneal, <http://amneal.com/about/locations/united-states/> (last visited April 22, 2015).

<sup>5</sup> Asia/India | Amneal, <http://amneal.com/about/locations/asia-india> (last visited April 22, 2015).

Tenex<sup>®</sup>), Oxycodone Hydrochloride Tablets (5 mg, 10 mg, 15 mg, 20 mg, and 30 mg) (reference brand Roxicodone<sup>®</sup>), and Venlafaxine Hydrochloride Tablets (25 mg, 37.5 mg, 50 mg, 75 mg, and 100 mg) (reference brand Effexor<sup>®</sup>). Upon information and belief, Amneal derives substantial revenue from the sale of such generic pharmaceutical products.

21. Upon information and belief, Amneal New York manufactures and Amneal Pharmaceuticals distributes generic pharmaceutical products for which Amneal New York is the ANDA applicant, including Ranitidine Hydrochloride Tablets (150 mg and 300 mg) (reference brand Zantac<sup>®</sup>) and Gabapentin Capsules (100 mg, 300 mg, and 400 mg) (reference brand Neurontin<sup>®</sup>). Upon information and belief, Amneal derives substantial revenue from the sale of such generic pharmaceutical products.

22. Upon information and belief, Defendants hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products.

23. Upon information and belief, Defendants work in concert with each other to obtain regulatory approval and with respect to manufacturing, selling, marketing, distribution, and importation of generic drug products throughout the United States, including in New Jersey.

#### **JURISDICTION AND VENUE**

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

25. This Court has personal jurisdiction over Amneal Pharmaceuticals because, *inter alia*: (i) Amneal Pharmaceuticals' principal place of business is located in New Jersey; (ii) Amneal Pharmaceuticals, together with Amneal New York and Amneal India has committed,

induced, or contributed to acts of patent infringement in New Jersey; (iii) Amneal Pharmaceuticals is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iv) Amneal Pharmaceuticals has submitted to the jurisdiction of this Court in at least seventeen prior New Jersey litigations;<sup>6</sup> and (v) Amneal Pharmaceuticals is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under registration number 5002991.

26. This Court has personal jurisdiction over Amneal New York because, *inter alia*: (i) Amneal New York is in the business of manufacturing, marketing, importing, selling, and distributing pharmaceutical drug products, including generic drug products, directly or indirectly, and in partnership or agency with its parent Amneal Pharmaceuticals in the State of New Jersey; (ii) Amneal New York, together with Amneal Pharmaceuticals, has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Amneal New York has submitted to the jurisdiction of this Court in at least six prior New Jersey litigations;<sup>7</sup> and (iv) Amneal New York is registered as a drug manufacturer in the State of New Jersey under registration number 5003663.

27. This Court has personal jurisdiction over Amneal India because, *inter alia*: (i) upon information and belief, Amneal India manufactures generic pharmaceutical products that are imported throughout the United States and thus avail themselves of the privileges and benefits of the laws and commerce of the United States and New Jersey; (ii) Amneal India is in the business of developing and manufacturing pharmaceutical drug products, including generic

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<sup>6</sup> See, e.g., *Otsuka Pharm. Co., Ltd. v. Amneal Pharms., LLC, et al.*, Civil Action No. 15-1585; *Jazz Pharms., Inc., et al. v. Amneal Pharms., LLC*, Civil Action No. 15-1043; *Roxane Labs., Inc. v. Amneal Pharms., LLC*, Civil Action No. 14-5420; *Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Amneal Pharms., LLC*, Civil Action No. 14-4726; and *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, Civil Action No. 14-3235.

