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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

Dear Sir or Madam:

Hyman, Phelps & McNamara, P.C. ("HPM") submits this petition on behalf of a client, a generic drug manufacturer, that has a tentatively approved Abbreviated New Drug Application ("ANDA") that the United States Food and Drug Administration ("FDA") has not finally approved due to special treatment afforded Ranbaxy Laboratories, Ltd. ("Ranbaxy"). By refusing to approve other generic products while waiting for Ranbaxy to submit ANDAs to FDA that do not raise issue of data integrity and to comply with FDA's current Good Manufacturing Practice ("cGMP") requirements, FDA has distorted laws and regulations concerning generic drug approvals to benefit Ranbaxy as opposed to serving the public health by making available low cost, high quality generic drugs.

This petition seeks to level the playing field for all generic drug manufacturers who have not submitted fraudulent applications and seek to comply with FDA's requirements. More importantly, this petition seeks to lift the roadblock created by FDA that prevents patients and health care providers from accessing generic versions of drugs while FDA chooses to honor Ranbaxy's first-to-file status. As discussed below, FDA can, and must, declare that Ranbaxy is not eligible for 180-day marketing exclusivity in connection with ANDAs that are subject to FDA's Application Integrity Policy ("AIP"), and must immediately approve those ANDAs that have met FDA's standards and are tentatively approved.

I. ACTIONS REQUESTED

This petition requests the Commissioner to take the following actions:

1. FDA must determine that Ranbaxy has forfeited or is not eligible for first-to-file status for any ANDA subject to the AIP (*e.g.*, valsartan, esomeprazole magnesium, and valganciclovir hydrochloride); and

2. FDA must immediately approve all tentatively approved ANDAs for these drugs and any other tentatively approved drugs for which final approval is blocked by Ranbaxy's alleged eligibility for 180-day exclusivity.

II. STATEMENT OF GROUNDS

A. Introduction

Decades of experience have established that generic drugs can provide an enormous benefit to American consumers without sacrificing the safety and efficacy of medicines they need. The use of generic drug products is estimated to have saved Americans over $1.2 trillion since 2003.[1] Data also demonstrate that, while the addition of one generic version of a brand drug to the market marginally reduces the cost paid by Americans, the market entry of multiple generics lowers costs exponentially (to between 6% and 52% of the cost of the branded drug).[2] The Government Accountability Office ("GAO") reports that "the retail price of a generic drug is 75% lower than the retail price of a brand-name

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1 *See* Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, Fifth Ed., 2013, at 2. The Congressional Budget Office ("CBO") estimates that Medicare saved on the order of $33 billion just in 2007 by substituting generic drugs for their brand name counterparts. *See* U.S. CBO Study, Effects of Using Generic Drugs on Medicare's Prescription Drug Spending (Sept. 2010), http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf.

2 *See* FDA, Office of Medical Products and Tobacco, Generic Competition and Drug Prices, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

drug."[3] It follows that delays in generic competition come at a high cost to consumers and to insurers, including the government.

In order to speed the entry of low cost, high quality generic drugs to the market, Congress established incentives for generic drug manufacturers to risk litigation and other expenses in exchange for a period of 180-days to exclusively market a generic drug before other generic drug competitors can enter the marketplace. Exclusivity is not an absolute right. Congress actively tried to prevent an exclusivity-holding generic manufacturer from blocking market entry by other generics indefinitely under the 180-day exclusivity provision (called "exclusivity 'parking'"). Specifically, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("MMA"), set out circumstances under which a first applicant otherwise entitled to 180-day exclusivity would be deemed to forfeit that exclusivity. 21 U.S.C. § 355(j)(5)(D). Section 355(j)(5)(D) defines "forfeiture events," including failure to market within a specified period of time, failure to obtain timely approval from FDA, and withdrawal of the ANDA. *Id.* Equally important, FDA is not obligated to review fraudulent data and reward applicants who submit such data with 180-day exclusivity.

