UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: RANBAXY GENERIC DRUG APPLICATION ANTITRUST LITIGATION	MDL No. 19-md-2878-NMG
THIS DOCUMENT RELATES TO: *United Food and Commercial Workers Health and Welfare Fund of Northeastern Pennsylvania v. Ranbaxy Inc., et al.*, No. 19-cv-10356 (D. Mass) *Louisiana Health Services & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana, et al. v. Ranbaxy Inc., et al.*, No. 19-cv-10274 (D. Mass)	Class Action Jury Trial Demanded LEAVE TO FILE GRANTED ON FEBRUARY 26, 2021

SECOND AMENDED CONSOLIDATED END-PAYOR CLASS ACTION COMPLAINT AND JURY DEMAND

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United Food and Commercial Workers Health and Welfare Fund of Northeastern Pennsylvania ("UFCW"); Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana ("BCBSLA"); and HMO Louisiana, Inc. (collectively "Plaintiffs"), on behalf of themselves and a proposed class of similarly situated end-payors ("EPPs"), bring this action against Ranbaxy Inc., Ranbaxy Laboratories, Ltd., Ranbaxy U.S.A., Inc., and Sun Pharmaceutical Industries Ltd. and allege the following based on (a) personal knowledge as to themselves, (b) investigation of counsel, and (c) information and belief.

I. INTRODUCTION

1. Today, most of the drugs U.S. Consumers take (4 in every 5 prescriptions) are generic drugs. Over the past three decades, the generic drug industry has made enormous progress in gaining widespread acceptance for their generally safe, effective, and affordable prescription drugs. In the pharmaceutical industry, generic drugs offer consumers substantial cost savings compared to their brand alternatives but must conform to regulatory requirements to ensure they are truly safe and effective alternatives to brand medication.

2. While new brand or "innovator" drugs require years of research, development, testing, and trials before they can gain approval for sale in the United States, Congress recognized that an expedited application and approval process for the nearly identical generic drug would benefit U.S. consumers by generating competition and driving down costs. To accomplish this end, Congress passed the Hatch-Waxman Amendments and established the Abbreviated New Drug Application ("ANDA").

3. To balance the desire to bring generic drugs to market faster with the need to ensure a generic drug's safety, effectiveness, and equivalence to the brand drug, the United States Food and

Drug Administration ("FDA") oversees the ANDA application process, which requires generic manufacturers to submit to certain testing, documentation, and storage protocols.

4. Beginning in the early 2000s, Ranbaxy, one of the world's largest generic pharmaceutical manufacturers, pursued an aggressive business growth strategy at the expense of quality and integrity. Ranbaxy recklessly and fraudulently bogged down the FDA generic approval process because its manufacturing conditions were grossly inadequate, wrongfully acquiring the ability to preclude or stall the efforts of other generic companies that were responsibly seeking to enter U.S. markets, all at the direct expense of U.S. drug purchasers. Ranbaxy's actions delayed the market entry of generic drugs, hurting consumers and end-payors who paid supracompetitive prices for brand medication, or a lone generic drug, when more affordable generic alternatives should have been available.

5. Instead of abiding by the limited regulations required of ANDA applicants, Ranbaxy adopted a practice of blatantly disregarding testing, storage, and documentation protocols. While most generic pharmaceutical companies devote an average of 18 months to the necessary testing before filing an ANDA, Ranbaxy required only 12 months. As a result, Ranbaxy was routinely able to acquire "first-to-file" status.

6. Ranbaxy exploited these shortcuts to achieve its objective: as coveted first-filers, Ranbaxy positioned itself to reap enormous profits. First-to-file status guaranteed Ranbaxy 180 days of exclusivity over the generics market. During the 180-day exclusivity period, no other generic manufacturer can gain final FDA approval and enter the market. The 180-day or 6-month window begins from the date Ranbaxy starts to sell its product. As the first-entry generic and only ANDA-based competitor to the brand product, Ranbaxy can price its drug slightly below the brand competitor, gain most of the market share, and all the associated profits with none of the front-end research and development costs required to develop new drugs.

7. If the first-filer diligently pursues final approval from the FDA, consumers can enjoy a 20-30% percent reduction in costs when the first generic enters the market and often an 80-90% reduction once the 180-day exclusionary period is over and additional generic competitors enter the market.

8. Ranbaxy, however, exploited the ANDA process by ignoring FDA documenting, testing, and storage protocols designed to ensure the drug's safety, efficacy, and equivalency to the brand drug. Ranbaxy convinced unknowing regulators reviewing these applications that Ranbaxy's facilities and procedures were, or would soon be, in compliance, when in fact the facilities would remain noncompliant for years. Ranbaxy did so with little regard for whether it would be able to promptly bring the generic drug to market. With a single-minded focus on obtaining first-to-file status, Ranbaxy routinely submitted as many ANDA applications as possible in order to obtain "tentative approval" from the FDA, regardless of whether Ranbaxy itself could eventually get its own product to the market in a timely manner, if at all.

9. In order to preserve their first-to-file status, once the FDA accepts "receipt" of the ANDA, the filer must obtain "tentative approval" by a certain date and bring the drug to market in a "timely" fashion following final approval. During the period between the filing of the ANDA and tentative approval, as well as the period between tentative approval and final approval, the FDA undertakes further review of the ANDA applications, which must continue to comply with Current Good Manufacturing Practice ("cGMP") regulations and meet the required standards for safety, efficacy, and stability.

10. In 2004 and 2005, Ranbaxy filed 52 new ANDAs, claiming first-to-file status on 19, including those for valsartan tablets (sold under the brand name Diovan); valganciclovir hydrochloride tablets (sold under the brand name Valcyte), and esomeprazole magnesium (sold under the brand name Nexium).

11. A series of reports, inspections, and investigations would ultimately reveal an internal corporate culture at Ranbaxy that promoted fraud over accuracy and compliance. Ranbaxy corporate leadership had numerous opportunities to correct their manufacturing practices, comply with regulations, and conform to cGMP standards. Instead, they actively pursued a strategy of delay and deception. An audit in 2003, a World Health Organization audit in 2004, an internal employee investigation in 2004, and another audit in 2005 all revealed a pattern of tainted formulas, falsification and fabrication of data and studies, misrepresentations to regulators, use of substandard ingredients, and many other failures vital to ensure the safety, efficacy, and stability of generic drugs. In early 2006, FDA inspections of Ranbaxy facilities would document similar findings.

12. In June 2006, when Ranbaxy failed to satisfactorily respond to the FDA's findings of cGMP compliance failures, the FDA issued a warning letter and recommended withholding approval of all ANDAs originating from Ranbaxy's Paonta Sahib facility in India. In 2007 and again in 2008, Ranbaxy misleadingly represented to the FDA that the processes in place at its Paonta Sahib plant were (or as a practical matter soon would be) in compliance with FDA requirements concerning cGMP. In fact, those conditions were so poor that Ranbaxy could not fix them for more than eight years (and Ranbaxy remains out of compliance to this day).

13. In order to maintain first-to-file status and with it the coveted 180-day exclusivity, Ranbaxy needed to secure tentative approval for their generic Diovan, Nexium, and Valcyte ANDAs by October 2007, February 2008, and June 2008, respectively. Tentative approval requires the ANDA applicant to meet all the substantive requirements for approval, including cGMP compliance. Though Ranbaxy's facilities, testing, and storage practices were woefully non-compliant, and the FDA had identified cGMP issues, the FDA ultimately granted tentative approval for these ANDAs based on Ranbaxy's continuous false reassurances that remedial actions were taken and that the regulatory failures were resolved.

14. Ranbaxy even validated their compliance through purportedly independent attorneys and consultant auditors. The auditor supposedly conducted audits of each Ranbaxy ANDA, but in coordination with Ranbaxy and the attorneys, continued to delay production of their audit reports while providing false representations that any compliance deficiencies had been remedied, all to prevent adverse action by the FDA against Ranbaxy.

15. Armed with tentative approvals, Ranbaxy had the authority to bring Diovan, Nexium, Valcyte, and other drugs to market pending the resolution of litigation. Instead of diligently pursuing market entry, Ranbaxy, supported by their law firm and consultant, employed further delay tactics: settling patent infringement litigation with corresponding brand manufacturers which delayed entry of their generic product; misleading the FDA by preventing the agency from obtaining access to the full audit reports of Ranbaxy's facilities; and ultimately failing to bring their facilities into compliance such that they could adequately manufacture the generic drugs approaching eligibility for market-entry. It would take years for the FDA to untangle Ranbaxy's web of lies. Ranbaxy would hold onto their 180-day exclusivity period as Ranbaxy's overall course of misconduct not only snarled its own ANDAs from being approved, but also prevented other would-be generic manufacturers from entering each particular generic drug market.

16. In 2012, after issuing subpoenas, executing search warrants, and launching a criminal investigation, the U.S. Department of Justice ("DOJ") filed a civil complaint and consent decree. Ranbaxy agreed to remedy its misconduct and bring its drug manufacturing operations into compliance. Many Ranbaxy ANDAs were withdrawn, resubmitted, or placed on hold. In 2013, Ranbaxy entered into a plea agreement with the federal government, paying $350 million in fines for selling adulterated drugs in the United States. Ranbaxy pled to serious compliance violations and multiple examples of fraud related to their regulatory submissions. Under the government settlements, Ranbaxy still maintained their first-to-file status for five "Excepted Applications,"

including Nexium, Diovan, and Valcyte. These drugs were subject to additional FDA audits, but did not lose their right to the 180-day exclusivity period.

17. Despite the opportunity to once again comply and bring these Excepted Application drugs to market, Ranbaxy's obstinate delay tactics and excessive compliance failures continued. Their scheme of fraud and deception prevented generic alternatives for Nexium, Diovan, and Valcyte from promptly entering the market. Ranbaxy originally applied for the Diovan, Nexium, and Valcyte ANDAs in 2004-2005. Patent settlements did not allow for the entry of generic Diovan, Nexium, and Valcyte until 2012, 2014, and 2013, respectively. Still, Ranbaxy's failure to comply delayed the entry of a generic product onto the market for at least another 28 months for Diovan, 9 months for Nexium, and 20 months for Valcyte.

18. This lawsuit seeks monetary relief on behalf of all end-payors of drugs for which generic entry was delayed in substantial part by Ranbaxy's wrongful acquisition and maintenance of 180-day exclusivities. This action pleads with particularity that (i) the end-payors of the brand drug Valcyte (valganciclovir hydrochloride) and its A/B-rated generic equivalents overpaid for that product because Ranbaxy's wrongful conduct delayed the generic entry for valganciclovir hydrochloride at least between August 1, 2014 and November 20, 2014, (ii) the end-payors of the brand drug Diovan (valsartan) and its A/B-rated generic equivalents overpaid for the product because Ranbaxy's wrongful conduct delayed the generic entry for valsartan at least between September 28, 2012, and July 7, 2014, and (iii) the end-payors of the A/B-rated generic equivalents of Nexium (esomeprazole magnesium) overpaid for that product because Ranbaxy's wrongful conduct delayed the generic entry for esomeprazole magnesium at least between May 27, 2014 and January 27, 2015.

19. Plaintiffs seek relief under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"). Ranbaxy effectuated its fraudulent scheme, the "Ranbaxy ANDA

Enterprise," only through the knowing assistance of others, including a group of lawyers (to shield otherwise routine quality control documentation from FDA scrutiny) and a purportedly independent regulatory consultant (to give an untrue air of prompt action and truthful reporting). By means of a pattern of repeated mail and wire fraud through these enterprises, Ranbaxy wrongfully obtained, fraudulently locked-in, and abused the first-to-file, 180-day exclusivity period for several drugs, including generic Diovan, Valcyte, and Nexium. Because of Ranbaxy's fraud and delay tactics, end-payors paid supracompetitive prices for brand and/or generic Diovan, Nexium, and Valcyte products when a safe, effective, and cheaper generic alternative(s) should have been available. Ranbaxy's conduct violated sections 1962(c) and (d) of RICO and is civilly actionable under section 1964 of that law.

20. Plaintiffs seek relief under state antitrust and consumer protection laws. Ranbaxy wrongfully obtained, fraudulently locked-in, and then abused the first-to-file, 180-day exclusivity period for several drugs, including generic Diovan, Nexium, and Valcyte. By fraudulently acquiring and later using this exclusivity to exclude other would-be generics, Ranbaxy acquired and misused market power with respect to these drugs, causing prices to remain at supracompetitive levels, and resulting in Plaintiffs and the Classes paying far more for these drugs than they otherwise would have.

II. PARTIES

21. Plaintiff United Food and Commercial Workers Health and Welfare Fund of Northeastern Pennsylvania ("UFCW") maintains its principal place of business at 3031B Walton Road, Plymouth Meeting, Pennsylvania 19462. UFCW operates a health and welfare benefit plan for its members, retirees, and/or plan beneficiaries and pays and/or provides reimbursement for the purchase of prescription drugs. UFCW purchased, paid and/or provided reimbursement for substantial quantities of Nexium, Diovan, Valcyte, and their AB-rated generic equivalents during the

relevant time period for each drug. UFCW paid grossly inflated prices for these drugs due to the fraudulent and deceptive practices alleged in this Complaint and was injured as a result of the illegal and wrongful conduct alleged herein.

22. Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana is a domestic health insurance corporation licensed to conduct business in the state of Louisiana. Blue Cross and Blue Shield of Louisiana provides and manages health benefits to more than 1 million insureds and members. Blue Cross and Blue Shield of Louisiana also provides third-party administrative services for insureds and members. Blue Cross and Blue Shield of Louisiana has paid all or part of the cost of its participants' purchases in Louisiana and throughout the United States of Nexium, Diovan, Valcyte, and their AB-rated generic equivalents during the relevant time period for each drug.

23. HMO Louisiana, Inc. is a domestic health maintenance organization licensed to conduct business in the state of Louisiana. HMO Louisiana, Inc. provides and manages health benefits to insureds and members and has paid all or part of the cost of its participants' purchases of Nexium, Diovan, Valcyte, and their AB-rated generic equivalents in Louisiana and throughout the United States during the relevant time period for each drug.

24. Blue Cross and Blue Shield of Louisiana and HMO Louisiana, Inc. are collectively referred to hereafter as "BCBSLA." BCBSLA paid grossly inflated prices for Nexium, Diovan, Valcyte, and their AB-rated generic equivalents due to the fraudulent and deceptive practices alleged in this Complaint and was injured as a result of the illegal and wrongful conduct alleged herein.

25. Defendant Ranbaxy Laboratories Limited ("Ranbaxy Labs") was a corporation that, until March 25, 2015, was organized and existed under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Ranbaxy Labs was the parent company to the entire Ranbaxy business empire, which was, until March 2015, the largest

generic drug manufacturer in India. It controlled manufacturing, research, and development, as well as the conduct and functioning of its Indian-based facilities, including a facility located at Paonta Sahib, India.

26. Defendant Ranbaxy, Inc. is a corporation that is organized and exists under the laws of the State of Delaware and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Inc. was responsible for (a) communications with the FDA on behalf of Ranbaxy Labs and its related entities; (b) prosecution of ANDAs on behalf of Ranbaxy Labs; and (c) management of U.S. litigation on behalf of Ranbaxy Labs and its related entities. At all relevant times, Ranbaxy, Inc. acted in its own right and as an agent of defendant Ranbaxy Labs.

27. Defendant Ranbaxy USA Inc. ("Ranbaxy USA"), was a corporation that, until October 24, 2014, was organized and existed under the laws of Florida and had a principal place of business located at 9431 Florida Mining Boulevard E, Jacksonville, FL 32257. Ranbaxy USA was a wholly-owned subsidiary of Ranbaxy, Inc. Ranbaxy USA was responsible for the distribution of Ranbaxy Lab's generic drug products in interstate commerce. In 2013, Ranbaxy USA pleaded guilty to making false claims to the U.S. government, and to introducing adulterated drugs into interstate commerce. On June 3, 2014, Ranbaxy Inc. authorized the dissolution of Ranbaxy USA, and this dissolution became effective October 24, 2014. At all relevant times, Ranbaxy USA acted in its own right and as an agent of Ranbaxy Labs.

28. Plaintiffs shall collectively refer to Defendants Ranbaxy Labs, Ranbaxy Inc., and Ranbaxy USA as "Ranbaxy."

29. Defendant Sun Pharmaceutical Industries Limited ("Sun Pharma") is a public limited company incorporated under the laws of India with its registered office at Sun Pharma Advanced Research Centre (SPARC), Tandalja, Vadodara – 390 020, Gujarat, India, and its corporate office at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai – 400 059, Maharashtra, India. Sun

Pharma is an international, integrated, specialty pharmaceutical company. Under a Scheme of Arrangement between Ranbaxy Labs and Sun Pharma, approved by the two companies' boards on April 6, 2014, Sun Pharma completed its acquisition of Ranbaxy Labs on or about March 25, 2015 and now owns Ranbaxy. Ranbaxy Labs is no longer listed on the Indian Stock Exchanges. All liabilities of Ranbaxy Labs, including contingent liabilities, were transferred to and vested in Sun Pharma in accordance with the Scheme of Arrangement as follows:

> All the liabilities including all secured and unsecured debts, whether in Indian rupees or foreign currency), sundry creditors, contingent liabilities, duties, obligations and undertakings of [Ranbaxy Laboratories Limited] of every kind, nature and description whatsoever and howsoever arising, raised or incurred or utilized for its business activities and operations (the "Liabilities") shall, without any further act, instrument or deed, be and the same shall stand transferred to and vested in or deemed to have been transferred to and vested in the Transferee Company without any further act, instrument or deed, along with any charge, lien, encumbrance or security thereon…

III. JURISDICTION AND VENUE

30. This action arises under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1962(c) and (d) and 1964. Plaintiffs and class members seek damages for their injuries, and those suffered by members of the EPP classes, resulting from the defendants' fraudulent and anticompetitive conduct that delayed the entry of generic drugs into the U.S. market.

31. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331(federal question), 1332 (diversity due to a qualifying class action), and 18 U.S.C. § 1964(c) (RICO).

32. The defendants transact business within this district, and they transact their affairs and carry out interstate trade and commerce, substantially, in this district and/or have an agent and/or can be found in this district. Venue, therefore, is appropriate within this district under 28 U.S.C. §1391 and under RICO, 18 U.S.C. § 1965(a).

33. The Court has supplemental jurisdiction over the claims for violations of state antitrust and consumer protection statutes.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The Regulatory Framework: The New Drug Approval Process

34. The FDA regulates the marketing and promotion of prescription drugs. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use and obtain FDA approval before marketing and selling a prescription drug.[1]

35. When a pharmaceutical company seeks to introduce a new drug product onto the market (commonly called a "brand" or "innovator" product), it must undergo extensive development, testing, and FDA approval – a time-intensive and costly process. The average testing phase is between 6-9 years, after which manufacturers file a New Drug Application ("NDA") with the FDA.[2] An NDA must include conical study data concerning the safety and effectiveness of the drug, testing and manufacturing processes that comply with federal regulations, and any information on applicable patents.[3] FDA approval of an NDA will take years and is dependent upon the patent filings, which may take as long as 2 years before a brand-name drug may be distributed and marketed. Because generic drugs are essentially replications of previously approved drugs (also called the "reference drug"), they can take advantage of an expedited process to gain approval and enter the market. In 1984, Congress enacted the Hatch-Waxman Amendments ("Hatch-Waxman") to the FDCA to encourage the production and sale of cheaper generic drugs by simplifying the regulatory hurdles that generic pharmaceutical manufacturers must clear to market and sell their low-cost drug products.[4]

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[1] See 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a), 360b(a).

[2] 21 U.S.C. §§ 301-392.

[3] 21 U.S.C. § 355(a), (b).

[4] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

36. With the implementation of the Hatch-Waxman Amendments, a generic manufacturer can file an Abbreviated New Drug Application ("ANDA") with the FDA to obtain approval for the marketing and distribution of a generic drug. An ANDA does not require a generic manufacturer to provide additional clinical studies supporting the safety and efficacy of the drug, and they may rely on the scientific safety and effectiveness included in the brand manufacturer's original NDA. Rather, an ANDA filer needs to show that a generic drug is both a pharmaceutical equivalent and bioequivalent to the brand name drug (collectively "therapeutically equivalent").

37. The FDCA and Hatch-Waxman operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[5]

38. Through Hatch-Waxman, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

39. Hatch-Waxman achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historically high profit margins for brand name pharmaceutical companies. In 1983, before Hatch-Waxman, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of

[5] 21 U.S.C. § 355(j)(8)(B).

prescriptions.[6] By 2013, total annual prescription drug revenue had soared to over $329 billion, with generic drugs accounting for 84% of prescriptions.[7]

i. ANDA Approval

40. Receipt of an ANDA marks the first step in a complex process involving reviews of the generic drug manufacturer's application by many disciplines within the FDA, including bioequivalence, chemistry, labeling, and manufacturing. Multiple "review cycles" by the Office of Generic Drugs ("OGD"), the generic application approval arm of the FDA's Center for Drug Evaluation and Research ("CDER"), are often required before an application may be deemed ready for approval.

41. Once an applicant files an ANDA, the FDA must determine whether it contains the information required under 21 U.S.C. § 355(j)(2)(A), such that it may be "received." In order for the FDA to accept "receipt" of an ANDA, it must make a threshold determination that the abbreviated application is "substantially complete" to permit a substantive review.[8] In order to be substantially complete, an ANDA must "on its face [be] sufficiently complete to permit a substantive review and contain[] all the information required by paragraph (2)(A)."[9]

42. The expedited ANDA approval process relieves the generic manufacturer from the burden of conducting clinical trials to demonstrate the safety and efficacy of their generic drugs. A generic drug company may rely on the clinical trials performed by the branded drug company, so long as it makes three key showings to demonstrate "therapeutic equivalence:"

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[6] *See* IMS Institute for Healthcare Informatics, Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013, 30, 51 (2014).

[7] *Id.* at 51.

[8] 21 C.F.R. § 314.101(b)(1); see also 21 U.S.C. § 355(j)(5)(B)(iv)(II)(cc) (an ANDA is "substantially complete" if, on its face, it "is sufficiently complete to permit a substantive review and contains all the information required by paragraphs (2)(A).").

