UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MEIJER, INC., and MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated, Plaintiffs v. RANBAXY INC., RANBAXY LABORATORIES, LTD., RANBAXY U.S.A., INC., and SUN PHARMACEUTICAL INDUSTRIES LTD. Defendants	Civil Action No. _____ Class Action Jury Trial Demanded

COMPLAINT AND JURY DEMAND

TABLE OF CONTENTS

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. So American consumers can generally be assured that the generic products sold in the United States will provide the same level of therapeutic clinical results, consistency, and quality as branded drugs.

2. Against this backdrop of reliable generic drug manufacturing there is one clear exception: rogue generic drug maker Ranbaxy Laboratories. This case is about how Ranbaxy 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. It is one thing for a corrupt company to run its affairs so poorly that it is unable to make, and document, a minimally acceptable product, thus hurting its own sales and profitability. But it is quite another thing for that company to recklessly and fraudulently bog down the FDA generic approval process, wrongfully acquire the ability to preclude or stall the efforts of *other* generic companies that are responsibly seeking to enter U.S. markets, and delay

generic entry while it struggles to get its own act together. When that happens, the harm is visited directly and only on U.S. drug purchasers.

4. In the early 2000s, Ranbaxy embraced an internal corporate culture displaying 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. They performed stability tests (important for establishing a drug's expiration date) on the same day, instead of at 3-, 6-, and 9-month intervals as required by regulations. And they performed bioequivalence and stability tests on research-and-development batches of drugs, instead of exhibit batches as the regulations required (exhibit batches take longer, and cost more, to produce).

5. Ranbaxy exploited these shortcuts to achieve its objective: filing as many abbreviated new drug applications ("ANDAs") as possible, especially if it could secure valuable first-to-file generic status and the lucrative 180-day exclusivity that came with it. Ranbaxy generated enough documentation – real or forged – to support these quick filings. Ranbaxy convinced unknowing regulators reviewing these applications that Ranbaxy's facilities and procedures were (or would be soon) in compliance, when in fact the facilities would remain in shameful condition for years. 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 in any timely way, if at all.

6. 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

served to lock in Ranbaxy's ability to block or delay the entrance of other generic makers into the applicable market. Among other things, in 2007 and again 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 *eight years* (and Ranbaxy remains out of compliance to this day). But it took years for the FDA to untangle Ranbaxy's web of lies. As each of the many ANDAs Ranbaxy had filed came up for review, Ranbaxy's overall course of conduct continually mucked up the FDA approval process, not only for the pending Ranbaxy ANDAs, but also for each of the would-be generic makers seeking to enter that particular generic drug market.

7. Over the years, Ranbaxy dragged out discussions with 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. 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. But even these efforts did not solve all of Ranbaxy's many problems, and product recalls continued to plague the company.

8. 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.

9. This lawsuit seeks monetary relief on behalf of all direct purchasers of drugs for which generic entry was delayed in substantial part by Ranbaxy's wrongful acquisition and maintenance of 180-day exclusivities, its business conduct that ultimately required it be subject to a consent decree, and its preclusion of other generic entrants while it floundered to get its own applications approved. At this time, this action pleads with particularity that (i) the direct purchasers of the brand drug Valcyte (valganciclovir hydrochloride) overpaid for that product because Ranbaxy's wrongful conduct delayed the generic entry for valganciclovir hydrochloride at least between March 15, 2013, and November 20, 2014, and (ii) the direct purchasers of the brand drug Diovan overpaid for the product because Ranbaxy's wrongful conduct delayed the generic entry for valsartan at least between September 21, 2012, and July 7, 2014. Discovery may determine that Ranbaxy's scheme delayed other generic products.

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

11. First, direct purchasers seek relief under federal antitrust law. For at least two drugs (valganciclovir hydrochloride and valsartan), Ranbaxy wrongfully obtained, fraudulently locked-in, and then abused the first-to-file, 180-day exclusivity period. By fraudulently acquiring and later using these exclusivities to exclude other would-be generics, Ranbaxy acquired and misused market power with respect to at least these two drugs, causing prices for these products 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.

12. 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, for at least two drugs (valganciclovir hydrochloride and valsartan) Ranbaxy wrongfully obtained, fraudulently locked-in, and used the first-to-file, 180-day exclusivity period. 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 for these products 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

13. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc., (collectively, "Meijer") are corporations organized under the laws of the state of Michigan, with their principal place of business located at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of Frank W. Kerr Co., which, during the relevant period, purchased Valcyte and Diovan directly from its manufacturer, and resold that Valcyte and Diovan to Meijer. Meijer suffered and continues to suffer antitrust injury as a result of defendants' unlawful conduct.

14. 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.

15. 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.

16. 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.

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

18. 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 Pharm 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

19. 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. Plaintiff seeks damages for its 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).

20. 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

21. 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.

22. 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.

23. 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.

24. 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.

25. 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

26. 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.

27. 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.

28. 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]

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[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

[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).

> conformity 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

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[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 timely to market the drug; (2) it withdraws the ANDA, or the FDA constructively withdraws it on the manufacturer's behalf because "the application does not meet the requirements for approval"; (3) it amends or withdraws its Paragraph IV certification; (4) it fails to obtain tentative approval "within 30 months after the date on which the application is filed";[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]

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[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. Founded in 1961, Ranbaxy spent its early years as a manufacturer of bulk drug ingredients. In the early 1990s, Ranbaxy shifted its focus to the development and sale of finished generic products. Ranbaxy filed its first ANDA with the FDA in 1995, targeting the United States as the source of its future revenue growth.

65. By the late 1990s or early 2000s, Ranbaxy had embarked on a high-growth business strategy of filing with the FDA numerous falsely-documented applications for approval of generic products. In just a few short years, Ranbaxy filed dozens of ANDAs, including many for which it secured first-to-file status. The company attributed this rapid pace to its ability to get an ANDA on file in just 12 months, while its competition often took 18 months or longer.

66. A key part of Ranbaxy's strategy was to win the race of filing the first ANDA for a high sales drug product, and to do so for as many ANDAs as possible. Doing so would enable

[22] 21 U.S.C. § 355(j)(4).

[23] 21 U.S.C. § 355(j)(4)(A).

it to claim the coveted first-to-file, 180-day exclusivity for that product. Even if Ranbaxy could not itself eventually get to market with its own generic product (because its manufacturing plants might be woefully unable to produce acceptable generic products), Ranbaxy could leverage its first-to-file status as a valuable bargaining chip with its brand and generic competitors.