<sup>7</sup> See, e.g., *Novo Nordisk Inc., et al. v. Amneal Pharms., LLC, et al.*, Civil Action No. 13-4915; *Luitpold Pharms., Inc. v. Amneal Pharms., LLC, et al.*, Civil Action No. 12-5064; *AstraZeneca Pharms., LP, et al. v. Amneal Pharms., LLC, et al.*, Civil Action No. 12-4841; *Warner Chilcott Co., LLC v. Amneal Pharms., LLC, et al.*, Civil Action No. 12-2928; *Otsuka Pharm. Co., Ltd. v. Amneal Pharms., LLC, et al.*, Civil Action No. 12-2487.

drug products, directly or indirectly, and in partnership or agency with its parent Amneal Pharmaceuticals for importation, sale, and/or distribution in the State of New Jersey; (iii) Amneal India, together with Amneal Pharmaceuticals and Amneal New York, has committed, induced, or contributed to acts of patent infringement in New Jersey; (iv) Amneal India has submitted to the jurisdiction of this Court in at least two prior New Jersey litigations;<sup>8</sup> and (v) Amneal India has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action.<sup>9</sup>

28. This Court has personal jurisdiction over Amneal Life Sciences because, *inter alia*: (i) upon information and belief, Amneal Life Sciences manufactures generic pharmaceutical products that are imported throughout the United States and thus avail themselves of the privileges and benefits of the laws and commerce of the United States and New Jersey; (ii) Amneal Life Sciences is in the business of developing and manufacturing pharmaceutical drug products, including generic drug products, directly or indirectly, and in partnership or agency with its parent Amneal Pharmaceuticals for importation, sale, and/or distribution in the State of New Jersey; and (iii) Amneal Life Sciences, together with Amneal Pharmaceuticals and Amneal New York, has committed, induced, or contributed to acts of patent infringement in New Jersey.

#### **FACTS AS TO ALL COUNTS**

29. Shire Development LLC is the owner of New Drug Application (“NDA”) No. 22-000, approved by the U.S. Food and Drug Administration (“FDA”) for the manufacture and sale of mesalamine delayed release tablets, containing 1.2g mesalamine, which are commercialized under the name of Lialda<sup>®</sup>. Lialda<sup>®</sup> is indicated for the induction of remission in adults with

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<sup>8</sup> See *AstraZeneca Pharms., LP, et al. v. Amneal Pharms., LLC, et al.*, Civil Action No. 12-4841; *Otsuka Pharm. Co., Ltd. v. Amneal Pharms., LLC, et al.*, Civil Action No. 12-2487.

<sup>9</sup> See *AstraZeneca Pharms., LP, et al. v. Amneal Pharms., LLC, et al.*, Civil Action No. 12-4841.



active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.

30. The '720 patent, entitled "Mesalazine Controlled Release Oral Pharmaceutical Compositions" was duly and legally issued by the United States Patent and Trademark Office on August 10, 2004, to Cosmo Pharmaceuticals S.p.A. (now known as Cosmo Pharmaceuticals S.A.) upon assignment from inventors Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati. Cosmo S.p.A. granted Giuliani S.p.A. an exclusive license to the '720 patent. Giuliani S.p.A., in turn, granted Shire Pharmaceutical Development Inc. an exclusive sublicense to the '720 patent. Subsequently, Giuliani S.p.A. assigned the license agreement with Shire Pharmaceutical Development Inc. to Nogra (formerly known as "Giuliani International Limited"), and Cosmo became the owner of the '720 patent on assignment from Cosmo S.p.A.

31. Pursuant to 21 U.S.C. § 355(b)(1), the patent-in-suit is listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering Lialda<sup>®</sup>.

32. Upon information and belief, Defendants worked in concert to prepare, submit, and file ANDA No. 207205 (the "Amneal ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic mesalamine delayed-release tablets, containing 1.2g of mesalamine as the active ingredient (the "Amneal ANDA Product") and included a "paragraph IV" certification seeking approval before patent expiration. The filing of an ANDA with a paragraph IV certification is an act of infringement alone. *See* 35 U.S.C. § 271(e)(2).

33. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include “[a] detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement must include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation.” 21 C.F.R. § 314.95(c)(6)(i)-(ii).

34. Amneal Pharmaceuticals sent letters addressed to Shire Development Inc. and Cosmo Technologies Ltd. dated March 9, 2015, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), regarding the Amneal ANDA Product (the “Amneal Notice Letter”).