[9] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(cc).

a. First, an ANDA must demonstrate that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug – that is, that the generic drug is bioequivalent to the brand name drug.

b. Second, it must demonstrate that the generic manufacturer can reliably manufacture a safe, stable drug product.[10]

c. Third, an ANDA must contain information demonstrating compliance with cGMP regulations. cGMPs are the main regulatory standard for pharmaceutical quality and establish protocols to ensure proper design, monitoring, and control of manufacturing processes and facilities. These procedures require, among others: detailed, written steps describing the receipt, identification, storage, handling, sampling, and testing of drug products;[11] testing to ensure the identity, purity, strength, and quality of the drug;[12] and regular stability testing of the products.[13]

43. When the FDA approves an ANDA, that generic drug receives an "AB rating" from the FDA, signifying that the drug is therapeutically equivalent to a referenced brand-name drug. The premise is that two drug products containing the same active pharmaceutical ingredient, in the same dose, delivered in the same way, and absorbed into the blood stream at a similar rate over a similar period are expected to be equally safe and effective.

44. Because a generic drug does not undergo the same rigorous clinical testing as the brand drug, the therapeutic equivalence requirements are critical to ensure the drug is safe and effective. The FDA may not approve a drug for sale, and a manufacturer may not sell a drug, if:

[10] 21 U.S.C. § 355(j)(2)(A).

[11] 21 C.F.R. § 211.80(a).

[12] 21 C.F.R. § 211.84(d).

[13] 21 C.F.R. § 211.166.

> 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 current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.[14]

The Office of Compliance ("OC"), a division of CDER, is charged with ensuring that a manufacturer complies with FDA regulations, including those related to cGMP.

45. Stability testing is an integral component of cGMPs. Tests typically performed at extended intervals - for example, at 3, 6, and 9 months after a batch of the drug is manufactured – determine how long the drug remains safe and effective for use and dictate the expiration date for the tested drug. The cGMP regulations require a drug manufacturer to develop, implement, and follow a written testing program to assess the stability of each drug it manufactures. The results of stability testing are used by the FDA to determine appropriate storage conditions and expiration dates for a drug.

46. In its ANDA application, a generic manufacturer must also certify that the generic drug addressed in its ANDA will not infringe on any valid patents covering the brand version of the drug. An applicant can make one of four certifications:

a. that no patent for the brand name drug has been filed with the FDA;

b. that the patent for the brand name drug has expired;

c. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").[15]

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[14] 21 U.S.C. § 335(j)(4)(A); 21 U.S.C. §§ 331, 351(a)(2)(B); 21 C.F.R. Parts 210 and 211 (cGMP requirements for drugs)

[15] 21 U.S.C. § 355(j)(2)(A)(vii).

i. Incentive to File the First ANDA Despite Potential Litigation

47. A pharmaceutical company developing a new drug files a series of patents throughout the research and development stages to protect their new "invention." The typical patent portfolio for a brand drug begins with the most significant patents initially issued around the active compound in a prescription drug. As the research and testing progress, the patents they file continue to narrow in relation to specific formulations, usages, or processes for each drug. Each time a new, narrower patent is filed, it incorporates the original patent as "prior art."

48. While these later filed patents attempt to deter generic drug entry, they become increasingly difficult to obtain and enforce and thus, more susceptible to litigation. Earlier, broad patents covering a drug's active ingredient – if valid and enforceable – may prove impossible to design around, but they were also filed in the very early stages of the drug's development and are therefore the first to expire. As the number of patent filings for the drug grows, so too does the brand company's difficulty in obtaining valid, enforceable patents. Later patents, covering only a particular formulation or release profile may be easier to design around.

49. Generics may be classified as (i) first-filer generics, (ii) later generic filers, or (iii) authorized generics.

50. The Hatch-Waxman Amendments encouraged generic manufacturers to bring generic options to market sooner by providing an incentive to file ANDAs earlier. The first generic manufacturer to file a substantially complete ANDA under a Paragraph IV certification ("first-filers," challenging an existing brand's patent) receives a 180-day exclusivity period, so no other generic manufacturers can enter the market for 180 days.[16] The 180-day exclusivity period does not

[16] 21 U.S.C. § 355(j)(5)(B)(iv), (D). There is a minor exception to this exclusivity period. Other ANDA-approved generic makers must wait six months from the first filer's market entry to receive FDA approval, but the brand's "authorized generic," marked under the authority of the brand manufacturer's NDA, may enter at any time.

begin until the first-filer enters the market with distribution and sale of their drug. Because state substitution laws allow generics to rapidly gain substantial market share and the price discount that occurs is modest until another generic enters the market, the first-to-file status provides a significant financial advantage to the generic manufacturer. They often earn the vast majority of their profits during that 6-month period, which even the Supreme Court has acknowledged is potentially worth "several hundred million dollars."[17]

51. The Paragraph IV certification and the accompanying exclusionary period for first-filers also comes with risk. If a generic manufacturer files a Paragraph IV certification, the brand name manufacturer can delay FDA approval of the ANDA by initiating a patent infringement action. If that action is filed within 45 days of receiving notification of the Paragraph IV certification ("Hatch-Waxman Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months (commonly called the "30-month stay") or (b) a final decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[18] If a generic manufacturer files a Paragraph IV Certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. However, the generic manufacturer maintains their "first-to-file" status through this waiting period and receives their 180-day exclusivity upon the FDA's final approval.

ii. Tentative Approval

52. When an ANDA otherwise meets the substantive requirements for approval but cannot receive final approval because of pending Hatch-Waxman litigation or some form of

[17] *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 144 (2013)

[18] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30-month stay." The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

exclusivity (*i.e.*, a valid patent or marketing exclusivity granted by the FDA), the FDA may grant the application "tentative approval."[19]

53. To receive tentative approval, an ANDA must meet all of the requirements for approval generally; that is, the only barrier to outright approval must be the pendency of litigation or an exclusivity period.[20] Therefore, an ANDA may not receive tentative approval if, for example, bioequivalence is not shown, or if cGMP compliance is not established.

54. An ANDA that receives tentative approval may not legally be marketed until the FDA conducts any necessary additional review of the application, confirms that the application continues to meet the standards for approval, and issues a final approval letter.[21]

iii. Revocation of 180-Day Exclusivity

55. The Hatch-Waxman regulatory scheme was intended to incentivize early generic entry to market, but brand and generic companies sometimes abuse this scheme. The 180-day exclusivity obtained by the first-to-file generic is valuable to both the generic and the brand because it delays substantial competition to the brand drug. Recognizing that the Hatch-Waxman scheme imposed no penalty on first-to-file ANDA applicants that delayed coming to market, brand name companies would use Paragraph IV patent litigation as a pretext to enter settlements, essentially paying the first-filer to stay off the market. Because that first-filer also held the 180-day exclusivity, by preventing the first-filer from entering the market, the brand also prevented all other generic competitors from entering the market, creating a "bottleneck." Generic companies holding first-to-file exclusivity would leverage their first-to-file status into a large payment from the brand company, often substantially delaying the timely appearance of generic drugs in the marketplace.

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[19] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.107(b)(3)(v)

[20] 21 U.S.C. § 355(j)(5)(B)(iv)(dd)(AA)

[21] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB); 21 C.F.R. §§ 314,105(d), 314.107(b)(3)(v).

56. To prevent this abuse, Congress amended the FDCA, passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA").[22] The MMA codified the FDA's long-standing practice of issuing tentative approval for generic drugs ensnared in litigation and it enumerated conditions under which a first-to-file ANDA applicant may forfeit its 180-day exclusivity. Congress added these provisions to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition."[23]

57. A first-to-file generic applicant forfeits its 180-day exclusivity if: (1) it fails timely to market the drug; (2) it withdraws the ANDA, or the FDA constructively withdraws it on the manufacturer's behalf because "the application does not meet the requirements for approval;" (3) it amends or withdraws its Paragraph IV certification; (4) it fails to obtain tentative approval "within 30 months after the date on which the application is filed;"[24] (5) it enters into an anticompetitive agreement with another applicant; or (6) all valid patents over the brand version of the drug expire.[25]

58. Because of the MMA, a generic applicant must obtain at least tentative approval within 30 months of the date the ANDA was filed to preserve its 180-day exclusivity period.

iv. Final Approval

59. The FDCA states that the FDA "shall approve" an ANDA "unless" the agency finds that one or more specified conditions are present. As with tentative approval, the FDA cannot grant final approval if, inter alia, "the methods used in, or the facilities and controls used for, the

[22] Pub. L. No. 108-173, Stat. 2066 (Dec. 8, 2003)

[23] 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer)

[24] A narrow exception to this condition exists where "the failure [to obtain tentative approval within 30 months] is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed." 21 U.S.C. § 355(j)(5)(D)(i)(IV).

[25] 21 U.S.C. § 355(j)(5)(D)(i)(I)-(VI)

manufacture, processing, and packing of the drugs are inadequate to assure and preserve its identity, strength, quality, and purity."[26]

60. Once the FDA issues final approval, the first-to-file generic drug can be marketed, sold, and distributed to United States consumers

B. Generic Drugs Provide a Cheaper Alternative to Brand Name Drugs

61. Generic drugs provide a lower-cost but therapeutically equivalent substitute for brand-name drugs. Generic versions of a brand name drug contain the same active ingredient and, upon regulatory approval, are determined by the FDA to be just as safe and effective as their brand-name counterparts. Generic drugs approved by the FDA must be "therapeutically equivalent" to their brand counterpart, which grants them an "AB rating."

62. Because AB-rated generic drugs are therapeutically equivalent to both a referenced brand-name drug and each other, generic drugs referencing the same brand drug but manufactured by different companies can be readily substituted for one another. The only material difference between therapeutically equivalent generic drugs and their corresponding brand name versions is price. The products behave like commodities, where the basis for competition is price. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers.

63. In the United States, a licensed pharmacist must dispense a prescription drug to a patient under a doctor's prescription that identifies the drug. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). When a prescription

[26] 21 U.S.C. § 355(j)(4)(A).

identifies a brand-name drug, pharmacists may (and, in most states, must) substitute an AB-rated generic for the brand-name drug without seeking or obtaining permission from the prescribing doctor pursuant to these laws.

64. The institutional features of pharmaceutical distribution create a unique economic dynamic: AB-rated generic drugs, once they enter the market, gain market share rapidly while the brand-name drug swiftly loses market share, causing rapid price decline. The generic drug company typically captures 80% or more of the market within the first six months. In a study by the Federal Trade Commission ("FTC"), within a year of generic entry, on average, the generics captured 90% of the corresponding brand's drug sales and prices dropped (with multiple generics on the market) an average of 85%.[27]

65. Because of the regulatory structure, the first generic drug to enter the market typically enjoys a 180-day market exclusivity period. During this exclusivity period, other generic manufacturers cannot market and distribute their AB-rated generic versions of the brand name drug. The first-entry generic, therefore, is the only ANDA-approved generic manufacturer on the market.

66. With the launch of the first, substitutable AB-rated generic drug, average prices for that drug decrease significantly. When there is a single generic on the market, the drug typically offers a 20-30% discount from its brand-name competitor.[28] The brand-name competitor rarely lowers their prices to match the single competitor, so the generic typically captures an overwhelming majority of unit sales while offering a relatively modest discount. As such, generic drugs that obtain

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[27] *See* FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

[28] FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact ii-iii, vi, 34 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at

the 180-day exclusivity period have a significant financial advantage, and the Supreme Court has recognized it is often the case that most of a first-filer's profits with respect to an ANDA product are earned during the exclusivity period.[29]

67. According to the FDA and FTC, the greatest price reductions occur when the number of generic competitors increases from one to two, which brings prices down to about a 50% discount. Once multiple generic manufacturers enter the market, prices decrease to their lowest levels, with discounts up to 85-90% as price competition increases.[30]

68. Until a generic version of the brand drug enters the market, there is no bioequivalent generic to substitute for and compete with the brand drug. Without competition, the brand manufacturer can continue to charge supracompetitive prices and reap the profits. Brand name drug manufacturers, therefore, view competition from generic drugs as a dire threat to their profits and resort to any means possible to extend their monopoly.

69. Generic competition enables all end-payors of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 billion to $10 billion a year at retail pharmacies and hospitals.[31]

V. FACTS

A. Ranbaxy's Business Model Focused on First-to-File ANDAs

[29] *See Actavis*, 570 U.S. at 144.

[30] *See, e.g.* https://www.ftc.gov/system/files/documents/videos/understanding-competition-prescription-drug-markets-intro-keynote-remarks/ftc_understanding_competition_in_prescription_drug_markets_-_transcript_segment_1.pdf; Tracy Regan, Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market, 26 Int'l J. Indus. Org. 930 (2008); Richard G. Frank, The Ongoing Regulation of Generic Drugs, 357 New Eng. J. Med. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, Does Regulation Drive Out Competition in Pharmaceutical Markets?, 43 J.L. & Econ. 311 (2000).

[31] *See* Generic Drugs: Questions and Answers, FDA, http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last visited February 21, 2019).

70. Ranbaxy was originally founded in 1961 as a manufacturer of bulk ingredients. Beginning in the early 1990s, Ranbaxy shifted its focus to the development and sale of generic pharmaceutical products. Ranbaxy filed its first ANDA with the FDA in 1995, targeting the United States as the source of its future revenue growth.

71. By the late 1990s and early 2000s, Ranbaxy initiated a new business strategy of filing the first ANDA for as many high sales drug products as possible. Doing so enabled Ranbaxy to claim the coveted, first-to-file 180-day exclusivity for that product, which it leveraged for huge profits despite compliance failures that might prevent or delay its own market entry.

72. As part of its strategy, Ranbaxy leveraged its first-to-file status with brand name and generic competitors, regardless of whether Ranbaxy could bring the generic drug to market (because its manufacturing plants might be woefully unable to produce acceptable generic products). After a generic company files an ANDA under Paragraph IV certification, brand manufacturers often initiate patent infringement lawsuits against the Paragraph IV filer. Ranbaxy often negotiated "settlements" with brand companies, typically after receiving tentative approval and locking in its 180-day exclusivity. Settlement negotiations served as business deals, whereby Ranbaxy agreed to a delayed entry date (often years later) for the generic drug in order to avoid patent infringement and the brand company payed Ranbaxy. During this time, because of Ranbaxy's exclusivity, no other generic manufacturer could come to market either. Ranbaxy could also leverage its exclusivity with other generic manufacturers by releasing its 180-day exclusivity in exchange for up-front payments or a piece of the competitor's sales.

73. With a sole focus on speed instead of truthfulness and accuracy, Ranbaxy's averaged 12 months to complete the necessary testing and file an ANDA, while its competition averaged 18 months or longer. Ranbaxy achieved this rapid pace by filing applications for approval of generic products, many of which would later be the subject of false documentation and misrepresentations.

For years, Ranbaxy submitted to the FDA fraudulent and forged data, including false or misleading reports of product tests and manufacturing processes that could not ensure a safe and consistent generic drug product. Ranbaxy knew these manufacturing deficiencies could impact its ability to bring the generic drug product to market.

74. Utilizing this business model, Ranbaxy proliferated huge numbers of ANDAs. By 2002, it filed 23 ANDAs – the most in company history; and that number continued to increase over the following years. Ranbaxy touted these numbers and their ability to secure first-to-file 180-day exclusivity to increase its profitability. Their CEO credited the company's low research and development and manufacturing costs as the basis for its impressive drug pipeline, when in reality it was their lax compliance standards and false representations to the FDA that allowed them to obtain tentative approvals so quickly.

75. Between 2002 and 2005, Ranbaxy's stock skyrocketed on India's two leading stock exchanges, the Bombay Stock Exchange (BSE) and National Stock Exchange (NSE).

76. From 2002 to 2003, Ranbaxy's U.S. revenue increased from $296 million to $412 million, becoming one of the top 10 generic drug makers in the United States.[32] It filed 26 new ANDAs in 2003.[33]

77. In 2004, Ranbaxy filed 26 new ANDAs, including the first ANDA for valsartan tablets, sold under the brand name Diovan ("the Diovan ANDA") [34] on December 24, 2004.[35]

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[32] Ranbaxy Laboratories Ltd., Annual Report 2003.

[33] *Id.*

[34] ANDA 077492

[35] Diovan was first approved by the FDA for sale in the United States in 1998. By 2012, sales exceeded $1.9 billion, climbing to $2.1 billion in 2013. Ranbaxy's original Diovan ANDA contained a Paragraph III certification regarding one of the listed patents and a Paragraph IV certification regarding another. To preserve its first-to-file exclusivity, Ranbaxy needed to obtain at least tentative approval by June 28, 2007 unless the failure to obtain tentative approval was caused by a change in, or a review of, the requirements for approval of the application imposed after the date on which the application was filed.

Ranbaxy was now India's largest pharmaceutical company, with $1 billion in revenues and 36% of its sales in the U.S. market.

78. In 2005, Ranbaxy again filed 26 new ANDAs, including the first for delayed release capsules of 20 mg and 40 mg of esomeprazole magnesium, sold under the brand name Nexium ("the Nexium ANDA")[36] and accepted by the FDA on August 5, 2005.[37] Ranbaxy also submitted the first ANDA for valganciclovir hydrochloride tablets, sold under the brand name Valcyte ("the Valcyte ANDA")[38] on December 22, 2005.[39] By year-end, Ranbaxy had 59 ANDAs pending with the FDA and held first-to-file status on at least 19 of them.

B. Ranbaxy's Rapid Growth Came at the Expense of Truthfulness, Accuracy, and Compliance with Federal Regulations.

79. During these years of rapid growth marked by prolific ANDA filings, Ranbaxy's internal compliance problems and federal regulatory violations came to the forefront, raised internally by employees and auditors and publicly by national organizations and regulatory bodies. Yet, management ignored these pernicious regulatory problems. Instead, Ranbaxy's management adopted a corporate culture of deception and fraud, dictating the desired test results and allowing employees to fabricate data to support that outcome.

80. In 2003, an external consultant performed an audit that concluded no formalized training existed, as required by cGMP, resulting in numerous discrepancies in the company's drug

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[36] ANDA 077830

[37] Nexium was first approved by the FDA for sale in the United States in 2001. The Nexium ANDA was accepted for filing by the FDA on August 5, 2005. To preserve its first-to-file exclusivity, Ranbaxy needed to secure at least tentative approval of its Nexium ANDA by February 4, 2008.

[38] ANDA 078078

[39] Valcyte was first approved by the FDA for sale in the United States in 2001. By 2012, sales exceeded $1.9 billion. The Valcyte ANDA was submitted December 22, 2005 and accepted for filing by the FDA on December 27, 2005. To preserve its first-to-file exclusivity, Ranbaxy needed to secure at least tentative approval by June 27, 2008.

testing data and incomplete documentation of product complaints. Ranbaxy did not disclose this audit to regulators or take any corrective action.

81. In 2004, an audit by the World Health Organization revealed flaws in anti-retroviral drugs manufactured by Ranbaxy being supplied to immuno-compromised AIDS patients in Africa, resulting in a recall.

82. In late 2004, an internal employee investigation revealed to Ranbaxy Lab's board of directors that fraudulent testing data underlay hundreds of regulatory filings, including:

a. Bioequivalence studies filed with regulatory authorities were based on formulations that differed from the approved formulation;

b. Bioequivalence data and stability studies submitted to regulators were falsified;

c. Bioequivalence studies for some generic filings were conducted on ground up batches of the brand-name drug, which was misrepresented as a formulation developed by Ranbaxy;

d. Bioequivalence and stability studies were conducted on small research and development batches, not exhibit batches (which were more expensive and time consuming to produce);

e. Stability studies filed with regulators were based on formulations differing from that which was disclosed to the regulators;

f. Stability studies performed at one location were submitted as if they occurred at another location;

g. Individual dissolution values in stability studies were fabricated;

h. Stability shelf-life data was fabricated and submitted as part of Ranbaxy's registration package;

i. Substandard active pharmaceutical ingredients ("API") that failed testing and inspections were blended with good API in an effort to have the drug meet specification; and

j. Research, development, and commercial manufacturing of Ranbaxy's generic drugs were not being done in accordance with cGMP as required by the FDA.

83. Despite the employee presenting these findings of his audit to Ranbaxy's board of directors and its scientific sub-committee in 2004, the board did not report these irregularities to government regulators or act to alter its business practices.

84. In 2005, another external audit documented Ranbaxy's cGMP compliance issues relating to process validation, equipment qualification, master production records, procedures, documentation practices and stability testing. The auditor recommended corrective action, even offering to conduct a series of training programs to align the facilities with acceptable United States' compliance procedures and warned Ranbaxy that the FDA could take regulatory action if the issues were not corrected. Ranbaxy again took no corrective action and never utilized the training programs.

85. The FDA remained unaware of the compliance issues until late 2005, when a whistleblower – the same employee who had conducted the internal audit presented to the board of directors - contacted the agency with allegations of compliance issues at certain Ranbaxy facilities.

C. FDA Scrutiny Necessitates the Development of a RICO Enterprise to Conceal Violations and Gain or Maintain ANDA Approvals

86. In early 2006, the FDA instituted a series of inspections at Ranbaxy facilities, which uncovered serious and systemic compliance and documentation issues. These inspections documented numerous violations of cGMP regulations, including:

a. Failure to maintain a complete record of all data collected during tests, as required by 21 C.F.R. § 211.194(a)(4). Ranbaxy standard operating procedures expressly called for some test results to be "discarded." While FDA regulations permit anomalous test results to be invalidated under certain circumstances, all data must be retained.

b. Failure to establish and follow written protocols for assessing the stability of certain drug products, as required by 21 C.F.R. § 211.166. The FDA found evidence that Ranbaxy ran a series of tests on the same day, then doctored the test dates to make it appear as if they were run at 3-, 6- and 9-month intervals.

c. Failure to determine appropriate drug storage conditions and expiration dates, as required by 21 C.F.R. § 211.166. Stability samples, including some for generic

Nexium, that should have been studied for their degradation profile at warmer temperatures (30°C) were stored in a refrigerator and held at 4°C.

d. Failure to maintain logbooks for all storage chambers containing stability samples, as required by 21 C.F.R. § 211.166(a)(1). After finding thousands of stability samples stored in two stability chambers, the FDA requested the log books for those chambers. Ranbaxy employees stated none existed.

e. Inadequate resources, including personnel and equipment, in the quality control unit, as required by 21 C.F.R. § 211.22(b), resulting in substantial backlog of samples to be tested in 2006.

f. Failure to keep accurate, detailed documentation relating to the production and control of each batch of a drug produced at the facility, as required by 21 C.F.R. § 211.188.

g. Failure to investigate unexplained discrepancies, flaws, or deviations from the required standards for a given batch of a generic drug, as required by 21 C.F.R. § 211.192, including some batches that were distributed for public consumption.

