IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.:
	)	
RANBAXY LABORATORIES, LTD., and RANBAXY, INC., corporations, and	)	
	)	
DALE ADKISSON, ARUN SAWHNEY, VENKATACHALAM KRISHNAN, individuals,	)	
	)	
Defendants.	)	

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Ranbaxy Laboratories, Ltd. and Ranbaxy, Inc., corporations ("Ranbaxy"), and Dale Adkisson, Arun Sawhney, and Venkatachalam Krishnan, individuals (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, and causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (b) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (c) violating 21 U.S.C. § 331(d) by introducing

or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i); and/or (d) violating 21 U.S.C. § 331(e) by failing to make reports required under 21 U.S.C. § 355(k).

JURISDICTION

2. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Ranbaxy Laboratories, Ltd. ("RLL") was established as an Indian corporation in 1961, and is currently India's largest generic drug pharmaceutical company. RLL owns and operates numerous drug manufacturing facilities in India, including ones located at Sirmour District, Himanchal Pradesh, India (hereafter, "Paonta Sahib"); Unit II, P.O. Batamandi, Paonta Sahib, Dirst Sirmour, Batamandi, Himanchal Pradesh, India (hereafter, "Batamandi"); and Industrial Area-3, Dewas, India (hereafter, "Dewas") that manufacture or have manufactured drugs that are the subject of new drug applications ("NDAs") and/or abbreviated new drug applications ("ANDAs") on file with FDA. The Paonta Sahib and Dewas facilities also manufacture active pharmaceutical ingredients ("APIs") used by Defendants to manufacture finished drug products. RLL's products are sold in more than one hundred countries, including throughout the United States and in the District of Maryland. RLL's corporate headquarters are located at Plot No. 90, Sector 32, Gurgaon, India. RLL is the global parent company of Defendant Ranbaxy, Inc.

5. Defendant Ranbaxy, Inc., located at 600 College Road East, Princeton, NJ, has been incorporated in the State of Delaware since 1999. Ranbaxy, Inc., is the parent company to its wholly owned subsidiaries: Ohm Laboratories, Inc. ("Ohm"); Ranbaxy Laboratories, Inc. ("RLI"); Ranbaxy Pharmaceuticals, Inc. ("RPI"); and Ranbaxy USA. Ranbaxy, Inc. performs all corporate administration and regulatory functions for its wholly owned subsidiaries, including submitting drug applications to FDA for marketing approval. Up until October, 13, 2011, Ohm operated a drug manufacturing site at 34 West Fulton St., Gloversville, NY ("Gloversville").

6. Defendant Dale Adkisson, an individual, has been RLL's Senior Vice President, Head Global Quality since January 2010. Mr. Adkisson is responsible for implementing drug quality at all of Ranbaxy's drug manufacturing sites. Mr. Adkisson performs his duties at 77B IFFCO Road, Sector 18, Udyog Vihar Industrial Area, Gurgaon, 122015, India.

7. Defendant Arun Sawhney, an individual, became RLL's Managing Director on August 20, 2010, and assumed his current role as Chief Executive Officer and Managing Director of RLL on August 5, 2011. Mr. Sawhney is responsible for and oversees all facets of Ranbaxy's business, including but not limited to: manufacturing, quality operations, regulatory affairs, purchasing, sales, marketing, business administration, and human resources. Mr. Sawhney performs his duties at Plot No. 90, Sector 32, Gurgaon, 122001. Mr. Sawhney is the highest ranking corporate official and most responsible person at RLL, and he also sits on RLL's Board of Directors.

8. Defendant Venkatachalam Krishnan, an individual, is Ranbaxy, Inc.'s Regional Director Americas. Mr. Krishnan is the most responsible person for all of Ranbaxy, Inc.'s operations in the United States and Canada. Among other things, Mr. Krishnan oversees manufacturing, sales, and business development for all of Ranbaxy, Inc.'s U.S. operations, and

has oversight over the regulatory affairs department, which is responsible for submitting annual reports to FDA for drug products manufactured in India and North America. Mr. Krishnan performs his duties at 600 College Road East, Princeton, NJ.