35. The Amneal Notice Letter included an “Offer of Confidential Access” purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Although the parties have been unable to negotiate mutually agreeable terms for access to information about the Amneal ANDA Product, Amneal produced, on April 17, 2015, a disc purporting to contain a copy of its ANDA, designated as “Outside Counsel Eyes Only.” In addition, Plaintiffs requested samples of the Amneal ANDA Product, which defendants refused to produce.

36. Plaintiffs believe that infringement of valid patent claims exist, but must resort to the judicial process to fully assess Amneal’s potential defenses to Plaintiffs’ claims. *See e.g.*, 21 U.S.C. § 355(j)(2)(B)(iv)(II); 21 C.F.R. § 314.95(c)(6).

**FIRST COUNT**  
**(Defendants' Infringement of the '720 Patent)**

37. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

38. Upon information and belief, Amneal seeks FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Amneal ANDA Product.

39. Upon information and belief, Amneal Pharmaceuticals included a paragraph IV certification to the '720 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Amneal's ANDA Product before the expiration of the '720 patent.

40. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Amneal ANDA Product immediately upon FDA approval.

41. Upon information and belief, as of the date of the Amneal Notice Letter, Defendants were aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

42. Amneal Pharmaceuticals filed ANDA No. 207205 with a paragraph IV certification. Upon information and belief, Amneal Pharmaceuticals, Amneal New York, Amneal India, and Amneal Life Sciences all worked together, in concert to file this ANDA.

43. The submission and filing of ANDA No. 207205 with a paragraph IV certification to the '720 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amneal ANDA Product before the expiration of the '720 patent is an act of infringement by Defendants of one or more claims of the '720 patent under 35 U.S.C. § 271(e)(2)(A).

44. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the Amneal ANDA Product that is the subject of ANDA No. 207205 will infringe one or more claims of the '720 patent under U.S.C. § 271.

45. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation in the United States of the Amneal ANDA Product by Amneal would induce and/or contribute to third party infringement of one of more claims of the '720 patent under 35 U.S.C. § 271.

46. Upon information and belief, as of the date of the Amneal Notice Letter, Defendants were aware of the existence of the '720 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '720 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

47. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court. .

#### **SECOND COUNT**

##### **(Defendants' Induced and/or Contributory Infringement of the '720 Patent)**

48. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

49. Amneal Pharmaceuticals is jointly and severally liable for Amneal New York's, Amneal India's, and/or Amneal Life Sciences' infringement of one or more claims of the '720 patent.

50. Upon information and belief, Amneal Pharmaceuticals knowingly induced Amneal New York to infringe and/or contributed to Amneal New York's infringement of one of more claims of the '720 patent.

51. Upon information and belief, Amneal Pharmaceuticals knowingly induced Amneal India to infringe and/or contributed to Amneal India's infringement of one of more claims of the '720 patent.

52. Upon information and belief, Amneal Pharmaceuticals knowingly induced Amneal Life Sciences to infringe and/or contributed to Amneal Life Sciences' infringement of one of more claims of the '720 patent.

53. Upon information and belief, Amneal New York has actively induced, encouraged, aided, or abetted Amneal Pharmaceuticals' preparation, submission, and filing of ANDA No. 207205 with a paragraph IV certification to the '720 patent. Amneal New York's inducement, encouragement, aiding, or abetting of Amneal Pharmaceuticals' preparation, submission, and filing of ANDA No. 207205 with a paragraph IV certification constitutes infringement of the '720 patent under 35 U.S.C. § 271 (e)(2)(A).

54. Upon information and belief, Amneal India has actively induced, encouraged, aided, or abetted Amneal Pharmaceuticals' preparation, submission, and filing of ANDA No. 207205 with a paragraph IV certification to the '720 patent. Amneal India's inducement, encouragement, aiding, or abetting of Amneal Pharmaceuticals' preparation, submission, and filing of ANDA No. 207205 with a paragraph IV certification constitutes infringement of the '720 patent under 35 U.S.C. § 271 (e)(2)(A).