87. Ranbaxy's compliance failures were so blatant and pervasive that the FDA identified each of these findings despite providing advanced notice of the inspection to Ranbaxy Labs and despite Ranbaxy's efforts to cover up flaws and falsify data.

88. After each inspection, the FDA provided Ranbaxy with a report of its findings. The FDA expressed particular concern about Ranbaxy's lack of documentation for critical testing to ensure product quality, stability, and consistency and their handling of stability samples.

89. By 2006, Ranbaxy needed to respond to regulatory requests – particularly from the FDA - regarding its product development, testing, manufacturing, and reporting. So, Ranbaxy chose to form a group comprised of itself, some outside lawyers, and an ostensibly independent consulting company it hand-selected, in order to address FDA regulatory demands.

90. Ranbaxy Labs engaged the law firm of Buc & Beardsley LLP (using two lawyers, Kate Beardsley and Carmen Shepard, herein "Beardsley"). In turn, Ranbaxy and Beardsley retained Parexel Consulting LLC ("Parexel") and Ron Tetzlaff, its Corporate Vice President and a former FDA expert on cGMP compliance.

91. On or about May 11, 2006, Beardsley and Parexel entered into an agreement (the "Parexel Agreement") structured to shield Parexel's audit work from any FDA scrutiny. Parexel would perform a series of ostensibly independent audits reviewing the facilities and addressing the FDA's findings, while Ranbaxy and Beardsley controlled the audits and information shared with the FDA, including the level of cGMP compliance at Ranbaxy's facilities. Parexel also agreed to run all drafts of its audit reports through lawyers (*i.e.* Beardsley) for comment and approval; every page of its work would be labeled as attorney work product and identified as privileged; and Parexel would follow Beardsley's instructions as to any subpoenas that might seek the audit reports.

92. Through the Parexel Agreement, Ranbaxy was able to defer FDA regulatory scrutiny and bring (ultimately unwarranted) validity to their misrepresentations of compliance when, in reality, little action was taken to correct their cGMP violations. Ranbaxy would not, and could not, produce requested documentation to the FDA to prove that they were maintaining compliance.

93. Ranbaxy Labs and Ranbaxy Inc. mailed a series of letters to the FDA discounting the FDA's observations from the site inspections and deflecting blame for the compliance failures raised in the inspection report. Some form of an explanation was offered, or it was claimed that new practices had been adopted. During the inspections, the FDA requested certain documents, such as lists documenting the storage of drugs, and employees responded that such lists did not exist. Following the inspections, Ranbaxy sent documents to the FDA, purporting to be master lists and working logs of samples stored in their facilities. But the documents (a) did not document any samples received before January 2006; and (b) for the samples received from January through May 2006, failed to document the date(s) on which the samples had been removed from/returned to storage as part of stability testing.

94. Unsatisfied with Ranbaxy's responses, the FDA issued a warning letter to Ranbaxy's facility in Paonta Sahib, India on June 15, 2006, recommending a hold be placed on ANDAs

originating from that facility, citing "significant deviations from [cGMP] Regulations … in the manufacture of drug products."[40] Among the FDA's ongoing concerns was a lack of assurance that Ranbaxy had reliably performed stability sample tests. Dozens of Ranbaxy's ANDAs, including many of its lucrative first-to-file ANDAs, originated at Paonta Sahib. Many would soon be approaching the statutory 30-month deadline for tentative approval and a hold on the applications would put Ranbaxy's valuable 180-day exclusivity at risk.

95. Ranbaxy threatened to sue the FDA if it held up final approval of the drug Zocor (simvastatin)[41] due to the compliance hold. In a meeting with the FDA, Ranbaxy, assisted by Beardsley and Parexel, persuaded the FDA not to deny or delay final approval of the Zocor ANDA and the FDA granted final approval on June 23, 2006.

96. In August 2006, Alok Ghosh, Ranbaxy Inc.'s Vice President of Global Quality, responded to the June warning letter by mailing a letter intended to mislead the FDA, with false statements and misrepresentations that Ranbaxy completed remedial steps to ensure its facilities were cGMP compliant.[42] Ghosh pledged that they were "undertaking a number of activities to improve [its] quality programs and enhance [its] operational performance at the Paonta Sahib facility."[43] As a sign of the company's commitment to compliance, Ghosh even touted the retention of "Ron Tetzlaff and his colleagues at PAREXEL Consulting . . . to verify that our stability

[40] Letter from Nicholas Buhay, Acting Director, CDER, to Ramesh Parekh, VP, Ranbaxy Laboratories Limited (June 15, 2006)

[41] Tentative approval had been granted years before, but patents prevented final approval. In an effort to remove the basis for granting 180-day exclusivity, the brand company sought to "de-list" the two patents as to which paragraph IV certifications had been filed. Litigation ensued, eventually resulting in the patents being re-listed with the FDA, and Ranbaxy's 180-day exclusivity period being preserved.

[42] Letter from Alok Ghosh, VP, Ranbaxy Laboratories Ltd., to Nicholas Buhay, Acting Director, CDER (Aug. 29, 2006).

[43] *Id.*

laboratory program improvements are effective and systemic, and to verify the effectiveness of our commitments made in response to the Warning Letter."[44]

97. Ghosh included a detailed, point-by-point response to the warning letter, largely denying that any compliance issues existed, instead blaming the FDA for misunderstanding. For example:[45]

a. In response to the FDA's concern that Ranbaxy's standard operating procedure required employees to discard inconsistent data, Ranbaxy claimed no data was ever "discarded." Rather, according to Ranbaxy, "discard" was synonymous with "invalidate" and employees invalidated but retained the data.

b. During the inspection, Ranbaxy employees told the FDA that no log books existed for two 4°C chambers containing stability samples, which the FDA referred to as "stability chambers." To explain why Ranbaxy was later able to produce those same log books, Ranbaxy claimed the log books always existed, but were not provided because the chambers were known as "refrigerators," not "stability chambers."

98. The FDA then requested copies of Parexel's audit reports, but Ranbaxy, Beardsley and Parexel stonewalled, claiming that release of the audits would stifle employee candor in the audit process. In a letter from Gosh dated October 13, 2006, Ranbaxy offered to provide other materials of its own choosing instead of providing the audits themselves.[46]

99. On or about November 29, 2006, seven Ranbaxy representatives, including Malvinder Singh (CEO & Managing Director), Pushpinder Bindra (President and CTO), Alok Ghosh (Vice President of Global Quality), Jay Deshmukh (Senior Vice President, Global IP), Dr. T.G. Chandrashekhar (Director, Analytical Research and Stability), and Abha Pant (Associate Vice President, Regulatory Affairs), traveled from India to the FDA. They were joined by Tetzlaff and

[44] *Id.*

[45] *Id.*

[46] Letter from Alok Ghosh, VP, Ranbaxy Laboratories Ltd., to Karen K.M. Takahashi, Compliance Officer, Foreign Inspection Team, CDER (Oct. 13, 2006).

Beardsley. Twelve FDA representatives were present. The FDA was concerned that no corrective action was taking place and questioned Ranbaxy, Parexel, and Beardsley extensively.

100. While most of the FDA's inquiries went unanswered, all three organizations falsely assured the FDA that remedial action had been taken. Bindra, on behalf of Ranbaxy, represented to the FDA that they "[r]esolved issues raised" by the FDA's warning letter and "[c]ompleted commitments made in FDA responses." He claimed that Ranbaxy "[c]omprehensively addressed all . . . Warning Letter issues," and "[p]rovided FDA with evidence to show that all Warning Letter issues have been adequately addressed." Ranbaxy provided the FDA with a chart classifying 56 remedial actions as "complete," 1 as "nearly complete," and 1 as "awaiting FDA approval."

101. Tetzlaff provided a presentation on the Parexel audits, representing that Parexel was "doing a retrospective verification of stability samples" along with a review of the accuracy of "all current and future ANDA filings." Tetzlaff told the FDA he expected the audit results for all pending ANDAs to be completed and provided to the FDA by year end. Tetzlaff blamed some of the purported issues on the FDA: "Several FDA responses conveyed unclear messages that seemed to have resulted from unfortunate choices of words," but assured the FDA that "[n]one of [Ranbaxy's] statements appeared to be an attempt to provide misleading information." Tetzlaff told the FDA that "PAREXEL found Ranbaxy has addressed every audit observation and is making effective progress to complete remaining improvements within their timeframes." He stated that "[f]or each of the 8 observations [made during the February 2006 inspection], PAREXEL verified the commitments made in Ranbaxy's" August 2006 letter, and "found that appropriate improvements had been put into place for each of the 8 observations."

102. The audits remained hidden from the FDA. Ranbaxy, Beardsley, and Parexel continued to maintain that the audits were privileged, arguing that disclosure of the audits would impact the candor necessary for a successful audit.

103. Shortly after the meeting with the FDA, Parexel entered into a second agreement, this time directly with Ranbaxy. Once again, the contract was structured to cloak the audit work most relevant to the concerns of the FDA – the operational testing, manufacturing and reporting conditions at Ranbaxy – in the garb of attorney-client privilege.

104. On February 14, 2007, federal agents executed search warrants at Ranbaxy Inc.'s facilities in New Jersey, seizing computers and documents. In those documents and on those computers were copies of communications between Ranbaxy Labs, Ranbaxy Inc., Beardsley, and Parexel relating to Parexel's audits. To prevent the government or the FDA from reviewing the audits that Ranbaxy and Parexel had earlier refused to produce, Ranbaxy's criminal lawyers wrote the Department of Justice, invoking attorney-client and work-product privileges over any documents referencing Beardsley or Parexel.

105. On March 8, 2007, the federal government served an administrative subpoena on Ranbaxy, demanding the production of numerous documents and records associated with Ranbaxy's regulatory filings and interactions with regulatory agencies. This subpoena was issued under the authority of the Health Insurance Portability and Accountability Act ("HIPAA"), 18 U.S.C. § 3486, to facilitate a federal criminal investigation relating to allegations of health care fraud.

106. On March 27, 2007, Beardsley left a voicemail with the FDA requesting a conference call. The FDA had, at Beardsley's insistence, re-inspected a portion of the Paonta Sahib facility in January 2007.[47] Beardsley asked about that inspection and informed the FDA that Ranbaxy addressed the only three observations made by the FDA during that inspection. She also mentioned having heard rumors about adverse regulatory action soon to be taken against Ranbaxy's Ohm facility in Gloversville, NY.

[47] Motion to Enforce Subpoenas, Ex. 14, *U.S. v. Ranbaxy, Inc., et al.*, No. 08-cv-01764-PJM (D. Md. July 3, 2008)

107. On an April 5, 2007 conference call between Beardsley and the FDA, the FDA informed Beardsley that the inspection of Paonta Sahib suggested the site was acceptable for API production, after which Beardsley acknowledged that Ranbaxy had not yet addressed all the concerns raised in the 2006 warning letter and that the audits requested by the FDA remained ongoing.[48] The FDA clarified during the telephone call that until the audit was received and found to be satisfactory, the Paonta Sahib facility would remain non-compliant with cGMP.

108. In April 2007, a whistleblower with intimate knowledge of the company's wrongful business practices (the same employee who conducted the 2004 internal investigation) filed a False Claims Act complaint against Ranbaxy, alleging serious violations of cGMP leading to the introduction of adulterated drugs in the U.S. market.[49]

109. On May 8, 2007, the federal government served Parexel with an administrative subpoena seeking documents related to Ranbaxy's regulatory filings and audits. This subpoena was similar to the one served on Ranbaxy in March. But Ranbaxy, Beardsley, and Parexel persisted in their claims of privilege and challenged the scope of the subpoenas, substantially delaying the production of documents under the subpoenas.

D. Compliance Failures Threaten to Prevent Tentative Approval and Cause the Forfeiture of Ranbaxy's 180-Day Exclusivity.

110. Meanwhile, Ranbaxy had several pending first-to-file ANDAs approaching the 30-month deadline, in danger of forfeiting the 180-day exclusivity. First-to-file ANDAs forfeit their exclusivity if they don't obtain tentative approval from the FDA within 30 months of filing. To preserve their status and exclusivity rights, Ranbaxy once again provided false and misleading information to the FDA regarding their compliance.

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[48] *Id.*

[49] *Thakur, et al. v. Ranbaxy USA, Inc. et al*, No. 07-cv-00962-JFM (D.Md.)

111. Ranbaxy's first-to-file ANDA for generic Flomax (a widely used alpha-blocker that aids urination) was approaching a 30-month forfeiture date of June 20, 2007, and Ranbaxy had yet to receive tentative FDA approval.

112. On June 18, 2007, Ranbaxy, in coordination with Beardsley and Parexel, mailed letters to two different divisions within the FDA, each intended to cause the FDA act upon false or misleading information.

113. First, Ranbaxy mailed a letter to CDER, giving it the false impression that all outstanding compliance issues had been corrected. Ranbaxy wrote that "the retrospective stability verification promised during the November 29, 2006 meeting between Ranbaxy and FDA has been completed, and that the company's ANDA submissions are being updated today to reflect changes identified in the course of the review."[50] Ranbaxy explicitly represented that, while three categories of errors were found, "in no case did the corrections affect the previous conclusions about the stability of the sample."[51] Ranbaxy insisted there was no longer a justification for the compliance hold. In reality, and unknown to the FDA, Ranbaxy's long-standing manufacturing problems remained, and they affected many pending applications.

114. Second, Ranbaxy mailed a letter to the OGD (the FDA's generic drug approval division) giving it the false impression that all outstanding issues for the grant of tentative approval had been (or soon would be) corrected. Ranbaxy represented that the retrospective stability verification had recently been completed and the results would be sent to OGD and the OC (the FDA division charged with ensuring manufacturer's compliance with FDA regulations). Ranbaxy intended to create the impression that the information provided would cause a release of the

[50] Motion to Enforce Subpoenas, Ex. 15, *U.S. v. Ranbaxy, Inc., et al.*, No. 08-cv-01764-PJM (D. Md. July 3, 2008).

[51] *Id.*

compliance hold. Ranbaxy specifically stated that its Flomax ANDA was "ready for tentative approval" "[e]xcept for the compliance hold at Paonta Sahib."[52]

115. In other words, Ranbaxy represented to the FDA that it rectified all of the issues identified by the 2006 warning letter and none of the issues affected the integrity of the data in the ANDAs originating from Paonta Sahib. These letters contained numerous misleading misstatements. As the FDA would later learn, the compliance issues were not yet addressed and, in fact, would remain unresolved more than seven years later. Even as it made these false assurances, Ranbaxy knew their facilities remained noncompliant. Ranbaxy would later admit that gabapentin (a drug used to treat epilepsy also manufactured in Paonta Sahib) tested positive for "unknown impurities" in the summer of 2007 and had an unreliable shelf life. Though gabapentin exported for sale in the U.S., Ranbaxy did not reveal these findings to the FDA until October of that year when it issued a recall of more than 73 million pills.

116. Ranbaxy made these misstatements knowing that they would be material to the FDA's consideration of whether to overlook the compliance hold in place on applications originating from the Paonta Sahib facility. Ranbaxy intended these misstatements to induce the FDA to grant tentative approval as to Ranbaxy's pending ANDAs and to further Ranbaxy's fraudulent scheme.

117. Ranbaxy also threatened to sue if the FDA failed to immediately confirm that Ranbaxy would maintain its first-to-file exclusivity on June 20, 2007.[53] Under threat of litigation, the OGD granted tentative approval for Ranbaxy's Flomax ANDA, relying upon Ranbaxy's

[52] Defs.' Mem. In Opp'n to Pls.' Mot. for a Prelim. Inj., *Ranbaxy Labs., Ltd v. Burwell*, No. 14-cv-01923-BAH (D.D.C. Dec. 22, 2014)

[53] *Ranbaxy Labs., Ltd v. Burwell*, 82 F. Supp. 3d 159, 177 (D.D.C. 2015).

representations of remediation.[54] The OGD concluded that Ranbaxy appeared to have addressed the only outstanding issue from the 2006 warning letter and thus appeared to comply with cGMP.[55]

118. The misleading information within Ranbaxy's letters regarding Flomax informed not only the FDA's response to the Flomax ANDA, but its responses to several later ANDAs, including those for generic Diovan, Valcyte, and Nexium. Operating under the mistaken impression that Ranbaxy was now compliant with cGMP, the FDA also reactivated Ranbaxy's Diovan ANDA, another of Ranbaxy's first-to-file ANDAs facing an imminent forfeiture date. However, a change in the USP monograph applicable to the drug suspended the deadline for obtaining tentative approval. With the sense of urgency eliminated, the FDA took no immediate action on the Diovan ANDA.

119. In July of 2007, following another meeting with the FDA, Beardsley provided some of Parexel's work, defined as "Ranbaxy and Parexel protocols and final reports," while still maintaining that the audits constituted privileged material. Beardsley summarized the reports as showing a tiny proportion of errors and assured the FDA that Ranbaxy had "taken exhaustive steps to assure the accuracy of data contained in its stability reports and ANDA submissions."[56]

120. But Beardsley's letter did not contain the critical information requested by the FDA, including "information about the revised dating convention…, frequency of transcription errors, and a list of ANDAs amended with a summary of changes made to each."[57] Beardsley represented

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[54] Ranbaxy would later use the first-to-file exclusivity it secured to enter a settlement with the brand company delaying generic entry until March 2, 2010. When Ranbaxy's ongoing manufacturing and compliance issues rendered it unable to launch at that time, Ranbaxy selectively waived its exclusivity, allowing another generic to come to market on March 2, 2010. In exchange, Ranbaxy received $50 million.

[55] Much later, the FDA would discover that these representations were false. In December 2014, the FDA publicly stated that the factual basis for this determination – *i.e.*, the representations that Ranbaxy had made to CDER and OGD on June 18, 2007 – were incorrect.

[56] *Ranbaxy Labs., Ltd v. Burwell*, 82 F. Supp. 3d 159, 173 (D.D.C. 2015)

[57] Defs.' Mem. In Opp'n to Pls.' Mot. for a Prelim. Inj., *Ranbaxy Labs., Ltd v. Burwell*, No. 14-cv-01923-BAH (D.D.C. Dec. 22, 2014)

that Ranbaxy was in the process of compiling that information and would forward it to the FDA when completed.

121. In late December 2007, Ranbaxy sought final approval on its clarithromycin ANDA. Ranbaxy did not have first-to-file exclusivity on this ANDA but was seeking to launch its generic clarithromycin on January 2, 2008 along with other generic manufacturers.

122. Beardsley emailed the FDA, acknowledging that the FDA "could not consider Ranbaxy's request that FDA approve the clarithromycin ANDA unless Ranbaxy provides certain of the Parexel audits."[58] She asked what specific information the FDA would require before granting final approval. The FDA reiterated that the audits would have to be produced for final approval to be considered.

123. After internal discussions, Beardsley informed the FDA that Ranbaxy needed "to think through the implications for the criminal case of providing the audits."[59] Ranbaxy provided none, and as a result, Ranbaxy's clarithromycin request was withdrawn.

124. During a teleconference on February 27, 2008, Ranbaxy sought approval from the FDA for a new, separate drug manufacturing facility, which it called the Batamandi plant. Ranbaxy insisted that Batamandi facility, also located in the city of Paonta Sahib, was independent of the Paonta Sahib facility, shared no staff with Paonta Sahib, and suffered none of its compliance problems. To the contrary, an FDA inspection on March 3-7, 2008 revealed that "the Batamandi (Unit II) site is under the same production and quality management as the existing Paonta Sahib site

[58] Motion to Enforce Subpoenas, Ex. 18, *U.S. v. Ranbaxy, Inc., et al.*, No. 08-cv-01764-PJM (D. Md. July 3, 2008)

[59] *Id.*

[and] that the existing Paonta Sahib site was involved in various aspects of testing and production for the Batamandi site."[60]

125. In May 2008, the FDA canceled the separate facility registration for Batamandi and treated it instead as an extension of the Paonta Sahib facility; the numerous violations uncovered there would be considered indicative of the ongoing problems at Paonta Sahib. The inspectors recommended that the FDA implement its rarely-used data integrity protocols against Ranbaxy "for submitting information to FDA that may have been fabricated."

126. In early April of 2008, Beardsley sent the FDA a few of the requested audits but claimed others were never completed and/or did not exist.[61] The FDA continued to press for complete audits, including those relating to selected manufacturing and laboratory areas at Paonta Sahib, validation protocol reports, and certain quality control laboratory procedures.

E. FDA Inquiries Don't Prevent Tentative Approval of Diovan, Nexium, and Valcyte.

i. Diovan

127. In October 2007, Ranbaxy needed to obtain tentative approval of its Diovan ANDA or its 180-day exclusivity would be forfeited.[62] Invoking the misstatements made earlier to obtain

[60] Letter from Richard L. Friedman, Director, CDER, to Malvinder Singh, CEO, Ranbaxy Laboratories Ltd. (Sept. 16, 2008).

[61] Motion to Enforce Subpoenas, Ex. 20, *U.S. v. Ranbaxy, Inc., et al.*, No. 08-cv-01764-PJM (D. Md. July 3, 2008).

[62] The 30-month forfeiture date for Diovan was originally June 28, 2007. However, a change in the USP monograph (which provides standards for identity, quality, purity, strength, packaging, and labelling for ingredients) applicable to the drug suspended the deadline for obtaining tentative approval. The FDA required compliance with the USP monograph before the FDA would approve the Ranbaxy Diovan ANDA product. On May 1, 2007, the official USP drug substance monograph for valsartan was published. On June 26, 2007 and July 5, 2007, Ranbaxy submitted amendments to its ANDA proposing changes to its drug substance specifications and test methods to comply with the USP monograph. By October 2007, the changes required by the new USP monograph for Diovan had been addressed.

tentative approval of its generic Flomax, Ranbaxy once again misrepresented to the FDA that its cGMP compliance issues were resolved, as purportedly verified by the undisclosed Parexel audits.