67. Another part of Ranbaxy's strategy was that Ranbaxy might eventually negotiate patent "settlements" with brand companies. In reality, these were business deals under which Ranbaxy and a brand company would log jam the ability of other generics to enter the market (in exchange for the brand company paying Ranbaxy in some valuable way). Or Ranbaxy might turn to its generic competitors, and agree to free-up the log jam in exchange for a piece of a generic competitor's sales and/or an up-front payment. Or Ranbaxy might stubbornly hold onto its bottlenecking 180-day exclusivity, allowing the brand company to reap huge profits during a lengthy period of stalled generic entry while Ranbaxy might (in vain) try to get its own act together for its own ANDA-approved product.

68. Of course, the race to acquire first-to-file status is not unique to Ranbaxy. Many generic makers seek to be the first ANDA filer for a large product market. But among generic drug makers, Ranbaxy stands out as one willing to intentionally deceive the FDA in order to win that race.

69. The speed and volume Ranbaxy's numerous filings came at the expense of truthfulness and accuracy. Unbeknownst to the FDA, for years Ranbaxy had been cutting corners, making submissions based on false, fraudulent, and forged data. 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. Meanwhile, Ranbaxy publicly touted its huge application numbers, the size of the markets into which those products might eventually enter, and its ability to secure the coveted first-to-file 180-day exclusivity for many high-sales drugs. Ranbaxy used its ANDA filing machine to promise huge future returns, and (as was hoped) Ranbaxy's stock skyrocketed on India's two leading stock exchanges, the Bombay Stock Exchange (BSE) and National Stock Exchange (NSE).

71. By 2002, Ranbaxy's ANDA filings had proliferated. It filed 23 ANDAs with the FDA that year, the most in company history. Its CEO at the time credited Ranbaxy's low research and development and manufacturing costs as the primary basis for its impressive drug pipeline. 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.

76. Including the Flomax and Diovan ANDAs, by the end of 2004, Ranbaxy had *fifty* pending ANDAs before the FDA.

77. 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.

78. 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] and one for esomeprazole magnesium, sold under the brand name Nexium (the "Nexium ANDA").

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[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.

[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.

79. 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.

80. During these years of rapid growth and metastatic ANDA filings, Ranbaxy's internal troubles grew. Issues were brought to the attention of its highest officials, including the board itself, yet left ignored.

81. 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. Nor did it take corrective action.

82. A 2004 World Health Organization audit revealed stunning flaws in Ranbaxy's antiretroviral drugs being supplied to AIDS-ravaged countries in Africa.

83. And in late 2004, internal employee investigations brought a lengthy list of issues to the attention of Ranbaxy Lab's board of directors. The board was told that fraudulent testing data underlay hundreds of regulatory filings:

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

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

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

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

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

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

g. Individual dissolution values in stability studies were fabricated;

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

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

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

84. These findings were presented to Ranbaxy Lab'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 irregularities to governmental regulators. Nor did it alter the company's business practices.

85. 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.

86. The FDA, and other regulators around the world, remained unaware of the extent of the problems within Ranbaxy.

87. In late 2005, the FDA got its first glimpse into Ranbaxy's suspect business practices when a whistleblower contacted FDA officials making allegations of compliance issues at certain of Ranbaxy's manufacturing facilities.

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

88. Beginning in early 2006, the FDA instituted a series of inspections at Ranbaxy facilities. Despite advance notice given to Ranbaxy Labs (and despite Ranbaxy's hurried efforts to cover up flaws and create false reports), the FDA discovered serious, and systemic, compliance and documentation issues.

89. The inspections documented a number of violations and deviations from cGMP regulations, including:

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

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

c. Failure to determine appropriate drug storage conditions and expiration dates, as required by 21 C.F.R. § 211.166. Stability samples, including some for generic Nexium, that should have been studied for their degradation profile at warmer temperatures (30^{o}C) were stored in a refrigerator and held at 4^{o}C.

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

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

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

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

90. At the end of each inspection, the FDA provided Ranbaxy with an inspection report summarizing its findings. The FDA expressed concern about the 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.

91. 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. Many 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.

92. By 2006, internally, Ranbaxy appreciated 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. Of course, these were operational issues needing full and (as typically occurs with responsible companies) transparent reporting. Technicians and regulatory employees, not lawyers, would have the information to implement sound practices and truthful reporting.

93. But Ranbaxy apparently believed it had too much to hide. And it recognized that 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. So in 2006, Ranbaxy chose to form a group comprised of itself, some outside lawyers, and an ostensibly independent consulting company it hand-selected, in order to address FDA regulatory demands.

94. 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.[27]

95. The notion was that Parexel, which generally enjoyed a good reputation, would be hired to perform a series of audits addressing the FDA's findings. Parexel and Ranbaxy would hold Parexel out as conducting ostensibly "independent" reviews of Ranbaxy's facilities. However, 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. Parexel also agreed to run all drafts of its audit reports through the lawyers (*i.e.*, Beardsley) for comment and approval; every page of its work would be labeled as attorney work product and identified as privileged; and Parexel would follow Beardsley's instructions as to any subpoenas that might seek the audit reports.

96. Ranbaxy, by associating itself with the outside lawyers and an ostensibly independent consulting firm, could create with them that which it could not create on its own: a patina of legitimacy. In reality, little if any actual progress would be made in Ranbaxy's India-based facilities. But Ranbaxy, working with Beardsley and Parexel, could forestall FDA regulatory scrutiny for *years*.

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

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

report. Some form of an explanation was offered, or it was claimed that new practices had been adopted. During the inspections the FDA requested certain documents, such as lists documenting the storage of drugs. Ranbaxy employees stated that such lists did not exist. Following the inspections, Ranbaxy sent documents to the FDA, purporting to be master lists and working logs of samples stored in their facilities. But the documents (a) did not document any samples received before January 2006, and (b) contained no information for the samples received from January through May 2006, concerning the date(s) on which the samples had been removed from/returned to storage as part of stability testing.

98. Unconvinced by Ranbaxy's explanations and excuses, on June 15, 2006, the FDA issued a Warning Letter, 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. The FDA imposed a compliance hold on agency approval, impacting 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 things were just fine at Paonta Sahib.

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

99. As the FDA was assessing the results of the Ranbaxy inspections, it was also reviewing an ANDA Ranbaxy had previously filed for Zocor (simvastatin).[28] The only patent that was blocking final approval was expiring on June 23, 2006, and Ranbaxy wanted to come to market. But the recent regulatory scrutiny was a complication.

[28] 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.

100. Pulling out a common tool in its arsenal, Ranbaxy threatened to sue the FDA if it held up final approval due to the recent 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.

101. On August 26, 2006, Alok Ghosh, Ranbaxy Inc.'s Vice President of Global Quality, responded to the 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. For example, Ranbaxy, through Ghosh, falsely represented to the FDA that Ranbaxy was "undertaking a number of activities to improve [its] quality programs and enhance [its] operational performance at the Paonta Sahib facility." He told the FDA that "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." Ghosh personally assured the FDA that Ranbaxy would take remedial steps, touting the fact that that it had "retained Ron Tetzlaff and his colleagues at PAREXEL Consulting . . . to verify that our stability laboratory program improvements are effective and systemic, and to verify the effectiveness of our commitments made in response to the Warning Letter."