DEFENDANTS' OPERATIONS

9. Defendants have been and are now engaged in manufacturing, processing, packing, labeling, holding, and distributing drugs within the meaning of 21 U.S.C. § 321(g).

10. Certain of Defendants' drugs have been and are now being entered into interstate commerce within the meaning of 21 U.S.C. § 321(b).

11. Certain of Defendants drugs have been and are now manufactured using components they receive in interstate commerce.

12. Defendants' drugs are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

13. Defendants are required to submit certain post-marketing reports for their drugs, pursuant to 21 U.S.C. § 355(k) and the regulations governing post-marketing drug reports found in 21 C.F.R. § 314.81.

ADULTERATED DRUGS

14. The Act requires manufacturers of drug products to operate in compliance with the current good manufacturing practice ("CGMP") requirements for drugs, 21 U.S.C. § 351(a)(2)(B), to ensure that drugs meet the requirements of the Act as to safety and have the identity and strength and meet the quality and purity characteristics that they purport or are represented to possess. Drugs not manufactured, processed, packed, or held in conformance with

CGMP are deemed adulterated as a matter of law, without any showing of actual defect. Regulations implementing the CGMP provisions are set forth at 21 C.F.R. Parts 210 and 211.

15. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

16. Defendants also violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

17. Inspections of Ranbaxy's Paonta Sahib, Batamandi, Dewas, and Gloversville facilities establish that Defendants' drugs manufactured at and distributed from such facilities are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, or holding do not conform to and are not operated or administered in conformity with CGMP.

INSPECTIONS AT THE PAONTA SAHIB AND BATAMANDI FACILITIES

18. FDA inspected RLL's Batamandi facility from March 3-7, 2008. During that inspection, FDA investigators documented many significant deviations from CGMP in the manufacture of finished drug products. These observations include, but are not limited to, the following:

a. Failure to keep written records of major equipment cleaning and use adequate to show that persons double-checked the performance of equipment cleaning, as required by 21 C.F.R. § 211.182;

b. Failure to include complete information in the batch production and control records prepared for each batch of drug product produced, as required by 21 C.F.R. § 211.188(b)(l1);

c. Failure to have adequate procedures for review and approval of drug product production and control records by the quality unit, including those for packaging and labeling, to determine compliance with all established, approved written procedures before a batch is released or distributed, as required by 21 C.F.R. § 211.192; and

d. Failure to extend investigations into any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy, whether or not the batch has already been distributed, as required by 21 C.F.R. § 211.192.

19. During the March 3-7, 2008 inspection, FDA investigators determined that the Batamandi facility was under the same production and quality management as the Paonta Sahib facility, and that the Paonta Sahib facility was involved in various aspects of testing and production for the Batamandi facility. In a letter dated May 12, 2008, FDA informed RLL that it considered the Batamandi facility to be a part of the existing Paonta Sahib facility, and that FDA was cancelling the separate FDA registration for the Batamandi facility. Although FDA had cancelled the separate FDA registration for the Batamandi facility on May 12, 2008, FDA reinstated a separate FDA registration for the Batamandi facility on November 12, 2010.

20. FDA previously inspected the Paonta Sahib facility from February 20 - 25, 2006. During that inspection, FDA investigators documented numerous significant deviations from CGMP in the manufacture of drug products, which include, but are not limited to:

a. Failure to include in laboratory records a complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific drug product and lot tested, as required by 21 C.F.R. § 211.194(a)(4);

b. Failure to establish and follow an adequate written testing program designed to assess the stability characteristics of drug products and to determine appropriate drug storage conditions and expiration dates, as required by 21 C.F.R. § 211.166; and

c. Failure of the quality control unit to have adequate laboratory resources, including personnel and equipment, for conducting stability testing of drugs, as required by 21 C.F.R. § 211.22(b).