B. Factual Background

FDA has long been aware of issues at Ranbaxy.

In 2004, the World Health Organization ("WHO"), not FDA, first uncovered the rampant and widespread problems at Ranbaxy. The WHO conducted a routine audit of one of Ranbaxy's contract testing laboratories and uncovered fraudulent test results in the bioequivalence studies Ranbaxy had submitted in support of three antiretroviral drugs used to treat human immunodeficiency virus ("HIV") and acquired immunodeficiency syndrome ("AIDS")patients. As a result, Ranbaxy agreed to withdraw ***all*** of its antiretroviral products from WHO's prequalified list.

Two years later in 2006, FDA decided to conduct its own investigation of Ranbaxy. Since that time FDA has issued four Warning Letters to the company, issued an Import Alert on all products sold to the United States market, and exercised the rarely used AIP following discovery of fraud to withhold approval of applications from the company.

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[3] *See* GAO, Drug Pricing: Research on Savings from Generic Drug Use (Jan. 31, 2012), *available at* http://www.gao.gov/assets/590/588064.pdf.

There have been countless recalls of Ranbaxy's products. Ranbaxy has agreed to a Consent Decree that requires compliance with cGMP, paid a multi-million dollar civil settlement and agreed to a criminal conviction of the company. Despite all this, FDA continues to honor Ranbaxy's first-to-file status on applications that cannot be approved absent submission of credible data, and FDA continues to block other manufacturers who have met FDA's requirements from obtaining approval of their applications. FDA's actions serve only to benefit a company that has committed criminal acts to the detriment of public health.

1. Inspections, Warning Letters, and Import Bans

A Warning Letter is an advisory action intended to allow a company to take voluntary and prompt corrective action before FDA initiates an enforcement action. FDA, Regulatory Procedures Manual § 4-1-1. FDA specifically contemplates that it may be appropriate to issue a ***second*** Warning Letter to the same company if they operate multiple facilities and produce a variety of products. In the case of Ranbaxy, FDA issued four separate Warning Letters for essentially the same violations. But, the Ranbaxy Warning Letters were notable not just because of their number. The severity of observations and the concerns expressed regarding data integrity were a recurring theme. Yet history shows a clear disconnect between the findings cited in the enforcement letters and the pace and scope of FDA's actions to protect consumers from the company's continuing fraudulent conduct.

The first Warning Letter was issued to Ranbaxy's Paonta Sahib facility in June 2006.[4] The Warning Letter to Ranbaxy management cited broad cGMP violations concerning the company's "analytical raw data, undocumented stability sample test intervals, the unclear purpose of 'standby samples,' [] FDA lab results for [Ranbaxy's] Isotretinoin capsules, and the inadequate staffing and resources in the stability laboratory." FDA expressed a "heightened" concern over the company's "conduct, adequacy and oversight of [its] drug product stability testing and monitoring program."[5]

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4 *See* FDA, Warning Letter to Ramesh Parekh, Vice President, Manufacturing, Ranbaxy Laboratories Limited (June 15, 2006), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054346.pdf (hereinafter "2006 Warning Letter").

5 *Id.* at 1.

FDA investigators were sufficiently concerned by the findings at Paonta Sahib that they questioned the veracity of data underlying applications for drug products manufactured at that site. The Warning Letter stated that the investigators would recommend that FDA withhold approval for any pending applications that listed Paonta Sahib as the manufacturer of drug products.[6]

As part of the 2006 Paonta Sahib inspection, FDA also noted that two drugs, lamivudine and zidovudine, were also manufactured at Ranbaxy's Dewas facility. FDA explicitly questioned whether the Dewas facility had similarly widespread cGMP problems as Paonta Sahib: "Until these matters are resolved as they pertain to the Dewas facility we can not make a final determination on the compliance status of the Dewas facility."[7] Notwithstanding the widespread violations at one Paonta Sahib, FDA's contemporaneous inspection of Dewas yielded several cGMP deviations, but did not result in a Warning Letter for Dewas. It took two more years for FDA to reinspect the Dewas facility and to act on the suspicion raised in 2006.