128. On October 25, 2007, relying again on the misrepresentations made by Ranbaxy about the audits and its cGMP compliance, and for many of the same reasons it had granted tentative approval to the Flomax ANDA, the FDA granted tentative approval to the Diovan ANDA.[63] Ranbaxy's 180-day exclusivity was (wrongfully) preserved.

ii. Nexium

129. In early January 2008, the FDA held internal discussions about Ranbaxy's Nexium ANDA, which was facing the tentative approval deadline of February 5, 2008.

130. The FDA had not yet received the complete audits, but it was still operating under the mistaken belief (created by Ranbaxy's summer 2007 submissions) that Ranbaxy resolved its cGMP compliance issues and that none of the issues identified in the 2006 warning letter affected the accuracy of any of Ranbaxy's ANDA submissions. Once again, Ranbaxy exploited this misunderstanding – created by Ranbaxy's own misrepresentations – to coerce the FDA into granting a tentative approval to which Ranbaxy was not entitled. And once again, Ranbaxy's ploy worked.

131. The FDA granted tentative approval to Ranbaxy's Nexium ANDA on February 5, 2008, noting its decision was "based upon information presented [to the] agency."[64] This allowed Ranbaxy to (wrongfully) preserve its first-to-file exclusivity regarding its generic Nexium products.

iii. Valcyte

[63] Letter from Gary Buehler, Director, CDER, to Scott Tomsky, U.S. Agent, Ranbaxy Laboratories Ltd. (Oct. 25, 2007)

[64] Letter from Gary Buehler, Director, CDER, to Scott Tomsky, Ranbaxy Laboratories Ltd. (Feb. 5, 2008).

132. On June 4, 2008, internal discussions began at the FDA about Ranbaxy's Valcyte ANDA. The thirty-month forfeiture deadline of June 27th was fast approaching and Ranbaxy once again pressured the FDA for tentative approval.

133. Having not received any contrary information, such as the audits it had been requesting for months, the FDA continued under the mistaken belief (based on Ranbaxy's representations) that Ranbaxy rectified the issues identified in the 2006 warning letter and that none of the issues affected the integrity of the data in ANDAs originating from Paonta Sahib.

134. The FDA granted tentative approval to Ranbaxy's Valcyte ANDA on June 20, 2008, allowing Ranbaxy to (wrongfully) preserve first-to-file exclusivity.[65]

F. Federal Investigations and Settlements Force Ranbaxy to Admit It's Wrongdoing and Misconduct

135. On July 3, 2008 – almost two years after it requested Parexel's audits and a year after issuing subpoenas – the government sued in the U.S. District Court for the District of Maryland to enforce the subpoenas and obtain complete copies of Parexel's audits of the Paonta Sahib facility.[66]

136. In the fall of 2008, Ranbaxy and Parexel finally produced the complete audit information. Upon review of the complete audit files, the FDA realized that the prior representations made by Ranbaxy, Beardsley, and Parexel about the audits were false. While awaiting production of the full audit reports, the FDA relied upon Ranbaxy's false statements and assurances regarding cGMP compliance to grant tentative approval of the Flomax, Diovan, Nexium, and Valcyte ANDAs (among others).

137. The full audits revealed that Ranbaxy conducted stability testing several weeks or months later than they reported to the FDA in drug applications and annual reports. Stability tests

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[65] Letter from Gary Buehler, Director, CDER, to Michael Yefimenko, U.S. Agent, Ranbaxy Laboratories Ltd. (June 20, 2008).

[66] *U.S. v. Ranbaxy, Inc., et al*, No. 08-cv-01764- (D.Md.)

that Ranbaxy reportedly conducted at different time intervals (i.e., 3, 6, and 9 months) were, in fact, conducted on the same day. Ranbaxy's compliance failures were clearly ongoing and affected numerous pending ANDAs.

138. On September 16, 2008, the FDA issued additional warning letters to Ranbaxy about both its Paonta Sahib and Dewas facilities.[67] Unlike the June 2006 letter, which merely recommended a compliance hold, these letters contained an import alert, barring the commercial importation of almost 30 Ranbaxy drugs into the United States. After detailing multiple, ongoing deficiencies in the quality systems at the facilities, the FDA informed Ranbaxy that if it desired to continue shipping drug products to the United States, it needed to assure compliance with all cGMP standards.

139. On February 25, 2009, the FDA went a step further and determined that Ranbaxy "submitted untrue statements of material fact in abbreviated and new drug applications files with the Agency."[68] The FDA found "a pattern and practice of submitting untrue statements of material fact and other wrongful conduct, which raise significant questions regarding the reliability of the data and information contained in applications (pending and approved) . . . filed with the Agency."[69] The FDA would be ceasing any assessment of the scientific merits of Ranbaxy's pending ANDAs, and would instead focus on assessing "the validity of the data and information in all of Ranbaxy's affected applications[70]

[67] Letters from Richard L. Friedman, Director, CDER, to Malvinder Singh, CEO, Ranbaxy Laboratories Ltd. (Sept. 16, 2008).

[68] Memorandum from Janet Woodcock, Director, CDER, to Malvinder Mohan Singh, CEO, Ranbaxy Laboratories Ltd. (Feb. 25, 2009).

[69] *Id.*

[70] *Id.*

140. The FDA turned to a rarely-used procedure, invoking its Application Integrity Policy ("AIP"). On February 25, 2009, the FDA froze all of Ranbaxy's applications originating from Paonta Sahib and ceased any further review or approval pending an assessment of the validity of the data and information in all of Ranbaxy's affected applications."[71] At the FDA's request, Ranbaxy provided the FDA with a "priority list" of the ANDAs covered by the AIP, ranking 65 then-pending ANDAs in order of importance, both from a commercial and a public health perspective. Among the ANDAs identified by Ranbaxy as most important were its first-to-file ANDAs for generic Valcyte, Diovan and Nexium.

141. The FDA's initial solution to its Ranbaxy problem was simple: on August 13, 2010, it presented Ranbaxy with a proposed consent decree, which would impose upon Ranbaxy a permanent injunction intended to remedy the significant cGMP compliance problems at Paonta Sahib and many other Ranbaxy facilities. The draft consent decree proposed that Ranbaxy immediately relinquish its claims to 180-day exclusivity for 16 different ANDAs, including Diovan, Valcyte and Nexium.

142. Forfeiture of its first-to-file status on these drugs would represent a loss of many hundreds of millions of dollars to Ranbaxy. Without exclusivity, Ranbaxy would not capture the majority of sales, could not block other generic entrants, and would have no ability to charge supracompetitive prices on those sales (or to sell the right to another company to do so). The generic versions would be immediately commoditized, eliminating the huge profit incentive Ranbaxy had spent years pursuing and years lying to preserve.

143. During 2010 and 2011, the FDA and Ranbaxy negotiated the terms of a consent decree to address Ranbaxy's pending, India-based ANDAs. Eventually, the FDA compromised.

[71] *Id.*

Although Ranbaxy agreed to relinquish some of its pending applications, Ranbaxy could maintain most of its first-to-file ANDAs, including Diovan, Valcyte, and Nexium so long as Ranbaxy met additional regulatory requirements set out in the consent decree.

i. The 2012 Civil Consent Decree

144. On January 25, 2012, the Department of Justice ("DOJ") filed a civil complaint and consent decree of permanent injunction against Ranbaxy in the U.S. District Court for the District of Maryland.[72] Through the consent decree, Ranbaxy promised to take substantial steps to remedy its prior misconduct and ensure that its drug manufacturing operations were brought into cGMP compliance. The consent decree largely superseded, and significantly broadened, the restrictions that the February 2009 AIP placed on Ranbaxy.

145. Under the consent decree, Ranbaxy was required to, *inter alia*, establish new practices and offices to ensure compliance, withdraw certain ANDAs, submit other ANDAs to new audits, and ensure cGMP compliance at Paonta Sahib and Dewas.

146. The consent decree required Ranbaxy to take several affirmative steps to ensure quality assurance ("QA") and quality control ("QC"). Ranbaxy had to create an Office of Data Reliability within the United States responsible for conducting pre-submission audits of all applications submitted from nine Ranbaxy facilities, including Paonta Sahib (referred to as the "Covered Facilities"). The consent decree imposed on Ranbaxy strict requirements for ensuring that all future submissions were reliable and documented and obligated Ranbaxy to retain an independent data integrity expert and a cGMP expert. It also imposed significant prohibitions on Ranbaxy. Ranbaxy could not manufacture any U.S. drugs at Paonta Sahib, Dewas, or Batamandi

[72] Consent Decree of Permanent Injunction, *U.S. v. Ranbaxy Laboratories, Ltd., et al.*, No. 12-cv-00250-JFM (D. Md. Jan. 25, 2012)

until audits were performed, a comprehensive set of remedial cGMP measures were implemented, and the FDA re-inspected the facilities.

147. Ranbaxy withdrew all NDAs and ANDAs that contained data or other information generated at Batamandi and agreed not to submit another application for those drugs or transfer the applications to a third party.

148. Most of Ranbaxy's applications remained on hold. But the consent decree divided Ranbaxy's remaining ANDAs into two categories: (1) "Affected Applications," defined as any application containing data or information generated at Paonta Sahib and/or Dewas, which were subject to an internal review, third-party audit, and corrective action operating plan; and (2) "Excepted Applications," of which there were five.

149. The group of Excepted Applications included the Diovan, Nexium and Valcyte ANDAs. Ranbaxy could maintain 180-day exclusivity for the five Excepted Applications pending the results of an audit. For each, a specific deadline was set by which Ranbaxy's data integrity expert had to complete an audit of the ANDA. Following each audit, Ranbaxy had to supply information to the FDA sufficient to demonstrate that the applications were, in fact, substantially complete at the time of submission. If the audit uncovered untrue statements or data irregularities, the application would be withdrawn; if the results of the audit were acceptable, the FDA would resume consideration of the application.

150. Ranbaxy retained Quintiles, Inc. ("Quintiles") to conduct audits required under the consent decree. Audits for the Valcyte, Diovan, and Nexium ANDAs were eventually submitted to and reviewed by the FDA.

ii. The 2013 Civil Settlement and Criminal Plea Agreement

151. In early 2013, Ranbaxy entered into a civil settlement and related criminal plea agreement with the federal government.[73] The civil settlement resolved the 2007 whistleblower action. Ranbaxy admitted to making false statements to the FDA concerning numerous lots and batches of its drugs. Ranbaxy and various subsidiaries agreed to pay a $350 million penalty for selling adulterated drugs in the United States from April 1, 2003, through September 16, 2010.

152. Under the plea agreement,[74] Ranbaxy USA admitted to committing numerous criminal violations, including introducing adulterated drugs into interstate commerce, failing to timely file required reports, and making false statements to the FDA. Ranbaxy USA paid a criminal fine of $130 million and a criminal forfeiture penalty of $20 million, agreeing that Ranbaxy engaged in a fraudulent course of conduct before the FDA.

153. For several years following the 2006 Paonta Sahib inspection, Ranbaxy misrepresented its cGMP compliance status to the FDA and misled the FDA about the company's efforts to improve in order to delay adverse action. Ranbaxy continued to manufacture drugs and secure valuable tentative approval for many of its pending ANDAs – including those for generic Diovan, Valcyte, and Nexium – because it delayed the FDA's adverse regulatory action through a pervasive pattern of material misstatements it made or caused to be made:

a. On August 26, 2006, Ghosh, on behalf of Ranbaxy, sent the FDA a letter through the mail, which stated that Ranbaxy was "undertaking a number of activities to improve [its] quality programs and enhance [its] operational performance at the Paonta Sahib facility." He also stated that Ranbaxy's "senior management [was] focusing resources and expertise on [Ranbaxy's] stability program and [its] analytical systems for testing samples for [its] stability program and batch release." [75] These representations were false and/or materially misleading: subsequent inspections of Paonta Sahib and audit reports prepared contemporaneously with his letter to the FDA revealed continued, unresolved problems at Paonta Sahib.

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[73] Press Release, DOJ, Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA (May 13, 2013).

[74] Plea Agreement, *U.S. v. Ranbaxy USA, Inc.*, No. 13-cr-00238-JFM (D. Md. May 13, 2013).

[75] Letter from Alok Ghosh, VP, Ranbaxy Laboratories Ltd., to Nicholas Buhay, Acting Director, CDER (Aug. 29, 2006)

b. At the November 27, 2006 meeting between the FDA, Ranbaxy, Beardsley, and Tetzlaff; Bindra, on behalf of Ranbaxy, stated that Ranbaxy had, at that time, comprehensively addressed and resolved all issues identified in the June 2006 warning letter. The statement was false and/or misleading: as Beardsley would admit the following year, Ranbaxy had not addressed all issues described in the warning letter.

c. At the same meeting, Tetzlaff stated that Parexel confirmed Ranbaxy resolved all issues identified in the February 2006 Paonta Sahib inspection. This statement was false and/or misleading: the issues identified in the February 2006 inspection were coextensive with the issues identified in the June 2006 warning letter, which Beardsley would later admit had not been addressed.

d. On March 27, 2007, Beardsley contacted the FDA by phone, informing the FDA that Ranbaxy had resolved the issues identified in its inspection of Paonta Sahib. This was false, as Beardsley herself would later admit.

e. On June 18, 2007, a Ranbaxy representative mailed a letter to the CDER, stating that Ranbaxy's stability verification was complete and "in no case did the corrections affect the previous conclusions about the stability of the sample." [76] As the FDA would learn more than a year later, that representation was false: once the FDA obtained copies of the audit reports, which purportedly confirmed there were no discrepancies in the ANDA stability data, it shut down scientific review of Ranbaxy's ANDAs until Ranbaxy submitted correct data. Therefore, upon information and belief, the stability verification and Parexel's audits showed that discrepancies and irregularities in the stability data did impact then-pending ANDAs.

f. On June 18, 2008, a Ranbaxy representative mailed a second letter, this time to the OGD, informing OGD that Ranbaxy's generic Flomax ANDA was "ready for tentative approval." [77] This was false: as the FDA would later learn, despite Ranbaxy's representations regarding its cGMP compliance, the Paonta Sahib facility was not in compliance with cGMP regulations, rendering Ranbaxy's pending ANDAs incomplete at best and more likely false.

g. In late July 2007, Beardsley mailed the FDA a letter, enclosing some of Parexel's audits, and representing that Ranbaxy was in the process of compiling other requested information, which it would provide when completed. [78] Beardsley's representation that Ranbaxy intended to provide the audit information was false: as would become apparent, Ranbaxy and Beardsley intended to, and tried to, shield that information from discovery behind claims of attorney-client privilege.

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[76] *Id.*

[77] Defs.' Mem. In Opp'n to Pls.' Mot. for a Prelim. Inj., *Ranbaxy Labs., Ltd v. Burwell*, No. 14-cv-01923-BAH (D.D.C. Dec. 22, 2014)

[78] *Ranbaxy Labs., Ltd v. Burwell*, 82 F. Supp. 3d 159, 173 (D.D.C. 2015)

h. In that same letter, Beardsley stated that the reports showed only an inconsequential number of errors in Ranbaxy's stability data and assured the FDA that Ranbaxy had "taken exhaustive steps to assure the accuracy of data contained in its . . . ANDA submissions."[79] As noted above, this statement would be proven false when the FDA reviewed the results of Parexel's audits, which, upon information and belief, showed that false data was submitted in conjunction with ANDAs.

i. On February 27, 2008, a Ranbaxy representative informed the FDA by telephone that the Batamandi facility was independent of Paonta Sahib and shared none of Paonta Sahib's staff or compliance issues. This was false: as the FDA discovered when it inspected the Batamandi facility in March 2007, Batamandi was "under the same production and quality management as the existing Paonta Sahib site" and Paonta Sahib handled much of Batamandi's testing and production.

j. In April 2008, Beardsley mailed the FDA several audit reports, but failed to submit some of the reports requested.[80] As to those reports not provided, Beardsley stated that they were completed and/or did not exist. This was false. In the face of a federal lawsuit, Ranbaxy would later produce several of these reports.

154. In making (or causing to be made) each of these statements, Ranbaxy, Beardsley, and Parexel intended to – and did – deceive the FDA as to the status of Ranbaxy's cGMP compliance, the effect of its non-compliance on the safety of drugs for sale in the U.S., and the need for regulatory action. Each of these misrepresentations was made in order to delay, forestall, or avoid adverse action by the FDA. And each was made to enable Ranbaxy to gain tentative approval for – and preserve valuable first-to-file status for – several Ranbaxy's then-pending ANDAs, including those for generic Diovan, Valcyte, and Nexium.

155. The plea agreement contained a detailed statement of facts outlining Ranbaxy's corrupt business model.[81]

[79] *Ranbaxy Labs., Ltd v. Burwell*, 82 F. Supp. 3d 159, 173 (D.D.C. 2015)

[80] Motion to Enforce Subpoenas, Ex. 18, *U.S. v. Ranbaxy, Inc., et al.*, No. 08-cv-01764-PJM (D. Md. July 3, 2008)

[81] Plea Agreement, Ex. A, *U.S. v. Ranbaxy USA, Inc.*, No. 13-cr-00238-JFM (D. Md. May 13, 2013).

156. Ranbaxy admitted that the 2006 FDA inspection at Paonta Sahib found significant problems, including incomplete data and records, failure to follow protocols, and inadequate resources to comply with FDA regulations.

157. Ranbaxy admitted that it falsified stability sample testing data. Although Ranbaxy claimed it followed FDA-approved testing protocols, Ranbaxy stored the drugs in a refrigerator for a significant period of time because there was a testing backlog. It "conducted stability testing of certain batches of these drugs several weeks or months later than the dates that were reported to the FDA . . . and in many instances, the stability test results that were reported as having occurred at three, six, nine, twelve, and eighteen months['] time intervals were actually conducted on the same day."

158. Ranbaxy admitted its awareness since October 2003 of substantial cGMP compliance problems, when an auditor informed Ranbaxy that:

a. "formalized training, as required by the cGMPs . . . was essentially nonexistent;"

b. there were serious deficiencies in Ranbaxy's process validation, equipment qualification, master production records (including batch records), procedures, documentation practices, and stability program;

c. "the need for the company to overhaul the batch records . . . to ensure consistency in the manufactured batches;" and

d. "a procedure on good documentation practices was found to be lacking."

159. Ranbaxy finally admitted that, despite these known cGMP deficiencies in 2003, and despite consultants urging Ranbaxy to conduct additional cGMP training for its staff, "Ranbaxy never presented any of the training programs recommended for it by [the auditor]."

160. Despite the 2012 consent decree and the 2013 DOJ settlement and plea, Ranbaxy continued to suffer poor performance reviews at several of its facilities worldwide. FDA inspections continued to reveal cGMP violations at a variety of Ranbaxy facilities. Inspections of Ranbaxy's Ohm facility in Gloversville, NY revealed cGMP violations that caused Ranbaxy to, rather than

correct the violations, close the facility. Inspections of Ranbaxy's Mohali, India, plant in September and December 2012 led to the issuance of an import alert on that facility in September 2013. Violations found at a plant in Toansa, India in 2013 resulted in restrictions on that plant.

iii. The Consent Decree and Required Audits

161. The January 25, 2012 Consent Decree classified the Nexium, Valcyte, and Diovan ANDAs as "Excepted Applications." After reviewing written submissions made by Ranbaxy under paragraph XIV.A of the Consent Decree, the FDA notified Ranbaxy in May 2012[82] that it would proceed with evaluating the audit reports submitted by Ranbaxy and its experts for the Nexium, Valcyte, and Diovan ANDAs. On August 10, 2012, the FDA also informed Ranbaxy it would begin or resume reviewing the Valcyte ANDA.[83]

162. However, Ranbaxy's Paonta Sahib facility would remain non-compliant with cGMP regulations and thus would remain unqualified to manufacture generic Nexium, Diovan, or Valcyte. Despite its inability to manufacture the product within cGMP regulations, Ranbaxy continued for years to hold onto its 180-day exclusivity for generic Nexium and Valcyte, bottlenecking other generic manufacturers from entering the market.

G. Ranbaxy sues the FDA

163. On November 4, 2014, the FDA notified Ranbaxy that it erred in tentatively approving the Nexium and Valcyte ANDAs.[84] On November 14, 2014, Ranbaxy sued the FDA and the Department of Health and Human Services ("DHHS") in the U.S. District Court for the District

[82] The letters related to Nexium and Diovan were dated May 4, 2012 and the letter related to Valcyte was dated May 15, 2012.

[83] Letter from Steven Lynn, Director, CDER, to Arun Sawhney, CEO, Ranbaxy Laboratories Ltd. (Aug. 10, 2012).

[84] Letter from Kathleen Uhl, Acting Director, CDER, to Sameer Manan, Director Regulatory Affairs, Ranbaxy Inc. (Nov. 4, 2014).

of Columbia, alleging that the FDA overstepped its statutory authority and violated Ranbaxy's constitutional rights by revoking tentative approval for Ranbaxy's Valcyte and Nexium ANDAs.[85]

164. Ranbaxy sought injunctive relief, contending that the FDA's revocation harmed the company despite being unable to come to market with generic versions of Nexium or Valcyte. The loss of tentative approval would eliminate Ranbaxy's ability to monetize its first-to-file status, either through payment from another generic company for a selective waiver of its 180-day exclusivity or through payment from the brand company in exchange for Ranbaxy's promise not to exercise its right to come to market.

165. Ranbaxy's primary argument against the FDA's action was that, in passing the MMA in 2003, Congress diminished the level of proof required for tentative approval as it related to cGMP compliance.

166. Ranbaxy acknowledged that an applicant needed to prove certain items – *e.g.*, the bioequivalence of its generic drug and the consistency in labelling– because 21 U.S.C. § 355(j)(2)(A) requires that the ANDA contain "information to show" it met these preconditions. But, according to Ranbaxy, the MMA eliminated the FDA's long-standing requirement that an applicant prove the cGMP compliance of its manufacturing facilities. Rather, Ranbaxy argued, post-MMA, § 355(j)(2)(A) "merely requires 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug.'" Ranbaxy claimed, under the post-MMA statutory scheme, that it need only describe how it would eventually meet cGMP compliance; the statute did not require that Ranbaxy actually be cGMP compliant to receive tentative approval.

