UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

CÉSAR CASTILLO, INC., individually and on behalf of all those similarly situated, Plaintiffs v. RANBAXY INC., RANBAXY LABORATORIES, LTD., RANBAXY U.S.A., INC., and SUN PHARMACEUTICAL INDUSTRIES LTD. Defendants	Civil Action No. 18-cv-6126 Class Action Jury Trial Demanded

COMPLAINT AND JURY DEMAND

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I. INTRODUCTION

1. Over the past 30 years, the generic drug industry has made enormous progress in gaining widespread acceptance for their generally safe, effective, and affordable pharmaceuticals. The Food and Drug Administration ("FDA") imposes on *all* drug makers – whether for branded or generic products – intense regulatory review, requiring compliance with the same standards for current good manufacturing practices ("cGMP") to ensure that drug products are consistent in quality, stability, and reliability. Today, most of the drugs taken by U.S. consumers (4 in every 5 prescriptions) are generic drugs. Scores of global generic drug manufacturers take seriously the need to comply with FDA reporting and manufacturing practices.

2. This case is about how one such drug manufacturer, Ranbaxy Laboratories, recklessly stuffed the generic drug approval queues with grossly inadequate applications, deceived the FDA into granting tentative approvals to lock in statutory exclusivities to which Ranbaxy was not entitled, and brandished these undeserved exclusivities to exclude others while its own applications floundered, all at the direct expense of U.S. drug purchasers.

3. Beginning in the early 2000s, Ranbaxy embraced an internal corporate culture that displayed utter disregard for regulatory requirements, truthful reporting, and responsible business behavior. To meet management's unrealistic expectations, employees often forged test results, changed data, and retroactively created documentation.

4. Ranbaxy took these shortcuts in order to file as many abbreviated new drug applications ("ANDAs") as possible, especially if it thought it could secure valuable first-to-file generic status and the lucrative 180-day exclusivity that came with it. Ranbaxy did so with little regard for whether it would be able to promptly bring the generic drug to market. So long as Ranbaxy could secure the coveted first-to-file exclusivity position, it could profit off these

undeserved regulatory exclusivities, regardless of whether Ranbaxy itself could eventually get its own product to market.

5. Eventually, Ranbaxy resorted to misleading the FDA into granting it tentative approval for several of these hastily prepared, first-to-file ANDAs, a regulatory decision that allowed Ranbaxy to block or delay the entrance of other generic makers into the applicable market.

6. Among other things, in 2007 and again in 2008 Ranbaxy misleadingly represented to the FDA that the condition of Ranbaxy's cGMP (i.e., its current good manufacturing practices) at its Paonta Sahib, India plant was (or as a practical matter soon would be) in compliance with FDA requirements. In fact, those conditions were so poor that Ranbaxy could not fix them for more than *eight years*.

7. Ranbaxy dragged out discussions with the FDA concerning remedial efforts that Ranbaxy was purportedly undertaking. And, working with its outside lawyers and purportedly "independent" (but in reality, Ranbaxy-controlled) consultant, deflected the ability of the FDA to act on Ranbaxy's pending ANDAs in the ordinary course. Ranbaxy's overall course of conduct continually frustrated the FDA approval process, not only for Ranbaxy's ANDAs, but also for each of the would-be generic makers seeking to enter that particular generic drug market.

8. In 2012, the FDA was finally able to get a consent decree in place to address some of Ranbaxy's regulatory compliance issues. And in 2013, the Department of Justice was able to impose a criminal fine and civil penalty of $500 million addressing some of Ranbaxy's past transgressions. Even these efforts did not solve all of Ranbaxy's many problems, and product recalls continued to plague the company.

9. In 2014, after spending years trying to untangle Ranbaxy's deceptions and ensure that its operations were sufficient to produce safe drugs, the FDA realized that Ranbaxy's first-to-file status was blocking other generic drug makers from coming to market. The FDA revoked tentative approvals that Ranbaxy had fraudulently obtained, finally allowing more affordable – and safer – generic alternatives to come to market.

10. This lawsuit seeks monetary relief on behalf of all direct purchasers of Nexium or its AB-rated generic equivalents, for which generic entry was delayed in substantial part by Ranbaxy's wrongful acquisition and maintenance of 180-day exclusivity, its business conduct that ultimately required it be subject to a consent decree, and its preclusion of other generic entrants while its own applications floundered. Specifically, this action pleads with particularity that the direct purchasers of the brand drug Nexium (esomeprazole magnesium) overpaid for the product because Ranbaxy's wrongful conduct delayed the generic entry for esomeprazole magnesium at least between May 27, 2014 and January 26, 2015.

11. Relief is grounded in federal antitrust and racketeering law.

12. First, direct purchasers seek relief under federal antitrust law. Ranbaxy wrongfully obtained, fraudulently locked-in, and then abused the first-to-file, 180-day exclusivity period for several drugs, including generic Nexium. 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 supra-competitive levels, and resulting in direct purchasers paying far more for these drugs than they otherwise would have. Ranbaxy's conduct violated section 2 of the Sherman Act and is civilly actionable under the Clayton Act.

13. Second, direct purchasers 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 used the first-to-file, 180-day exclusivity period for several drugs, including esomeprazole magnesium. By fraudulently acquiring and later using wrongfully acquired first-to-file exclusivities for these products, Ranbaxy caused prices for these products to remain at supra-competitive levels, directly causing U.S. drug purchasers to pay far more than they otherwise would have. Ranbaxy's conduct violated sections 1962(c) and (d) of RICO, and is civilly actionable under section 1964 of that law.

II. PARTIES

14. Plaintiff César Castillo, Inc. ("CCI") is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926. During the class period, CCI purchased brand Nexium directly from the manufacturer and also purchased generic Nexium. CCI suffered and continues to suffer antitrust injury as a result of defendants' unlawful conduct. CCI is sometimes referred to herein as "the purchasers" or "the Plaintiffs."

15. 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.

16. 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.

17. 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.

18. Herein, "Ranbaxy" refers to Defendants Ranbaxy Labs, Ranbaxy Inc., and Ranbaxy USA, collectively.

19. 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 is at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai – 400 059, Maharashtra, India. Sun Pharma is an international, integrated, specialty pharmaceutical company. Pursuant to a Scheme of Arrangement between Ranbaxy Labs and Sun Pharma approved by the two companies' boards on April 6, 2014, and completed on or about March 25, 2015, Ranbaxy Labs was merged into Sun Pharma, and all liabilities of Ranbaxy Labs, including contingent liabilities, have been transferred to and vested in Sun Pharma.

III. JURISDICTION AND VENUE

20. This action arises under section 2 of the Sherman Act, 15 U.S.C. § 2, section 4 of the Clayton Act, 15 U.S.C. § 15(a), and the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1962(c) and (d) and 1964. The purchasers seeks damages for their injuries, and those suffered by members of the Direct Purchaser Class, resulting from the defendants' fraudulent and anticompetitive conduct that delayed the entry of generic drugs into the U.S. market. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331(federal question), 1332 (diversity due to a qualifying class action) and 1337(a) (antitrust), 15 U.S.C. § 15 (antitrust), and 18 U.S.C. § 1964(c) (RICO).

21. The defendants transact business within this district, and they transact their affairs and carry out interstate trade and commerce, in substantial part, in this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b) and (c) (general venue provisions). Venue is appropriate within this district under RICO, 18 U.S.C. § 1965(a).

IV. REGULATORY BACKGROUND

A. The Competitive Effects of AB-Rated Generic Competition

22. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. Generic drugs meeting these standards receive an "AB rating." The only material difference between generic drugs and their corresponding brand name versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price.

23. Typically, generics are at least 25% less expensive than their brand name counterparts when there is a single generic competitor. And this discount often reaches 50% to 80% (or more) when multiple generic competitors are on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

24. Every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents when filling prescriptions for the brand (unless the prescribing physician has specifically directed otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create a simple economic dynamic: the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing.

25. Once a generic equivalent hits the market, it quickly captures sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months. This results in a loss of revenue for the brand drug company, but dramatic savings for the American public. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug

sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generic drugs is viewed by brand name drug companies as a grave threat to their bottom lines.

26. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug. The brand manufacturer can continue to profitably charge supra-competitive prices. Brand manufacturers are well aware of generics' rapid erosion of their brand sales, and seek to extend their monopoly for as long as possible, often resorting to any means possible.

1. The first AB-rated generic is priced below the brand

27. Experience and economic research show that the first generic manufacturer to launch sets its prices below the prices of its branded counterpart. The substitution laws almost always result in the first generic manufacturer capturing a large share of sales from the branded form of the molecule. This leads to a reduction in the average price paid for a prescription for the molecule.

28. As explained in more detail below, under certain circumstances, the first generic manufacturer is eligible to receive 180 days of market exclusivity. This means that subsequent generic ANDA filers cannot launch their generic products for at least six months after the first generic – known as the "first filer" – launches its product. During the exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, 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.[1]

[1] *See F.T.C. v. Actavis*, *Inc.*, 570 U.S. ---, 133 S. Ct. 2223, 2229 (2013).

29. If the only versions of a drug on the market are the brand and the first filer's product, then the first filer prices its product below the brand product, but not as low as if it were facing competition from other generics. When the first filer's product competes only with the brand, the brand company rarely drops the brand price to match the first filer, so the first filer typically captures an overwhelming majority of unit sales while offering only a relatively modest discount off the price of the brand.

2. Later generics drive prices down further

30. Once multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

31. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near-term retail price reduction of at least 10%, but that with two generic entrants, near-term retail price reduction reaches about 50%.

32. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shifts to generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid before generic entry. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 billion to $10 billion a year at retail pharmacies. Even more billions of dollars are saved when hospitals use generics.

B. The Regulatory Structure for Approval of New Drugs

1. The Food, Drug and Cosmetic Act

33. Before being sold in the United States, a prescription drug must be proven safe and effective for its intended use. The Food, Drug and Cosmetic Act ("FDCA") requires a drug manufacturer to prove that its drugs are manufactured using known, safe, and sterile procedures, and that its drugs are pure and have a stable shelf life. Drug manufacturers must maintain meticulous written records of the manufacturing process to ensure safety and compliance. The FDA is the federal agency charged with monitoring compliance with the FDCA and ensuring that only safe drugs get to market

34. Manufacturers that create a new drug product (commonly referred to as a "brand" or "innovator" product) seek approval from the FDA to sell the new drug by filing a New Drug Application ("NDA").[2] The information needed in an acceptable NDA encompasses three areas: (i) it must include adequate, well-controlled clinical studies supporting the drug's safety and efficacy, (ii) it must show that the testing, manufacturing processes, and reporting complies with cGMP,[3] and (iii) it must show that the labeling proposed to accompany the drug is scientifically accurate and adequately describes the drug's indications, risks, and benefits. Because the timing of the FDA's ability to approve a drug product often dovetails with various patent filing requirements (soon to be discussed), the NDA applicant must also supply a list of applicable patents.

[2] 21 U.S.C. §§ 301-392.

[3] 21 U.S.C. § 355(b)(1)(D) (requiring "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing" of the drug).

2. Patent protection for blockbuster drugs

35. Brand drug companies develop their patent portfolios for blockbuster drugs in a predictable pattern. The first group of patents usually covers the active compound in a prescription drug or a particular pharmaceutical composition and may be robust.

36. As the brand company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow-on patents that can be obtained. Over time, as the number of patent filings for the drug grows, so too does the brand company's difficulty in obtaining valid, enforceable patents.

37. Patents present, at minimum, obstacles for would-be generic competitors to design around. Patents broadly covering a drug's active ingredient – if valid and enforceable – may prove impossible to design around while meeting the FDA's criteria for equivalence. But later patents covering only a particular formulation or release profile, for example, may be more easily designed around.

38. Therefore, a typical patent portfolio for a brand drug has its most significant patents issuing first; over time, the later-issued patents generally become increasingly narrow and more difficult to obtain and enforce. But brand and generic companies use these later, weaker patents as a pretext for litigation settlements, delaying generic entry beyond the legitimate period of patent protection. Such settlements are anti-competitive, with the brand companies enjoying unlawfully extended monopoly profits, generic companies receiving substantial payments for delaying entry, and consumers paying substantially more.

C. The Hatch-Waxman Amendments

39. Between 1962 and 1984, companies wishing to manufacture generic versions of already-approved drugs had to follow the same steps as an applicant filing an NDA, including conducting clinical trials to establish safety and efficacy. This requirement imposed an onerous burden and significant expense on generic drug companies. And it delayed approval of generic drugs, or deterred companies from even seeking to manufacture generic drugs. This deprived the American public of the benefits of generic competition – safe and effective drugs at reduced costs.

40. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting generic manufacturers to file ANDAs relying on the scientific findings of safety and efficacy included in the brand drug manufacturer's original NDA. The generic manufacturer simply needs to show that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise – codified by Congress and implemented by the FDA for the past thirty years – 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 of time, are expected to be equally safe and effective.

41. At the same time, the Hatch-Waxman Amendments also sought to protect pharmaceutical companies' incentives to create new and innovative products by, among other things, permitting a brand company to file a legitimate patent infringement lawsuit against a generic before the generic actually brings its product to market.

42. The Hatch-Waxman Amendments 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 the Hatch-Waxman Amendments, 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 prescriptions. By 2013, total annual prescription drug revenue had soared to over $329 billion, with generic drugs accounting for 84% of prescriptions.

D. ANDA Approval Process

1. Step One: Receipt of a substantially complete ANDA

43. 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. These reviews include 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.

44. 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 sufficiently complete to permit a substantive review.[4] 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)."[5]

[4] 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).").

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

a) Scientific Contents

45. The Hatch-Waxman Amendments relieved generic drug manufacturers of the cost and burden of conducting clinical trials in order to demonstrate the safety and effectiveness of their generic drugs. Instead, a generic drug company may rely on the clinical trials performed by the branded drug company, so long as it makes three key showings.

46. 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.

47. Second, it must demonstrate that the generic manufacturer can reliably manufacture a safe, stable drug product.[6]

48. Third, an ANDA must contain information demonstrating compliance with cGMP. These procedures require, *inter alia*: detailed, written steps describing the receipt, identification, storage, handling, sampling, and testing of drug products;[7] testing to ensure the identity, purity, strength, and quality of the drug;[8] and regular stability testing of the products.[9]

49. The FDA may not approve a drug for sale if "the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity."[10] A manufacturer may not sell a drug if:

> [t]he methods used in, or the facilities and controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity

[6] 21 U.S.C. § 355(j)(2)(A).

[7] 21 C.F.R. §211.80(a).

[8] 21 C.F.R. § 211.84(d)(1)-(2).

[9] 21 C.F.R. § 211.166.

[10] 21 U.S.C. § 335(j)(4)(A).

> with current good manufacturing practice to assure that such drug meets the requirements of [the FDCA] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.[11]

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.

50. Stability testing is an integral component of cGMP. 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 that it manufactures. And the results of stability testing are used by the FDA in determining appropriate storage conditions and expiration dates for a drug.

b) Intellectual Property Contents

51. To obtain FDA approval of an ANDA, a generic manufacturer must also certify that the generic drug addressed in its ANDA will not infringe 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").

[11] 21 U.S.C. §§ 331, 351(a)(2)(B); 21 C.F.R. Parts 210 and 211 (CGMP requirements for drugs).

52. If a generic manufacturer files a Paragraph IV certification, the brand name manufacturer may initiate 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.

53. Hatch-Waxman litigations can, and often do, delay final approval of a generic ANDA and, by extension, market entry of generic drugs. The high profit margins on brand name drugs, and the predictable effects of generic entry – sales switch quickly from the brand to the generic – virtually assure that a brand name manufacturer will sue the ANDA filer in order to delay final FDA approval of an ANDA.

c) The Importance of Substantial Completeness: a first-to-file generic company's 180-day exclusivity

54. As an incentive to spur generic companies to bring generic alternatives to market, the first generic manufacturer to file a substantially complete ANDA containing a Paragraph IV certification gets a 180-day period of protection from competition with other ANDA-based generic versions of the drug.[12]

55. This 180-day window is referred to as the first filer's six-month or 180-day "exclusivity."[13] The automatic substitution laws and the lack of other generic options allow this first-filer to reap substantial profits during this period of exclusivity. The Supreme Court has

[12] 21 U.S.C. § 355(j)(5)(B)(iv).