INSPECTIONS AT THE DEWAS FACILITY

21. FDA inspected RLL's Dewas facility from January 28 - February 12, 2008. During that inspection, FDA investigators documented significant deviations from CGMP in the manufacture of sterile and non-sterile finished products and in the manufacture and control of APIs. These observations include, but are not limited to, the following:

a. Failure to adequately establish separate or defined areas for the manufacture and processing of non-penicillin beta-lactam products to prevent contamination and mixups, and failure to separate adequately the operations related to the manufacturing, processing, and packaging of penicillins from non-penicillin products, as required by 21 C.F.R. § 211.42(c)(5) and (d);

b. Failure to include required information relating to the production and control of each batch produced in batch production and control records, as required by 21 C.F.R. § 211.188(b);

c. Failure to have procedures that provide for a thorough review of unexplained discrepancies or failure of a batch or any of its components to meet its specifications, whether or not the batch has already been distributed, as required by 21 C.F.R. § 211.192;

d. Failure of the quality control unit to ensure that its organizational structure, procedures, processes, resources, and activities are adequate to ensure that APIs and drug products, sterile and non-sterile, meet their intended specifications for quality and purity, as required by 21 C.F.R. § 211.22;

e. Failure to have and follow adequate written procedures designed to prevent microbiological contamination of drug products and APIs purported to be sterile, as required by 21 C.F.R. § 211.113(b); and

f. Failure to have adequate controls established to prevent contamination or mix-ups in aseptic processing operations, as required by 21 C.F.R. § 211.42(c)(10).

22. FDA also inspected RLL's Dewas facility from February 27 - March 2, 2006. During that inspection, FDA investigators documented deviations from CGMP including, but not limited to:

a. Failure to maintain complete data derived from all tests necessary to assure compliance with established specifications and standards, as required by 21 C.F.R. § 211.194;

b. Failure to have batch production and control records for each batch of drug product produced that includes complete information relating to the production and control of each batch, as required by 21 C.F.R. § 211.188; and

c. Failure to extend investigations into any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy, whether or not the batch has already been distributed, as required by 21 C.F.R. § 211.192.

INSPECTION AT THE GLOVERSVILLE FACILITY

23. FDA inspected Ranbaxy, Inc.'s Gloversville facility from July 13 - August 12, 2009, and documented numerous and significant deviations from CGMP in the manufacture of finished drugs. These observations include, but are not limited to, the following:

a. Failure to investigate thoroughly the failure of a batch or any of its components to meet its specifications, whether or not the batch has already been distributed, and failure to extend the investigation to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy, as required by 21 C.F.R. § 211.192;

b. Failure to comply with the firm's written stability program; failure to establish and follow an adequate written testing program designed to assess the stability characteristics of drug products and to determine appropriate drug storage conditions and expiration dates; and failure to maintain a record of the number of batches of each drug product that are tested to determine an appropriate expiration date, as required by 21 C.F.R § 211.166(a) and (b);

c. Failure to establish laboratory control procedures and document the execution of laboratory control functions at the time of performance, as required by 21 C.F.R. § 211.160(a);

d. Failure to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b);

e. Failure to exercise appropriate controls over computer and related systems to assure that changes in control records and other records are instituted only by authorized personnel, as required by 21 C.F.R. § 211.68(b);

f. Failure to establish written procedures to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product, as required by 21 C.F.R. § 211.110(a);

g. Failure to have an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product, as required by 21 C.F.R. § 211.25(c); and

h. Failure to use equipment that is routinely calibrated, inspected, and checked according to a written program designed to assure proper performance, as required by 21 C.F.R. § 211.68(a).

UNAPPROVED NEW DRUGS

24. The Act prohibits causing the introduction, delivery for introduction into interstate commerce, and introducing and delivering for introduction into interstate commerce new drugs that are not the subject of an approved marketing or investigational application. 21 U.S.C. §§ 331(d) and 355. Approved marketing and investigational applications include NDAs, ANDAs, and investigational new drug applications. 21 U.S.C. § 355.

25. Ranbaxy has distributed the prescription drugs Desquam X Wash 5% and Desquam X Wash 10%, which were not the subject of approved drug applications on file with FDA, in interstate commerce beginning in August 2008, and May 2008, respectively.

26. FDA's July 13 - August 12, 2009 inspection at Ohm's Gloverville facility referenced in paragraph 23 also determined that Gloversville was manufacturing and distributing the prescription drug Opium Tincture USP (Deodorized - 10 mg/mL), for which no approved application was on file with FDA.

