IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

THE UNITED STATES OF AMERICA *ex rel.* (UNDER SEAL),	:	
Plaintiffs,	:	
	:	Civ. No. 1:07-cv-00962-JFM
v.	:	
(UNDER SEAL)	:	
Defendants.	:	
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FILED *IN CAMERA* AND UNDER SEAL
PURSUANT TO 31 U.S.C. § 3730(b)(2)

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

THE UNITED STATES OF AMERICA
ex rel. DINESH S. THAKUR

and

STATE OF ARKANSAS
ex rel. DINESH S. THAKUR

and

STATE OF CALIFORNIA
ex rel. DINESH S. THAKUR

and

STATE OF DELAWARE
ex rel. DINESH S. THAKUR

and

DISTRICT OF COLUMBIA
ex rel. DINESH S. THAKUR

and

STATE OF FLORIDA
ex rel. DINESH S. THAKUR

and

STATE OF GEORGIA
ex rel. DINESH S. THAKUR

and

STATE OF HAWAII
ex rel. DINESH S. THAKUR

and

Civ. No. 1:07-cv-00962-JFM

SECOND AMENDED COMPLAINT UNDER FEDERAL AND STATE FALSE CLAIM ACTS

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STATE OF ILLINOIS
ex rel. DINESH S. THAKUR

and

STATE OF INDIANA
ex rel. DINESH S. THAKUR

and

STATE OF LOUISIANA
ex rel. DINESH S. THAKUR

and

COMMONWEALTH OF MASSACHUSETTS
ex rel. DINESH S. THAKUR

and

STATE OF MICHIGAN
ex rel. DINESH S. THAKUR

and

STATE OF MONTANA
ex rel. DINESH S. THAKUR

and

STATE OF NEVADA
ex rel. DINESH S. THAKUR

and

STATE OF NEW HAMPSHIRE
ex rel. DINESH S. THAKUR

and

STATE OF NEW JERSEY
ex rel. DINESH S. THAKUR

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and

STATE OF NEW MEXICO
ex rel. DINESH S. THAKUR

and

STATE OF NEW YORK
ex rel. DINESH S. THAKUR

and

STATE OF OKLAHOMA
ex rel. DINESH S. THAKUR

and

STATE OF TENNESSEE
ex rel. DINESH S. THAKUR

and

STATE OF TEXAS
ex rel. DINESH S. THAKUR

and

COMMONWEALTH OF VIRGINIA
ex rel. DINESH S. THAKUR

and

STATE OF UTAH
ex rel. DINESH S. THAKUR

and

STATE OF WISCONSIN
ex rel. DINESH S. THAKUR

and

STATE OF COLORADO
ex rel. DINESH S. THAKUR

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and :
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STATE OF CONNECTICUT :
ex. rel. DINESH S. THAKUR :
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STATE OF IOWA :
ex. rel. DINESH S. THAKUR :
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STATE OF MARYLAND :
ex. rel. DINESH S. THAKUR :
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STATE OF MINNESOTA :
ex. rel. DINESH S. THAKUR :
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STATE OF MISSOURI :
ex. rel. DINESH S. THAKUR :
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and :
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STATE OF NORTH CAROLINA :
ex. rel. DINESH S. THAKUR :
:
and :
:
STATE OF RHODE ISLAND :
ex. rel. DINESH S. THAKUR :
:
Plaintiffs, :
:
v. :
:
RANBAXY USA, INC. :
9431 Florida Mining Boulevard East :
Jacksonville, Florida 32257 :

SERVE ON REGISTERED AGENT:
John P. Reilly, Esq.
LeClairRyan, P.C.
One Riverfront Plaza
1037 Raymond Boulevard
Sixteenth Floor
Newark, New Jersey 07102

and

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9431 Florida Mining Boulevard East
Jacksonville, Florida 32257

SERVE ON REGISTERED AGENT:
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1201 Hays Street
Tallahassee, Florida 32301

and

RANBAXY LABORATORIES, INC.
600 College Road East, Suite 2100
Princeton, New Jersey 08540

SERVE ON REGISTERED AGENT:
Corporation Service Company
830 Bear Tavern Road
West Trenton, New Jersey 08628

and

RANBAXY, INC.
600 College Road East, Suite 2100
Princeton, New Jersey 08540

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SERVE ON REGISTERED AGENT:
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and

OHM LABORATORIES, INC.
1385 Livingston Avenue
New Brunswick, New Jersey 08901

SERVE ON REGISTERED AGENT:
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Newark, New Jersey 07102

and

RANBAXY LABORATORIES LTD.
Plot No. 90, Sector 32
Gurgaon (Haryana) 122001
India

Defendants.