[13] The label is partially erroneous because, while later ANDA-approved generic makers must wait six months after the first filer's market entry to get FDA approval, a brand's "authorized" generic, marketed under the authority of the brand manufacturer's NDA, may enter at any time.

recognized that "this 180-day period of exclusivity can prove very valuable, possibly worth several hundred million dollars"[14] to the first filer.

2. Step Two: Tentative Approval

56. When an ANDA otherwise meets the substantive requirements for approval, but cannot receive effective approval because of pending Hatch-Waxman litigation or some form of exclusivity (*i.e.*, a valid patent or marketing exclusivity granted by the FDA), the FDA may grant the application "tentative approval."[15]

57. 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.[16] Therefore, an ANDA may not receive tentative approval if, for example, bioequivalence is not shown, or if cGMP compliance is not established.

58. An ANDA that has received tentative approval is not approved, and the drug 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.[17]

59. The Hatch-Waxman regulatory scheme was intended to incentivize early generic entry to market. But brand and generic companies were, through collusive agreements and other unlawful tactics, abusing this scheme. Recognizing that the Hatch-Waxman scheme imposed no penalty on a first-to-file ANDA applicant that delayed coming to market, brand name companies

[14] *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (citation omitted). The 180-day period is even more valuable to the first filer – likely far more than twice as valuable – if the brand does not launch an authorized generic. Without the authorized generic, the first filer is left with all generic sales during the 180 day period -- and possibly beyond, if no other generic is ready, willing or able to launch a generic pursuant to an approved ANDA after 180 days.

[15] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.107(b)(3)(v).

[16] 21 U.S.C. § 355(j)(5)(B)(iv)(dd)(AA)

[17] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB); 21 C.F.R. §§ 314,105(d), 314.107(b)(3)(v).

would simply pay generic companies to stay off the market. 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.

60. To prevent this abuse, Congress amended the FDCA, passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA").[18] 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 days of exclusivity. Congress added these provisions in an effort 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."[19]

61. A first-to-file generic applicant forfeits its 180-day exclusivity if: (1) it fails to timely 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";[20] (5) it enters into an anticompetitive agreement with another applicant; or (6) all valid patents over the brand version of the drug expire.[21]

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

[19] 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer).

[20] 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).

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

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

3. Step Three: Final Approval

63. The FDCA states that the FDA "shall approve" an ANDA "unless" the agency finds that one or more specified conditions are present.[22] 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 manufacture, processing, and packing of the drugs are inadequate to assure and preserve its identity, strength, quality, and purity."[23]

V. FACTS

A. Ranbaxy develops a business model focused on first-to-file ANDAs.

64. Ranbaxy was founded in 1961 as a manufacturer of bulk drug ingredients. In the early 1990s, however, Ranbaxy shifted its focus to the development and sale of finished generic products. By the early 2000s, Ranbaxy had adopted a high-growth business strategy of filing with the FDA numerous falsely-documented applications for approval of generic products and in just a few short years, Ranbaxy filed dozens of ANDAs, including many for which it secured first-to-file status.

65. As first-filer, Ranbaxy was eligible to claim the coveted first-to-file, 180-day exclusivity for these products. Even if Ranbaxy knew it could not come to market with its own generics because its manufacturing plants were unable to produce an acceptable generic product,

[22] 21 U.S.C. § 355(j)(4).

[23] 21 U.S.C. § 355(j)(4)(A).

Ranbaxy also knew that it could still leverage its first-to-file status as a valuable bargaining chip with its brand and generic competitors.

66. Ranbaxy knew that as first-to-file, it would be in a position to negotiate lucrative patent "settlements" with brand companies. These settlements were in fact business deals under which Ranbaxy would use its first-to-file status as bottleneck to block other generics from entering the market in exchange for the brand company paying Ranbaxy in some valuable way.

67. Ranbaxy might also turn to its generic competitors, and agree to free-up this bottleneck in exchange for a piece of a generic competitor's sales and/or an up-front payment.

68. Or Ranbaxy might stubbornly hold onto its 180-day exclusivity, allowing the brand company to reap huge profits during a lengthy period of stalled generic entry while Ranbaxy struggled to get its own ANDA product approved.

69. But the speed and volume of Ranbaxy's numerous filings came at the expense of truthfulness and accuracy. Unbeknownst to the FDA, for years Ranbaxy was cutting corners and making submissions based on false, fraudulent, and forged data. All the while, Ranbaxy knew that its numerous ANDA filings often included false or misleading reports of product tests, and that its current manufacturing processes could not make consistent generic products meeting required specifications. And Ranbaxy knew that these deficiencies could impact its ability to successfully bring many of these drugs to market.

70. By 2002, Ranbaxy's ANDA filings had proliferated. It filed 23 ANDAs with the FDA that year, the most in company history.

71. Publicly, Ranbaxy portrayed an image of the good corporate citizen, concerned with ensuring compliance with important governmental safety and efficacy laws and regulations. But internally, the company's singular focus on the bottom line had resulted in lax regulatory

compliance and virtually non-existent manufacturing and testing standards. Management would dictate the test results that it wanted to see and expected employees to return data supporting that outcome. Oftentimes, such data had to be fabricated to satisfy management.

72. In 2003 Ranbaxy's U.S. revenue had climbed to $412 million (up from $296 million in 2002), and it became one of the top 10 generic drug makers in the United States. The company filed an additional 26 ANDAs in 2003.

73. By 2004, Ranbaxy was approaching $1 billion in revenues, making it India's largest generic pharmaceutical company. The U.S. market was Ranbaxy's largest, delivering more than 36% of all sales. During that year, the company filed another 26 ANDAs.

74. Included among these was a first-to-file ANDA for tamsulosin hydrochloride, sold under the brand name Flomax (the "Flomax ANDA"), which Ranbaxy filed on December 20, 2004.[24] As described in greater detail below, Ranbaxy's profit-driven focus lead it to deceive the FDA to obtain tentative approval of that ANDA, setting off a pattern of deceit and resulting in multiple tentative approvals to which it was not entitled.

75. Four days later, on December 24, 2004, Ranbaxy Inc. filed the first substantially complete ANDA for valsartan tablets, sold under the brand name Diovan (the "Diovan ANDA").[25] Ranbaxy's original Diovan ANDA contained a Paragraph III certification with respect to one of the listed patents, and a Paragraph IV certification with respect to another. Including the Flomax and Diovan ANDAs, by the end of 2004, Ranbaxy had *fifty* pending ANDAs before the FDA.

[24] By 2007, Flomax was a $1.2 billion a year drug. To preserve its lucrative first-to-file status, Ranbaxy needed to secure tentative approval of the Flomax ANDA no later than June 20, 2007.

[25] Diovan had first been 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. 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.

76. In 2005, Ranbaxy's revenues surpassed $1 billion, with $328 million generated in the U.S. alone. It continued apace in its ANDA filings, filing 26 new ANDAs. Among the first-to-file ANDAs submitted by Ranbaxy Inc. in 2005 was one for valganciclovir hydrochloride tablets, sold under the brand name Valcyte (the "Valcyte ANDA").[26] The company also submitted an ANDA for delayed release capsules 20 mg and 40 mg of esomeprazole magnesium, sold under the brand name Nexium (the "Nexium ANDA") in August 2005.[27] By year end Ranbaxy had 59 pending ANDAs. Its annual report touted valuable first-to-file status on 19 ANDAs.

B. Ranbaxy puts profits ahead of compliance, repeatedly ignoring its internal troubles.

77. During these years of rapid growth, Ranbaxy's internal troubles grew. For example, in 2003 an internal consultant determined that formalized training of the sort required by cGMP was non-existent within the company, identifying numerous discrepancies in the company's drug testing data. Ranbaxy did not disclose this audit to regulators and took no corrective action.