FAILURE TO SUBMIT REQUIRED REPORTS

27. The Act requires drug manufacturers to notify FDA within three working days after receiving any information concerning a failure of one or more distributed batches of a drug product to meet the specifications established for it in its approved drug application. 21 U.S.C. § 355(k); 21 C.F.R. § 314.81(b)(1). This notification is called a "field alert report."

28. For each drug product for which it has an approved ANDA, a manufacturer also must submit an annual report to FDA. The annual report must be submitted each year within sixty days of the anniversary date of FDA's approval of the ANDA. 21 C.F.R. § 314.81(b)(2). The annual report must include a summary of new information that might affect the safety, effectiveness, or labeling of the drug, and any actions taken or anticipated in response to that information. 21 C.F.R. § 314.81(b)(2)(i). The annual report also must include a full description, listed by date in the order in which they were implemented, of any minor changes made to the drug substance, drug product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product, as those factors relate to the safety or effectiveness of the drug. 21 C.F.R. §§ 314.70(d)(1), 314.81(b)(2)(iv). The annual report also must include a status report on

each postmarketing study of the drug product that the applicant committed to conduct at the time of approval, including ongoing stability studies. 21 C.F.R. § 314.81(b)(2)(vii).

29. Failure to file a required field alert report or annual report is a violation of the Act. 21 U.S.C. § 331(e).

30. FDA's 2009 inspection of the Gloversville facility revealed that Ranbaxy, Inc., failed to submit at least two field alert reports within three working days of receiving information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in its drug application, as required by 21 C.F.R. § 314.81(b)(1)(ii), as follows:

a. Ohm received a complaint on March 23, 2009, related to particles in Metformin Oral Solution, which was confirmed on April 1, 2009. The firm's May 22, 2009, investigation concluded that the particles may be attributed to a worn nozzle seal on the filling machine. This event was not reported as a field alert report; and

b. Ohm became aware of an out-of-specification result for an antioxidant at the 24-month stability point on March 17, 2009, for Sertraline Hydrochloride Oral Concentrate, but did not file a field alert report until March 26, 2009.

31. FDA inspected Ranbaxy, Inc.'s corporate headquarters in Princeton, NJ, from December 3-19, 2007, and documented that the firm failed to report stability failures in field alert reports for Gabapentin 600 mg and 800 mg tablets manufactured at Paonta Sahib within the required three-day time frame. The inspection further revealed that Ranbaxy submitted 115 late (past the 60 day window after the approval date anniversary) annual reports between 2005 and 2007.

APPLICATION INTEGRITY

32. Corporate Defendants have submitted numerous untrue statements of material fact in submissions to FDA from the Paonta Sahib, Batamandi, and Dewas facilities. These falsified submissions, in addition to Defendants' inadequate control measures for ensuring the integrity of data discovered by FDA through inspections and by other means, demonstrate that Defendants have had a persistent problem with data integrity. Defendants' wrongful acts raise significant questions regarding the reliability of data that originated at their Paonta Sahib, Batamandi, and Dewas facilities.

33. At the Paonta Sahib and Batamandi facilities, RLL, among other things:

a. Conducted stability testing several weeks or months later than the dates that were reported to FDA in drug applications or annual reports. Additionally, in many instances, the stability test results reported at different time intervals (e.g., 3, 6, and 9 months) actually were conducted on the same day or within a few days of each other; and

b. Submitted batch records for FDA approval of pending ANDAs that contained the signatures or initials of RLL employees who were not present in the facility on the dates documented in the batch records. The employees' signatures or initials appeared in blocks documenting the performance and verification of certain manufacturing steps.

34. FDA determined that the data integrity findings at Paonta Sahib and Batamandi indicate a pattern and practice of submitting untrue statements of material fact and other wrongful conduct that raise significant questions regarding the reliability of the data and information contained in applications (pending and approved) that Ranbaxy has filed with FDA and which contain data developed at the Paonta Sahib and Batamandi sites. FDA notified

Ranbaxy of this decision and invoked its Application Integrity Policy ("AIP") against the Paonta Sahib and Batamandi facilities by letter to RLL dated February 25, 2009.