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SECOND AMENDED COMPLAINT

COMES NOW, Relator Dinesh S. Thakur, through the undersigned counsel, on behalf of himself and the United States of America ("United States"), the States of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, and Utah, the Commonwealths of Massachusetts and Virginia, and the District of Columbia ("States"), and brings this *qui tam* action under the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("Federal FCA") and false claim statutes enacted by the States, to recover monetary damages, civil penalties, and all other remedies for violations of Federal and State health benefit programs and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), by Defendants Ranbaxy USA, Inc., Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ranbaxy, Inc., Ohm Laboratories, Inc., and Ranbaxy Laboratories Ltd. (collectively "Ranbaxy"), and hereby alleges as follows.

1. This is a *qui tam* action to recover treble damages, civil penalties, and all other available remedies on behalf of the United States and the States under the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), and analogous statutes enforced by the States, arising from Defendants' scheme to knowingly cause false and fraudulent claims for payment or approval for adulterated and misbranded generic drugs to be presented to the United States and the States under the Medicare program, the Medicaid program, CHAMPUS/TRICARE, the Civilian Health and Medical Program of Veterans Affairs, the

Federal Employee Health Benefits Program, and other health benefit and relief programs, including, but not limited to, the President's Emergency Plan for AIDS Relief ("PEPFAR") program (collectively the "Benefit Programs").

2. Two categories of false claims and statements generally are challenged in the First Amended Complaint. First, Defendants falsified, and conspired to falsify, dossier and other data and documentation filed with the United States Food and Drug Administration ("FDA") in order to gain and retain approval, including First-to-File ("FTF") status, to market and sell their generic drugs in the United States in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). Under the Benefit Programs, the United States and the States purchased Defendants' adulterated and misbranded generic drugs, which were not properly demonstrated to be, and in fact were not, bioequivalent to the branded drugs, stable, and/or efficacious to therapeutically treat the diseases for which the drugs were labeled, marketed, and sold. Second, Defendants submitted false data and statements to the United States to gain approval for adulterated generic antiretroviral ("ARV") drugs that were purchased for Federally appropriated relief programs, such as PEPFAR and other initiatives administered by the United States Agency for International Development ("USAID"), in order to provide ARV drug treatments to human immunodeficiency virus ("HIV") patients in developing countries. In each instance, Defendants' fraudulent scheme resulted in false claims and statements made to FDA, the Benefit Programs, health care providers, and private payor programs to induce payment or approval for their adulterated and misbranded drugs.

3. This First Amended Complaint has been filed *in camera* and under seal pursuant to 31 U.S.C. § 3730(b)(2). It will not be served on Defendants until the Court so orders. A copy of the original Complaint and initial written disclosure of substantially all material evidence and information Relator possesses previously were served on the Attorney General of the United States and the United States Attorney for the District of Maryland pursuant to 31 U.S.C. § 3730(b)(2) and Fed. R. Civ. P. 4.

JURISDICTION AND VENUE

4. This Court possesses subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. §§ 3730 and 3732 because Relator seeks remedies on behalf of the United States and the States for Defendants' violations of 31 U.S.C. § 3729, some of which occurred in the District of Maryland. Defendants transact substantial business within the District of Maryland by marketing and selling generic drugs and regularly interacting with FDA, which is located within this District.

5. The Court may exercise personal jurisdiction over Defendants pursuant to MD. CODE ANN., CTS. & JUD. PROC. § 6-103.

6. This Court has pendant jurisdiction over the Government Entity claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367.