78. In late 2004, internal employee investigations uncovered that fraudulent bioequivalence and stability testing data underlay hundreds of regulatory filings. These findings were presented to Ranbaxy's board of directors in September 2004, and to the scientific sub-committee of the Board in December 2004. But the Board took no steps to report these

[26] 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 dated 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.

[27] 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.

irregularities to governmental regulators and did nothing to address the company's business practices.

79. In the spring of 2005, another auditor retained to review Ranbaxy's manufacturing facilities documented multiple cGMP compliance issues relating to process validation, equipment qualification, master production records, procedures, documentation practices, and stability testing. The auditor provided a series of recommendations, warning Ranbaxy that if the issues were not addressed, the FDA could take regulatory action against the company, and offering to conduct training programs to assist Ranbaxy in getting its facilities in compliance. Again, Ranbaxy took no action.

C. In 2006, the FDA begins to scrutinize Ranbaxy's operations.

80. For years, the FDA, and other regulators around the world, remained unaware of the extent of the problems within Ranbaxy. However, in late 2005, a whistleblower contacted FDA officials making allegations of compliance issues at certain of Ranbaxy's manufacturing facilities.

81. Beginning in early 2006, the FDA instituted a series of inspections at Ranbaxy facilities that would uncover serious, and systemic, compliance and documentation issues. The FDA expressed concern about its findings, particularly Ranbaxy's lack of documentation for critical testing to ensure product quality, stability, and consistency. Ranbaxy's handling of stability samples was particularly concerning.

82. On June 16, 2006, the FDA issued a warning letter to Ranbaxy's facility in Paonta Sahib, India, recommending a hold be placed on ANDAs originating from that facility. Dozens of Ranbaxy's ANDAs, including many of its lucrative first-to-file ANDAs, had originated at Paonta Sahib. Because many of these ANDAs would soon be approaching the statutory 30-

month deadline for tentative approval, a hold on the applications put Ranbaxy's valuable 180-day exclusivity periods at risk.

D. The Ranbaxy ANDA enterprise begins

83. By 2006, Ranbaxy knew that it had reached a crisis stage. It needed to respond to regulatory requests – particularly from the FDA – regarding its product development, testing, manufacturing, and reporting. But the consequences of timely and full disclosure would cost Ranbaxy too much of what it had gained over the years through the false impressions it had garnered.

84. In 2006, Ranbaxy decided the solution to this dilemma was 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. 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. On or about May 11, 2006, Beardsley and Parexel entered into an agreement (the "Parexel I Agreement"), structured to shield Parexel's audit work from any FDA scrutiny.[28]

85. Ranbaxy would have Parexel (which generally enjoyed a good reputation) perform a series of "independent" audits addressing the FDA's findings. What the FDA did not know, however, was that Parexel had agreed that Beardsley and Ranbaxy would control what was told to the FDA, what documents were shared with the FDA, and what the FDA could learn about the level of cGMP compliance at Ranbaxy's facilities.

[28] Counsel for Ranbaxy, Jayadeep Deshmukh also signed the agreement, and Ranbaxy remained responsible for paying Parexel's bills.

86. By associating itself with the outside lawyers and an ostensibly independent consulting firm, Ranbaxy hoped to create an impression of legitimacy that it could not create on its own. Although little if any progress would be made in Ranbaxy's India-based facilities, Ranbaxy, along with Beardsley and Parexel, could forestall FDA regulatory scrutiny for *years*.

87. Ranbaxy Labs and Ranbaxy Inc. mailed a series of letters to the FDA, discounting the observations and deflecting blame for the compliance issues raised in the FDA's inspection report.

88. Unconvinced by Ranbaxy's explanations and excuses, the FDA issued a Warning Letter on June 15, 2006, citing "significant deviations from [cGMP] Regulations … in the manufacture of drug products." Among the FDA's ongoing concerns was a lack of assurance that Ranbaxy had reliably performed stability sample tests.

89. The FDA imposed a compliance hold on agency approval, impacting the approval of any Ranbaxy ANDAs originating from that facility. As many of Ranbaxy's first-to-file ANDAs had originated from Paonta Sahib, Ranbaxy needed to convince the FDA that Paonta Sahib was safe.

E. Ranbaxy threatens litigation to secure final approval for Zocor.

90. As the FDA was assessing the results of the Ranbaxy inspections, it was also reviewing an ANDA Ranbaxy had previously filed for Zocor (simvastatin).[29] The only patent that was blocking final approval was expiring on June 23, 2006, and Ranbaxy wanted to come to market. The regulatory scrutiny was a complication.

[29] 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.

91. Ranbaxy threatened to sue the FDA if it held up final approval due to the compliance hold. Ranbaxy demanded a meeting with the FDA and, with the assistance of Beardsley and Parexel, persuaded the FDA not to hold up final approval. On June 23, 2006, the FDA granted final approval to Ranbaxy's 80 mg Zocor ANDA.

F. Ranbaxy continues to stall FDA review.

92. On August 26, 2006, Alok Ghosh, Ranbaxy Inc.'s Vice President of Global Quality, responded to the FDA's June warning letter with a letter of his own. Ghosh's letter was laced with false statements and material misrepresentations intended to mislead the FDA and further Ranbaxy's scheme to unlawfully obtain as many ANDA tentative approvals as possible. In it, Ghosh personally assured the FDA that Ranbaxy would take remedial steps to ensure that Ranbaxy's "stability laboratory program improvements are effective and systemic, and to verify the effectiveness of our commitments made in response to the Warning Letter."

93. In late September, the FDA requested copies of Parexel's audit reports and findings. But, beginning a pattern that would last for two years, Ranbaxy, Beardsley, and Parexel stonewalled. In a letter dated October 13, 2006, Ghosh informed the FDA that Ranbaxy would "much prefer not to provide the audit report." Instead, Ranbaxy offered to provide other materials of its own choosing.

94. On or about November 29, 2006, seven Ranbaxy representatives, including Malvinder Singh (CEO & Managing Director), Pushpinder Bindra (President and CTO), Ghosh, 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 Beardsley. Twelve FDA representatives were present.

95. During the meeting, the FDA expressed its concern that, despite the repeated representations from Ranbaxy and Beardsley, there appeared to be a lack of global corrective action taking place.

96. Bindra represented to the FDA that Ranbaxy had "[r]esolved issues raised" by the FDA's Warning Letter and "[c]ompleted commitments made in FDA responses." Ranbaxy provided the FDA with a chart classifying 56 remedial actions as "complete," 1 as "nearly complete," and 1 as "awaiting FDA approval." The representations were untrue or misleading.

97. Tetzlaff assured the FDA that Ranbaxy's response to its concerns was complete and sufficient and that "[n]one of [Ranbaxy's] statements appeared to be an attempt to provide misleading information." Tetzlaff also told the FDA that he expected the audit results for all pending ANDAs to be completed and provided to the FDA by year end.

G. Ranbaxy's legal woes begin to mount.

98. Unbeknownst to Ranbaxy, the FDA's ongoing and unresolved concerns from its inspections had spawned a federal criminal investigation into whether Ranbaxy had, among other things, lied to the FDA in its ANDAs and other submissions, defrauded the United States, or made false statements to the government.

99. On February 14, 2007, federal agents executed search warrants at Ranbaxy Inc.'s facilities in New Jersey, seizing computers and documents, including 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.

100. 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.

101. On March 27, 2007, Beardsley left a voicemail with the FDA, requesting a conference call. The requested conference call took place on April 5, 2007. The FDA informed Beardsley that none of the six Ohm facilities in the FDA database was at risk, and that the inspection of Paonta Sahib had suggested that the site was acceptable for API production. However, the FDA made clear during the telephone call that, until the audit was received, and found to be satisfactory, Paonta Sahib would remain out of compliance with cGMP.