The 2008 Dewas inspection found similarly egregious cGMP violations as those found at Paonta Sahib.[8] For example, FDA identified problems with the lack of information in batch records, incomplete failure investigations, failures related to the Quality Control Unit, and procedures related to aseptic operations. In September 2008, FDA issued a second Warning Letter to Ranbaxy, specific to the Dewas facility.[9] At the same time, FDA issued a third Warning Letter to Ranbaxy based on a follow-up inspection of the Paonta Sahib facility, expressing concern "that these instances of discrepancies observed during the March 2008 inspection, are indications of continuing, systemic CGMP deficiencies at the Paonta Sahib facility."[10] Again, the investigators stated that they would

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6 *Id.* at 6.

7 *Id.*

8 *See* FDA, Warning Letter to Malvinder Singh, CEO and Managing Director, Ranbaxy Laboratories Ltd. (Sept. 16, 2008), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048134.htm (hereinafter "2008 Dewas Warning Letter").

9 *Id.*

10 *See* FDA, Warning Letter to Malvinder Singh, CEO and Managing Director, Ranbaxy Laboratories Ltd. (Sept. 16, 2008), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048133.htm

recommend that FDA disapprove any new applications or supplements listing Ranbaxy as a manufacturing location of finished dosage forms and active pharmaceutical ingredients.[11] Yet FDA continued to approve new products manufactured at Ranbaxy facilities for another year before finally following its own internal recommendations and policies.

In 2009, FDA conducted a domestic inspection of the company's Ohm Laboratories facility in Gloversville, New York. Again, FDA's inspection found multiple serious cGMP violations, including a failure to investigate unexplained black particles in Metformin HCl Oral solution, fiber and cardboard particles in ranitidine HCl solution, and a failure to comply with stability procedures.[12] In the fourth Warning Letter to Ranbaxy, FDA recognized that the cGMP violations uncovered at Ohm were similar to those cited in the three earlier Warning Letters. FDA stated the obvious: "It is apparent that Ranbaxy's attempts to make global corrections after past regulatory actions by the FDA have been inadequate."[13] FDA added a threat of legal action if Ranbaxy failed to promptly correct the violations. FDA asked, but did not require, Ranbaxy to immediately undertake a "comprehensive assessment of its global manufacturing operations to ensure that all sites manufacturing drug for the US market conform to US requirements."[14]

As a result of the continuing problems at Ranbaxy, FDA imposed an Import Alert in 2008 banning the import into the United States of the more than 30 drugs Ranbaxy manufactured at the Dewas and Paonta Sahib facilities for the United States market. The Import Alert was intended to remain in place until Ranbaxy resolved the deficiencies identified by FDA in the Warning Letters and brought the facilities into compliance with cGMP requirements. It not only remains in place today, but was expanded in 2013 to include a facility in Mohali that had the same issues as those found in Paonta Sahib and Dewas.

(hereinafter "2008 Paonta Sahib Warning Letter").

11 *Id.*

12 *See* FDA, Warning Letter to Robert Patton, Vice President, General Manager, Ohm Laboratories, Inc. (Dec. 21, 2009), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm204903.htm (hereinafter "2009 Warning Letter").

13 *Id.*

14 *Id.*

2. *Application Integrity Policy*

FDA's AIP is a powerful, yet rarely used, tool to address a company's pattern or practice of wrongful conduct that raises questions about the reliability of data submitted in support of that company's applications.[15] The policy has two goals: (1) "to ensure validity of data submissions called into question by the Agency's discovery of wrongful acts;" and (2) "to withdraw approval of, or refuse to approve, applications containing fraudulent data." *Id.* If FDA determines that the criteria for approval cannot be met because of unresolved data integrity issues, it will not approve a pending application.