102. Ghosh included a detailed, point-by-point response to the warning letter, presenting Ranbaxy's explanations. While Ranbaxy purportedly committed to remediating compliance issues, many, if not most, of Ranbaxy's responses denied that any compliance issue actually existed, often instead blaming the FDA for a misunderstanding. For example:

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

"discard" was synonymous with "invalidate." Ranbaxy claimed employees always invalidated but retained the data.

b. During the inspection the FDA was told no log books existed for two 4^{o}C chambers containing stability samples, which the FDA referred to as "stability chambers." To explain why Ranbaxy was later able to produce those same log books, Ranbaxy contended that log books had always existed, but were not provided because the chambers were not "stability chambers," but rather "refrigerators."

103. 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.

104. In a letter dated October 13, 2006, Ghosh informed the FDA that Ranbaxy would "much prefer not to provide the audit report." Instead of providing the audits themselves, Ranbaxy offered to provide other materials of its own choosing. Ranbaxy and Parexel maintained that providing the audit work would adversely affect employee candor in the audit process, telling the FDA that its own policy was not to review such audits.

105. 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.

106. 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. The FDA peppered Ranbaxy, Beardsley, and Parexel with questions, many of which went unanswered. But Tetzlaff vouched for Ranbaxy's efforts and good intentions.

107. Bindra, on behalf of Ranbaxy, represented to the FDA that it had "[r]esolved issues raised" by the FDA's Warning Letter and "[c]ompleted commitments made in FDA responses." He claimed that Ranbaxy had "[c]omprehensively addressed all . . . Warning Letter issues," and "[p]rovided FDA with evidence to show that all Warning Letter issues have been adequately addressed." Ranbaxy provided the FDA with a chart classifying 56 remedial actions as "complete," 1 as "nearly complete," and 1 as "awaiting FDA approval." The representations were untrue or misleading.

108. Tetzlaff made a presentation concerning the Parexel audits, representing that Parexel was "doing a retrospective verification of stability samples" along with a review of the accuracy of "all current and future ANDA filings." Tetzlaff told the FDA that he expected the audit results for all pending ANDAs to be completed and provided to the FDA by year end.

109. Tetzlaff blamed some of the purported issues on the FDA: "Several FDA responses conveyed unclear messages that seemed to have resulted from unfortunate choices of words," but assured the FDA that "[n]one of [Ranbaxy's] statements appeared to be an attempt to provide misleading information."

110. Tetzlaff told the FDA that "PAREXEL found Ranbaxy has addressed every audit observation and is making effective progress to complete remaining improvements within their timeframes." He stated that "[f]or each of the 8 observations [made during the February 2006 inspection], PAREXEL verified the commitments made in Ranbaxy's" August 2006 letter, and "found that appropriate improvements had been put into place for each of the 8 observations."

111. Tetzlaff assured the FDA that Ranbaxy's response to its concerns was complete and sufficient. But the audits themselves remained hidden from the FDA.

112. Ranbaxy, Beardsley, and Parexel continued to maintain that the audits were privileged, arguing that disclosure of the audits would impact the candor necessary for a successful audit. But it was clear from the meeting that the FDA was not giving up in its quest to obtain the complete audits.

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

G. Ranbaxy's legal woes begin to mount with the issuance of governmental subpoenas, a search warrant, and the filing of a false claims act complaint.

114. 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 Ranbaxy's ANDAs and other submissions, defrauded the United States, or made false statements to the government.

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

116. 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.

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

118. 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.

119. Only after being provided with this information did Beardsley acknowledge that Ranbaxy had not yet addressed all of the concerns raised in the 2006 warning letter, and that the audits requested by the FDA remained ongoing. She would not commit to a date on which the audits would be provided to the FDA.

120. 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.

121. 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 this whistleblower who had undertaken the 2004 internal company investigation documenting the multiple examples of fraud within Ranbaxy's

regulatory submission. Years later, this complaint would be part of a settlement with the federal government in which Ranbaxy paid $350 million.

122. 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. But 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.

123. In the spring of 2007, Ranbaxy faced the first in a series of potential crises with respect to its pending first-to-file ANDAs. Recall that, in order for the first-to-file ANDA holder to secure its 180-day exclusivity for a product, the ANDA holder has to receive tentative approval from the FDA for its application within 30 months of filing.

124. 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 a 30-month forfeiture date of June 20, 2007, without Ranbaxy yet having received tentative FDA approval. If Ranbaxy did not secure tentative approval for its Flomax ANDA by June 20th, it would forfeit first-to-file exclusivity.

125. 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. So Ranbaxy, working through its Ranbaxy ANDA Enterprise, resorted to fraud and misdirection, seeking to obtain tentative approval through grift rather than honest negotiations.

126. On June 18, 2007, Ranbaxy mailed letters to two different divisions within the FDA, each intended to have the FDA act upon false or misleading information.

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

128. Second, Ranbaxy mailed a letter to the OGD (the FDA's generic drug approval division), giving it the false impression that all outstanding issues for the grant of tentative approval had been (or soon would be) corrected. Ranbaxy represented that the retrospective stability verification had recently been completed and the results would be sent to OGD and the OC (the FDA division charged with ensuring manufacturer's compliance with FDA regulations), and sought to give the impression that that information would cause a release of the compliance hold. Ranbaxy represented that its Flomax ANDA was "ready for tentative approval," "[e]xcept for the compliance hold at Paonta Sahib."

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

130. Noting that its first-to-file exclusivity was at risk in the absence of tentative approval, Ranbaxy again threatened a lawsuit – as it had one year earlier when strong-arming the FDA into granting final approval to its Zocor ANDA. If the FDA failed to immediately confirm that Ranbaxy would not forfeit its first-to-file exclusivity on June 20, 2007, Ranbaxy would sue.

131. Under the threat of litigation, and while CDER was still processing the audit-related representations made in Ranbaxy's June 18th letter, the OGD granted tentative approval for Ranbaxy's Flomax ANDA.[29] In doing so, the OGD believed and relied upon Ranbaxy's representations concerning its remedial efforts, which lead OGD to conclude that Ranbaxy appeared to have addressed the only outstanding issue from the 2006 warning letter, and thus appeared to be in compliance with cGMP.[30]

132. And it worked: the misleading information contained within Ranbaxy's letters regarding Flomax informed not only the FDA's response to the Flomax ANDA, but its responses to several later ANDAs, including those for generic Diovan and Valcyte. Operating under the mistaken impression that Ranbaxy was in compliance with cGMP, the FDA also reactivated Ranbaxy's Diovan ANDA, another of Ranbaxy's first-to-file ANDAs facing an imminent forfeiture date. However, a change in the USP monograph applicable to the drug suspended the

[29] 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.