55. Upon information and belief, Amneal Life Sciences has actively induced, encouraged, aided, or abetted Amneal Pharmaceuticals' preparation, submission, and filing of ANDA No. 207205 with a paragraph IV certification to the '720 patent. Amneal Life Sciences' inducement, encouragement, aiding, or abetting of Amneal Pharmaceuticals' preparation,

submission, and filing of ANDA No. 207205 with a paragraph IV certification constitutes infringement of the '720 patent under 35 U.S.C. § 271 (e)(2)(A).

56. Amneal New York's, Amneal India's, and/or Amneal Life Sciences' commercial use, manufacture, sale, offer for sale and/or importation of the Amneal ANDA Product would induce and/or contribute to Amneal Pharmaceuticals' infringement of the '720 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

57. Upon information and belief, Amneal Pharmaceutical's sale or offer for sale of the Amneal ANDA Product would induce and/or contribute to third party infringement of one or more claims of the '720 patent under 35 U.S.C. § 271.

58. Upon information and belief, as of the date of the Amneal Notice Letter, Amneal Pharmaceuticals was aware of the existence of the '720 patent and acted without a reasonable basis for pursuing an ANDA and seeking to market an infringing product. Upon information and belief, Amneal New York, Amneal India, and/or Amneal Life Sciences was either similarly aware of the '720 patent or willfully blind as to its existence and acted without a reasonable basis for aiding and abetting Amneal Pharmaceuticals in the pursuit of ANDA No. 207205, thus rendering this case "exceptional" under 35 U.S.C. § 285.

59. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

- (a) A Judgment declaring that the '720 patent is valid and enforceable;

(b) A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 207205 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of Amneal's ANDA Product was an act of infringement of the '720 patent by Defendants;

(c) A Judgment declaring that, pursuant to 35 U.S.C. 271 § (e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of Amneal's ANDA Product prior to the expiration of the '720 patent, including any regulatory extensions will constitute an act of infringement by Defendants or would induce and/or contribute to third party infringement of the '720 patent;

(d) A Judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Amneal Pharmaceuticals would induce Amneal New York's, Amneal India's, and/or Amneal Life Sciences' infringement and/or contributory infringement of the '720 patent based on the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the Amneal ANDA Product prior to the expiration of the '720 patent;

(e) A Judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Amneal Pharmaceuticals' inducement, encouragement, aiding, or abetting of Amneal New York's, Amneal India's, and/or Amneal Life Sciences' commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the Amneal ANDA Product would induce and/or contribute to third party infringement of the '720 patent;

(f) An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of Amneal's ANDA Product shall be no earlier than the date on which the '720 patent expires, including any regulatory extensions;

(g) A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the Amneal ANDA Product until the expiration of the '720 patent, including any regulatory extensions;

(h) A Judgment awarding Plaintiffs damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import into the United States any products that the subject of ANDA No. 207205 prior to the expiration of the '720 patent;

(i) If Defendants commercially manufacture, use, sell, offer to sell, and/or import any products that are the subject of ANDA No. 207205 prior to the expiration of the '720 patent, a Judgment declaring that Defendants' infringement of the '720 patent based on ANDA No. 207205 is willful;

(j) A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs their attorneys' fees and costs;

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



Dated: April 22, 2015

Respectfully submitted,

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Cosmo Technologies Limited, and  
Nogra Pharma Limited*

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1**

I hereby certify that the following matters: (1) *Shire Development LLC, et al. v. Cadila Healthcare Limited (d/b/a Zyclus Cadila), et al.*, No. 1:10-cv-00581-KAJ (D. Del.); (2) *Shire Development LLC, et al. v. Osmotica Pharmaceutical Corp., et al.*, No. 1:12-cv-00904-AT (N.D. Ga.); (3) *Shire Development LLC, et al. v. Watson Pharmaceuticals, Inc., et al.*, No. 0:12-cv-60862-DMM (S.D. Fla.), No. 13-1409 (Fed. Cir.); and (4) *Coalition for Affordable Drugs II LLC v. Cosmo Technologies Ltd.*, Case IPR2015-00988 (PTAB) are related to the matter in controversy because the matter in controversy involves some of the same Plaintiffs and the same patent.

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: April 22, 2015

Respectfully submitted,

By: s/ Charles M. Lizza  
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