Few firms have been subject to AIP actions since it was first published in 1991. But in 2009, after the third Warning Letter to Ranbaxy, FDA invoked the AIP against Ranbaxy because FDA had "determined that [Ranbaxy] submitted untrue statements of material fact in abbreviated and new drug applications filed with the Agency."[16] FDA had concluded that Ranbaxy had engaged in a pattern of making untrue statements of material fact, including (1) the omission of critical information regarding stability testing storage conditions; (2) a Warning Letter response submitting test dates that differed from dates originally submitted in a marketing application; (3) reports prepared by outside consultants that identified storage times and conditions different from those in protocols submitted to the agency; (4) verification reports identifying errors in testing dates, data results and changes of specification limits; (5) falsifying stability test results; and (6) submission of falsified batch records. *Id.*

FDA limited the AIP to cover only those applications that rely on data generated by the Paonta Sahib facility, even though the violations at the Dewas facility were well-known at the time. FDA stated that it would stop all substantive scientific review of any new or pending drug approval applications that contained data generated by Paonta Sahib. On

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15 *See* Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46,191 (Sept. 10, 1991), available as Compliance Policy Guide 7150.09 ("AIP"), *at* http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134741.htm.

16 Letter from Dr. Janet Woodcock, Center for Drug Evaluation and Research ("CDER") Director, to Mr. Malvinder Mohan Singh, Ranbaxy CEO and Managing Director (Feb. 25, 2009), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm118418.pdf.

information and belief, the applications for valsartan, valganciclovir hydrochloride, and esomeprazole all were submitted based on data generated at Paonta Sahib. Like the import ban, the AIP remains in effect to this day.

3. 2012 Consent Decree

Nearly three years after invoking the AIP, FDA, on January 25, 2012, announced that it had entered into a Consent Decree of Permanent Injunction (hereinafter "Consent Decree") with Ranbaxy and several management officials, which addressed the cGMP and data integrity issues at the Paonta Sahib, Dewas, and Gloversville, New York facilities. FDA has since added two other Ranbaxy facilities to the Consent Decree (Mohali and Toansa).

Like the AIP, the Consent Decree required Ranbaxy to take certain steps before FDA would review ANDAs containing data from the Paonta Sahib and Dewas facilities. For example, the company was required to:

(1) hire a third party expert to conduct a thorough internal review and audit of all applications it determined to contain data from the affected facilities;

(2) implement procedures and controls sufficient to ensure data integrity in the company's drug applications; and

(3) withdraw some—but not all—applications found to contain untrue statements of material fact and/or a pattern or practice of data irregularities that could affect approval of the application.[17]

It is unknown whether Ranbaxy has withdrawn any applications based on this audit. Considering that the timeframe for such activities has long passed, and FDA has not approved ***any*** generic versions of the drugs at issue in this petition, the public can assume that Ranbaxy continues to hold the first-to-file status related to these pending applications.

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17 *See* FDA, Press Release, Department of Justice Files Consent Decree of Permanent Injunction Against Ranbaxy (Jan. 25, 2013), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm289224.htm.

The data integrity provisions of the Consent Decree relate to:

(1) any Application that, at the time of entry of this Decree, is pending or approved and contains any data or other information generated or developed at Paonta Sahib and/or Dewas;

(2) all Applications that contain data or other information generated or developed at Dewas and were withdrawn between August 1, 2009 and the entry of this Decree; and

(3) all Applications that contain data or other information generated or developed at Dewas and were withdrawn between August 2, 2003 and the entry of this Decree . . . .

Consent Decree ¶ VII.G, *United States v. Ranbaxy Labs., Ltd.*, No. 12-250 (D. Md. Jan, 26, 2012). Thus, the Consent Decree provides Ranbaxy with FDA-condoned ways to block generic competition for certain unnamed drugs that would not have been available to the Company through normal application of the AIP.