[30] 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.

deadline for obtaining tentative approval. With the sense of urgency eliminated, the FDA took no immediate action on the Diovan ANDA.

I. Ranbaxy continues to conceal its manufacturing problems.

133. But even though Ranbaxy assured the FDA that none its cGMP compliance issues threatened the safety or efficacy of its medications, Ranbaxy knew that was not true.

134. In the early summer of 2007, internal testing of certain batches of gabapentin, a generic drug Ranbaxy exported to the U.S. market, revealed that the product contained unknown impurities and that the drug did not meet its expected shelf life.

135. But Ranbaxy did not immediately disclose these findings to the FDA, as it was required to do. When it eventually did many months later, over 73 million Ranbaxy gabapentin tablets were recalled.

J. The FDA continued to press for the concealed Parexel audits.

136. Having been given a (false) impression about the contents of the Parexel audits, the FDA still (of course) wanted to *see* them. In late July of 2007, following another meeting with the FDA, Beardsley provided some of Parexel's work, defined as "Ranbaxy and Parexel protocols and final reports," while still maintaining that they constituted privileged material.

137. Beardsley summarized the reports as showing a tiny proportion of errors and assuring the FDA that Ranbaxy had "taken exhaustive steps to assure the accuracy of data contained in its stability reports and ANDA submissions."

138. But Beardsley's letter did not contain the critical information that had been requested by the FDA, including "information about the revised dating convention . . . , frequency of transcription errors, and a list of ANDAs amended with a summary of changes made to each." Beardsley represented that Ranbaxy was in the process of compiling that information, and would forward it to the FDA when completed.

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

139. Meanwhile, Ranbaxy and the FDA had been engaged in discussions since June concerning the Diovan ANDA. By October 2007, the changes required by the new USP monograph for Diovan had been addressed. And so once again Ranbaxy faced a potential crisis. It needed to obtain tentative approval of its Diovan ANDA, or its 180-day exclusivity would be forfeited. And again, Ranbaxy resorted to conning the FDA into mistakenly granting tentative approval.

140. Capitalizing upon the misimpressions provided to the FDA earlier that year that led to its generic Flomax tentative approval, Ranbaxy once again gave the FDA the misimpression that its cGMP compliance issues were in the past, and that the undisclosed Parexel audits verified that there were no major concerns.

141. On October 25, 2007, relying again on the misrepresentations made by Ranbaxy 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.

142. But Ranbaxy was not resolving its compliance issues. In early December, an FDA inspection at Ranbaxy Inc.'s corporate headquarters in Princeton, NJ, revealed additional documentation failures by the company. And approval deadlines continued to crop up.

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

144. Beardsley emailed the FDA, acknowledging that the FDA "could not consider Ranbaxy's request that FDA approve the clarithromycin ANDA unless Ranbaxy provides certain of the Parexel audits." She asked what specific information the FDA would require before

granting final approval. The FDA reiterated that the audits would have to be produced for final approval to be considered.

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

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

146. In early January 2008, internal discussions began at the FDA concerning Ranbaxy's Nexium ANDA, which was facing the tentative approval deadline.

147. 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. Once again, Ranbaxy exploited this misunderstanding – created by Ranbaxy's own misrepresentations – to coerce the FDA into granting a tentative approval to which Ranbaxy was not entitled. And once again, its ploy worked: the FDA granted tentative approval to Ranbaxy's Nexium ANDA on February 5, 2008, allowing Ranbaxy to preserve its first-to-file exclusivity.

M. The Batamandi rabbit hole.

148. During a teleconference on February 27, 2008, Ranbaxy informed the FDA that it had opened a new, separate drug manufacturing facility, which it referred to as the Batamandi plant, for which it was seeking FDA approval. This plant, Ranbaxy maintained, was independent of Paonta Sahib. Ranbaxy claimed Batamandi shared no staff with Paonta Sahib, and suffered none of Paonta Sahib's compliance problems.

149. The FDA inspected the Batamandi facility from March 3 -7, 2008. Ranbaxy employees interacting with the FDA investigators seemed agitated and desperate, often repeating

themselves, and inquiring as to whether the inspectors would be using words like "falsified" or "integrity" in the FDA's post-inspection report.

150. Contrary to Ranbaxy's representations, the inspection revealed "that the Batamandi (Unit II) site is under the same production and quality management as the existing Paonta Sahib site [and] that the existing Paonta Sahib site was involved in various aspects of testing and production for the Batamandi site." In May, after considering Ranbaxy's response to the Batamandi inspection report, the FDA notified Ranbaxy that it was canceling the separate facility registration for Batamandi. The facility would be treated as an extension of the Paonta Sahib facility. And the numerous violations uncovered there would be considered indicative of ongoing problems at Paonta Sahib.

151. The inspectors recommended that the FDA implement its rarely-used data integrity protocols against Ranbaxy "for submitting information to FDA that may have been fabricated."

152. 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. The FDA continued to press for complete audits, including those relating to selected manufacturing and laboratory areas at Paonta Sahib, validation protocol reports, and certain quality control laboratory procedures.

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

153. 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.

154. 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.

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

O. The 2008 efforts to get the concealed Parexel audits.

156. 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.

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

158. 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. 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.

159. The FDA now knew that Ranbaxy had conducted stability testing several weeks or months later than had been reported to the FDA in drug applications and annual reports.

Stability tests that Ranbaxy had reported as having been conducted at different time intervals (i.e., 3, 6, and 9 months) had, in fact, been conducted on the same day. The FDA knew that Ranbaxy's problems were ongoing. And it knew that those problems impacted numerous pending applications.

P. The 2008 Import Alert.

160. 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.

Q. The 2009 invocation of the FDA Application Integrity Policy.

161. 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."

162. 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").

163. In short, as of February 25, 2009, the FDA had frozen all of Ranbaxy's applications originating from Paonta Sahib, and would be taking no further steps toward approving those applications until the review of Ranbaxy's data was complete.

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

164. 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.

165. 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.

166. 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.

167. 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 and Diovan.

168. 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 and Valcyte ANDAs.

169. 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 tosell 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.

170. 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, Ranbaxy would be allowed to maintain most of its first-to-file ANDAs, including Diovan and Valcyte, so long as Ranbaxy met additional regulatory requirements set out in the consent decree.

S. The 2012 Consent Decree.

171. 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. The consent decree largely superseded, and significantly broadened, the restrictions that the February 2009 AIP had placed on Ranbaxy.

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

173. The consent decree required Ranbaxy to take several affirmative steps to ensure control over quality assurance ("QA") and quality control ("QC"). Ranbaxy had to create an Office of Data Reliability within the United States that would be responsible for conducting pre-submission audits of all applications submitted from nine Ranbaxy facilities, including Paonta Sahib (referred to as the "Covered Facilities"). The consent decree imposed on Ranbaxy strict requirements for ensuring that all future submissions were reliable and documented. And it obligated Ranbaxy to retain an independent Data Integrity Expert and a cGMP Expert. 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.