167. DHHS and the FDA moved immediately for summary judgment, arguing that Ranbaxy's interpretation of the law was meritless.[86] As the FDA explained, Ranbaxy's interpretation

[85] Compl., *Ranbaxy Labs., Ltd v. Burwell*, No. 14-cv-01923-BAH (D.D.C. Nov. 14, 2014)

[86] Mot. For Summ. J., *Ranbaxy Labs., Ltd v. Burwell*, No. 14-cv-01923-BAH (D.D.C. Dec. 18, 2014)

conflated the requirements for an ANDA to be "substantially complete" (such that it may be received by the FDA) with the requirements for tentative approval. Substantial completeness requires merely that an ANDA "***contains all of the information*** required by paragraph (2)(A)." (emphasis added). Tentative approval requires that the ANDA ***meet all of the requirements*** of paragraph (2)(A). As the FDA explained, 21 U.S.C. §355(j)(5)(B)(iv)(II)(dd)(AA), governing an ANDA's eligibility for tentative approval, requires that the "*only* obstacle keeping an ANDA from receiving final approval – thereby compelling a tentative approval instead – must relate to timing,"[87] that is, the existence of a period of exclusivity or a stay. Properly interpreted, the statute requires an ANDA applicant to meet the cGMP compliance requirements to obtain tentative approval.

168. The FDA admitted that its initial tentative approvals for the Valcyte and Nexium ANDAs were granted in error, explaining that the mistake was caused by its reliance on Ranbaxy's misrepresentations to the FDA, including Ranbaxy's purported resolution of its cGMP deficiencies and the purported verification that all pending ANDAs contained no fraudulent data. As the FDA explained, Ranbaxy falsely represented in 2007 that it resolved all cGMP issues: "Ranbaxy's cGMP problems at Paonta Sahib were so significant they remain unresolved today (more than seven years after [the relevant] tentative approval letter was issued)."[88]

169. The FDA explained that the delay in rescinding tentative approval – and therefore the delay in permitting generic entry by other manufacturers' generic Valcyte and Nexium – "was largely of Ranbaxy's own making," based on Ranbaxy's obfuscation and delay.[89]

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[87] Def.'s Mem. In Opp'n to Pl.'s Mot. For a Prelim. Inj., *Ranbaxy Labs., Ltd v. Burwell*, No. 14-cv-01923-BAH (D.D.C. Dec. 22, 2014).

[88] *Id.*

[89] *Id.*

170. In February 2015, the court agreed with the FDA, rejecting Ranbaxy's interpretation of the tentative approval statutes – the same interpretation it urged the FDA to adopt in 2007 – because it "would, quite simply, lead to absurd results in at least two ways."[90]

171. First, the court explained, Ranbaxy's interpretation would mean that any description of methods, facilities and controls used in manufacturing would suffice – even if an applicant "state[d] in its ANDA that it planned to manufacture a generic drug in an outhouse behind the applicant's house using a child's chemistry set."[91] Under Ranbaxy's interpretation, "the FDA would have no power to deny tentative approval to that application on the grounds that the applicant could never, as submitted, be granted final approval since the application does not comply with cGMP."[92]

172. Second, Ranbaxy's interpretation would lead to the "patently absurd" result that the FDA "could not withhold tentative approval of an ANDA even if the FDA knew . . . that the ANDA contained an untrue statement of material fact."[93] The court observed that Ranbaxy could not "argue seriously that the FDA is prevented from denying tentative approval to an ANDA in such circumstances."[94]

173. Ranbaxy's misconduct could not be used as an excuse to circumvent clear regulatory requirements. The problems that plagued Ranbaxy for years leading to the consent decree, the criminal plea, and the civil settlement supported the FDA's determination that Ranbaxy fraudulently obtained tentative approvals to which it was not entitled.

H. The Impact on the Entry of Generic Nexium, Valcyte, and Diovan

[90] *Ranbaxy Labs., Ltd v. Burwell*, 82 F. Supp. 3d 159, 187 (D.D.C. 2015).

[91] *Id.* at 188.

[92] *Id.*

[93] *Id.*

[94] *Id.*

174. As federal regulators and law enforcement uncovered Ranbaxy's deceptive statements, fraudulent submissions, and non-compliant practices at manufacturing plants, many of Ranbaxy's ANDAs maintained their first-to-file status, including those for Nexium, Valcyte, and Diovan. Relying on Ranbaxy's misstatements, the FDA granted tentative approval to Ranbaxy's Nexium, Valcyte, and Diovan ANDAs.

175. After obtaining tentative approval, ongoing litigation or settlements still prevented the drugs from gaining final approval for market entry until an agreed upon entry date. Though this additional delay would grant Ranbaxy additional time to bring their facilities in compliance, Ranbaxy would prove unable to do so and their fraudulently obtained 180-day exclusivity period would prevent other generic manufacturers from coming to market as well even long after the agreed upon entry date. Ranbaxy unlawfully used their 180-day exclusivity as a "bottleneck to prevent additional generic competition."[95]

i. Ranbaxy Used 180-Day Exclusivity to Bottleneck Generic Diovan Competitors

176. As previously alleged, Ranbaxy filed the first ANDA for generic Diovan in 2004, and in 2007, it unlawfully gained tentative approval and locked in 180-day exclusivity for that product from the FDA.[96] The subsequent proceedings regarding Ranbaxy's ANDA for generic Diovan show that Ranbaxy's unlawful conduct delayed the entry of generic Diovan from at least September 21, 2012 until July 7, 2014.

[95] 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer)

[96] Ranbaxy filed the first ANDA for generic Diovan in 2004 and because it made a Paragraph IV certification with respect to one of the listed Diovan patents, it was eligible for the 180-day exclusivity period. The USP monograph (which provides standards for identity, quality, purity, strength, packaging, and labelling for ingredients) changed and compliance with the change extended the 30-month forfeiture deadline for tentative approval.

177. In the spring of 2007, over two years after filing its Diovan ANDA, Ranbaxy amended its filing, changing its Paragraph III certification regarding one of the listed patents to a Paragraph IV certification. (Ranbaxy continued its Paragraph IV certification on the other listed patent).

178. On August 9, 2007, Novartis Pharmaceuticals Corp. ("Novartis"), the brand company selling Diovan, sued Ranbaxy for patent infringement regarding the newly-challenged patent in the U.S. District Court for the District of New Jersey (the "Diovan ANDA Litigation").[97]

179. On September 13, 2007, Ranbaxy filed with the FDA a Patent Certification Amendment to its Diovan ANDA, changing its new Paragraph IV certification back to a Paragraph III certification.

180. On September 20, 2007, Ranbaxy and Novartis filed a stipulation of dismissal regarding the Diovan ANDA Litigation.[98] Under this stipulation, Ranbaxy agreed to delay launching its generic Diovan product until September 21, 2012 (the expiration date of the six-month pediatric exclusivity granted by the FDA beyond the March 21, 2012 expiration date for the '578 patent). The Diovan ANDA Litigation was dismissed on October 23, 2007.[99]

181. On October 25, 2007, Ranbaxy misled the FDA into mistakenly granting tentative approval for Ranbaxy's Diovan ANDA.

182. Ranbaxy's ongoing compliance failures and efforts to gain unlawful tentative approval for its generic Diovan ANDA may have impacted settlement negotiations with Novartis, which delayed entry from September 2007 to September 2012. The forfeiture of Ranbaxy's first-to-

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[97] *Novartis Pharmaceuticals Corporation et al. v. Ranbaxy Inc. et al.*, No. 3:07-cv-03755-MLC (D.N.J.)

[98] Stipulation and Dismissal, *Novartis Pharmaceuticals Corporation et al. v. Ranbaxy Inc. et al.*, No. 3:07-cv-03755-MLC (D.N.J. Sept. 20, 2007)

[99] Stipulation and Dismissal, *Novartis Pharmaceuticals Corporation et al. v. Ranbaxy Inc. et al.*, No. 3:07-cv-03755-MLC (D.N.J. Oct. 23, 2007)

file exclusivity may have impacted the efforts of other generic ANDA filers seeking to bring generic Diovan to market. As a result of the September 2007 agreement, any patent issues regarding the launch of generic Diovan were resolved such that, if Ranbaxy was otherwise in a position to gain final FDA approval, it should have been able to launch a generic Diovan on or about September 21, 2012 without repercussions from the holder of Diovan patents.

183. On September 21, 2012, the pediatric exclusivity associated with the relevant patent expired. While other listed patents for Diovan remained in force, Novartis had not asserted those patents against Ranbaxy, and they did not prevent Ranbaxy from gaining final approval. Ranbaxy, absent its reckless conduct, should have been in a position to gain final FDA approval for generic Diovan by this time.

184. By September 28, 2012, Mylan Pharmaceuticals, Inc. ("Mylan"), had obtained tentative approval in-hand for their generic Diovan ANDA and was ready to come to market.[100] But the FDA informed Mylan it could not receive final approval due to Ranbaxy's first-to-file status.

185. The January 26, 2012, Consent Decree classified the Diovan ANDA as an "Excepted Application." After reviewing written submissions made by Ranbaxy under paragraph XIV.A of the Consent Decree, the FDA notified Ranbaxy by letter dated May 4, 2012, that the FDA would begin reviewing audit reports submitted by Ranbaxy and its auditors for the Diovan ANDA.

186. However, Ranbaxy could not get the Paonta Sahib facility qualified to manufacture generic Diovan in compliance with applicable regulations; Ranbaxy had to give up the possibility of making generic Diovan in India.

187. Since Ranbaxy gave up the possibility of manufacturing generic Diovan in India, at some point, Ranbaxy found it necessary to undertake a full site transfer. After the consent decree

[100] *Mylan Labs. Ltd. v. U.S. Food & Drug Admin.*, 910 F. Supp. 2d 299, 304 (D.D.C. 2012)

was signed, but well before June 26, 2014, Ranbaxy requested, and received from the FDA, permission to manufacture generic Diovan at its Ohm Laboratories facility in New Brunswick, New Jersey. The active pharmaceutical ingredient ("API") in the Ranbaxy generic Diovan product was obtained from a third party, because the Ranbaxy facility at which the API would have been made was subject to the FDA import ban.

188. On June 26, 2014, the FDA finally granted final approval to Ranbaxy's Diovan ANDA.[101] In its approval letter, the FDA noted that despite Ranbaxy's failure to obtain tentative approval within the 30-month forfeiture date, the FDA "determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed" and that Ranbaxy was eligible for 180 days of exclusivity regarding its generic Diovan product.

189. Ranbaxy launched its generic Diovan product in the United States on or about July 7, 2014. On July 8, 2014, Sandoz, the generic pharmaceuticals division of Novartis, launched an authorized generic version of Diovan in the United States. Due to Ranbaxy's 180-day exclusivity, no other generic versions of Diovan could obtain approval from the FDA for six months after the launch of Ranbaxy's generic Diovan product.

190. On January 5, 2015, the FDA approved several other ANDAs for generic Diovan, including ANDAs submitted by Teva (Ivax) and Mylan. Mylan launched its generic Diovan product on the same day, and Teva launched its generic Diovan product the next day.

191. Were it not for Ranbaxy's wrongful conduct, generic Diovan would have become available at least as early as September 28, 2012, and all EPPs would have paid substantially less for valsartan than they did. If Ranbaxy had not wrongfully acquired, maintained, or used the

[101] Letter from Kathleen Uhl, Acting Director, CDER, to Sameer Manan, Official Agent, Ohm Laboratories Inc. (June 26, 2014).

bottlenecking 180-day exclusivity for valsartan, there would have been no bottleneck for the entry of other generics, and other generic companies could and would have entered the market for valsartan by gaining FDA approval and launching generic products at least as early as September 28, 2012.

ii. Ranbaxy Used 180-Day Exclusivity to Bottleneck Generic Nexium Competitors

192. As previously alleged, Ranbaxy submitted the first ANDA for generic Nexium on August 5, 2005 and in February 2008, it unlawfully gained tentative approval, locking in its 180-day exclusivity (and bottlenecking). The subsequent proceedings regarding Ranbaxy's ANDA for generic Nexium show that Ranbaxy's unlawful conduct unnecessarily delayed the entry of generic Nexium from at least May 27, 2014 until January 27, 2015.

193. On October 14, 2005, Ranbaxy sent a notice of certification of non-infringement to AstraZeneca, the brand company selling Nexium. On November 21, 2005, AstraZeneca sued Ranbaxy for patent infringement regarding the patents covering branded Nexium in the U.S. District Court for the District of New Jersey (the "Nexium ANDA Litigation").[102] Since the Nexium ANDA litigation was filed within 45 days of when AstraZeneca received notification of Ranbaxy's Paragraph IV certification, final approval of Ranbaxy's ANDA was effectively stayed for thirty months (or until the court ruled that the patents at issue did not prevent the launch of Ranbaxy's Nexium products).

194. In addition, AstraZeneca then sued Teva and Dr. Reddy's for patent infringement in 2006 and 2008, respectively, after those companies each filed paragraph IV ANDAs seeking to market generic Nexium products.

195. On April 14, 2008, on or around the expiration of the 30-month stay on FDA approval of Ranbaxy's generic Nexium ANDA, Ranbaxy and AstraZeneca settled the Nexium ANDA Litigation. Under the settlement agreement, AstraZeneca agreed to dismiss its lawsuit in

[102] *AstraZeneca AB, et al. v. Ranbaxy Pharmaceuticals Inc., et al.*, No. 3:05-cv-05553 (D.N.J.)

exchange for Ranbaxy agreeing to (1) admit that certain of AstraZeneca's Nexium-related patents were enforceable and valid; (2) admit that Ranbaxy's generic Nexium ANDA would infringe the Nexium-related patents; and (3) delay launching a generic version of Nexium until May 27, 2014. Ranbaxy allegedly received additional compensation, including lucrative manufacturing and distribution agreements and marketing privileges.

196. Ranbaxy's ongoing compliance failures and efforts to gain unlawful tentative approval for its generic Nexium ANDA may have impacted its settlement negotiations with AstraZeneca, which delayed the entry from April 2008 until May 2014. The forfeiture of Ranbaxy's first-to-file exclusivity may have impacted the efforts of other generic ANDA filers seeking to bring generic Nexium to market. As a result of the April 2008 agreement, any patent issues regarding the launch of generic Nexium were resolved such that, if Ranbaxy was otherwise in a position to gain final FDA approval, it should have been able to launch a generic Nexium product on or about May 27, 2014 without repercussions from AstraZeneca.

197. After settling with Ranbaxy, AstraZeneca settled its patent cases with Teva and Dr. Reddy's. On January 7, 2010, AstraZeneca settled with Teva, whereby, among other terms, AstraZeneca agreed to dismiss its lawsuit against Teva while Teva agreed to make similar admissions as Ranbaxy with respect to the Nexium-related patents and delay launching its generic Nexium product until May 27, 2014. AstraZeneca similarly settled with Dr. Reddy's on January 28, 2011, where AstraZeneca agreed to drop the patent litigation while Dr. Reddy's agreed to not challenge the Nexium related patents and to defer entering the market with its generic Nexium product until May 27, 2014.

198. Each of the patent litigation settlement agreements with Ranbaxy, Teva and Dr. Reddy's contained nearly identical contingent launch provisions, which effectively committed each

generic manufacturer to delay launch of generic Nexium until May 27, 2014 unless another generic manufacturer found a way to legally enter the market on an earlier date.

199. The January 26, 2012 Consent Decree classified the Nexium ANDA as an "Excepted Application." After reviewing written submissions made by Ranbaxy under paragraph XIV.A of the Consent Decree, the FDA notified Ranbaxy by letter dated May 4, 2012, that the FDA would proceed with the evaluation of the audit reports submitted by Ranbaxy and its auditors for the Nexium ANDA.

200. However, despite its misleading representations to the FDA otherwise, Ranbaxy could not get the Paonta Sahib facility qualified to manufacture generic Nexium in compliance with applicable regulations. Despite its inability to manufacture the product within cGMP regulations, Ranbaxy continued for years to stubbornly hold onto its 180-day exclusivity for generic Nexium, blocking entry for any other would-be generic manufacturer while Ranbaxy attempted to get its act together.

201. Two years later, as the agreed upon entry date approached, Ranbaxy was still unable to bring Nexium to market. In the spring of 2014, a series of citizen petitions were filed with the FDA. These petitions highlighted that Ranbaxy's wrongfully acquired 180-day exclusivities, like the one acquired for generic Nexium, bottlenecked ANDAs filed by other would-be generic competitors. The petitioners demanded that the FDA revoke Ranbaxy's first-to-file exclusivity and that it approve other ANDAs to foster competition. One such citizen petition, submitted May 5, 2014 by the law firm of Hyman, Phelps & McNamara, P.C. noted that the availability of generic Nexium would save the State of New York's Medicaid program approximately $83 million annually.[103]

[103] Hyman, Phelps & McNamara, P.C., Citizen Petition, FDA-2014-P-0594 (May 5, 2014) (on file with FDA Division of Docket Management).

202. After Ranbaxy's agreed-upon entry date of May 27, 2014 passed, consumer groups and state officials submitted comments to the citizen petitions arguing for the FDA to revoke Ranbaxy's first-to-file exclusivity. The Consumer Federation of California estimated that a 50 percent price reduction could result from the market entry of a generic substitute for Nexium, which "could save California consumers and health insurance payers $375 million a year; nationwide savings could exceed $3 billion."[104]

203. The Attorney General for the State of Connecticut noted that "Ranbaxy's actions have stalled FDA approval of any other generic drug alternatives to AstraZeneca's Nexium. Consumers, including the state of Connecticut's health programs, municipal and private payers and individual consumers have no access to more affordable, lower-priced generic Nexium. The manifest result of this inaction is higher prices and a dead-stop bottleneck preventing more than a half-dozen generic drug manufacturers lined up behind Ranbaxy from entering the market."[105]

204. On November 4, 2014, the FDA notified Ranbaxy that it erred in tentatively approving the Nexium ANDA because "the compliance status of the facilities referenced in the ANDA[] at the time the ANDA[] [was] granted tentative approval was inadequate to support approval or tentative approval." [106] The FDA rescinded its previously granted tentative approval of Ranbaxy's Nexium ANDA.

205. On January 26, 2015, the FDA notified Ranbaxy it forfeited its eligibility for 180-day exclusivity for generic Nexium. On the same date, the FDA issued final approval of 20mg/40 mg

[104] Consumer Federation of California, Response to Citizen Petition, FDA-2014-P-0594-0007 (Aug. 1, 2014) (on file with FDA Division of Docket Management)

[105] Office of the Attorney General, State of Connecticut, Response to Citizen Petition, FDA-2014-P-0594-0009 (Sept. 4, 2014).

[106] Letter from Thomas Cosgrove, Acting Director, CDER, to Arun Sawhney, CEO, Ranbaxy Laboratories Ltd. (Nov. 4, 2014).

versions of Teva's proposed generic Nexium product.[107] Teva launched its generic Nexium product a mere three weeks later, on or around February 17, 2015.

206. The FDA then granted final approval to several additional manufacturers seeking to bring generic Nexium products to market, including Mylan (August 3, 2015),[108] Dr. Reddy's Labs (September 25, 2015),[109] Torrent (October 19, 2015) and Aurobindo (April 21, 2016).

207. Were it not for Ranbaxy's wrongful conduct, generic Nexium would have become available at least as early as May 27, 2014, and all EPPs would have paid substantially less for esomeprazole magnesium than they did. If Ranbaxy had not wrongfully acquired, maintained, or used the bottlenecking 180-day exclusivity for esomeprazole magnesium, there would have been no bottleneck for the entry of other generics, and other generic companies could and would have entered the market for esomeprazole magnesium by gaining FDA approval and launching generic products at least as early as May 27, 2014.

iii. Ranbaxy Used 180-Day Exclusivity to Bottleneck Generic Valcyte Competitors

208. As previously alleged, Ranbaxy filed the first ANDA for generic Valcyte in 2005, and in 2008, it unlawfully gained tentative approval and locked in 180-day exclusivity. The subsequent proceedings regarding Ranbaxy's ANDA for generic Valcyte show that Ranbaxy's unlawful conduct delayed the entry of generic valganciclovir hydrochloride.

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[107] Defs.' Notice of Admin. Action, *Ranbaxy Labs., Ltd v. Burwell*, No. 14-cv-01923-BAH (D.D.C. Jan. 26, 2015)

[108] Letter from Carol Holquist, Acting Deputy Director, CDER, to Shane Shupe, U.S. Agent, Mylan Pharmaceuticals, Inc. (Aug. 3, 2015)

[109] Letter from Carol Holquist, Acting Deputy Director, CDER, to Dr. Reddy's Laboratories, Inc. (Sept. 25, 2015)

209. On April 28, 2006, Roche Palo Alto, LLC ("Roche"), the brand manufacturer selling Valcyte, sued Ranbaxy for patent infringement regarding the Valcyte ANDA in the U.S. District Court for the District of New Jersey (the "Valcyte ANDA Litigation").[110]

210. In June 2008, Ranbaxy misled the FDA into granting tentative approval for Ranbaxy's Valcyte ANDA.

211. On or about August 26, 2010, Ranbaxy and Roche entered into a settlement of the Valcyte ANDA Litigation. Under the settlement, Ranbaxy agreed to delay launching its generic Valcyte product until March 15, 2013.

212. Ranbaxy's ongoing compliance failures and efforts to wrongfully acquired tentative approval for its generic Valcyte ANDA may have impacted the settlement agreement with Roche, which delayed entry from August of 2010 to March of 2013. The forfeiture of Ranbaxy's first-to-file exclusivity may have impacted the efforts of other generic ANDA filers seeking to bring generic Valcyte to market. As a result of the August 2010 agreement, any patent issues with respect to the launch of generic Valcyte were resolved such that, if Ranbaxy was otherwise in a position to gain final FDA approval, it should have been able to launch a generic Valcyte on or about March 15, 2013, without repercussions from the holder of Valcyte patents.

213. The January 26, 2012, Consent Decree classified the Valcyte ANDA as an "Excepted Application." After reviewing written submissions made by Ranbaxy under paragraph XIV.A of the Consent Decree, the FDA notified Ranbaxy by letter dated May 15, 2012, that the FDA would begin reviewing the audit reports submitted by Ranbaxy and its auditors for the Valcyte ANDA.