7. The Complaint has been filed timely within the period prescribed by 31 U.S.C. § 3731(b).

8. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) and (c) because at least one of Defendants resides or transacts business in this

District. In addition, the acts proscribed by the Federal FCA, including the false statements and filings with FDA, were committed by Defendants in this judicial district.

PARTIES

A. Plaintiffs.

9. Plaintiff, the United States of America, by and through its administrative agencies including FDA and the Centers for Medicare & Medicaid Services ("CMS"), is responsible for the administration of all Federal health care programs. FDA, in particular, is responsible for protecting the public health by assuring the safety, efficacy, and security of generic drugs marketed and promoted in the United States.

10. The States of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Indiana, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, and Utah, the Commonwealths of Massachusetts and Virginia, and the District of Columbia are named as Plaintiffs pursuant to the Court's pendant jurisdiction under 31 U.S.C. § 3732 with respect to the related States' false claims statutes.

B. Relator.

11. Relator is a citizen of the United States and a resident of the Commonwealth of Massachusetts. From June 2003 until April 2005, Relator was the Director of Project & Information Management with Defendant Ranbaxy Laboratories Limited in Gurgaon, Haryana, India. Pursuant to 31 U.S.C. § 3730(e)(4)(B), Relator is the "original source" of the information given to the United States regarding Defendants'

illegal conduct in violation of Federal and State laws. He has direct and independent knowledge of the allegations set forth herein. Relator states that the information concerning Defendants' misconduct was not disclosed publicly prior to his original disclosure to the United States in August 2005.

C. Defendants.

12. Defendant Ranbaxy Laboratories, Ltd. ("Defendant RLL") is a foreign pharmaceutical company organized and existing under the laws of India with its principal place of business located at Plot No. 90, Sector 32, Gurgaon 122001, Haryana, India. Directly and through the other Defendants, Defendant RLL manufacturers, markets and sells finished generic drugs and active pharmaceutical ingredients in the United States and within this District. Service upon Defendant RLL is proper through the means authorized by The Hague Convention on the Service Abroad of Judicial and Extra-Judicial Documents in Civil or Commercial Matters ("The Hague Convention") as provided under Fed. R. Civ. P. 4(f). Under Articles Three and Five of The Hague Convention, a request, summons, and complaint may be forwarded to the Central Authority of India located at The Ministry of Law and Justice, Department of Legal Affairs, 4th Floor, A-Wing, Shastri Bhavan, 110 001 New Delhi, India.

13. In 2008, Daiichi Sankyo Company, Ltd. assumed the majority control of Defendant RLL by acquiring 63.92% of Ranbaxy shares in a transaction valued at $4.6 billion. Daiichi Sankyo is a foreign pharmaceutical company organized under the laws of Japan with its principal place of business located at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan. It markets and sells finished pharmaceuticals throughout the

United States, including within this District. Pursuant to the acquisition, Defendant RLL is a subsidiary of Daiichi Sankyo. Daiichi Sankyo exercises control over Defendant RLL's operations, including those within the United States, and maintains majority control over Defendant RLL's board of directors.

14. As a generic pharmaceutical company doing business in the United States, Defendant RLL and its subsidiaries manufacture, market, and sell finished drugs purchased by the Benefit Programs for program beneficiaries. Defendant RLL claims to possess 241 approved or pending Abbreviated New Drug Applications ("ANDAs") filed with FDA, including 142 approved and 99 pending ANDAs. This includes 19 potential "Paragraph IV" First-to-File ("FTF") ANDAs with a value in excess of $27 billion at innovator prices.[1] In addition to sales to the Medicare and Medicaid programs, Defendant RLL is a major producer of ARV drugs purchased directly or indirectly by the United States under Federal programs for humanitarian assistance such as PEPFAR.

15. Defendant Ranbaxy Pharmaceuticals, Inc. ("RPI") is a wholly owned subsidiary of Defendant RLL with a principal place of business located at 9431 Florida Mining Boulevard East, Jacksonville, Florida 32257. Its operations in the United States include locations in New Jersey (Princeton and New Brunswick), Jacksonville, Florida,

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[1] A FTF ANDA filed with a Paragraph IV certification contains a written certification attesting to the generic manufacturer's belief that a patent for a new drug is "invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A generic company with a FTF ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity if the company prevails in litigation to invalidate the innovator patent. During this exclusivity period, the only competition for the generic manufacturer is the branded product.

and Gloversville, New York. Defendant RPI markets and sells finished generic drugs and active pharmaceutical ingredients manufactured by Ranbaxy. Upon information and belief, the profits from these sales and those of all subsidiaries of Defendant RLL were repatriated in whole or in part to Defendant RLL.