102. In April 2007, a False Claims Act complaint was filed against Ranbaxy, alleging serious violations of cGMP leading to the introduction of adulterated drugs into the U.S. market. This complaint was brought by a whistleblower with intimate knowledge of the company's wrongful business practices. Indeed, it was the same individual who had undertaken the 2004 internal company investigation documenting the multiple examples of fraud within Ranbaxy's regulatory submission.

103. 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 that had been served on Ranbaxy in March. Ranbaxy, Beardsley, and Parexel persisted in their claims of privilege, and challenged the scope of the subpoenas, substantially delaying the production of documents pursuant to the subpoenas.

H. Ranbaxy locks in first-to-file exclusivity on its Flomax ANDA.

104. During the first half of 2007, Ranbaxy's first-to-file ANDA for generic Flomax (a widely used alpha-blocker that aids urination) was approaching the 30-month forfeiture date of

June 20, 2007. If Ranbaxy did not secure tentative approval for its Flomax ANDA by June 20th, it would forfeit first-to-file exclusivity.

105. The problem, of course, was that Ranbaxy's India-based facilities were run so poorly, and were so inadequate that they did not comply with applicable U.S. law and regulation, that Ranbaxy was not entitled to tentative approval for its generic Flomax ANDA.

106. Once again, Ranbaxy resorted to fraud and misdirection, mailing letters to two different divisions within the FDA, each intended to have the FDA act upon false or misleading information.

107. First, Ranbaxy mailed a letter to CDER, giving it the false impression that all outstanding stability and other issues had been corrected. 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 its Flomax ANDA was "ready for tentative approval," "[e]xcept for the compliance hold at Paonta Sahib."

108. These letters contained misstatements. As the FDA would later learn, the compliance issues had *not* been addressed, and, in fact, would remain unresolved for more than seven years. 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.

109. With first-to-file exclusivity for its Flomax ANDA at risk in the absence of tentative approval, Ranbaxy again threatened a lawsuit if the FDA failed to immediately confirm

that Ranbaxy would not forfeit its first-to-file exclusivity on June 20, 2007.[30] Under the threat of litigation, and relying on Ranbaxy's misrepresentations concerning its remedial efforts, the OGD granted tentative approval for Ranbaxy's Flomax ANDA.[31]

I. Ranbaxy locks in first-to-file exclusivity on its Diovan ANDA.

110. Meanwhile, Ranbaxy and the FDA were also engaged in discussions concerning Ranbaxy's Diovan ANDA. As with Flomax, Ranbaxy needed to obtain tentative approval of its Diovan ANDA, or it would lose its 180-day exclusivity.

111. Relying on the misrepresentations provided to the FDA earlier that year that led to its generic Flomax tentative approval, Ranbaxy once again gave the FDA the false impression that its cGMP compliance issues were in the past, and that the undisclosed Parexel audits verified that there were no major concerns.

112. On October 25, 2007, relying on these misrepresentations concerning 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. Ranbaxy's 180-day exclusivity was (wrongfully) preserved.

J. Ranbaxy locks in first-to-file exclusivity on its Nexium ANDA.

113. In early January 2008, internal discussions began at the FDA concerning Ranbaxy's Nexium ANDA, which faced a tentative approval deadline of February 4, 2008.

[30] 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.

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

114. The FDA had still not received the complete audits. But it was still operating under the mistaken belief (created by Ranbaxy's summer 2007 submissions) that Ranbaxy had resolved its cGMP compliance issues, and that none of the issues identified in the 2006 Warning Letter impacted the accuracy of any of Ranbaxy's ANDA submissions.

115. 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. 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."[32] This allowed Ranbaxy to wrongfully preserve its first-to-file exclusivity with respect to its generic Nexium products.

K. Ranbaxy locks in first-to-file exclusivity on its Valcyte ANDA.

116. On June 4, 2008, internal discussions began at the FDA concerning Ranbaxy's Valcyte ANDA. The thirty-month forfeiture deadline was approaching, and Ranbaxy was once again pressuring the FDA for approval.

117. 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 had rectified the issues identified in the 2006 Warning Letter, and that none of the issues had impacted the integrity of the data in ANDAs originating from Paonta Sahib.

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

[32] GGR-01313-316.

L. FDA's continued efforts to obtain the Parexel audits.

119. In early April of 2008, Beardsley sent the FDA a few of the audits it had been seeking, but claimed that others had never been completed and/or did not exist.

120. By the summer of 2008, the FDA had been seeking complete copies of Parexel's audits of the Paonta Sahib facility for nearly two years. The government had subpoenaed the documents more than a year earlier. Yet Ranbaxy, Beardsley, and Parexel had still refused to turn them over. So, on or about July 3, 2008, the government filed an action in the U.S. District Court for the District of Maryland, to enforce the subpoenas and obtain the documents.

121. In the fall of 2008, Ranbaxy and Parexel finally produced the complete audit information that the FDA had been seeking, and upon reviewing the complete audit files, the FDA realized that the prior representations made by Ranbaxy, Beardsley, and Parexel concerning the audits were false.

122. For more than two years, the FDA had taken Ranbaxy at its word when the company downplayed the extent of the problems at Paonta Sahib, promised the FDA that improvements had been made, and assured the FDA that the compliance problems in no way affected the integrity of data in Ranbaxy's ANDAs nor its ability to produce products in compliance with applicable regulations.

123. In reliance upon Ranbaxy's statements, the FDA had granted tentative approval to the Flomax, Diovan, Nexium, and Valcyte ANDAs (among others) during the same period of time that it had been seeking the full audit reports.

M. The FDA attempts to deal with the aftermath of Ranbaxy's conduct.

124. On September 16, 2008, the FDA issued additional warning letters to Ranbaxy concerning both its Paonta Sahib and Dewas facilities. Unlike the June 2006 letter, which had 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.

125. On February 25, 2009, the FDA went a step further, informing Ranbaxy of the FDA's determination that Ranbaxy had "submitted untrue statements of material fact in abbreviated and new drug applications files with the Agency." Citing the observations from the 2006 and 2008 inspections, as well as the numerous subsequent representations made by, or on behalf of, Ranbaxy, 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."

126. 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." The FDA turned to a rarely used procedure, invoking its Application Integrity Policy ("AIP").

127. Following invocation of the AIP, the FDA faced a practical reality. Ranbaxy was one of the largest generic drug manufacturers in the world, holding over 240 ANDAs that had either been approved by, or were then pending before, the FDA. Almost 20 first-to-file ANDAs were under active consideration by the FDA. But the FDA now had evidence calling into question the accuracy of the data supporting those ANDAs.

128. And the FDA had proof that cGMP compliance issues were affecting drugs being sold in the U.S. market. Ranbaxy was forced to recall thousands of cartons of its isotretinoin

capsules – not once, but twice – because cGMP compliance issues undermined the drug's safety. And thousands of bottles of Ranbaxy's amoxicillin and clavulanate potassium had to be recalled when the white pills turned brown without explanation.

129. Resolving Ranbaxy's myriad manufacturing and compliance issues would take a substantial amount of time and resources. So, the FDA focused its initial attention on the Ranbaxy ANDAs that were most suspect and most directly affected by the AIP – *i.e.*, those that originated from the Paonta Sahib facility.

130. 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 being of highest importance were its first-to-file ANDAs for generic Valcyte, Diovan and Nexium.

131. The FDA's initial solution to its Ranbaxy problem was simple: on August 13, 2010, it presented Ranbaxy with a proposed consent decree imposing 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. Among those 16 were the Diovan, Valcyte and Nexium ANDAs.

132. Forfeiture of its first-to-file status on these drugs would have represented a loss to Ranbaxy of many hundreds of millions of dollars. Without exclusivity, Ranbaxy would not capture the majority of sales, could not block other generic entrants, and would have no ability to charge supra-competitive 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.

133. 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. Although Ranbaxy agreed to relinquish some of its pending applications, it would be allowed to 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.

N. The 2012 Consent Decree.

134. 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. 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.

135. The consent decree required Ranbaxy to take affirmative steps to ensure control over quality assurance ("QA") and quality control ("QC") and imposed strict requirements for ensuring that all future submissions were reliable and documented, obligating Ranbaxy to retain an independent Data Integrity Expert and a cGMP Expert.