35. At the Dewas facility, RLL, among other things:

a. Submitted stability data for stability stations when no stability samples existed. Specifically, in at least five ANDAs, RLL submitted stability data in at least nineteen instances in which no stability samples were available, and therefore, valid stability data do not exist to support the claimed expiration dates for the five drug products covered by these ANDAs;

b. Submitted stability data for specific times in many approved and pending applications when, in fact, RLL had not tested the samples at those times. Specifically, for at least fifteen ANDAs, there were 110 instances on which submitted stability data samples were not actually tested at the reported times, and in at least 89 batches, RLL had not yet tested samples months after the reported test dates, with a delay ranging from one to eighteen months.

36. FDA verbally notified Defendants of the data integrity concerns at the Dewas facility during a meeting at FDA Headquarters on April 5, 2011.

HISTORY OF VIOLATIONS

37. Ranbaxy has a history of continuing violations of the Act. The drug CGMP deviations observed at Paonta Sahib, Batamandi, Dewas, and Gloversville are all similar, and demonstrate that the firm has not established and documented management control over quality assurance and quality control functions at these facilities to ensure continuous compliance with the Act and its implementing regulations.

38. At the close of each of the FDA inspections referenced in paragraphs 18, 20, 21, 22, and 23, FDA investigators issued a detailed List of Inspectional Observations ("Form FDA-483") to Ranbaxy's management, notifying it of the drug CGMP deficiencies observed during

the inspection. At the close of the inspection referenced in paragraph 31, FDA investigators issued a detailed Form FDA-483 to Defendant Venkatachalam Krishnan, notifying him of Ranbaxy's failure to submit timely post-marketing reports.

39. RLL submitted a written response dated May 1, 2008, to the Form FDA-483 issued after the March 3-7, 2008 Batamandi inspection discussed in paragraph 18. The response noted that some corrections had been implemented, including withdrawal of an ANDA due to deficiencies noted in equipment cleaning logs and batch production and control records for the exhibit batches of that drug manufactured in July - August, 2006. RLL's response was inadequate, however, because FDA had concerns that the instances of discrepancies observed during the inspection were indications of continuing, systemic CGMP deficiencies at the Paonta Sahib and Batamandi facilities.

40. On September 16, 2008, FDA issued a Warning Letter to the then CEO and Managing Director of RLL in Gurgaon, India, stating that, based on the violations observed during FDA's March 3-7, 2008 inspection at Paonta Sahib and Batamandi and taking into account RLL's response described in paragraph 39, the finished drugs manufactured at these facilities were adulterated under 21 U.S.C. § 351(a)(2)(B), because they were manufactured in violation of CGMP. This Warning Letter noted the continuing CGMP deficiencies in the quality systems at the Paonta Sahib facility, including the failure of production and quality management to prevent such deficiencies, and referenced a prior Warning Letter issued by FDA on June 15, 2006, to RLL's then Vice-President, Manufacturing at the Paonta Sahib facility, citing significant CGMP deficiencies relating to Paonta Sahib's stability testing program observed during FDA's February 20-26, 2006 inspection of that facility.

41. RLL submitted a written response dated April 3, 2008, to the Form FDA-483 issued after the January 28 - February 12, 2008 Dewas inspection discussed in paragraph 21. The response noted that some corrections had been completed or would soon be implemented, but the response inadequately addressed the multiple, serious deficiencies including the beta-lactam containment program and inadequacies in batch production and control records, failure investigations, quality control program, and aseptic operations.

42. On September 16, 2008, FDA issued a Warning Letter to the then CEO and Managing Director of RLL in Gurgaon, India, stating that, based on the violations observed during FDA's January 28 - February 12, 2008 inspection at Dewas and taking into account the firm's April 3, 2008 response described in paragraph 41, the sterile and non-sterile finished products and APIs manufactured at the facility were adulterated under 21 U.S.C. § 351(a)(2)(B), because they were manufactured in violation of CGMP.

43. In addition to issuing the Warning Letters referenced in paragraphs 40 and 42, FDA placed the Paonta Sahib, Batamandi, and Dewas facilities on import alert, and, since September 16, 2008, FDA has been refusing admission into the United States of drugs from such facilities under 21 U.S.C. § 381(a)(3), because they are not manufactured in compliance with CGMP.