214. The FDA informed Ranbaxy that it would resume reviewing the Valcyte ANDA. However, Ranbaxy could not get the Paonta Sahib facility qualified to manufacture generic Valcyte

[110] *Roche Palo Alto, LLC v. Ranbaxy Laboratories Limited, et al.*, No. 06-cv-02003-FLW (D.N.J.)

in compliance with applicable regulations; Ranbaxy continued for years to stubbornly hold onto its 180-day exclusivity for generic Valcyte, completely restricting any other generic manufacturer's ability to enter the market while Ranbaxy attempted to get its act together.

215. Two years later, Ranbaxy had yet to bring generic Valcyte to market. In the spring of 2014, a series of citizen petitions were filed with the FDA. These petitions pointed out that Ranbaxy's wrongfully acquired 180-day exclusivity bottlenecked ANDAs filed by other would-be generic competitors. The petitioners demanded that the FDA revoke Ranbaxy's first-to-file exclusivity and that it approve other ANDAs to foster competition.

216. On November 4, 2014, the FDA notified Ranbaxy that it erred in tentatively approving the Valcyte ANDA because "the compliance status of the facilities referenced in the ANDA[] at the time the ANDA[] [was] granted tentative approval was inadequate to support approval or tentative approval." [111] The FDA rescinded its previously granted tentative approval of Ranbaxy's Valcyte ANDA and determined that Ranbaxy forfeited its eligibility for 180-day exclusivity.[112]

217. On the same day that the FDA rescinded the tentative approval of Ranbaxy's Valcyte ANDA, the FDA approved two other ANDAs for valganciclovir hydrochloride tablets: (1) ANDA No. 200790 submitted by Endo Pharmaceuticals[113] and (2) ANDA No. 203511 submitted by Dr. Reddy's Laboratories, Inc.[114]

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[111] Letter from Kathleen Uhl, Acting Director, CDER, to Sameer Manan, Director Regulatory Affairs, Ranbaxy Inc. (Nov. 4, 2014).

[112] In that same letter, and for the same reasons, the FDA notified Ranbaxy that it was rescinding the tentative approval that had been granted to Ranbaxy's Nexium ANDA. The FDA made no determination at that time concerning 180-day exclusivity on the Nexium ANDA. On January 26, 2015, the FDA notified Ranbaxy that it had forfeited its eligibility for 180-day exclusivity for generic Nexium.

[113] Letter from Jason J.Y. Woo, Acting Director, CDER, to Cynthia Holdos, RA Principal, Endo Pharmaceuticals (Nov. 4, 2014).

[114] Letter from Jason J.Y. Woo, Acting Director, CDER, to Srinivasa Rao, U.S. Agent, Dr. Reddy's Laboratories Inc. (Nov. 4, 2014).

218. On or about November 20, 2014, Endo launched its generic Valcyte product in the U.S. market. On December 18, 2014, Dr. Reddy's Laboratories launched its generic Valcyte.

219. Were it not for Ranbaxy's wrongful conduct, generic Valcyte would have become available in the U.S. market at least as early as August 1, 2014, and all EPPs would have paid substantially less for valganciclovir hydrochloride than they did. If Ranbaxy had not wrongfully acquired, maintained or used the bottlenecking 180-day exclusivity for valganciclovir hydrochloride, there would have been no bottleneck for the entry of other generics, and other generic companies could and would have entered the market for valganciclovir hydrochloride by gaining FDA approval and launching generic products at least as early as March 15, 2013.

VI. MARKET POWER AND MARKET DEFINITION

220. Ranbaxy wrongfully acquired, locked in, and used market power over the markets for valsartan, esomeprazole magnesium, and valganciclovir hydrochloride, or narrower markets contained therein.

221. The Hatch-Waxman Amendments empower the holder of a lawfully acquired first-to-file, 180-day exclusivity to exclude all other would-be generics from gaining ANDA approval of their applications until expiration of the exclusivity. This exclusivity enables the holder to exert market power in several ways.

222. First, the holder of the 180-day exclusivity largely can determine when the first generic entrant will appear in the market. Of course, as a general rule, generic companies seek to enter the market at the earliest reasonable time they can, close on the heels of promptly acquired FDA approval, and as soon as patent obstacles might be removed. But since ANDA filers who are behind a locked-in, 180-day exclusivity generally must wait for the exclusivity to lapse, the first-filer has the ability to control when generics enter. Moreover, by delaying entry of generics, the first-filer extends the period of time during which the brand company is able to charge supracompetitive

prices for branded versions of the drugs. This causes consumers and payors, like EPPs, to pay supracompetitive prices for branded versions of the drugs for longer than they otherwise would have.

223. Second, the holder of the 180-day exclusivity largely has the power, once it enters, to exclude other ANDA-based generic manufacturers' products from entering those markets. While ANDA filers who are behind a locked-in, 180-day exclusivity wait for the exclusivity to lapse, the first-filer can capture an overwhelming majority of the market in a very short span of time.

224. Third, while the first-filer is the only ANDA-approved generic on the market for the first six months, it can charge much higher prices that are close to, albeit lower than, the brand price, without losing substantial sales to other products prescribed and/or used for the same purposes, including brand name versions of the drug.

225. Valsartan tablets, esomeprazole magnesium capsules, and valganciclovir hydrochloride tablets do not exhibit significant, positive cross-elasticity of demand at the competitive price with any product other than its AB-rated generic equivalents. Further, with respect to ANDA-based generics of valganciclovir hydrochloride tablets, valsartan tablets and esomeprazole magnesium capsules, such products do not exhibit significant, positive cross-elasticity of demand at the competitive price with any product other than other, ANDA-based AB-rated generic equivalents.

226. A small, but significant, non-transitory price increase for these drugs by Ranbaxy, as the first-filer, would not have caused a significant loss of sales to other medications and would not have made such a price increase unprofitable.

227. Valsartan is an angiotensin II receptor antagonist (commonly called an "ARB"), approved by the FDA to treat hypertension and heart failure and to reduce cardiovascular mortality in patients with problems of the left ventricle of the heart following myocardial infarction. The FDA

approved the drug for sale in 2001. Novartis brought it to market under the brand name Diovan. In 2003, U.S. sales of Diovan were $632 million; by 2008, sales had reached $1.2 billion; by 2012, sales had reached $1.9 billion; and in 2013, they exceeded $2.1 billion. There is no reasonably interchangeable drug product for the indications for which valsartan is prescribed. Valsartan has attributes significantly differentiating it from other medications for similar indications, making it unique. Because, among other reasons, it was the only drug approved to treat a trio of conditions – hypertension, high-risk heart attack survivors, and patients with heart failure – valsartan is differentiated from all products.

228. Esomeprazole magnesium is a proton pump inhibiter (PPI) prescribed to treat heartburn and related conditions. The FDA approved the drug for sale in the United States in 2001. AstraZeneca brought it to market in tablet form under the brand name Nexium, which produced annual U.S. sales of approximately $3 billion. Nexium's pharmacological profile, its side effect and efficacy profile differs from other proton pump inhibitors, H2 blocks, and non-prescription antacids used to treat the same or similar conditions. These other drugs are not AB-rated to Nexium, cannot automatically be substituted for Nexium by pharmacists, and do not exhibit cross-price elasticity of demand regarding Nexium. Esomeprazole magnesium is therefore differentiated from all products.

229. Valganciclovir hydrochloride is an orally administered antiviral medication, approved by the FDA to treat cytomegalovirus ("CMV") retinitis in AIDS patients and for the prevention of CMV disease in organ transplant recipients. It is one of only two drugs approved to treat CMV in kidney transplant patients. The FDA approved the drug for sale in the United States in 2001. Roche brought it to market in tablet form under the brand name Valcyte. In 2008, U.S. sales of Valcyte were $160 million; and by 2013, that figure had reached $500 million. There is no reasonably interchangeable drug product for the indications for which valganciclovir hydrochloride is prescribed. Valganciclovir hydrochloride has superior bioavailability to the other CMV drug, called

ganciclovir, meaning that patients can take smaller doses of the drug less often. And, unlike other medications to treat CMV, which must be administered intravenously, Valcyte tablets can be taken orally. According to Roche, Valcyte satisfied a long-felt, but unsatisfied need, in the drug marketplace. Roche has called it the "gold standard," the "drug of choice," the "treatment of choice," and the "standard of care" for the prevention and treatment of CMV disease. In its 2004 annual report, Roche reported that Valcyte remained "the leading drug for the treatment of CMV retinitis in HIV patients." Valganciclovir hydrochloride is therefore differentiated from all products.

230. The pharmaceutical marketplace is characterized by a disconnect between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products to patients without a prescription written by a doctor, including valsartan, valganciclovir hydrochloride, and esomeprazole magnesium. This prohibition divorces the payment obligation and the product selection: the patient (and usually his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

231. Studies show that doctors typically are not aware of the relative costs of pharmaceuticals, and, even when they are, they are insensitive to price differences because they do not have to pay for the products.

232. Unlike many consumer products, where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the initial purchasing decision for prescription drugs is made by the physician, not by consumers of these products.

233. To be a substitute for antitrust purposes, a functionally similar product must exert sufficient pressure on prices and sales of another product, so the price of that product cannot be maintained above levels maintained in a competitive market. No other antiviral medication (except

for ANDA-based AB-rated generic versions of Valcyte), no other ARB (except for ANDA-based AB-rated generic versions of Diovan), and no other PPI (except ANDA-based AB-rated generic versions of Nexium) will, or would, take away sufficient sales from these drugs to prevent Ranbaxy from raising or maintaining the price of its AB-rated generic equivalent above levels that would prevail in a competitive market.

234. Ranbaxy has had, and exercised, the power to exclude competition from the relevant markets.

235. Ranbaxy needed to control only its ANDA-based AB-rated generic equivalents of its products, and no other products, in order to raise prices of Valcyte, Diovan, and Nexium substantially above competitive levels. Only the market entry of a competing, ANDA-based AB-rated generic version of Diovan, Nexium, and Valcyte would diminish Ranbaxy's ability to maintain its dominance over the market.

236. Due to its first-filer status and possession of 180-day exclusivity, while Ranbaxy awaited final approval of its ANDAs with full knowledge that it did not possess the ability to safely manufacture generic Valcyte, Nexium, and Diovan, Ranbaxy's power to exclude competitors reduced output of generic Valcyte, Nexium and Diovan and restricted competition in these markets, while Ranbaxy maintained enormous profits. Ranbaxy sold or expected to sell its generic products at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoy high profit margins.

237. Accordingly, while Ranbaxy maintained its ANDAs for Valcyte, Nexium, and Diovan, purchasers and payors, like EPPs, were denied the competitive effects of other generic manufacturers entering the market and a reduction of the supracompetitive prices caused by Ranbaxy's misconduct.

238. If Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant markets are (a)valsartan tablets, generic valsartan tablets, or ANDA-based versions of valsartan tablets; (b) valganciclovir hydrochloride tablets, valganciclovir hydrochloride tablets, or ANDA-based versions of valganciclovir hydrochloride tablets; and (c)esomeprazole magnesium tablets, generic esomeprazole magnesium tablets, or ANDA-based versions of esomeprazole magnesium tablets. During the relevant period to this case, Ranbaxy has controlled competition in these markets.

239. Ranbaxy, at all relevant times, enjoyed high barriers to entry regarding competition to the above defined relevant markets due to patent and other regulatory protections, and high costs of entry and expansion.

240. The relevant geographic market is the United States and its territories.

VII. MARKET EFFECTS

241. Ranbaxy, acting alone and/or in concert with Beardsley and Parexel, willfully and unlawfully obtained, maintained, or attempted to achieve market power by engaging in an overarching scheme to exclude competition. Ranbaxy designed this scheme, which discouraged competition on the merits, for the anticompetitive purpose of forestalling generic competition and monopolizing the relevant markets, and carried out the scheme with the anticompetitive effect of maintaining supracompetitive prices for the relevant products. Ranbaxy implemented its scheme by, *inter alia*, engaging in protracted misrepresentations and falsehoods to secure tentative approvals to which it was not lawfully entitled. It used the deceptively obtained first-to-file exclusivity, both to obtain settlements with brand companies that secured benefits for itself and delayed generic entry far longer than would have otherwise occurred, and to exclude other generics from entering the market. And its deficient manufacturing operations, which it shielded from FDA scrutiny when obtaining tentative approvals, resulted in Ranbaxy being unable to bring its generic drugs to market

in a timely manner. These acts, in combination and individually, were all undertaken to serve Ranbaxy's anticompetitive goals.

242. Ranbaxy's acts and practices, including its conspiracy with Beardsley and Parexel, had the purpose and effect of unreasonably restraining competition and injuring competition by protecting its generic products from other generic competition. Ranbaxy's actions, including its conspiracy with Beardsley and Parexel, allowed it to maintain a monopoly and exclude competition in the markets for the aforementioned drugs, *i.e.*, Diovan, Valcyte, Nexium, and their AB-rated generic equivalents (or in the narrower markets for ANDA-based generic versions of those products), to the detriment of Plaintiffs and all other members of the EPP class.

243. Ranbaxy's exclusionary conduct, including its conspiracy with Beardsley and Parexel, delayed generic competition for Diovan, Valcyte, and Nexium, and unlawfully enabled it to sell generic Diovan without other ANDA-based generic competition. But for Ranbaxy's illegal conduct, one or more generic competitors could have begun marketing AB-rated generic versions of these drugs much sooner than they were marketed.

244. By way of examples and not limitation, absent Ranbaxy's unlawful conduct, along and in concert with Beardsley and Parexel: (i) Ranbaxy would not have received tentative approval of its Diovan, Valcyte, and Nexium ANDAs within the time period established by applicable regulations, but would have forfeited its 180-day exclusivity, removing a substantial barrier to the market entry of multiple other generic companies; (ii) any settlement that Ranbaxy reached with a brand firm would not have foreclosed earlier entry by other generic companies; and (iii) other generic ANDA filers would have known, in October 2007 for Diovan, in February 2008 for Nexium, and in June 2008 for Valcyte, that there would be no generic ANDA applicant entitled to 180-day exclusivity, which would have incentivized other ANDA filers to proceed more rapidly with their own ANDA efforts for those drugs.

245. Other generic manufacturers seeking to sell generic Diovan, Nexium, and/or Valcyte all had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and at least several of these generic manufacturers would have been ready, willing, and able to effectuate earlier launches of their generic versions of Diovan (no later than September 28, 2012), Nexium (no later than May 27, 2014) and Valcyte (no later than August 1, 2014) were it not for Ranbaxy's illegal and unlawful acts and conspiracies with Beardsley and Parexel.

246. Ranbaxy's illegal acts and conspiracies with Beardsley and Parexel to delay the introduction into the U.S. marketplace of any other generic versions of Diovan, Nexium, and Valcyte caused Plaintiffs and all members of the class to pay more than they would have paid for these drugs (both branded and, eventually, generic versions) absent this illegal conduct.

247. Typically, generic versions of brand-name drugs are initially priced significantly below the branded counterpart. Consequently, upon generic entry, EPPs substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generics. This price competition enables all end-payors of the drugs to purchase generic versions of a drug at a substantially lower price, and/or purchase the brand name drug at a reduced price.

248. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, EPPs, such as Plaintiffs and members of the class, would have paid less for these drugs by (a) receiving discounts on their remaining brand purchases of these drugs, (b) substituting purchases of less-expense generic versions for their purchases of

more-expensive brand versions, and/or (c) purchasing the generic versions of these drugs at lower prices sooner.

249. Due to Ranbaxy's fraud, other generic manufacturers were discouraged from and/or delayed in developing their own generic versions of these drugs, and/or challenging the validity or infringement of the patents purporting to cover these drugs in court.

250. Thus, Ranbaxy's unlawful conduct deprived the Plaintiffs and the members of the EPP class of the benefits from competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

251. During the relevant period, Plaintiffs and members of the EPP class purchased substantial amounts of Diovan, Nexium, and Valcyte. Because of Defendants' illegal conduct, members of the EPP class were compelled to pay, and did pay, artificially inflated prices for their drug requirements on these purchases. Those prices were substantially greater than the prices that members of the EPP class would have paid absent the alleged illegal conduct because: (1) the price of brand-name Diovan, Nexium, and Valcyte was artificially inflated by Defendants' illegal conduct; (2) EPP class members were deprived of the opportunity to purchase lower-priced generic versions of Diovan, Nexium, and Valcyte sooner; and/or (3) the price of generic Diovan, Nexium, and Valcyte was artificially inflated by Defendants' illegal conduct.

252. As a consequence, Plaintiffs and members of the EPP class have sustained substantial losses and damage to their business and property in overcharges. The full amount, form, and components of such damages will be calculated after discovery and upon proof at trial.

253. Ranbaxy's efforts to monopolize and restrain competition in the markets for these drugs, and/or the markets for ANDA-based AB-rated versions of these products, substantially affected interstate and foreign commerce.

254. At all material times, Ranbaxy manufactured, promoted, distributed, and sold, and/or prevented the manufacturing, promotion, distribution, and sale of, substantial amounts of these drugs in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

255. At all material times, Ranbaxy transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of these drugs.

256. To further their efforts to monopolize and restrain competition in the market for these drugs, Ranbaxy employed the U.S. mail and interstate and international wire lines, as well as means of interstate and international travel. Ranbaxy's activities were within the flow of and have substantially affected interstate commerce.

IX. CLASS ACTION ALLEGATIONS

257. Plaintiffs bring this action on behalf of themselves and all others similarly situated as a class action under Federal Rule of Civil Procedure 23(a) and (b)(3), seeking damages, measured as overcharges, trebled against Defendants based on allegations of anticompetitive and fraudulent conduct in the markets for Diovan, Nexium, and Valcyte, and their AB-rated generic equivalents, and/or in the markets for ANDA-based AB-rated generic equivalents of these products, on behalf of the following class (the "Nationwide Classes"):

> All persons or entities in the United States and its territories that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Diovan and/or AB-rated generic versions of Diovan from any of the Defendants or any brand or generic manufacturer at any time during the class period September 28, 2012, through and until the anticompetitive effects of the Defendants' conduct cease (the "Diovan Class Period");
>
> All persons or entities in the United States and its territories that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of AB-rated generic versions of Nexium from any of the Defendants or any brand or generic manufacturer,

> other than for resale, at any time during the class period May 27, 2014, through and until the anticompetitive effects of the Defendants' conduct cease (the "Nexium Class Period"); and
>
> All persons or entities in the United States and its territories that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Valcyte and/or AB-rated generic versions of Valcyte from any of the Defendants or any brand or generic manufacturer, other than for resale, at any time during the class period August 1, 2014, through and until the anticompetitive effects of the Defendants' conduct cease (the "Valcyte Class Period").
>
> These classes exclude: (a) natural person consumers; (b) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (c) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (d) all persons or entities who purchased Diovan, Nexium, Valcyte, or their AB-rated generic versions for purposes of resale from any of the Defendants or any brand or generic manufacturer; (e) fully insured health plans (i.e., health plans that purchased insurance covering 100% of their reimbursement obligation to members); and (f) pharmacy benefit managers.

258. Plaintiffs also bring this action on behalf of themselves and all others similarly situated as a class action under Federal Rule of Civil Procedure 23(a) and (b)(3), seeking damages pursuant to the state antitrust, unfair competition, and consumer protection laws of the states and territories listed below (the "Indirect Purchaser States")[115] on behalf of the following classes (the "Indirect Purchaser States Classes"):

> All persons or entities in the Indirect Purchaser States that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Diovan and/or AB-rated generic versions of Diovan from any of the Defendants or any brand or generic manufacturer, other than for resale, at any time during the class period September 28, 2012, through and until the anticompetitive effects of the Defendants' conduct cease (the "Diovan Class Period");
>
> All persons or entities in the Indirect Purchaser States that indirectly purchased, paid, and/or provided reimbursement for some or all of

[115] The "Indirect Purchaser States" include Arizona, California, the District of Columbia, Florida, Hawaii, Iowa, Massachusetts, Maine, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Pennsylvania, South Dakota, Vermont, West Virginia, and Wisconsin.

> the purchase price of AB-rated generic versions of Nexium from any of the Defendants or any brand or generic manufacturer, other than for resale, at any time during the class period May 27, 2014, through and until the anticompetitive effects of the Defendants' conduct cease (the "Nexium Class Period"); and
>
> All persons or entities in the Indirect Purchaser States that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Valcyte and/or AB-rated generic versions of Valcyte from any of the Defendants or any brand or generic manufacturer, other than for resale, at any time during the class period August 1, 2014, through and until the anticompetitive effects of the Defendants' conduct cease (the "Valcyte Class Period").
>
> These classes exclude: (a) natural person consumers; (b) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (c) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (d) all persons or entities who purchased Diovan, Nexium, Valcyte, or their AB-rated generic versions for purposes of resale from any of the Defendants or any brand or generic manufacturer; (e) fully insured health plans (i.e., health plans that purchased insurance covering 100% of their reimbursement obligation to members); and (f) pharmacy benefit managers.

259. The Nationwide Classes and the Indirect Purchaser States Classes are referred to herein as the "Classes."

260. Members of the Classes are so numerous that joinder is impracticable. Plaintiffs believe there are thousands of members of the in each class.

261. Plaintiffs' claims are typical of the claims of the members of the Classes. Plaintiffs and all members of the Classes were damaged by the same wrongful conduct of the Defendants, *i.e.*, they paid artificially inflated prices for valganciclovir hydrochloride, esomeprazole magnesium, and valsartan and were deprived of earlier and more robust competition from cheaper generic versions of Diovan, Nexium, and Valcyte because of Defendants' wrongful conduct.

262. Plaintiffs will fairly and adequately protect and represent the interests of the Classes. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the Classes.

263. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

264. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual class members because Defendants have acted on grounds generally applicable to all the members of both Classes, thereby making appropriate relief with respect to the Classes as a whole. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

265. Questions of law and fact common to the Classes include, but are not limited to:

a. whether a RICO enterprise existed between and among Ranbaxy, Beardsley and Parexel;

b. whether Ranbaxy participated, directly or indirectly, in the conduct of the enterprise;

c. whether Ranbaxy participated through a pattern of racketeering activity, that is, whether Ranbaxy committed at least two, distinct predicate acts, related to one another and the overall conspiracy;

d. whether Ranbaxy agreed with Beardsley and/or Parexel to attempt to accomplish an unlawful plan to engage in a pattern of racketeering activity;

e. whether Ranbaxy agreed to the overall objective of the conspiracy – gaining tentative approval for Diovan/Valcyte/Nexium;

f. whether Ranbaxy unlawfully obtained tentative approval of its ANDA for generic Diovan/Valcyte/Nexium;

g. whether Ranbaxy willfully obtained and/or maintained market power over Diovan and its generic equivalents;

h. whether Ranbaxy willfully obtained and/or maintained market power over Nexium and its generic equivalents;

i. whether Ranbaxy willfully obtained and/or maintained market power over Valcyte and its generic equivalents;

j. whether Ranbaxy unlawfully excluded competitors and potential competitors from the market for Diovan, Nexium, and Valcyte and their AB-rated generic bioequivalents;

k. whether Ranbaxy unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

l. whether Ranbaxy maintained market power, itself and/or in conspiracy with Beardsley and Parexel, by delaying generic entry;

m. whether the law requires definition of a relevant market when direct proof of market power is available, and if so the definition of the relevant market;

n. whether Ranbaxy's activities as alleged herein have substantially affected interstate commerce;

o. whether, and if so to what extent, Ranbaxy's conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the classes; and

p. the quantum of overcharges paid by the Classes; and

q. the appropriate class-wide measure of damages for the Classes.

266. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

267. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

X. CLAIMS FOR RELIEF

COUNT ONE - VIOLATION OF RICO, 18 U.S.C. § 1962(c)
(Asserted Against Ranbaxy Labs, Ranbaxy Inc. and Sun Pharma)

268. Plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations, as though fully set forth herein.

269. Defendant Ranbaxy Labs is a "person" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of an enterprise, the Ranbaxy ANDA Enterprise, through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

270. Defendant Ranbaxy Inc. is a "person" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Ranbaxy ANDA Enterprise, through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

271. The Ranbaxy ANDA Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of: (i) Defendant Ranbaxy Labs, including its employees and agents; (ii) Defendant Ranbaxy Inc., including its employees and agents; (iii) the law firm of Buc Beardsley LLP, including its employees and agents; and (iv) Parexel Consulting LLC, including its employees and agents. The Ranbaxy ANDA Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. The defendant "persons" are distinct from the Ranbaxy ANDA Enterprise.

272. The Ranbaxy ANDA Enterprise fits within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" that created and maintained systematic links for a common purpose: to aid in protecting and profiting from Ranbaxy's first-to-file status associated with a number of Ranbaxy ANDAs – including the ANDAs for generic Diovan, Valcyte and Nexium – by misleading, through affirmative statements and omissions, the FDA regarding the compliance status of Ranbaxy's Paonta Sahib facility, the truthfulness of the data within the ANDAs, and the completeness of the ANDAs.

273. Defendants have conducted and participated in the affairs of the Ranbaxy ANDA Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and

multiple instances of wire fraud in violation of 18 U.S.C. § 1343, and travel in interstate and foreign commerce in aid of racketeering enterprises in violation of 18 U.S.C. § 1952, as described above.

274. Beardsley participated in the conduct of the Ranbaxy ANDA Enterprise's affairs, sharing the common purpose to enable Ranbaxy to unlawfully obtain 180-day exclusivity for generic versions of Diovan, Valcyte, and Nexium, and potentially for other drugs. Ranbaxy and Beardsley knew that Ranbaxy alone could not conceal unfavorable facts regarding the state of its Paonta Sahib facility. Ranbaxy and Beardsley also knew that the damning conclusions of Parexel's audit reports, if funneled through a law firm, could be cloaked in frivolous claims of attorney work product. Ranbaxy and Beardsley knew that Ranbaxy needed to recruit an attorney or law firm willing to aid in that concealment. Ranbaxy found a willing and knowing participant in Beardsley.

275. Beardsley knowingly made material misstatements to the FDA in furtherance of the fraudulent scheme regarding: (1) the state of Ranbaxy's cGMP compliance, (2) Ranbaxy's efforts (or lack thereof) to remediate those compliance issues, (3) the extent to which those cGMP violations affected the integrity of Ranbaxy's pending ANDA submissions, and (4) the extent to which Parexel's audits were shielded from FDA scrutiny by the attorney-client privilege or attorney work product doctrine. Beardsley transmitted those statements via mail or wire, with the intent to aid Ranbaxy in wrongfully securing its first-to-file ANDA tentative approvals. And the firm aided Ranbaxy's fraudulent endeavors through multiple communications with the FDA and assertions of attorney-client privilege and attorney work product, knowing that Ranbaxy intended to – and did – use these contributions in furtherance of its scheme to defraud the FDA.

276. Parexel also participated in the conduct of the Ranbaxy ANDA Enterprise's affairs, and shared Ranbaxy's common purpose to unlawfully obtain 180-day exclusivity for generic versions of Diovan, Valcyte and Nexium, and potentially for other drugs. Ranbaxy, Beardsley, and Parexel knew that, without assistance, Ranbaxy could not successfully dupe the FDA into believing that the

compliance issues had been satisfactorily addressed. Ranbaxy, Beardsley, and Parexel knew that an esteemed audit firm – whose Vice President was a former high-ranking FDA official – would give Ranbaxy's responses to the FDA a patina of legitimacy. Parexel agreed to fill this role, knowing that the information transmitted to the FDA regarding its audits would be materially misleading. To assist in concealing the complete audit results from the FDA, Parexel agreed to allow its findings to be funneled through Beardsley. Parexel permitted its findings regarding noncompliance and tainted ANDAs to be hidden from the FDA. This was done so those ANDAs could be approved. Parexel agreed to, and did, make false statements of fact to the FDA with the intent to further the scheme to defraud the FDA.

277. The Ranbaxy ANDA Enterprise engaged in and affected interstate commerce, because, *inter alia*, it obtained approval to market – and in some cases marketed – drugs sold to dozens of class members and consumed by thousands of individuals throughout the United States, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

278. Defendants Ranbaxy Labs and Ranbaxy Inc. exerted control over the Ranbaxy ANDA Enterprise, and Defendants Ranbaxy Labs and Ranbaxy Inc. participated in the operation or management of the affairs of the Ranbaxy ANDA Enterprise, through many actions, including:

a. Recruiting Beardsley and Parexel to contribute to the operation of the enterprise, directing the actions of Beardsley and Parexel, and controlling what Beardsley and Parexel told the FDA, or did not tell the FDA;

b. Employing Beardsley and Parexel to confer upon the actions of the ANDA Enterprise an air of legitimacy;

c. Misrepresenting to the FDA the state of Ranbaxy's cGMP compliance at its Paonta Sahib facility;

d. Misrepresenting whether and to what extent Ranbaxy was attempting to remedy its cGMP compliance issues;

e. Misrepresenting whether the CGMP compliance issues at Paonta Sahib affected the integrity of any data contained within US-filed ANDAs; and

f. Refusing to provide to the FDA – and directing Beardsley and Parexel to refuse to provide to the FDA – copies of audits performed by Parexel at the Paonta Sahib facility, because those audits would have belied Ranbaxy's misrepresentations.

279. As detailed above, defendants Ranbaxy Labs' and Ranbaxy Inc.'s fraudulent scheme consisted of, *inter alia*: (a) manufacturing or otherwise falsifying data to be included with information submitted to the FDA to prosecute ANDAs, to keep development costs down and expedite the ANDA tentative approval process to obtain valuable first-to-file status; (b) submitting, or causing to be submitted, information to support ANDAs that contained materially false statements of fact and omissions of material information; (c) deceiving the FDA, either directly or through another member of the Ranbaxy ANDA Enterprise, regarding (i) whether Paonta Sahib complied with cGMP regulations, (ii) whether Ranbaxy was trying to bring Paonta Sahib into compliance with cGMP regulations, or (iii) whether known violations of cGMP regulations materially affected data submitted to the FDA in connection with various Ranbaxy ANDAs, including for generic Diovan, Valcyte, and Nexium; and (d) resisting, without a non-frivolous basis in law or fact, the FDA's and the government's reasonable requests and administrative subpoenas for documentation likely to establish the falsity of the statements by Defendants Ranbaxy Labs and Ranbaxy Inc., as well as other members of the Ranbaxy ANDA Enterprise.

280. The scheme devised and implemented by Defendants Ranbaxy Labs and Ranbaxy Inc., as well as other members of the Ranbaxy ANDA Enterprise, amounted to a common course of conduct intended to (a) deceive the FDA as to whether the Paonta Sahib facility was in compliance with cGMP regulations, and whether Ranbaxy's submissions to support tentative approval of ANDAs were truthful and in compliance with required regulations; and thereby (b) forestall or avoid adverse regulatory action by the FDA; such that (c) Defendants Ranbaxy Labs and Ranbaxy Inc. could fraudulently maintain their valuable first-to-file status for various Ranbaxy ANDAs, including

for generic Diovan, Valcyte and Nexium; to allow Ranbaxy to (d) exercise its market power and its 180-day period of exclusivity to improperly profit from the ANDAs.

281. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and the Nationwide Class.

282. The pattern of racketeering activity alleged herein, and the Ranbaxy ANDA Enterprise are separate and distinct from each other. Defendants Ranbaxy Labs and Ranbaxy Inc. engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Ranbaxy ANDA Enterprise.

283. Because of Defendants' fraudulent activities, generic versions of drugs, including Diovan, Nexium, and Valcyte, were kept off the market for longer than they would have been absent Defendants' fraudulent activities, resulting in increased costs to end-payors of those drugs in the form of payments and/or reimbursements, including the Plaintiffs and all members of the Nationwide Class.

284. Plaintiffs and others similarly situated have been injured in their business and property from Ranbaxy's fraudulent scheme and the success of the Ranbaxy ANDA Enterprise. Plaintiffs and others similarly situated have paid hundreds of millions, if not billions, of dollars more for Diovan, Nexium, and Valcyte, and their generic equivalents, than they would have absent the fraudulent conduct underlying the Ranbaxy ANDA Enterprise.

285. Injuries of Plaintiffs and Members of the Nationwide Classes were proximately caused by Defendants' racketeering activity. But for the misstatements made by Ranbaxy, Beardsley, and Parexel to the FDA, and the scheme to (wrongfully) capture and maintain 180-day exclusivity as to generic Diovan, Nexium, and Valcyte, generic versions of these drug would have been available for purchase sooner, resulting in savings to the Plaintiffs and others similarly situated in the form of

lower payments and/or reimbursements, amounting to hundreds of millions, if not billions of dollars.

286. Injuries of Plaintiffs and Members of the Nationwide Classes were directly caused by Defendants' racketeering activity. While Ranbaxy's fraudulent statements were conveyed to the FDA, the FDA sustained no damages to its business or property because of the fraud and has no incentive to sue in RICO. Although the Ranbaxy ANDA Enterprise was effectuated to give to Ranbaxy a wrongfully obtained competitive advantage over its competitors, the harm alleged – overcharges for prescription medications – was suffered by the Plaintiffs and the Nationwide Class when they paid for and/or provided reimbursement for some or all of the purchase price, not Ranbaxy's competitors.

287. As alleged herein, Plaintiffs and Members of the Nationwide Classes are primary victims of Defendants' wrongful and unlawful conduct. Plaintiffs' and the Nationwide Classes' injures were the direct, proximate, foreseeable, and natural consequences of Defendants' racketeering activity; depriving Plaintiffs and the Nationwide Classes access to affordable, safe generic drugs was the very purpose of the Defendants' scheme. Defendants knew that their wrongfully acquired exclusivity or attempts to acquire exclusivity would cause patients to purchase more expensive brand name or generic versions of Diovan, Nexium, and Valcyte, for which Plaintiffs would foot the bill. Defendants knew that many if not most of all prescriptions for Diovan, Nexium, and Valcyte and its generic equivalents were paid by EPPs such as Plaintiffs and Members of the Nationwide Classes. The fraudulent Ranbaxy ANDA Enterprise caused a delay in the availability of safe, affordable generic drugs. Plaintiffs and those similarly situated paid for more expensive brand name versions of Diovan, Nexium, and Valcyte and/or their generic equivalents in the form of payments and/or reimbursements long after one or more generic drugs should have entered the market.

288. By these violations of 18 U.S.C. § 1962(c), defendants are liable to the Plaintiffs and Members of the Nationwide Classes for three times the damages they have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT TWO - VIOLATION OF RICO, 18 U.S.C. § 1962(d)
(Asserted Against Ranbaxy Labs, Ranbaxy Inc., and Sun Pharma)

289. Plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations.

290. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

291. Defendants Ranbaxy Labs and Ranbaxy Inc. have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been to conduct or participate in, directly or indirectly, the affairs of the § 1962(c) Ranbaxy ANDA Enterprise, described previously, through a pattern of racketeering activity.

292. As demonstrated in detail above, Defendants' co-conspirators – including but not limited to Beardsley, Shepard, and Parexel – have engaged in overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations designed to permit defendants to benefit pecuniarily from their fraudulently-filed ANDAs.

293. The nature of Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violations of RICO by conspiring to violate 18 U.S.C. § 1962(c), but also that they were, and are, aware that their fraudulent acts have been and are part of an overall pattern of racketeering activity.

294. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs

and the Nationwide Classes have been and continue to be injured in their business or property, as set forth more fully above.

295. Defendants Ranbaxy Labs and Ranbaxy Inc. have sought to engage in, and have engaged in, the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346;

b. Multiple instances of wire fraud in violation of 18 U.S.C. §§1343 and 1346; and

c. Multiple instances of interstate and international travel in furtherance of aid of racketeering, in violation of 18 U.S.C. § 1952.

296. Defendants have sought to engage in, and have engaged in, the violations of the above federal laws and the effects thereof detailed above are continuing.

COUNT THREE – MONOPOLIZATION UNDER STATE LAW
(Asserted Against Ranbaxy Labs, Ranbaxy Inc. and Sun Pharma as to Valsartan)

297. Plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations, as though fully set forth herein.

298. As described above, from October 25, 2007 until at least January 5, 2015 (and with effects lasting far longer), Ranbaxy possessed monopoly power in the market for valsartan or narrower markets therein, and/or had a dangerous probability of achieving monopoly power. No other generic manufacturer sold a competing version of valsartan before January 5, 2015.

299. Ranbaxy willfully and unlawfully and with specific intent maintained, or attempted to obtain monopoly power in the valsartan market, or narrower markets therein, by engaging in an anticompetitive scheme to keep generic equivalents from the market – not as a result of providing a superior product, business acumen, or historical accident.

300. Ranbaxy knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of other AB-rated generic versions of valsartan to obtain, maintain, or attempt to obtain monopoly power. This scheme included:

a. Submitting false information to support its previously filed ANDAs;

b. Making repeated fraudulent statements to the FDA, with the specific purpose, intent, and effect of having the FDA rely upon those fraudulent statements in allowing Ranbaxy to secure tentative and final approval for its ANDAs; and

c. Using its fraudulently obtained first-to-file exclusivity to keep other generic manufacturers out of the market.

301. By means of this scheme, Ranbaxy intentionally and wrongfully obtained, maintained, or attempted to obtain monopoly power with respect to valsartan in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq*., with respect to Plaintiffs and Class Members' purchases of valsartan in Arizona.

b. Cal. Bus. & Prof. Code §§ 16700, *et seq*., with respect to Plaintiffs and Class Members' purchases of valsartan in California.

c. D.C. Code §§ 28-4503, *et seq*., with respect to Plaintiffs and Class Members' purchases of valsartan in the District of Columbia.

d. Fla. Stat. §§ 542, *et seq*., with respect to Plaintiffs and Class Members' purchases of valsartan in Florida.

e. Haw. Rev. Stat. § 480, *et seq*., with respect to Plaintiffs and Class Members' purchases of valsartan in Hawaii.

f. Iowa Code § 553.5 *et seq*., with respect to Plaintiffs and Class Members' purchases of valsartan in Iowa.

g. Mass. G.L. c. 93A, *et seq*., with respect to purchases in Massachusetts by Plaintiffs and Class members, who paid substantially higher prices for valsartan in actions and transactions occurring substantially within Massachusetts.

h. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq*., with respect to Plaintiffs and Class Members' purchases of valsartan in Maine.

i. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in Michigan.

j. Minn. Stat. §§ 325d.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in Minnesota.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in Nebraska.

l. Nev. Rev. Stat. Ann. §§ 598A.210, *et seq.*, with respect to purchases in Nevada by Plaintiffs and Class Members, who paid substantially higher prices for valsartan in actions and transactions occurring substantially within Nevada.

m. N.H. Rev. Stat. Ann. §§ 356, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in New Hampshire.

n. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in New Mexico.

o. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in North Carolina.

p. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in North Dakota.

q. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in Oregon.

r. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in South Dakota.

s. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in Vermont.

t. W.Va. Code §§ 47-18-1, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in West Virginia.

u. Wis. Stat. §§ 133.01, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valsartan in Wisconsin by Plaintiffs and Class Members, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiffs paid and substantially higher prices for valsartan purchased in Wisconsin.

302. As a result of this unlawful acquisition, maintenance, or attempt to obtain monopoly power, Plaintiffs and Members of the Indirect Purchaser States Class paid artificially inflated prices, in each of the jurisdictions in ¶301 above, for their valsartan tablets.

303. Plaintiffs and members of the Indirect Purchaser States Class have been injured in their business or property by Ranbaxy's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their valsartan tablet requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent and flows from that which makes Ranbaxy's conduct unlawful, and Plaintiffs and the Indirect Purchaser States Class are the proper entities to bring a case concerning this conduct.

304. Ranbaxy engaged in a knowing, direct fraud against a governmental entity (the FDA), that was empowered to grant a lawful period of market exclusivity (180-days market exclusivity to the first generic filer to submit a substantially complete ANDA, so long as that generic filer obtained tentative approval within 30 months of filing). Through a series of misrepresentations, fraud, and deceit, Ranbaxy deceived the FDA into believing that Ranbaxy's manufacturing and production operations were in compliance with applicable regulations, and that its data was reliable, when Ranbaxy knew that this was not true. In reliance upon these fraudulent statements, the FDA granted Ranbaxy a period of exclusivity to which it was not lawfully entitled. And, Ranbaxy asserted this wrongfully-obtained exclusivity to exclude competition from the marketplace.

305. Ranbaxy knowingly and intentionally engaged in sham petitioning before the FDA, making repeated misstatements concerning, *inter alia*, its manufacturing facilities, compliance with cGMP, and the reliability of its data, all designed to intentionally and deceptively convince the FDA to grant it first-to-file exclusivity, which it intended to, and did, use to keep (a) all generic competition (including itself) out of the market for an extended period of time, and (b) other generic competitors off the market for at least an additional 180 days. Ranbaxy's anticompetitive conduct is not entitled to qualified *Noerr-Pennington* immunity.

306. For each of the relevant ANDAs that Ranbaxy filed, Ranbaxy knew at the time it filed that it had no realistic likelihood of success; that is, no realistic likelihood that the FDA would, absent fraudulent conduct on the part of Ranbaxy, find the ANDA approvable and in compliance with applicable regulations. And for each relevant ANDA that Ranbaxy maintained, Ranbaxy knew that it had no realistic likelihood of success; that is, no realistic likelihood that that the FDA would, absent Ranbaxy's fraud, grant tentative or final approval to the ANDA.

307. Ranbaxy knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of ultimately succeeding on the merits of its ANDA filings absent fraud. Ranbaxy filed these ANDAs for the purposes of using a governmental process (including the 180-day exclusivity associated with the FDA's acceptance and tentative approval) to obtain an exclusivity to which it was not entitled, as an anticompetitive weapon to keep other generics off the market.

COUNT FOUR – MONOPOLIZATION UNDER STATE LAW
(Asserted Against Ranbaxy Labs, Ranbaxy Inc. and Sun Pharma as to Valganciclovir Hydrochloride)

308. Plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations, as though fully set forth herein.

309. As described above, from June 20, 2008, until at least November 4, 2014 (and with effects lasting far longer), Ranbaxy possessed monopoly power in the market for valganciclovir hydrochloride, or narrower markets therein, and/or had a dangerous probability of achieving monopoly power. No generic manufacturer, including Ranbaxy, sold any version of valganciclovir hydrochloride tablets until November 20, 2014.

310. Ranbaxy willfully and unlawfully and with specific intent obtained, maintained, or attempted to obtain its monopoly power in the valganciclovir hydrochloride market, or narrower

markets therein, by engaging in an anticompetitive scheme to keep generic equivalents from the market – not as a result of providing a superior product, business acumen, or historical accident.

311. Ranbaxy knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of other AB-rated generic versions of valganciclovir hydrochloride to obtain, maintain, or attempt to obtain monopoly power. This scheme included:

a. Submitting false information to support its previously filed ANDAs;

b. Making repeated fraudulent statements to the FDA, with the specific purpose, intent, and effect of having the FDA rely upon those fraudulent statements in allowing Ranbaxy to secure tentative and final approval for its ANDAs; and

c. Using its fraudulently obtained first-to-file exclusivity to keep other generic manufacturers out of the market.

312. By means of this scheme, Ranbaxy intentionally and wrongfully obtained, maintained, or attempted to obtain monopoly power with respect to valganciclovir hydrochloride tablets in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Arizona.

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in California.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in the District of Columbia.

d. Fla. Stat. §§ 542, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Florida.

e. Haw. Rev. Stat. § 480, *et seq.*, with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Hawaii.

f. Iowa Code § 553.5 *et seq.*, with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Iowa.

g. Mass. G.L. c. 93A, *et seq.*, with respect to purchases in Massachusetts by Plaintiffs and Class members, who paid substantially higher prices for valganciclovir hydrochloride tablets in actions and transactions occurring substantially within Massachusetts.

h. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Maine.

i. Mich. Comp. Laws Ann. §§ 445.771, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Michigan.

j. Minn. Stat. §§ 325d.49, *et seq*., and Minn. Stat. § 8.31, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Minnesota.

k. Neb. Code Ann. §§ 59-801, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Nebraska.

l. Nev. Rev. Stat. Ann. §§ 598A.210, *et seq*., with respect to purchases in Nevada by Plaintiffs and Class Members, who paid substantially higher prices for valganciclovir hydrochloride tablets in actions and transactions occurring substantially within Nevada.

m. N.H. Rev. Stat. Ann. §§ 356, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in New Hampshire.

n. N.M. Stat. Ann. §§ 57-1-2, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in New Mexico.

o. N.C. Gen. Stat. §§ 75-2.1, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in North Carolina.

p. N.D. Cent. Code §§ 51-08.1-01, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in North Dakota.

q. Or. Rev. Stat. §§ 646.705, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Oregon.

r. S.D. Codified Laws §§ 37-1-3.2, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in South Dakota.

s. Vt. Stat. Ann. 9, §§ 2453, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Vermont.

t. W.Va. Code §§ 47-18-1, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in West Virginia.

u. Wis. Stat. §§ 133.01, *et seq*., with respect to Plaintiffs and Class Members' purchases of valganciclovir hydrochloride tablets in Wisconsin by Plaintiffs

> and Class Members, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiffs paid and substantially higher prices for valganciclovir hydrochloride tablets purchased in Wisconsin.