136. The consent decree also imposed significant prohibitions on Ranbaxy. Ranbaxy could not manufacture any U.S. drugs at Paonta Sahib, Dewas, or Batamandi until audits were performed, a comprehensive set of remedial cGMP measures were implemented, and the FDA re-inspected the facilities.

137. Finally, the Consent Decree permitted the FDA to, without notice, inspect and collect samples from Ranbaxy's facilities.

138. 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.

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

140. Ranbaxy immediately relinquished its first-to-file exclusivity with respect to three Affected Applications. And it was given a deadline of March 3, 2013, by which to gain final approval over another or suffer forfeiture of 180-day exclusivity for that product as well.

141. Ranbaxy could maintain 180-day exclusivity for the five Excepted Applications, including Diovan, Nexium, and Valcyte, pending the results of an audit. 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. Audits for the Valcyte, Diovan, and Nexium ANDAs were eventually submitted to, and reviewed by, the FDA.

O. The 2013 plea agreement with the DOJ.

142. In early 2013, Ranbaxy entered into a civil settlement and related plea agreement with the federal government resolving the 2007 whistleblower action, whereby 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.

143. Under the plea agreement, Ranbaxy USA, Inc. admitted to having committed 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,

Inc. paid a criminal fine of $130 million and a criminal forfeiture penalty of $20 million, and agreed that Ranbaxy had engaged in a fraudulent course of conduct before the FDA.

144. For several years following the 2006 Paonta Sahib inspection, Ranbaxy had misrepresented its cGMP compliance status to the FDA, and had misled the FDA as to the company's efforts to improve, in order to delay adverse action by the FDA. Ranbaxy was able to continue manufacturing drugs, and to 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. Ranbaxy made, or caused to be made, the following material misstatements:

a. On August 26, 2006, Ghosh, on behalf of Ranbaxy, sent the FDA a letter through the mail, in which he 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." These representations were false and/or materially misleading: subsequent inspections of Paonta Sahib, and audit reports being prepared contemporaneously with his letter to the FDA revealed continued, unremediated problems at Paonta Sahib.

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 had confirmed that Ranbaxy had 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 had been completed, and "in no case did the

corrections affect the previous conclusions about the stability of the sample." As the FDA would learn more than a year later, that representation was false: once the FDA obtained copies of the audit reports that should have confirmed that 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 audit 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." 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, and it would provide the information when it was completed. 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.

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." 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. As to those reports not provided, Beardsley stated that they had never been completed and/or did not exist. This was false. In the face of a federal lawsuit, Ranbaxy would later produce several of these reports.

145. 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 for the purpose of delaying, forestalling, or avoiding 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 – a number of Ranbaxy's then-pending ANDAs, including those for generic Diovan, Valcyte.

146. Attached to the plea agreement was a statement of facts detailing Ranbaxy's corrupt business model. After seven years of denials, obfuscation, and delay, Ranbaxy was forced to admit what it had tried to hide all along.

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

148. Ranbaxy finally admitted that it had falsified stability sample testing data. Rather than storing the samples under the conditions required by the FDA-approved testing protocols, Ranbaxy stored the drugs in a refrigerator for a significant period of time, because there was a testing backlog, and that 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." Yet it conceded that it claimed to the FDA that its stability testing program was being conducted according to the FDA-approved protocols.

149. Ranbaxy finally admitted that it was aware of substantial cGMP compliance problems since at least October 2003 and that, despite consultants urging that Ranbaxy conduct

additional cGMP training for its staff, "Ranbaxy never presented any of the training programs recommended for it by [the auditor]."

P. The impact on the entry of generic Nexium

150. As previously alleged, on August 5, 2005 Ranbaxy submitted the first ANDA for generic Nexium, and in February 2008 it unlawfully locked-in 180-day exclusivity (and bottlenecking) for that product from the FDA. The additional course of proceedings for generic Nexium show how Ranbaxy's unlawful conduct had the effect of unnecessarily delaying the entry of generic Nexium until at least January 27, 2015.

151. 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 with respect to the patents covering branded Nexium in the U.S. District Court for the District of New Jersey (the "*Nexium* ANDA litigation"). 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).

152. In addition, AstraZeneca subsequently 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.

153. 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 terms of the settlement agreement, AstraZeneca agreed to dismiss its lawsuit against Ranbaxy in 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 in the form of lucrative manufacturing and distribution agreements and marketing privileges.

154. It is unknown at this time the extent to which, if at all, Ranbaxy's efforts in gaining unlawful tentative approvals played into the agreement to delay entry of generic Nexium until May 27, 2014. It is also unknown what impact a forfeiture of Ranbaxy's first-to-file exclusivity would have had on the efforts of other generic ANDA filers seeking to bring generic Nexium to market. In any event, as a result of the April 2008 agreement any patent issues with respect to the launch of generic Nexium had been 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.

155. 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 and 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. Similarly, on January 28, 2011, AstraZeneca reached a similar settlement with Dr. Reddy's, which terms included AstraZeneca agreeing to drop the patent litigation and Dr. Reddy's agreeing to refrain from challenging the Nexium-related patents and to defer entering the market with its generic Nexium product until May 27, 2014.

156. 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 refrain from launching generic Nexium until May 27, 2014 unless another generic manufacturer found a way to legally enter the market on an earlier date.

157. 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 experts for the Nexium ANDA.

158. However, 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 blocking 180-day exclusivity for generic Nexium. After almost two years of additional delay, the adverse impact that Ranbaxy's delay was having on healthcare consumers was brought front and center.

159. In the spring of 2014, a series of citizen petitions were filed with the FDA. These petitions pointed out that the ANDAs filed by other would-be generic companies were being blocked by Ranbaxy's wrongfully acquired 180-day exclusivity, including the generic Nexium ANDA. The petitioners demanded that the FDA revoke Ranbaxy's first-to-file exclusivity, and that it approve other ANDAs in order 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.

160. After Ranbaxy's agreed-upon entry date of May 27, 2014 passed, consumer groups and state officials submitted comments to the citizens petitions arguing for the FDA to

revoke Ranbaxy's first-to-file exclusivity. For instance, in August 2014, the Consumer Federal of California commented: "May 27, 2014 has come and gone [but] no generic esomeprazole product has entered the market. Consumers remain bereft of the benefit of cost-saving generic drugs until full generic entry into this market." The group estimated that a 50% price reduction for a generic substitute for Nexium "could save California consumers and health insurance payers $375 million a year; nationwide savings could exceed $3 billion."

161. The Attorney General for the State of Connecticut followed up in September, 2014, noting 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."

162. On November 4, 2014, the FDA notified Ranbaxy that the FDA had 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." The FDA rescinded its previously granted tentative approval of Ranbaxy's Nexium ANDA.

163. On January 26, 2015, the FDA notified Ranbaxy that it had forfeited its eligibility for 180-day exclusivity for generic Nexium. On the same date, the FDA issued final approval of 20mg/40 mg versions of Teva's proposed generic Nexium product. Teva launched its generic Nexium product a mere three weeks later, on or around February 17, 2015.

164. The FDA subsequently granted final approval to several additional manufacturers seeking to bring generic Nexium products to market, including Mylan (August 2 and 3, 2015), Dr. Reddy's Labs (September 25, 2015), Torrent (October 19, 2015) and Aurobindo (April 21, 2016).

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

Q. Ranbaxy sues the FDA.

166. 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 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.

167. Ranbaxy sought injunctive relief, contending that the FDA's revocation harmed it, even though it admitted that it was not ready 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 by receiving payment from another generic company for a selective waiver of its 180-day exclusivity, or through payments from the brand company in exchange for Ranbaxy's promise not to exercise its right to come to market.

168. 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.

169. According to Ranbaxy, the MMA eliminated the FDA's long-standing requirement that an applicant prove its manufacturing facilities were cGMP-compliant. 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.[33]

170. DHHS and the FDA moved immediately for summary judgment, arguing that Ranbaxy's interpretation of the law was meritless. 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," 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.