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

175. 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.

176. Most of Ranbaxy's applications remained on hold. But the consent decree divided Ranbaxy's remaining ANDAs into two categories: (1) "Affected Applications," defined as any application containing data or information generated at Paonta Sahib and/or Dewas and

made subject to an internal review, third-party audit, and corrective action operating plan, and (2) "Excepted Applications," of which there were five.

177. 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.

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

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

T. The 2013 plea agreement with the DOJ.

180. In early 2013, Ranbaxy entered into a civil settlement and related plea agreement with the federal government. The civil settlement resolved the 2007 whistleblower action. 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. And Ranbaxy admitted to making false statements to the FDA concerning numerous lots and batches of its drugs.

181. 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.

182. 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 and Valcyte – 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.

183. 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 and Valcyte.

184. 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.

185. 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.

186. 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.

187. Ranbaxy finally admitted that it was aware of substantial cGMP compliance problems since at least October 2003, when an auditor informed Ranbaxy that:

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

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

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

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

188. And Ranbaxy finally admitted that, despite these known cGMP deficiencies in 2003, and 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]."

U. Ongoing FDA inspections.

189. Despite the 2012 consent decree and the 2013 DOJ settlement and plea, Ranbaxy continued to suffer poor performance reviews at various of its facilities worldwide. FDA inspections continued to reveal cGMP violations at a variety of Ranbaxy facilities.

190. Inspections of Ranbaxy's Ohm facility in Gloversville, NY, revealed deviations from cGMP. The FDA issued Ranbaxy yet another warning letter. Rather than correct the problems, Ranbaxy simply closed the Ohm Gloversville facility.

191. Inspections of Ranbaxy's Mohali, India, plant in September and December 2012 led to the issuance of an import alert on that facility in September 2013. Inspections of Ranbaxy's Toansa, India, plant in late 2013 led to the FDA imposing restrictions on that facility as well.

V. The impact on the entry of generic Diovan.

192. All of these events occurred against the backdrop of Ranbaxy's pending ANDAs, most notably its first-to-file ANDAs for which Ranbaxy needed to secure tentative approval in

2007 and 2008 in order to maintain first-to-file, 180-day exclusivity and thereby prevent entry by other, later-filing generics.

193. While the FDA and DOJ actions addressed the overall testing, reporting, and manufacturing conditions at various Ranbaxy plants, the FDA would address the specific consequences for each Ranbaxy application ANDA-by-ANDA, as consideration of each application occurred.

194. As previously alleged, in 2004 Ranbaxy had filed the first ANDA for generic Diovan, and in 2007 had unlawfully locked-in 180-day exclusivity (and bottlenecking) for that product from the FDA.[31] The additional course of proceedings for generic Diovan show how Ranbaxy's unlawful conduct had the effect of delaying the entry of generic valsartan between at least September 21, 2012, and July 7, 2014.

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

196. On August 9, 2007, Novartis Pharmaceuticals Corp. ("Novartis"), the brand company selling Diovan, sued Ranbaxy for patent infringement with respect to the newly-challenged patent in the U.S. District Court for the District of New Jersey (the "*Diovan* ANDA litigation").

[31] Ranbaxy had filed the first ANDA for generic Diovan in 2004, and because it had made a Paragraph IV certification with respect to one of the listed Diovan patents, it was eligible by the 180-day exclusivity period. On May 1, 2007, the official USP drug substance monograph for valsartan was published. The FDA required compliance with the USP monograph before the FDA would approve the Ranbaxy Diovan ANDA product. On June 26, 2007, and July 5, 2007, Ranbaxy submitted amendments to its ANDA proposing changes to its drug substance specifications and test methods to comply with the USP monograph. Later in 2007, Ranbaxy duped the FDA into granting tentative approval to Ranbaxy for the generic Diovan ANDA

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

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

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

200. 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 Diovan from September 2007 to September 2012. 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 Diovan to market. In any event, as a result of the September 2007 agreement any patent issues with respect to the launch of generic Diovan 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 Diovan on or about September 21, 2012, without repercussions from the holder of Diovan patents.

201. On September 21, 2012, the pediatric exclusivity associated with the relevant patent expired. While other listed patents for Diovan remained in force, Novartis had not asserted those patents against Ranbaxy, and they did not prevent Ranbaxy from gaining final

approval. Ranbaxy, absent its reckless conduct, should have been in a position to gain final FDA approval for generic Diovan by this time.

202. By September 28, 2012, other generic manufacturers, including Mylan Pharmaceuticals, Inc. ("Mylan"), had tentative approvals in-hand for their generic Diovan ANDAs, and were ready to come to market. But the FDA informed Mylan that it could not receive final approval at that time due to Ranbaxy's first-to-file status.

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

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

205. As a result, at some point Ranbaxy found it necessary to undertake a full site transfer. Apparently after the consent decree was signed (but well before June 26, 2014), Ranbaxy requested and received from the FDA permission to manufacture its generic Diovan product at its Ohm Laboratories facility in New Brunswick, New Jersey.

206. On June 26, 2014, the FDA finally granted final approval to Ranbaxy's Diovan ANDA. In its approval letter, the FDA noted that Ranbaxy had failed to obtain tentative approval within 30 months of the submission date of the ANDA, but notified Ranbaxy that the FDA had "determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application

imposed after the date on which the application was filed," and that Ranbaxy was eligible for 180 days of exclusivity with respect to its generic Diovan product.