16. Defendant Ranbaxy Laboratories, Inc. ("RLI") is a wholly-owned subsidiary of Defendant RLL located at 600 College Road East, Suite 2100, Princeton, New Jersey 08540. It is the branded prescription division of Defendant RLL in the United States.

17. Defendant Ranbaxy, Inc. ("RI") is a Delaware corporation. It is the parent corporation of Defendant RPI in the United States.

18. Defendant Ranbaxy USA, Inc. is wholly-owned subsidiary of Defendant RLL located at 4801 Executive Park Court B-100, Jacksonville, Florida 32216.

19. Defendant Ohm Laboratories, Inc. ("Ohm") is a subsidiary of RPI. It is located at 600 College Road East, Suite 2100, Princeton, New Jersey 08540.

20. At all times hereinafter mentioned, Defendants conspired to violate the FDCA, the Federal FCA, and the false claim statutes enacted by the States in connection with the approval, marketing, and sale of adulterated and misbranded generic drugs throughout the United States.

THE HEALTH CARE AND FEDERALLY-FUNDED RELIEF PROGRAMS

21. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Medicare is a health financing program for the elderly. Entitlement to Medicare is based on age, disability, or affliction with end-

stage renal disease. 42 U.S.C. §§ 426, 426A. Medicare is administered by the Center for Medicare and Medicaid Services ("CMS").

22. Medicare pays for beneficiaries' use of generic drugs under Parts A or D. Part A covers prescription drugs received by beneficiaries while inpatients at hospitals or skilled nursing facilities during covered stays. In most instances, payment for the drugs are bundled together with other Medicare Part A reimbursable items. Part D refers to the Federal program to subsidize the costs of prescription drugs for Medicare beneficiaries enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act effective January 2006. Under Part D, the United States pays for outpatient prescription drugs of eligible Medicare participants by joining a qualified prescription drug plan or participating in the Medicare Advantage plan.

23. The Medicaid program is a health insurance program for qualified beneficiaries funded by Federal and State monies and enacted pursuant to Title XIX of the Social Security Act. 42 U.S.C. §§ 1396-1396v. Each State is permitted to design its own medical assistance plan. 42 U.S.C. § 1396a. The plans permit medical assistance in the form of outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A) & 1396d(a)(12).

24. CHAMPUS/TRICARE is a health care program providing health benefits, including prescription generic drug coverage for active duty military personnel, retirees, and their dependents. The Civilian Health and Medical Program of Veterans Affairs ("CHAMPVA") provides similar services and coverage for prescription generic drugs through the Veteran's Administration health system. The Federal Employee Health Benefits Program provides health care benefits, including prescription drugs, to Federal

employees, former employees, and survivors. In addition to these health care programs, the United States directly purchased Defendants' adulterated and misbranded drugs pursuant to programs administered by the Department of Veteran Affairs, which maintains medical facilities for approximately four million veterans, and the Department of Defense, which provides medical benefits to approximately eight million active duty military personnel, retirees, and their families.

25. The PEPFAR program is a Federally-appropriated relief program designed to, among other aspects, provide generic ARV drugs to HIV-infected patients in 120 countries. By early 2006, FDA had approved only 15 ARV products for PEPFAR, three of which were ANDAs filed by Defendants. Congress authorized the creation of an HIV/AIDS Working Capital Fund for the purpose of purchasing ARV drugs. 22 U.S.C. §§ 7612a(1)-(2). Each year, the United States funds the HIV/AIDS Working Capital Fund "for HIV/AIDS pharmaceuticals and products provides from the HIV/AIDS Fund received from applicable appropriations and funds" of USAID, the Department of Health and Human Services, the Department of Defense, "or other Federal agencies and other sources at actual cost of the HIV/AIDS pharmaceuticals and other products, actual cost plus the additional costs of provide such HIV/AIDSS pharmaceuticals and other products, or at any other price agreed to by the" Coordinator of the United States Government Activities to Combat HIV/AIDS Globally. 22 U.S.C. § 7612a(3). In addition to PEPFAR, the United States has purchased the ARV drugs as a part of other Federally-funded programs such as The Global Fund.