44. Ohm submitted a written response dated September 11, 2009, to the Form FDA-483 issued after the July 13 - August 12, 2009 inspection discussed in paragraph 23, which FDA found inadequate because it lacked sufficient corrective actions. Ohm also submitted updates dated October 12, November 11, and December 11, 2009, which included the status of and time frames for the proposed corrective actions.

45. On December 21, 2009, FDA issued a Warning Letter to Ohm's Gloversville facility, with a copy to the then CEO and Managing Director of RLL in Gurgaon, India, notifying them that, based on the July 13 - August 12, 2009 inspection at Gloversville and taking into account the firm's responses described in paragraph 44: there were significant violations from the CGMP requirements for finished pharmaceuticals causing that facility's drug products to be adulterated under 21 U.S.C. § 351(a)(2)(B); Gloversville distributed an unapproved new drug in violation of 21 U.S.C. §§ 355(a) and 331(d); and Gloversville failed to report the quantity of a drug product distributed in an annual report as required by 21 C.F.R. § 314.81(b)(2)(ii) and failed to submit a field alert report within three working days of receiving information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in its FDA-approved application, a required by 21 C.F.R. § 314.81(b)(I)(ii).

46. The CGMP violations observed at Defendants' Paonta Sahib, Batamandi, Dewas, and Gloversville facilities are similar, and they are the same as, or similar to, prior CGMP observations at Paonta Sahib that were brought to RLL's attention. Further, Defendants' history of significant data integrity problems at the Paonta Sahib, Batamandi, and Dewas facilities cast significant doubts on the validity of Ranbaxy data obtained from these facilities.

47. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and

assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

a. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, any article of drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

b. Violating 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drug is held for sale after shipment in interstate commerce;

c. Violating 21 U.S.C. § 331(d) by introducing into interstate commerce any new drug that does not comply with 21 U.S.C. § 355; and

d. Violating 21 U.S.C. § 331(e) by failing to make reports required under 21 U.S.C. § 355(k).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them from the following acts at Paonta Sahib, Batamandi, Dewas, and/or Gloversville, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug at a facility are established, operated, and administered in conformity with CGMP and the Act, in a manner that has been found acceptable by FDA:

a. Manufacturing, processing, packing, repacking, labeling, holding, or distributing any drugs at or from their Gloversville facility;

b. Manufacturing, processing, packing, repacking, labeling, holding, or distributing at or from Batamandi drugs that may or may not be intended for introduction into

interstate commerce, but are the subject of an application on file with FDA and must be manufactured in conformity with such application, including drugs associated with the President's Emergency Plan for AIDS Relief program ("PEPFAR drugs"), and introducing into interstate commerce any drugs manufactured at Batamandi;

c. Manufacturing, processing, packing, repacking, labeling, holding, or distributing at or from Paonta Sahib drugs that may or may not be intended for introduction into interstate commerce, but are the subject of an application on file with FDA and must be manufactured in conformity with such application, including PEPFAR drugs, and introducing into interstate commerce any drugs manufactured at Paonta Sahib;

d. Manufacturing, processing, packing, repacking, labeling, holding, or distributing at or from Dewas drugs that may or may not be intended for introduction into interstate commerce, but are the subject of an application on file with FDA and must be manufactured in conformity with such application, including PEPFAR drugs, and introducing into interstate commerce any drugs manufactured at Dewas.

III. Order that FDA be authorized, at its sole discretion, to withhold review of any and all of Corporate Defendants' applications or other submissions to FDA in support of or in connection with the approval or distribution of regulated products at or from the Paonta Sahib, Batamandi, and Dewas facilities, including, but not limited to, approved or pending NDAs or ANDAs, and any post-marketing submissions with respect to such applications, until Defendants resolve all data integrity issues in a manner that has been found acceptable by FDA.

IV. Order that FDA be authorized pursuant to this injunction to inspect Defendants' Paonta Sahib, Batamandi, Dewas, and Gloversville facilities, and all records relating to the receipt, manufacture, processing, packing, labeling, holding, or distribution of any drug at or

from such facilities to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

V. Order that Plaintiff be awarded costs and other such equitable relief as this Court deems just and proper.

DATED this 25th day of January, 2012

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