The Consent Decree required Ranbaxy to relinquish 180-day marketing exclusivity for three pending, but unnamed, ANDAs, and a fourth unnamed ANDA Ranbaxy it failed to obtain final FDA approval by March 25, 2013. *Id.* ¶¶ XII, XIII. It is unknown whether Ranbaxy ultimately relinquished exclusivity for any or all of these applications, because the drugs at issue are not identified anywhere in the public domain.

Strangely, the Consent Decree identified certain "excepted" applications that were not subject to the provisions of the Consent Decree, but only identified them as ANDA 1, ANDA 2, ANDA 3, ANDA 4, and ANDA 5. It is unclear what the basis for this exception was or whether they were equally exempt from the AIP. FDA could determine that these "excepted" applications were substantially complete at the time they were initially filed; if not, then Ranbaxy would be ineligible for exclusivity for that ANDA. *Id.* ¶ XV. Also, if FDA found data irregularities after an audit of those excepted applications, then the Consent Decree required Ranbaxy to withdraw any such applications containing such irregularities. It is not known whether an audit has been performed, whether FDA has acted to confirm or deny Ranbaxy's first-to-file status on ANDAs 1-5. It does not appear, however, that Ranbaxy has been required to withdraw any of its applications, to date.

4. 2013 Criminal Plea and Fraud Settlement

In May 2013, Ranbaxy pled guilty to three felony counts for violating the Food, Drug, and Cosmetic Act ("FDC Act"), and four felony counts of knowingly making material false statements to the FDA.[18] The generic drugs specifically identified in this criminal plea were manufactured at Ranbaxy's facilities in Paonta Sahib (isotretinoin, gabapentin, and ciproflaxin) and Dewas (cefaclor, cefadroxil, amoxicillin, and amoxicillin and clavulanate potassium). The counts enumerated in the charging document pertain to conduct predating 2008, including the dates of the second and third Warning Letters and the Import Alert against the company.

There is no doubt that Ranbaxy committed fraud related to the stability testing for its products. As part of its FDC Act felony plea, Ranbaxy admitted that it acted with the intent to defraud or mislead. The company agreed to pay a criminal fine of $130 million, and to forfeit $20 million, to resolve the criminal case.[19]

As part of a global resolution, Ranbaxy simultaneously settled a pending civil False Claims Act ("FCA") matter that was based on the theory that Ranbaxy had caused false claims to be submitted to government health care programs between April 1, 2003, and September 16, 2010.[20] Notably, the FCA settlement incorporated a damage calculation that was much broader in date range and scope of drugs than the criminal case. The civil settlement agreement defined "covered drugs" as any pharmaceutical products Ranbaxy distributed and sold in the United States that were manufactured at its facilities in Paonta Sahib and Dewas.[21] It is not limited to certain drugs, and as described, covers all drugs sold during this seven-year timeframe. The civil resolution required Ranbaxy to pay $350 million to reimburse the government for the false claims.[22]

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18 *See* Ranbaxy Settlement Agreement, *available at* http://www.justice.gov/iso/opa/resources/692013513142957691677.pdf (hereinafter "Settlement Agreement").

19 *See* Plea Agreement, *United States v. Ranbaxy USA, Inc.* (Jan. 2, 2013), *available at* http://www.corporatecrimereporter.com/wp-content/uploads/2013/05/ranbaxyplea.pdf.

20 Settlement Agreement at 3.

21 *Id.* at 1-2.

22 *Id.* at 5.

None of these actions has apparently been adequate to induce Ranbaxy to come into compliance with cGMP and data integrity requirements as shown by the addition of two more Ranbaxy facilities to the Consent Decree. Yet FDA continues to honor first-to-file status for applications Ranbaxy submitted during the same timeframe it committed continuous and widespread cGMP violations and engaged in fraudulent activities.