FEDERAL AND STATE FALSE CLAIMS ACTS

26. The Federal FCA, 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim made, is liable to the United States for a civil money penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

27. The Federal FCA also provides that any person who conspires to violate any provision of the Federal FCA is liable to the United States for a civil money penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(C).

28. The terms "knowing" and "knowingly" are defined to mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). These terms "require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B).

29. The term "claim" is defined to mean "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such

contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . ." 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

30. The States have enacted false claims statutes, the provisions of which mirror the Federal FCA provided in preceding paragraphs. Relator asserts claims under the statutes enacted by the States for the State portion of Medicaid false claims as stated herein. Relator's disclosure of substantially all material evidence and information Relator possesses will be served upon State officials as required by State law, including any supplemental disclosure statements.

FEDERAL REQUIREMENTS FOR GENERIC DRUGS

31. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, amended the FDCA by, among other aspects, enacting an Abbreviated New Drug Application ("ANDA") approval process allowing lower-priced generic drugs of previously approved innovator (listed) drugs to be approved and marketed in the United States. 21 U.S.C. § 355(j).

32. Among other requirements, ANDAs filed with FDA must include the following: (a) a statement that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a listed drug; (b) a statement that the active pharmaceutical ingredient in the drug is the same as the listed drug; (c) a statement that the route of administration, the dosage form, and the strength of the generic drug are the same as those of the listed drug; (d) a statement that the generic drug is bioequivalent to the listed drug; and (e) a statement that the labeling proposed for the new drug is the same as the labeling approved for the listed drug. 21

U.S.C. § 355(j)(2) and 21 C.F.R. § 314.94. An ANDA application must include a certification by the applicant that the underlying patent has not been filed (Paragraph I certification), the underlying patent has expired (Paragraph II certification), the date on which the patent will expire (Paragraph III certification), or a statement that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (Paragraph IV certification). In addition, a generic drug manufacturer is required by statute and regulation to timely file annual reports with FDA on Form FDA 2252 for each approved ANDA. The annual reports must identify chemistry, manufacturing, formulation, or control changes from those approved by FDA, along with batch-specific stability reports for the drug substance or product. 21 C.F.R. §§ 314.70 & 314.81. Mandatory annual reporting is designed to identify deviations that arise during commercialization of a drug, as compared to the protocols and specifications approved by FDA prior to commercial manufacturing, particularly as these deviations might affect the safety, effectiveness, or labeling of the product.

33. FDA has promulgated specific requirements for filing ANDAs and marketing generic drugs in the United States consistent with FDA's current good manufacturing practices ("cGMP"). The stated purpose of FDA's requirements is to ensure that drugs which are not safe and effective are not marketed and sold in the United States. 21 C.F.R. § 314.2.

34. Among other requirements, the generic drug subject to an ANDA must be demonstrated to be bioequivalent to the brand drug. Bioequivalence means "the absence of a significant difference in the rate and extent to which the active ingredient or active

moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1.

35. The generic drug also must be stable. Stability refers to the capacity of a finished drug or drug product to remain with established specifications and maintain its identity, strength, quality and purity throughout its shelf life. FDA requires a written stability testing program to assess and monitor the stability characteristics of drug products in order to determine the appropriate storage conditions and expiration dates. 21 C.F.R. § 211.166. FDA's stability regulations requires regular, reliable, and verifiable testing of the drug in the same container to be used in marketing the product.

36. The generic drug manufacturer, whether located in the United States or abroad, must comply with FDA's current good manufacturing practices ("cGMP") set forth at 21 C.F.R. § 211 *et seq.* in order to market and sell products in the United States. cGMP requirements regulate the control, management, and documentation of manufacturing and quality testing of generic drugs.