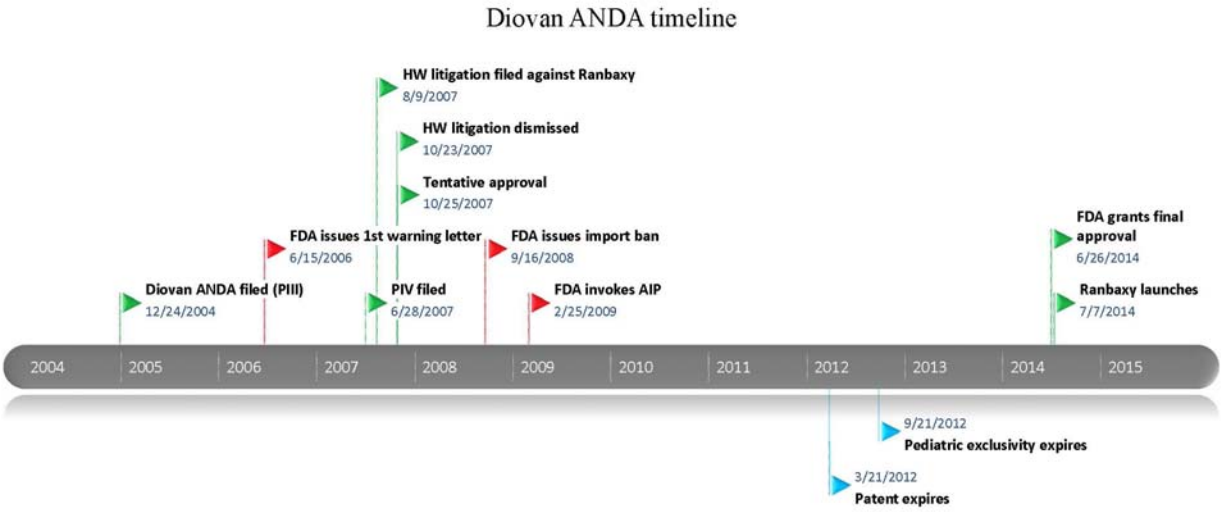
207. Ranbaxy's generic Diovan product is manufactured at its Ohm Laboratories facility in New Brunswick, New Jersey. The active pharmaceutical ingredient ("API") in the Ranbaxy generic Diovan product is obtained from a third party, because the Ranbaxy facility at which the API would have been made is subject to the FDA import ban.

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

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

210. Were it not for Ranbaxy's wrongful conduct, generic Diovan would have become available at least as early as September 21, 2012, and all direct purchasers would have paid substantially less for valsartan than they did. Among other things, if Ranbaxy had not wrongfully acquired, maintained, or used the bottlenecking, 180-day exclusivity for valsartan, there would have been no bottleneck for the entry of other generics, and other generic companies could and would have entered the market for valsartan by gaining FDA approval, and launching generic products, at least as early as September 21, 2012.

211. The below is a summary of Diovan ANDA facts as they unfolded given Ranbaxy's unlawful conduct.



W. The impact on the entry of generic Valcyte.

212. As previously alleged, in 2005 Ranbaxy had filed the first ANDA for generic Valcyte, and in 2008 had unlawfully locked in 180-day exclusivity for that product from the FDA. The additional course of ANDA proceedings for generic Valcyte show that Ranbaxy's unlawful conduct had the effect of delaying the entry of generic valganciclovir hydrochloride between at least March 15, 2013, and November 20, 2014.

213. On April 28, 2006, Roche Palo Alto, LLC ("Roche"), the brand manufacturer selling Valcyte, had sued Ranbaxy for patent infringement with respect to the Valcyte ANDA in the U.S. District Court for the District of New Jersey (the "*Valcyte* ANDA litigation").

214. In June 2008, Ranbaxy duped the FDA into mistakenly granting tentative approval for Ranbaxy's Valcyte ANDA.

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

216. It is unknown at this time the extent to which, if at all, Ranbaxy's wrongfully acquired tentative approval for its generic Valcyte ANDA played into the agreement to delay

entry from August of 2010 to March of 2013. 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 Valcyte to market. In any event, a result of the August 2010 agreement any patent issues with respect to the launch of generic Valcyte 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 Valcyte on or about March 15, 2013, without repercussions from the holder of Valcyte patents.

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

218. The FDA informed Ranbaxy that it would begin or resume reviewing the Valcyte ANDA. However, Ranbaxy could not get the Paonta Sahib facility qualified to manufacture generic Valcyte in compliance with applicable regulations; Ranbaxy continued for years to stubbornly hold onto its blocking 180-day exclusivity for generic Valcyte. After almost two years of additional delay, the adverse impact that Ranbaxy's delay was having on healthcare consumers was brought front and center.

219. 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. The petitioners demanded that the FDA revoke Ranbaxy's first-to-file exclusivity, and that it approve other ANDAs in order to foster competition.

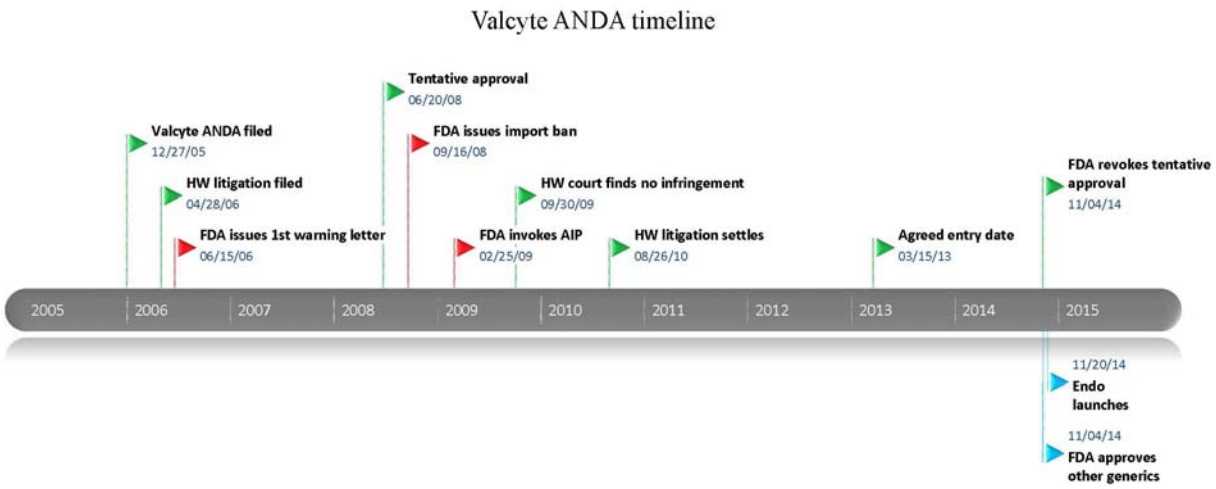
220. On November 4, 2014, the FDA notified Ranbaxy that the FDA had erred in tentatively approving the Valcyte ANDA because "the compliance status of the facilities referenced in the ANDA[] at the time the ANDA[] [was] granted tentative approval was inadequate to support approval or tentative approval." The FDA then rescinded its previously granted tentative approval of Ranbaxy's Valcyte ANDA. And, the FDA determined that Ranbaxy had forfeited its eligibility for 180-day exclusivity.[32]

221. On the same day that the FDA rescinded the tentative approval of Ranbaxy's Valcyte ANDA, the FDA gave final approval to two other ANDAs for valganciclovir hydrochloride tablets: ANDA No. 200790, submitted by Endo Pharmaceuticals, and ANDA No. 203511, submitted by Dr. Reddy's Laboratories, Inc.

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

223. Were it not for Ranbaxy's wrongful conduct, generic Valcyte would have launched into the U.S. market for valganciclovir hydrochloride at least as early as March 15, 2013, and all direct purchasers would have paid substantially less for valganciclovir hydrochloride than they did. Among other things, if Ranbaxy had not wrongfully acquired, maintained or used the bottlenecking, 180-day exclusivity for valganciclovir hydrochloride, there would have been no bottleneck for the entry of other generics, and other generic companies could and would have entered the market for valganciclovir hydrochloride by gaining FDA approval, and launching generic products, at least as early as March 15, 2013.