5. FDA's Special Treatment of Ranbaxy has Backfired

The widespread manufacturing troubles at Ranbaxy, including those confirming that Ranbaxy intentionally committed fraud, have been well-known to FDA since 2006. Yet FDA has bent over backwards to allow Ranbaxy opportunity to continue introducing new drugs into the marketplace, placing patients at risk. This is most evident by the fact that FDA approved twelve new generic drugs, in addition to many new strengths or dosage forms for existing Ranbaxy drugs, between 2006 and 2009, despite being fully informed and claiming to have a "heightened" concern of the problems at Ranbaxy. Just three years later, in 2008, FDA banned at least three of these drugs, among others, from import into the United States.[23] Had FDA actually withheld approval of pending applications, it could have prevented the potential risk associated with the thousands of patients exposed to adulterated drugs produced during the interim period.

The proof is in the pudding. Ranbaxy's cGMP problems could not be disguised forever, and ultimately manifested in recalls of several drug products FDA should never have approved in the first place. Isotretinoin is an example. FDA approved Ranbaxy's ANDA in 2002, and Ranbaxy was required to conduct a recall due to cGMP issues in mid-2009.[24] In November 2009, Ranbaxy was again required to recall the drug for recurrent cGMP problems.[25]

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23 *See* FDA, Press Release, FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs from Two Ranbaxy Plants in India Actions Affect over 30 Different Generic Drugs; Cites Serious Manufacturing Deficiencies (Sept. 16, 2008), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116949.htm.

24 *See* FDA Enforcement Report (July 8, 2009), *available at* http://www.fda.gov/safety/recalls/enforcementreports/ucm170893.htm.

25 *See* FDA Enforcement Report (Nov. 18, 2009), *available at* http://www.fda.gov/safety/recalls/enforcementreports/ucm191238.htm.

Similarly, FDA's treatment of Ranbaxy's atorvastatin application is antithetical to FDA's mission to protect public health. FDA approved Ranbaxy's ANDA for this drug product in November 2011, after four separate Warning Letters to the company; after FDA banned all products produced at Paonta Sahib, like atorvastatin; and after FDA invoked an AIP based on its documented concerns about fraud in the data submissions to the Agency. Regardless, Ranbaxy sought, and FDA inexplicably granted, a public health exception for atorvastatin, and approved Ranbaxy's atorvastatin application in 2011. Just a few months later, Ranbaxy found glass particles in its atorvastatin batches and recalled the product.[26] Again in January of this year, Ranbaxy was forced to recall 64,626 bottles of its atorvastatin product after a pharmacist discovered a 20 mg tablet of the drug inside a sealed bottle of atorvastatin 10 mg.[27] While FDA has claimed that its review and approval did not relate to the cGMP violations underlying Ranbaxy's recalls, this is barely credible. FDA should never have approved the drug in the first place, thus protecting the public from glass shards in drugs and potential dosing errors.

Several of the drugs implicated in the criminal plea for the company have been recalled due to cGMP violations. Throughout the course of investigating the company, FDA was clearly aware of the problems associated with these drug products, yet continued to approve applications from Ranbaxy pertaining to these same drug products. For example, in 2007, the company recalled gabapentin after it discovered that the product's impurity specifications were higher than expected during its shelf life.[28] At the time of the recall, the company estimated that there were over 73 million tablets in United States commerce. In 2009, the company recalled 1,303 cartons of isotretinoin based on dissolution tests showing out of specification results.[29] Given that each carton contained 100 capsules, over a million capsules were in nationwide distribution at the time of this recall. Later that same year, Ranbaxy conducted another voluntary recall of the same

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26 *See* FDA, Press Release, Ranbaxy Issues Voluntary Nationwide Recall of 41 Lots of Atorvastatin Calcium Tablets 10 mg and 40 mg Due to Presence of Foreign Substance (Nov. 28, 2012), *available at* http://www.fda.gov/safety/recalls/ucm329866.htm.

27 *See* FDA Enforcement Report (Mar. 5, 2014), *available at* http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=select&recall_number=D-1086-2014&w=03052014&lang=eng.