171. The FDA admitted that its initial tentative approvals for the Valcyte and Nexium ANDAs were granted in error and based on its reliance on Ranbaxy's misrepresentations, including Ranbaxy's purported resolution of its cGMP deficiencies and the purported lack of any false data in ANDAs. As the FDA explained, Ranbaxy's 2007 representations that it had resolved its cGMP issues were false: "Ranbaxy's CGMP problems at Paonta Sahib were so

[33] Compl., *Ranbaxy v. Burwell*, No. 14-cv-1923 (Dec. 22. 2014).

significant they remain unresolved today (more than seven years after [the relevant] tentative approval letter was issued)."

172. 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 doing," based on Ranbaxy's obfuscation and delay.

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

174. First, the court explained, Ranbaxy's interpretation would mean that *any* description of methods, facilities and controls used in manufacture 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." 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."

175. Second, the court explained, 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."[34] The court observed that Ranbaxy could not "argue seriously that the FDA is prevented from denying tentative approval to an ANDA in such circumstances."

176. Ranbaxy's misconduct could not be used as an excuse to overcome clear regulatory requirements. The problems that had plagued Ranbaxy for years, leading to the

[34] *Id.* at 51-52.

consent decree, the criminal plea, and the civil settlement supported the FDA's determination that Ranbaxy had fraudulently obtained tentative approvals to which it was not entitled.

R. Sun Pharma acquires Ranbaxy.

177. On April 6, 2014, Sun Pharma and Ranbaxy Labs announced that they had entered into an agreement pursuant to which Sun Pharma would acquire Ranbaxy in an all-stock merger transaction. The boards of directors of both companies approved the transaction that same day.

178. The Scheme of Arrangement approved by the companies and pursuant to which the merger took place provides that:

> 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….

179. On May 6, 2014, Sun Pharma and Ranbaxy Labs provided notice of the proposed merger to the Competition Commission of India. After investigating the proposed merger, the Commission approved it on December 5, 2014, subject to the companies' divesture of certain products. Sun Pharma and Ranbaxy Labs also agreed to divest Ranbaxy Labs' generic minocycline tablets to Torrent Pharmaceuticals, in response to a complaint brought by the U.S. Federal Trade Commission.

180. Sun Pharma completed its acquisition of Ranbaxy on or about March 25, 2015, and now owns Ranbaxy. Ranbaxy Labs is no longer listed on the Indian Stock Exchanges.

VI. MARKET POWER AND MARKET DEFINITION

181. Ranbaxy wrongfully acquired, locked in, and used market power over the market for esomprazole magnesium or narrower markets contained therein.

182. 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.

183. First, the holder of the 180-day exclusivity largely has the ability to 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. (For example, in some circumstances the holder of the 180-day exclusivity might reach an agreement with the brand company to delay the first filer's entry and get, in exchange, a large payment. By doing so the first filer delays not only its entry, but the entry of all other generic applicants. The first filer thus is able to provide the brand company with the ability to charge supra-competitive prices for branded versions of the drugs for longer than it would have otherwise been able, and in exchange get paid off to do so).

184. Second, the holder of the 180-day exclusivity largely has the power, once the first generic enters, to exclude other ANDA-based generic manufacturer's products from entering those markets. The first filer thus has the ability to capture an overwhelming majority of the market in a very short span of time.

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

186. Esomeprazole magnesium tablets do not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than its AB-rated generic equivalents.

187. A small, but significant, non-transitory price increase for this drug would not have caused a significant loss of sales to other medications, and would not have made such a price increase unprofitable.

188. 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 is different than 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 with respect to Nexium. Esomeprazole magnesium is therefore differentiated from all products other than its brand name equivalent.

189. 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. This prohibition divorces the payment obligation and the product selection: the patient (and in most

cases, 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.

190. 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.

191. Thus, 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.

192. To be a substitute for antitrust purposes, a functionally similar product must exert sufficient pressure on prices and sales of another product, so that the price of that product cannot be maintained above levels that would be maintained in a competitive market. No other PPI (except AB-rated generic versions of Nexium) will, or would, take away sufficient sales from this drug to prevent a manufacturer from raising or maintaining the price of its AB-rated generic equivalent above levels that would prevail in a competitive market.

193. Ranbaxy has had, and exercised, the power to exclude competition from the relevant market.

194. To the extent that the purchasers are legally required to prove market power circumstantially by first defining a relevant product market, the purchasers allege that the relevant markets are all esomeprazole magnesium tablets – i.e., Nexium (in all its forms and dosage strengths) and AB-rated bioequivalent esomeprazole magnesium tablets.

195. Ranbaxy, at all relevant times, enjoyed high barriers to entry with respect to competition to the above defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

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

VII. MARKET EFFECTS

197. Ranbaxy, acting alone and/or in concert with Beardsley and Parexel, willfully and unlawfully maintained its market power by engaging in an overarching scheme to exclude competition. Ranbaxy designed this scheme, which discouraged, rather than encouraged, competition on the merits, for the anticompetitive purpose of forestalling generic competition, and carried out the scheme with the anticompetitive effect of maintaining supra-competitive prices for the relevant product. Ranbaxy implemented its scheme by, *inter alia*, filing, maintaining, and pursuing ANDAs for drugs that it knew it was unlikely to ever be able to bring to market. It continued its scheme by engaging in a protracted series of misrepresentations and falsehoods to secure tentative approvals to which it was not lawfully entitled. It used the deceptively obtained first-to-file exclusivity both as leverage in settlements with brand companies that secured benefits for itself and delayed generic entry far longer than would have otherwise occurred, and as a means of excluding other generics from entering the market. And its deficient manufacturing operations, which it shielded from FDA scrutiny when obtaining the 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.

198. Ranbaxy's acts and practices, including its conspiracy with Beardsley and Parexel, had the purpose and effect of restraining competition unreasonably 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 exclude competition in the market for Nexium and uts AB-rated generic equivalents, to the detriment of the purchasers and all other members of the direct purchaser class.

199. Ranbaxy's exclusionary conduct, including its conspiracy with Beardsley and Parexel, has delayed generic competition. But for Ranbaxy's illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of these drugs much sooner than they actually were marketed.

200. By way of examples and not limitation, in the absence of Ranbaxy's conduct, along and in concert with Beardsley and Parexel: (i) Ranbaxy would not have obtained first-to-file bottlenecking exclusivity for Nexium, and would not have been able to trade that status into settlements with the brand companies, which delayed generic entry for years into the future; (ii) Ranbaxy would not have received tentative approval of its Nexium ANDA within the time period established by applicable regulations, but would have forfeited its 180-day exclusivity, thereby removing a substantial barrier to the market entry of multiple other generic companies; and (iii) other generic ANDA filers would have known, in February 2008, that there would be no generic ANDA applicant entitled to 180-day exclusivity with respect to generic Nexium, which would have incentivized other ANDA filers to proceed more rapidly with their own ANDA efforts for those drugs.

201. Other generic manufacturers seeking to sell generic Nexium 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 Nexium (no later than May 27, 2014), were it not for Ranbaxy's illegal and unlawful acts and conspiracies with Beardsley and Parexel.

202. Ranbaxy's illegal acts and conspiracies with Beardsley and Parexel to delay the introduction into the U.S. marketplace of any generic versions of Nexium caused the purchasers 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.

203. Typically, generic versions of brand-name drugs are initially priced significantly below the branded counterpart. As a result, upon generic entry, direct purchasers 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 direct purchasers 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. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition. Generic companies holding first-to-file exclusivity likewise have a keen financial interest in delaying their entry into the market in exchange for a share of the monopoly profits that their delay makes possible. And purchasers experience substantial cost inflation from these delays.

204. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant market, direct purchasers, such as the purchasers and members of the class, would have paid less for this drug by (a) receiving discounts on their remaining brand purchases of this drug, (b) substituting purchases of less-expense generic

versions for their purchases of the more-expensive brand version, and/or (c) purchasing the generic versions of this drug at lower prices sooner.

205. Moreover, due to Ranbaxy's fraud, other generic manufacturers were discouraged from and/or delayed in developing their own generic versions of this drug, and/or challenging the validity or infringement of the patents purporting to cover this drug in court.