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



X. Ranbaxy sues the FDA.

224. 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.

225. 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.

226. 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.

227. Ranbaxy acknowledged that an applicant needed to *prove* certain items – *e.g.*, its generic drug was bioequivalent, and the labelling was the same – because 21 U.S.C.

§ 355(j)(2)(A) required that the ANDA contain "information to show" these preconditions were met. But, 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.'"

228. 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]

229. DHHS and the FDA moved immediately for summary judgment, arguing that Ranbaxy's interpretation of the law was meritless. As the FDA explained, Ranbaxy's interpretation conflated what was necessary for an ANDA to be "substantially complete," such that it may be received by the FDA, with what was required for tentative approval. Substantial completeness requires merely that an ANDA "contains all of the information required by paragraph (2)(A)." Tentative approval requires that the ANDA meet all of the requirements of paragraph (2)(A). And, 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.

230. The FDA admitted that its initial tentative approvals for the Valcyte and Nexium ANDAs were granted in error – that it made a mistake. And it explained that the mistake was

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

caused by its reliance on Ranbaxy's misrepresentations to the FDA, 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 significant they remain unresolved today (more than seven years after [the relevant] tentative approval letter was issued)."

231. And 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.

232. 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."

233. 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."

234. 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

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

that Ranbaxy could not "argue seriously that the FDA is prevented from denying tentative approval to an ANDA in such circumstances."

235. 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 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.

Y. Sun Pharma acquires Ranbaxy.

236. 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.

237. 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….

238. 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.

239. 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

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

241. 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.

242. 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).

243. 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.

244. 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.

245. Valganciclovir hydrochloride tablets and valsartan tablets do not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than their AB-rated generic equivalents.

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

247. Valsartan is an angiotension II receptor antagonist (commonly referred to as an "ARB"), approved by the FDA for the treatment of hypertension and heart failure, as well as to reduce cardiovascular mortality in patients with problems of the left ventricle of the heart following myocardial infarction. The FDA approved the drug for sale in 2001. Novartis brought it to market under the brand name Diovan. In 2003, U.S. sales of Diovan were $632 million; by 2008 sales had reached $1.2 billion; by 2012 sales had reached $1.9 billion; and in 2013 they exceeded $2.1 billion. There is no reasonably interchangeable drug product (other than branded Diovan) for the indications for which valsartan is prescribed. Valsartan has attributes significantly differentiating it from other medications for similar indications, making it unique.

Because, among other reasons, it was the only drug approved to treat a trio of conditions – hypertension, high-risk heart attack survivors, and patients with heart failure – valsartan is differentiated from all products other than the brand name version of the drug, Diovan.

248. Valganciclovir hydrochloride is an orally administered antiviral medication, approved by the FDA for the treatment of cytomegalovirus ("CMV") retinitis in AIDS patients and for the prevention of CMV disease in organ transplant recipients. It is one of only two drugs approved for the treatment of CMV in kidney transplant patients. The FDA approved the drug for sale in the United States in 2001. Roche, brought it to market in tablet form under the brand name Valcyte. In 2008, U.S. sales of Valcyte were $160 million; and by 2013 that figure had reached $500 million. There is no reasonably interchangeable drug product (other than branded Valcyte) for the indications for which valganciclovir hydrochloride is prescribed. Valganciclovir hydrochloride has superior bioavailability to the other CMV drug, called ganciclovir, meaning that patients can take smaller doses of the drug, less often. And, unlike other medications for the treatment of CMV, which must be administered intravenously, Valcyte tablets can be taken orally. According to Roche, Valcyte satisfied a long-felt, but unsatisfied need, in the drug marketplace. Roche has called it the "gold standard," the "drug of choice," the "treatment of choice," and the "standard of care" for the prevention and treatment of CMV disease. In its 2004 annual report, Roche reported that Valcyte remained "the leading drug for the treatment of CMV retinitis in HIV patients." Valganciclovir hydrochloride is therefore differentiated from all products other than its brand name equivalent.

249. 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 – including valsartan and valganciclovir hydrochloride – 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.

250. 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.

251. 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.

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

253. Ranbaxy needed to control only its AB-rated generic equivalent, and no other products, in order to maintain the price of its product profitably at supra-competitive prices while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Ranbaxy's product would render Ranbaxy unable to profitably maintain its supra-competitive prices without losing substantial sales.

254. Ranbaxy also sold its generic products at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

255. Ranbaxy has had, and exercised, the power to exclude competition from each of the relevant markets.

256. To the extent that Plaintiff is legally required to prove market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant markets are (a) all valsartan tablets – *i.e.*, Diovan (in all its forms and dosage strengths) and AB-rated bioequivalent valsartan tablets; and (b) all valganciclovir hydrochloride tablets – *i.e.*, Valcyte (in all its forms and dosage strengths) and AB-rated bioequivalent valganciclovir hydrochloride tablets. During the period relevant to this case, Ranbaxy has been able to control competition in these markets and profitably maintain the price of these products well above competitive levels.

257. 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.

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

VII. MARKET EFFECTS

259. 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.

260. 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 maintain a monopoly and exclude competition in the markets for the aforementioned drugs, *i.e*., Diovan, Valcyte, and their AB-rated generic equivalents, to the detriment of Plaintiff and all other members of the direct purchaser class.

261. Ranbaxy's exclusionary conduct, including its conspiracy with Beardsley and Parexel, has delayed generic competition and unlawfully enabled it to sell its generic products without 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.

262. 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 Diovan and Valcyte, 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 Diovan and Valcyte ANDAs 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 October 2007 for Diovan, and in June 2008 for Valcyte, that there would be no generic ANDA applicant entitled to 180-day exclusivity, which would have incentivized other ANDA filers to proceed more rapidly with their own ANDA efforts for those drugs.

263. Other generic manufacturers seeking to sell generic Diovan and/or Valcyte all had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and at least several of these generic manufacturers would have been ready, willing, and able to effectuate earlier launches of their generic versions of Diovan (no later than September 21, 2012), and Valcyte (no later than March 15, 2013), were it not for Ranbaxy's illegal and unlawful acts and conspiracies with Beardsley and Parexel.

264. Ranbaxy's illegal acts and conspiracies with Beardsley and Parexel to delay the introduction into the U.S. marketplace of any other generic versions of Diovan and Valcyte caused Plaintiff 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.

265. 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.

266. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as Plaintiff and members of the class, would have paid less for these drugs by (a) receiving discounts on their remaining brand purchases of these drugs, (b) substituting purchases of less-expense generic versions for their purchases of more-expensive brand versions, and/or (c) purchasing the generic versions of these drugs at lower prices sooner.