28 FDA Enforcement Report (Nov. 7, 2007), *available at* http://www.fda.gov/safety/recalls/enforcementreports/2007/ucm120479.htm.

29 FDA Enforcement Report, *supra* n.26.

product, again for out of specification results.[30] Similarly, in 2010, the company recalled amoxicillin and clavulanate potassium, which Ranbaxy manufactured at its Dewas facility.[31] The complaints pertained to the product turning brown, when it should have been white. FDA was in a position to have stopped the company from shipping these products in the first instance but failed in its duty.

6. Ranbaxy Merger with Sun Pharmaceuticals

In what is a thinly veiled attempt to shed the stigma associated with the Ranbaxy name, the company recently announced that it was selling itself to Sun Pharmaceuticals (hereinafter "Sun") in a $3.2 billion deal to close later this year. Under the terms of the deal, Sun will acquire Ranbaxy, and the Ranbaxy entity will cease to exist.

This corporate change, however, does nothing to alleviate Ranbaxy's significant cGMP and data integrity issues. The Consent Decree clearly binds Sun as a successor corporation to Ranbaxy (*e.g.*, Consent Decree ¶ XXI, enjoining "each and all of [Ranbaxy's] directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them"). The ramifications of Ranbaxy's import bans, AIP, and fraud settlement will carry forward with Sun.

It is hoped that Sun will be able to address Ranbaxy's deep seeded and continuous issues. However, in March 2014, FDA banned imports of drugs made at Sun's Karkahdi plant in India.[32] That action follows a litany of other FDA enforcement actions against Sun and its sister company, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), including an August 2010 Warning Letter to Sun citing significant cGMP violations,[33] and an October

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30 FDA Enforcement Report, *supra* n.27.

31 FDA Enforcement Report (Apr. 7, 2010), *available at* http://www.fda.gov/safety/recalls/enforcementreports/ucm207761.htm.

32 *See* FDA Import Alert 66-40, *available at* http://www.accessdata.fda.gov/cms_ia/importalert_189.html; *see also* FiercePharma.com, Bloomberg: Sun Plant Banned by FDA Had Same Issues Faced by Ranbaxy (Apr. 25, 2014), *available at* http://www.fiercepharma.com/story/bloomberg-sun-plant-banned-fda-had-same-issues-faced-ranbaxy/2014-04-25 (reporting that FDA identified issues with basic cleanliness at the Sun plant, including "a strong aroma of urine . . . [and] what appeared to be human waste on a wall.").

33 *See* FDA, Warning Letter to Sun Pharmaceutical Industries, Inc. (Aug. 25, 2010), *available*

2008 Warning Letter to Caraco citing significant cGMP violations and that led Caraco to enter into a Consent Decree Of Condemnation, Forfeiture And Permanent Injunction.[34]

B. Drug Products at Issue

Amid all of these major cGMP issues, Ranbaxy continued to generate data to submit applications to FDA. FDA's decision to preclude generic competition in order to support Ranbaxy's first-to-file status has cost consumers hundreds of millions – if not billions – of dollars. Provided below are three examples of likely costs in just one state program.

1. Valsartan

Ranbaxy submitted an ANDA for valsartan in December 2004, and at the time, was the first applicant to submit an ANDA for this product. Our client understands that several other applicants subsequently filed ANDAs for valsartan, and FDA has tentatively approved several (if not all) of those applications.

Valsartan is the active ingredient in Diovan, which is made by Novartis Pharmaceuticals Corporation. Diovan is an angiotensin receptor blocker indicated for the treatment of high blood pressure, congestive heart failure, and post-myocardial infarction.[35] Diovan is a blockbuster drug, generating total sales of over $11 billion since 2009. The current Average Wholesale Price ("AWP") for Diovan is $456.36 for 90 tablets, or over $5 a pill.[36] The Diovan unit price has more than doubled since early 2009. *Id.* Full competition over generic Diovan would likely result in significant annual savings for individuals, as well as private and public payors. In fact, it has been estimated that projected entry of generic valsartan would save the State of New York's Medicaid program

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at http://www.fda.gov/iceci/enforcementactions/warningletters/2010/ucm224177.htm.