206. Thus, Ranbaxy's unlawful conduct deprived the purchasers and the members of the direct purchaser class of the benefits from competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

207. During the relevant period, the purchasers and members of the direct purchaser class purchased substantial amounts of Nexium directly from the branded manufacturer and/or purchased substantial amounts of generic versions of Nexium. As a result of Defendants' illegal conduct, members of the direct purchaser 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 direct purchaser class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Nexium was artificially inflated by Defendants' illegal conduct; (2) direct purchaser class members were deprived of the opportunity to purchase lower-priced generic versions of Nexium sooner; and/or (3) the price of generic Nexium was artificially inflated by Defendants' illegal conduct.

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

209. Ranbaxy's efforts to monopolize and restrain competition in the market for Nexium and its generic equivalents have substantially affected interstate and foreign commerce.

210. In furtherance of their efforts to monopolize and restrain competition in the market for this drug, 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

211. The purchasers, on behalf of themselves and all direct purchaser class members, seeks damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive and fraudulent conduct in the market for Nexium and its AB-rated generic equivalents.

212. The purchasers bring this action on behalf of itself and, under Federal Rule of Civil Procedure 23(a) and (b)(3), as a representative of a direct purchaser class defined as follows:

> All persons or entities in the United States and its territories who purchased Nexium and/or AB-rated generic versions of Nexium directly from any of the Defendants or any brand or generic manufacturer at any time during the period May 27, 2014, through and until the anticompetitive effects of the Defendants' conduct cease (the "Nexium Class Period")

Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

213. Members of the direct purchaser class are so numerous that joinder is impracticable. The purchasers believe that the class numbers in the many scores of entities. Further, the direct purchaser class is readily identifiable from information and records in Defendants' possession.

214. The purchasers' claims are typical of the claims of the members of the direct purchaser class. The purchasers and all members of the direct purchaser class were damaged by the same wrongful conduct of the Defendants, *i.e.*, they paid artificially inflated prices for esomeprazole magnesium and were deprived of earlier and more robust competition from cheaper generic versions of Nexium as a result of Defendants' wrongful conduct.

215. The purchasers will fairly and adequately protect and represent the interests of the direct purchaser class. The interests of the purchasers are coincident with, and not antagonistic to, those of the direct purchaser class.

216. The purchasers 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.

217. Questions of law and fact common to the members of the direct purchaser class predominate over questions that may affect only individual class members because Defendants have acted on grounds generally applicable to the entire direct purchaser class thereby making overcharge damages with respect to the direct purchaser class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

218. Questions of law and fact common to the direct purchaser class include:

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

b. whether Ranbaxy unlawfully excluded competitors and potential competitors from the market for Nexium and its AB-rated generic bioequivalent;

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

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

f. 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;

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

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

i. the quantum of aggregate overcharge damages to the class.

219. 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.

220. The purchasers 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 SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)

(Asserted Against All Defendants as to esomeprazole magnesium)

221. The purchasers repeat and incorporate by reference all preceding paragraphs and allegations.

222. As described above, from May 27, 2014 until at least January 26, 2015 (and with effects lasting far longer), Ranbaxy possessed market power in the market for esomeprazole

magnesium. No generic manufacturer, including Ranbaxy, sold any version of esomeprazole magnesium tablets until January 26, 2015.

223. Ranbaxy willfully and unlawfully maintained its market power in the esomeprazole magnesium market from May 27, 2014, through at least January 27, 2015, 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.

224. 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 maintain its market power. This scheme included:

a. Filing, pursuing, and maintaining ANDAs based upon falsified information;

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.

225. By means of this scheme, Ranbaxy intentionally and wrongfully maintained market power with respect to esomeprazole magnesium in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of market power, the purchasers and members of the class paid artificially inflated prices for esomeprazole magnesium.

226. The purchasers and members of the 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 Nexium 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 the purchasers and the class are the proper entities to bring a case concerning this conduct.

227. Ranbaxy's anticompetitive conduct is not entitled to qualified *Noerr-Pennington* immunity.

228. 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.

229. 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.

230. 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, accept the ANDA as being substantially complete 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.

231. 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. 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 TWO - VIOLATION OF RICO, 18 U.S.C. § 1962(c)

(Asserted Against Ranbaxy Labs, Ranbaxy Inc., and Sun Pharma)

232. The purchasers repeat and incorporate by reference all preceding paragraphs and allegations.

233. 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).

234. 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).

235. 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.

236. 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 ANDA 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 contained within the ANDAs, and the completeness of the ANDAs.

237. 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.

238. 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 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.

239. 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 some of 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.

240. 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 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. In an effort 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. All of this was done so that those ANDAs could be approved. And Parexel agreed to, and did, make false statements of fact to the FDA with the intent to further the scheme to defraud the FDA.

241. The Ranbaxy ANDA Enterprise engaged in and affected interstate commerce, because, *inter alia*, it obtained approval to market – and in some cases did market – drugs that were 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.

242. 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 a variety of actions, including the following:

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.

243. 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 within ANDAs submitted to the FDA, in order to keep development costs down and expedite the ANDA filing process so as to obtain valuable first-to-file status; (b) submitting, or causing to be

submitted, ANDAs containing 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 was in compliance with cGMP regulations, (ii) whether Ranbaxy was taking steps to bring Paonta Sahib into compliance with cGMP regulations, or (iii) whether known violations of cGMP violations materially affected data submitted to the FDA in connection with various Ranbaxy ANDAs, including for 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.

244. 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 previously-submitted 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.

245. 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 the purchasers.

246. 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.

247. As a result of Defendants' fraudulent activities, generic versions of drugs, including Nexium, were kept off the market for longer than they would have been absent Defendants' fraudulent activities, resulting in increased costs to direct purchasers of those drugs, including the purchasers and all members of the class.

248. The purchasers and others similarly situated have been injured in their business and property by reason of Ranbaxy's fraudulent scheme and the success of the Ranbaxy ANDA Enterprise. The purchasers and others similarly situated have paid hundreds of millions, if not billions, of dollars more for Nexium, and its generic equivalents, than they would have in the absence of the fraudulent course of conduct underlying the Ranbaxy ANDA Enterprise.

249. The purchaser's injuries 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 Nexium, generic versions of this drug would have been available for purchase sooner, resulting in savings to the purchases and others similarly situated amounting to hundreds of millions, if not billions of dollars.

250. The purchaser's injuries 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 as a result of the fraud, and has no incentive to sue in RICO. And 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 purchasers, not Ranbaxy's competitors.

251. The purchasers and those similarly situated were most directly harmed by the fraud, and there is no other plaintiff or class of plaintiffs better situated to seek a remedy for the economic harms of Ranbaxy's fraudulent scheme. In the pharmaceutical supply chain, direct purchasers – such as the purchasers and those similarly situated – purchase prescription drugs directly from manufacturers. The delay in availability of generic drugs occasioned by the fraudulent Ranbaxy ANDA Enterprise caused a delay in the availability of safe, affordable generic drugs. As a result, the purchasers and those similarly situated paid for vastly more expensive brand name versions of Nexium long after a generic drug should have entered the market.

252. By virtue of these violations of 18 U.S.C. § 1962(c), defendants are liable to the purchasers for three times the damages the purchasers have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT THREE - VIOLATION OF RICO, 18 U.S.C. § 1962(d)

(Asserted Against Ranbaxy Labs, Ranbaxy Inc., and Sun Pharma)

253. The purchasers repeat and incorporate by reference all preceding paragraphs and allegations.

254. 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."

255. 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.

256. 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 wrongfully from their fraudulently-filed ANDAs.

257. 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.

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

259. 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.

260. 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.

XI. DEMAND FOR JUDGMENT

WHEREFORE, the purchasers, on behalf of themselves and the Class, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to 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 class, and declare CCI as representative of the class;

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 the purchasers and the class;

D. Award the class damages (*i.e.*, three times overcharges 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 purchasers and the class 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, CCI, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: November 1, 2018

Respectfully submitted

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