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

268. Thus, Ranbaxy's unlawful conduct deprived the Plaintiff 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

269. During the relevant period, Plaintiff and members of the direct purchaser class purchased substantial amounts of Diovan and Valcyte directly from their branded manufacturers

and/or purchased substantial amounts of generic versions of Diovan and Valcyte directly from Ranbaxy. 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 Diovan and Valcyte was artificially inflated by Defendants' illegal conduct; (2) direct purchaser class members were deprived of the opportunity to purchase lower-priced generic versions of Diovan and Valcyte sooner; and/or (3) the price of generic Diovan and Valcyte was artificially inflated by Defendants' illegal conduct.

270. As a consequence, Plaintiff 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.

271. Ranbaxy's efforts to monopolize and restrain competition in the market for these drugs have substantially affected interstate and foreign commerce.

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

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

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

IX. CLASS ACTION ALLEGATIONS

275. Plaintiff, on behalf of itself 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 Diovan and Valcyte, and their AB-rated generic equivalents.

276. Plaintiff brings 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 Diovan and/or AB-rated generic versions of Diovan directly from any of the Defendants or any brand or generic manufacturer at any time during the period September 21, 2012, through and until the anticompetitive effects of the Defendants' conduct cease (the "Diovan Class Period");
>
> All persons or entities in the United States and its territories who purchased Valcyte and/or AB-rated generic versions of Valcyte directly from any of the Defendants or any brand or generic manufacturer at any time during the period March 15, 2013, through and until the anticompetitive effects of the Defendants' conduct cease (the "Valcyte Class Period").

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

277. Members of the direct purchaser class are so numerous that joinder is impracticable. Plaintiff believes 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.

278. Plaintiff's claims are typical of the claims of the members of the direct purchaser class. Plaintiff 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 valganciclovir hydrochloride and valsartan and were deprived of earlier and more robust competition from cheaper generic versions of Diovan and Valcyte as a result of Defendants' wrongful conduct.

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

280. Plaintiff is 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.

281. 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.

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

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

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

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

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 Plaintiff and the members of the class; and

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

283. 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.

284. Plaintiff knows 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 Valsartan)

285. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

286. As described above, from September 21, 2012, until at least January 5, 2015 (and with effects lasting far longer), Ranbaxy possessed market power in the market for valsartan. No other generic manufacturer sold a competing version of valsartan, before January 5, 2015.

287. Ranbaxy willfully and unlawfully maintained its market power in the valsartan market from September 21, 2012, through at least January 5, 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.

288. Ranbaxy knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of other AB-rated generic versions of valsartan 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.

289. By means of this scheme, Ranbaxy intentionally and wrongfully maintained market power with respect to valsartan in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of market power, Plaintiff and members of the class paid artificially inflated prices for their valsartan tablet requirements.

290. Plaintiff 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 valsartan tablet requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent and flows from that which makes Ranbaxy's conduct unlawful, and Plaintiff and the class are the proper entities to bring a case concerning this conduct.

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

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

293. Ranbaxy knowingly and intentionally engaged in sham petitioning before the FDA, making repeated misstatements concerning, *inter alia,* its manufacturing facilities, compliance with cGMP, and the reliability of its data, all designed to intentionally and deceptively convince the FDA to grant it first-to-file exclusivity, which it intended to, and did,

use to keep (a) all generic competition (including itself) out of the market for an extended period of time, and (b) other generic competitors off the market for at least an additional 180 days.

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

295. 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) to obtain an exclusivity to which it was not entitled, as an anticompetitive weapon to keep other generics off the market.

COUNT TWO - VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)

(Asserted Against All Defendants as to Valganciclovir Hydrochloride)

296. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

297. As described above, from March 15, 2013, until at least November 20, 2014 (and with effects lasting far longer), Ranbaxy possessed market power in the market for valganciclovir hydrochloride. No generic manufacturer, including Ranbaxy, sold any version of valganciclovir hydrochloride tablets until November 20, 2014.

298. Ranbaxy willfully and unlawfully maintained its market power in the valganciclovir hydrochloride market from March 15, 2013, through at least November 20, 2014, 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.

299. Ranbaxy knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of other AB-rated generic versions of valganciclovir hydrochloride to 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.

300. By means of this scheme, Ranbaxy intentionally and wrongfully maintained market power with respect to valganciclovir hydrochloride tablets in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of market power, Plaintiff and members of the class paid artificially inflated prices for their valganciclovir hydrochloride tablet requirements.

301. Plaintiff 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 valganciclovir hydrochloride 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, flows from that which makes Ranbaxy's conduct unlawful, and Plaintiff and the class are the proper entities to bring a case concerning this conduct.

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

303. 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.

304. 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.

305. 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.

306. 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 THREE - VIOLATION OF RICO, 18 U.S.C. § 1962(c)

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

307. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

308. 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).

309. 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).

310. 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.

311. The Ranbaxy ANDA Enterprise fits within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" that created and maintained systematic links for a common

purpose: to aid in protecting and profiting from Ranbaxy's first-to-file status associated with a number of Ranbaxy ANDAs – including the ANDAs for generic Diovan and Valcyte – 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.

312. 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.

313. 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 and Valcyte, 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.

314. 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.

315. 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 and Valcyte, 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.

316. 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.

317. 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.

318. 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 those for Diovan and Valcyte; 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.

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

320. 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 Plaintiff.

321. 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.

322. As a result of Defendants' fraudulent activities, generic versions of drugs, including Diovan and Valcyte, 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 Plaintiff and all members of the class.

323. Plaintiff 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. Plaintiff and others similarly situated have paid hundreds of millions, if not billions, of dollars, more for Diovan and Valcyte, and the generic equivalents of those drugs, than they would have in the absence of the fraudulent course of conduct underlying the Ranbaxy ANDA Enterprise.

324. Plaintiff'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 exclusivities as to generic Diovan and Valcyte, generic versions of these drugs would have been available for purchase sooner, resulting in savings to Plaintiff and others similarly situated amounting to hundreds of millions, if not billions of dollars.

325. Plaintiff'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 Plaintiff, not Ranbaxy's competitors.

326. Plaintiff 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 Plaintiff 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, Plaintiff and those similarly situated paid for vastly more expensive brand name versions of Diovan and Valcyte long after a generic drug should have entered the market.

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

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

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

328. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

329. 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."

330. 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.

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

332. 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.

333. 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), Plaintiff has been and continues to be injured in their business or property, as set forth more fully above.

334. 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.

335. 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, Plaintiff, on behalf of itself and the Class, respectfully requests 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 Meijer 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 Meijer 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 Meijer 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, Meijer, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: May 12, 2015

Respectfully submitted

/s/ Thomas M. Sobol

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