313. As a result of this unlawful acquisition, maintenance, or attempt to obtain monopoly power, Plaintiffs and members of the Indirect Purchaser States Class paid artificially inflated prices, in each of the jurisdictions in ¶312 above, for their valganciclovir hydrochloride tablets.

314. Plaintiffs and Members of the Indirect Purchaser States Class have been injured in their business or property by Ranbaxy's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their valganciclovir hydrochloride than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent and flows from that which makes Ranbaxy's conduct unlawful, and Plaintiffs and the Indirect Purchaser States Class are the proper entities to bring a case concerning this conduct.

315. Ranbaxy engaged in a knowing, direct fraud against a governmental entity (the FDA), which was empowered to grant a period of market exclusivity (180-days market exclusivity to the first generic filer to submit a substantially complete ANDA, so long as that generic filer obtained tentative approval within 30 months of filing). Through a series of misrepresentations, fraud, and deceit, Ranbaxy was able to deceive the FDA into believing that Ranbaxy's manufacturing and production operations were in compliance with applicable regulations, and that its data was reliable when Ranbaxy knew that this was not true. In reliance upon these fraudulent statements, the FDA granted Ranbaxy a period of exclusivity to which it was not lawfully entitled. And, Ranbaxy asserted this wrongfully-obtained exclusivity to exclude completion from the marketplace.

316. Ranbaxy knowingly and intentionally engaged in sham petitioning before the FDA, making repeated misstatements concerning, *inter alia*, its manufacturing facilities, compliance with cGMP, and the reliability of its data, all designed to intentionally and deceptively convince the FDA

to grant Ranbaxy first-to-file exclusivity, which it intended to, and did, use to keep (a) all generic competition (including itself) out of the market for an extended period of time, and (b) other generic competitors off the market for at least an additional 180 days. Ranbaxy's anticompetitive conduct is not entitled to qualified *Noerr-Pennington* immunity.

317. For each ANDA Ranbaxy filed, Ranbaxy knew at the time it filed that it had no realistic likelihood of success; that is, no realistic likelihood that the FDA would, absent fraudulent conduct on the part of Ranbaxy, find the ANDA approvable and in compliance with applicable regulations. And for each ANDA Ranbaxy maintained, Ranbaxy knew that it had no realistic likelihood of success; that is, no realistic likelihood that that the FDA would, absent Ranbaxy's fraud, grant tentative or final approval to the ANDA.

318. Ranbaxy knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of ultimately succeeding on the merits of its ANDA filings absent fraud. Ranbaxy filed these ANDAs for the purposes of using a governmental process (including the 180-day exclusivity associated with the FDA's acceptance and tentative approval) as an anticompetitive weapon to keep other generics off the market.

COUNT FIVE – MONOPOLIZATION UNDER STATE LAW
(Asserted Against Ranbaxy Labs, Ranbaxy Inc. and Sun Pharma as to Esomeprazole Magnesium)

319. Plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations, as though fully set forth herein.

320. As described above, from February 5, 2008 until at least November 4, 2014 (and with effects lasting far longer), Ranbaxy possessed monopoly power in the market for esomeprazole magnesium, or narrower markets therein, and/or had a dangerous probability of achieving monopoly power. No generic manufacturer, including Ranbaxy, sold any version of esomeprazole magnesium tablets until January 27, 2015.

321. Ranbaxy willfully and unlawfully and with specific intent obtained, maintained, or attempted to obtain monopoly power in the esomeprazole magnesium market, by engaging in an anticompetitive scheme to keep generic equivalents from the market – not as a result of providing a superior product, business acumen, or historical accident.

322. Ranbaxy knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of other AB-rated generic versions of esomeprazole magnesium to obtain, maintain, or attempt to obtain monopoly power. This scheme included:

a. Submitting false information to support its previously filed ANDAs;

b. Making repeated fraudulent statements to the FDA, with the specific purpose, intent, and effect of having the FDA rely upon those fraudulent statements in allowing Ranbaxy to secure tentative and final approval for its ANDAs; and

c. Using its fraudulently obtained first-to-file exclusivity to keep other generic manufacturers out of the market.

323. By means of this scheme, Ranbaxy intentionally and wrongfully obtained, maintained, or attempted to obtain monopoly power with respect to esomeprazole magnesium in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Arizona.

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in California.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in the District of Columbia.

d. Fla. Stat. §§ 542, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Florida.

e. Haw. Rev. Stat. § 480, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Hawaii.

f. Iowa Code § 553.5 *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Iowa.

g. Mass. G.L. c. 93A, *et seq.*, with respect to purchases in Massachusetts by Plaintiffs and Class members, who paid substantially higher prices for esomeprazole magnesium in actions and transactions occurring substantially within Massachusetts.

h. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Maine.

i. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Michigan.

j. Minn. Stat. §§ 325d.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Minnesota.

k. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Nebraska.

l. Nev. Rev. Stat. Ann. §§ 598A.210, *et seq.*, with respect to purchases in Nevada by Plaintiffs and Class Members, who paid substantially higher prices for esomeprazole magnesium in actions and transactions occurring substantially within Nevada.

m. N.H. Rev. Stat. Ann. §§ 356, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in New Hampshire.

n. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in New Mexico.

o. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in North Carolina.

p. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in North Dakota.

q. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Oregon.

r. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in South Dakota.

s. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Vermont.

t. W.Va. Code §§ 47-18-1, *et seq.*, with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in West Virginia.

u. Wis. Stat. §§ 133.01, *et seq*., with respect to Plaintiffs and Class Members' purchases of esomeprazole magnesium in Wisconsin by Plaintiffs and Class Members, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiffs paid and substantially higher prices for esomeprazole magnesium purchased in Wisconsin.

324. As a result of this unlawful acquisition, maintenance, or attempt to obtain monopoly power, Plaintiffs and members of the Indirect Purchaser States Class paid artificially inflated prices, in each of the jurisdictions in ¶323 above, for esomeprazole magnesium.

325. Plaintiffs and Members of the Indirect Purchaser States Class have been injured in their business or property by Ranbaxy's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their esomeprazole magnesium requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent and flows from that which makes Ranbaxy's conduct unlawful, and Plaintiffs and the Indirect Purchaser States Class are the proper entities to bring a case concerning this conduct.

326. Ranbaxy engaged in a knowing, direct fraud against a governmental entity (the FDA), that was empowered to grant a lawful period of market exclusivity (180-days market exclusivity to the first generic filer to submit a substantially complete ANDA, so long as that generic filer obtained tentative approval within 30 months of filing). Through a series of misrepresentations, fraud, and deceit, Ranbaxy deceived the FDA into believing that Ranbaxy's manufacturing and production operations were in compliance with applicable regulations, and that its data was reliable, when Ranbaxy knew that this was not true. In reliance upon these fraudulent statements, the FDA granted Ranbaxy a period of exclusivity to which it was not lawfully entitled. And, Ranbaxy asserted this wrongfully-obtained exclusivity to exclude competition from the marketplace.

327. Ranbaxy knowingly and intentionally engaged in sham petitioning before the FDA, making repeated misstatements concerning, *inter alia*, its manufacturing facilities, compliance with

cGMP, and the reliability of its data, all designed to intentionally and deceptively convince the FDA to grant it first-to-file exclusivity, which it intended to, and did, use to keep (a) all generic competition (including itself) out of the market for an extended period of time, and (b) other generic competitors off the market for at least an additional 180 days. Ranbaxy's anticompetitive conduct is not entitled to qualified *Noerr-Pennington* immunity.

328. For each of the relevant ANDAs that Ranbaxy filed, Ranbaxy knew at the time it filed that it had no realistic likelihood of success; that is, no realistic likelihood that the FDA would, absent fraudulent conduct on the part of Ranbaxy, find the ANDA approvable and in compliance with applicable regulations. And for each relevant ANDA that Ranbaxy maintained, Ranbaxy knew that it had no realistic likelihood of success; that is, no realistic likelihood that that the FDA would, absent Ranbaxy's fraud, grant tentative or final approval to the ANDA.

329. Ranbaxy knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of ultimately succeeding on the merits of its ANDA filings absent fraud. Ranbaxy filed these ANDAs for the purposes of using a governmental process (including the 180-day exclusivity associated with the FDA's acceptance and tentative approval) to obtain an exclusivity to which it was not entitled, as an anticompetitive weapon to keep other generics off the market.

COUNT SIX – UNFAIR AND DECEPTIVE PRACTICES UNDER STATE LAWS
(Sixteen States)
(Asserted Against Ranbaxy Labs, Ranbaxy Inc. and Sun Pharma as to Valsartan)

330. Plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations, as though fully set forth herein.

331. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed by, among other things:

a. Submitting false information to support its previously filed ANDAs;

b. Making repeated fraudulent statements to the FDA, with the specific purpose, intent, and effect of having the FDA rely upon those fraudulent statements in allowing Ranbaxy to secure tentative and final approval for its ANDAs, including: (1) Misrepresenting to the FDA the state of Ranbaxy's cGMP compliance at its Paonta Sahib facility; (2) Misrepresenting whether and to what extent Ranbaxy was attempting to remedy its cGMP compliance issues; (3) Misrepresenting whether the cGMP compliance issues at Paonta Sahib affected the integrity of any data contained within US-filed ANDAs; (4) Refusing to provide to the FDA – and directing Beardsley and Parexel to refuse to provide to the FDA – copies of audits performed by Parexel at the Paonta Sahib facility, because those audits would have belied Ranbaxy's misrepresentations; and

c. Using its fraudulently obtained first-to-file exclusivity to keep other generic manufacturers out of the market.

332. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, generic versions of valsartan were kept off the market from at least September 28, 2012 through at least July 7, 2014, longer than they would have been absent Defendants' fraudulent activities, resulting in increased costs to end-payors of those drugs, including the Plaintiffs and all members of the Indirect Purchaser States Class.

333. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state laws:

a. Cal. Civ. Code §§ 1750, *et seq.* and Cal. Bus. & Prof. Code §§ 17200, *et seq.*

b. Fla. Stat. §§ 501.201, *et seq.*

c. Mass. G.L. c. 93A, *et seq.*

d. 5 Me. Rev. Stat. §§ 205A, *et seq.*

e. Mich. Stat. §§ 445.901, *et seq.*

f. Minn. Stat. §§ 325d.43, *et. seq.*, Minn. Stat. §§ 325f.69, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*

g. Vernon's Missouri Stat. §§ 407.010, *et seq.*

h. Neb. Rev. Stat. §§ 59-1601, *et seq.*

i. Nev. Rev. Stat. §§ 598.0903, *et seq.*

j. N.M. Stat. §§ 57-12-1, *et seq.*

k. N.C. Gen. Stat. §§ 75-1.1, *et seq.*

l. N.D. Cent. Code §§ 51-15-01, *et seq.*

m. 73 Pa. Stat. §§ 201-1, *et seq.*

n. S.D. Code Laws §§ 37-24-1, *et seq.*

o. Vt. Stat. Ann. 9 §§ 2451, *et seq.*

p. W.Va. Code §§ 46A-6-101, *et seq.*

334. Plaintiffs need not send presuit notice letters as described in Cal. Civ. Code § 1782 because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of Cal. Civ. Code §§ 1750, *et seq.* and have not made any cure offers.

335. Plaintiffs need not send presuit notice letters as described in Me. Rev. Stat. § 213(1-A) because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of 5 Me. Rev. Stat. §§ 205A, *et seq* and have not made any cure offers.

336. Plaintiffs need not send presuit notice letters as described in W. Va. Code Ann. § 46A-6-106 because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of W.Va. Code §§ 46A-6-101, *et seq* and have not made any cure offers.

337. Plaintiffs and Indirect Purchaser States Class Members have paid more for valsartan than they would have absent Defendants' unfair, deceptive, or fraudulent acts, in each of the jurisdictions in ¶333 above, at supracompetitive prices, during the relevant time period, and were thereby injured.

338. The valsartan that Plaintiffs and Indirect Purchaser States Class Members have paid for during the relevant time period, in each of the jurisdictions in ¶333 above, is primarily for the personal family or household use and not for resale.

339. Plaintiffs and Indirect Purchaser States Class Members have been injured in their business and property by reason of Defendants' anticompetitive, unfair, or deceptive acts alleged in this Count. Plaintiffs' injury and that of the Indirect Purchaser States Class consists of paying higher prices for valsartan prescription drugs than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and proximately results from Defendants' unlawful conduct.

COUNT SEVEN – UNFAIR AND DECEPTIVE PRACTICES UNDER STATE LAWS (States)
(Asserted Against Ranbaxy Labs, Ranbaxy Inc. and Sun Pharma as to Valganciclovir Hydrochloride)

340. Plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations, as though fully set forth herein.

341. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed by, among other things:

a. Submitting false information to support previously filed ANDAs;

b. Making repeated fraudulent statements to the FDA, with the specific purpose, intent, and effect of having the FDA rely upon those fraudulent statements in allowing Ranbaxy to secure tentative and final approval for its ANDAs, including: (1) Misrepresenting to the FDA the state of Ranbaxy's cGMP compliance at its Paonta Sahib facility; (2) Misrepresenting whether and to what extent Ranbaxy was attempting to remedy its cGMP compliance issues; (3) Misrepresenting whether the cGMP compliance issues at Paonta Sahib affected the integrity of any data contained within US-filed ANDAs; (4) Refusing to provide to the FDA – and directing Beardsley and Parexel to refuse to provide to the FDA – copies of audits performed by Parexel at the Paonta Sahib facility, because those audits would have belied Ranbaxy's misrepresentations; and

c. Using its fraudulently obtained first-to-file exclusivity to keep other generic manufacturers out of the market.

342. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, generic versions of valganciclovir hydrochloride tablets

were kept off the market from at least August 1, 2014, until at least November 20, 2014, longer than they would have been absent Defendants' fraudulent activities, resulting in increased costs to end-payors of those drugs, including the Plaintiffs and all members of the Indirect Purchaser States Class.

343. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state laws:

a. Cal. Civ. Code §§ 1750, *et seq*. and Cal. Bus. & Prof. Code §§ 17200, *et seq*.

b. Fla. Stat. §§ 501.201, *et seq*.

c. Mass. G.L. c. 93A, *et seq*.

d. 5 Me. Rev. Stat. §§ 205A, *et seq*.

e. Mich. Stat. §§ 445.901, *et seq*.

f. Minn. Stat. §§ 325d.43, *et. seq*., Minn. Stat. §§ 325f.69, *et seq*., and Minn. Stat. §§ 8.31, *et seq*.

g. Vernon's Missouri Stat. §§ 407.010, *et seq*.

h. Neb. Rev. Stat. §§ 59-1601, *et seq*.

i. Nev. Rev. Stat. §§ 598.0903, *et seq*.

j. N.M. Stat. §§ 57-12-1, *et seq*.

k. N.C. Gen. Stat. §§ 75-1.1, *et seq*.

l. N.D. Cent. Code §§ 51-15-01, *et seq*.

m. 73 Pa. Stat. §§ 201-1, *et seq*.

n. S.D. Code Laws §§ 37-24-1, *et seq*.

o. Vt. Stat. Ann. 9 §§ 2451, *et seq*.

p. W.Va. Code §§ 46A-6-101, *et seq*.

344. Plaintiffs need not send presuit notice letters as described in Cal. Civ. Code § 1782 because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of Cal. Civ. Code §§ 1750, *et seq.* and have not made any cure offers.

345. Plaintiffs need not send presuit notice letters as described in Me. Rev. Stat. § 213(1-A) because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of 5 Me. Rev. Stat. §§ 205A, *et seq* and have not made any cure offers.

346. Plaintiffs need not send presuit notice letters as described in W. Va. Code Ann. § 46A-6-106 because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of W.Va. Code §§ 46A-6-101, *et seq* and have not made any cure offers.

347. Plaintiffs and Indirect Purchaser States Class Members have paid more for valganciclovir hydrochloride than they would have absent Defendant's unfair, deceptive, or fraudulent acts, in each of the jurisdictions in ¶343 above, at supracompetitive prices, during the relevant time period, and were thereby injured.

348. The valganciclovir hydrochloride that Plaintiffs and Indirect Purchaser States Class Members have paid for during the relevant time period, in each of the jurisdictions in ¶343 above, is primarily for the personal family or household use and not for resale.

349. Plaintiffs and Indirect Purchaser States Class Members have been injured in their business and property by reason of Defendants' anticompetitive, unfair, or deceptive acts alleged in this Count. Plaintiffs' injury and that of the Indirect Purchaser States Class consists of paying higher prices for valganciclovir hydrochloride prescription drugs than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and proximately results from Defendants' unlawful conduct.

COUNT EIGHT – UNFAIR AND DECEPTIVE PRACTICES UNDER STATE LAWS
(Sixteen States)
(Asserted Against Ranbaxy Labs, Ranbaxy Inc. and Sun Pharma as to Esomeprazole Magnesium)

350. Plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations, as though fully set forth herein.

351. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed by, among other things:

a. Submitting false information to support previously filed ANDAs;

b. Making repeated fraudulent statements to the FDA, with the specific purpose, intent, and effect of having the FDA rely upon those fraudulent statements in allowing Ranbaxy to secure tentative and final approval for its ANDAs, including: (1) Misrepresenting to the FDA the state of Ranbaxy's cGMP compliance at its Paonta Sahib facility; (2) Misrepresenting whether and to what extent Ranbaxy was attempting to remedy its cGMP compliance issues; (3) Misrepresenting whether the cGMP compliance issues at Paonta Sahib affected the integrity of any data contained within US-filed ANDAs; (4) Refusing to provide to the FDA – and directing Beardsley and Parexel to refuse to provide to the FDA – copies of audits performed by Parexel at the Paonta Sahib facility, because those audits would have belied Ranbaxy's misrepresentations; and

c. Using its fraudulently obtained first-to-file exclusivity to keep other generic manufacturers out of the market.

352. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, generic versions of esomeprazole magnesium were kept off the market from at least May 27, 2014 until at least January 27, 2015, longer than they would have been absent Defendants' fraudulent activities, resulting in increased costs to end-payors of those drugs, including the Plaintiffs and all members of the Indirect Purchaser States Class.

353. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state laws:

a. Cal. Civ. Code §§ 1750, *et seq.* and Cal. Bus. & Prof. Code §§ 17200, *et seq.*

b. Fla. Stat. §§ 501.201, *et seq.*

c. Mass. G.L. c. 93A, *et seq.*

d. 5 Me. Rev. Stat. §§ 205A, *et seq.*

e. Mich. Stat. §§ 445.901, *et seq.*

f. Minn. Stat. §§ 325d.43, *et. seq.*, Minn. Stat. §§ 325f.69, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*

g. Vernon's Missouri Stat. §§ 407.010, *et seq.*

h. Neb. Rev. Stat. §§ 59-1601, *et seq.*

i. Nev. Rev. Stat. §§ 598.0903, *et seq.*

j. N.M. Stat. §§ 57-12-1, *et seq.*

k. N.C. Gen. Stat. §§ 75-1.1, *et seq.*

l. N.D. Cent. Code §§ 51-15-01, *et seq.*

m. 73 Pa. Stat. §§ 201-1, *et seq.*

n. S.D. Code Laws §§ 37-24-1, *et seq.*

o. Vt. Stat. Ann. 9 §§ 2451, *et seq.*

p. W.Va. Code §§ 46A-6-101, *et seq.*

354. Plaintiffs need not send presuit notice letters as described in Cal. Civ. Code § 1782 because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of Cal. Civ. Code §§ 1750, *et seq.* and have not made any cure offers.

355. Plaintiffs need not send presuit notice letters as described in Me. Rev. Stat. § 213(1-A) because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of 5 Me. Rev. Stat. §§ 205A, *et seq* and have not made any cure offers.

356. Plaintiffs need not send presuit notice letters as described in W. Va. Code Ann. § 46A-6-106 because sending such letters is unnecessary and futile. Defendants already have notice of the proposed violations of W.Va. Code §§ 46A-6-101, *et seq* and have not made any cure offers.

357. Plaintiffs and Indirect Purchaser States Class Members have paid more for esomeprazole magnesium than they would have absent Defendants' unfair, deceptive, or fraudulent acts, in each of the jurisdictions in ¶353 above, at supracompetitive prices, during the relevant time period, and were thereby injured.

358. The esomeprazole magnesium that Plaintiffs and Indirect Purchaser States Class Members have paid for during the relevant time period, in each of the jurisdictions in ¶353 above, is primarily for the personal family or household use and not for resale.

359. Plaintiffs and Indirect Purchaser States Class Members have been injured in their business and property by reason of Defendants' anticompetitive, unfair, or deceptive acts alleged in this Count. Plaintiffs' injury and that of the Indirect Purchaser States Class consists of paying higher prices for esomeprazole magnesium prescription drugs than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and proximately results from Defendants' unlawful conduct.

XI. DEMAND FOR JUDGMENT

360. WHEREFORE, Plaintiffs, on behalf of themselves and the Classes, respectfully request that the Court:

a. Determine this action may be maintained as a class action under Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Classes, and declare UFCW and BCBSLA as representatives of the Classes;

b. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

c. Enter joint and several judgments against the defendants and in favor of Plaintiffs and the Classes;

d. Award the Classes damages, to the maximum extent allowed under law (*i.e.*, three times the amount they were injured and/or three times the damage attributable to the racketeering activity), in an amount to be determined at trial, plus interest in accordance with law;

e. Award the Plaintiffs and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

f. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by the defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the proposed Classes, demand a trial by jury on all issues so triable.

Dated: March 3, 2021

Respectfully submitted:

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CERTIFICATE OF SERVICE

I, Renee A. Nolan, hereby certify that this document was electronically filed with the Clerk of the Court for the District of Massachusetts by using the CM/ECF system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: March 3, 2021 /s/Renee A. Nolan