37. Deviation from cGMP regulations renders the generic drug adulterated or contaminated within the meaning of section 501(a)(2)(B) of the FDCA. 21 U.S.C. § 351(a)(1)(B). A generic drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with cGMPs to assure that the drug meets the requirements of the FDCA as to safety, identity, strength, quality, and purity characteristics it purports to possess. 21 U.S.C. § 351(a)(1)(B).

38. A generic drug is misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

39. FDA is authorized to reject an ANDA for any of the following reasons: (a) the application contains an untrue statement of material fact; (b) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity; (c) anomalies between the API in the innovator drug and the API in the ANDA, such as impurities or substandard API; (d) the information submitted in the ANDA is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug; or (e) the information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application. 21 U.S.C. § 355(j)(4).

40. The FDCA imposes civil and criminal penalties for violations of the FDCA or FDA's implementing regulations, including, for example, manufacturing, or shipping in interstate commerce an adulterated generic drug and the adulteration or misbranding of a generic drug. 21 U.S.C. § 331.

41. FDA is authorized to withdraw an ANDA if an approval was obtained through a material false statement or contains an untrue statement of material fact." 21 U.S.C. § 355(e).

DEFENDANTS' WRONGFUL ACTS

42. Relator is the former Director of Research Information & Project Management for Defendant RLL. He was hired on or about November 28, 2002. He

relocated from the United States to India and began working on-site at the company's Research and Development Center in Gurgaon, Haryana, India, at the end of June 2003. He resigned his position in or about April 2005.

43. Relator's job responsibilities gave him access to Defendants' portfolio of drugs sold in the United States and abroad. Relator had responsibility for portfolio and product management. He established a program management office which oversaw internal data created during the formulation and manufacturing of generic drugs. This complex process required Relator to compile information aggregating generic drug formulation, bioequivalence, and stability data, among other data. The purpose of the data management was to coordinate the filing and approval of ANDAs to coincide with two pivotal marketing opportunities: marketing exclusivity granted by FDA and patent invalidity. He prepared detailed status evaluations and revenue projections for each drug in Defendants' portfolio based on four global regions of business operations, including the United States market. Relator also was in charge of research and development informatics. This involved cutting-edge information technology initiatives designed and implemented by Relator to perform tasks, such as creating systems to file ANDAs electronically; collecting, managing, and reporting on Defendants' clinical data, including bioequivalence information; and creating an automated data archival system.

44. Relator's job responsibilities gave him comprehensive knowledge of, and access to, Defendant RLL's internal data pertaining to global operations, as well as specific data related to individual generic drugs under development, filed with regulatory

authorities, or approved by FDA in tentative or final form. Relator also had regular contact with Defendants' senior management.

45. In or about August 2004, Relator began a comprehensive, company-wide investigation and audit of Defendants' ARV drug and non-ARV drug portfolio. Relator undertook the investigation with the knowledge, authority, and support of Dr. Rajinder Kumar, then the Head of Research and Development for Defendant RLL. He reported to Dr. Kumar.

46. The purpose of the investigation was to assess whether Defendants and/or their authorized contract research organizations had falsified data for ARV and non-ARV drugs in order to gain approval for marketing the generic drugs in the United States and abroad.

47. Relator compiled a list of all Defendants' ARV drugs then in development or already approved for marketing. The list included, for example, (a) Lamivudine 150 mg plus Stavudine 30 mg; (b) Lamivudine 150 mg plus Stavudine 40 mg; (c) Lamivudine 150 mg plus Zidovudine 300 mg tablet; (d) Lamivudine 150 mg tablet; (e) Nevirapine 200 mg tablet; (f) Stavudine 30 mg capsule; (g) Zidovudine 300 mg tablet; and (h) Indinavir 400 mg capsule. The ARV drugs were sold in various combinations consistent with prescribed medical therapies to treat the HIV virus. Each of the products is a generic version of a patented (or then patented) listed drug.

48. After identifying the ARV drugs manufactured by Defendants, Relator contacted the functional groups responsible for the formulation, testing, and post-registration commercial manufacturing of the generic drugs. As part of his investigation,