34 *See* FDA, Warning Letter to Caraco Pharmaceutical Laboratories, Ltd. (Oct. 31, 2008), *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2008/ucm1048080.htm; *United States v. Adulterated Articles of Drug*, No. 09-12498 (E.D. Mich. Sept. 29, 2009).

35 *See* Diovan (valsartan) Label, National Institutes of Health ("NIH") Daily Med, http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=5ddba454-f3e6-43c2-a7a6-58365d297213.

36 *See* Micromedex® Red Book Online: Diovan 00078-0358-34.

approximately $38,352,520 annually.[37] On information and belief, Ranbaxy's original valsartan ANDA contained data generated at Paonta Sahib.

2. *Esomeprazole*

Another drug, esomeprazole magnesium, similarly is stuck in a regulatory quagmire due to Ranbaxy's first applicant status. Nexium, the brand version of esomeprazole magnesium, is manufactured by AstraZeneca and is widely used in this country, with annual United States sales of approximately $6 billion in 2013 alone.[38] Nexium is a proton pump inhibitor most commonly used to treat gastrointestinal esophageal reflux disease, or GERD, the main symptom of which is severe heartburn. The AWP for Nexium is $852.22 for 90 capsules, or nearly $9.50 per capsule. Nexium has increased in price by nearly 19 percent in the last year.[39] It is estimated that the generic availability of esomeprazole – projected at the time in May 2014 – would save the State of New York's Medicaid program approximately $83 million annually.[40] Our client understands that there are several pending ANDAs for generic esomeprazole in addition to Ranbaxy's, and Ranbaxy's application is blocking approval of the others. On information and belief, Ranbaxy's original esomeprazole ANDA contained data generated at Paonta Sahib.

3. *Valganciclovir Hydrochloride*

Ranbaxy also was the first to submit an ANDA for valganciclovir hydrochloride. Valcyte, the branded drug, has a smaller market in the United States than either Nexium or Diovan, but it is extremely important from a public health perspective. Valcyte is an anti-viral drug used to treat or prevent certain serious eye infections in immunocompromised patients, such as those with AIDS, or who have received an organ transplant.[41] Despite the

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37 *See* Excellus BCBS, Opportunities for Generic Savings in 2013 and 2014 (Winter 2013) (hereinafter "Excellus"), 2, *available at* https://www.excellusbcbs.com/wps/wcm/connect/3b077339-3270-41fc-90cb-1d781c5af698/Generic+Savings+2013-2014+FS-EX+FINAL+1.pdf?MOD=AJPERES&CACHEID=3b077339-3270-41fc-90cb-1d781c5af698.

38 *See* Drugs.com, Nexium Sales Data, *available at* http://www.drugs.com/stats/nexium.

39 *See* Micromedex® Red Book Online: Nexium 00186-5040-54.

40 *See* Excellus at 3.

41 *See* NIH, MedlinePlus: Valganciclovir,

relatively small patient population, Valcyte has generated total United States sales of over $1.5 billion for Hoffman-La Roche since 2009. The AWP for 60 tablets is up to $4,636.73, or approximately $77.28 ***per tablet***. Thus, even though there are only 292 Valcyte users in the State of New York's Medicaid program, a generic version of the product could save that program approximately $3.5 million a year.[42] Our client understands that there are several pending applications for generic valganciclovir hydrochloride, and Ranbaxy's application is blocking their approval. On information and belief, Ranbaxy's original valganciclovir ANDA contained data generated at Paonta Sahib.

C. Legal Framework

1. Approval of Generic Drugs

The FDC Act establishes the procedure for obtaining approval to market pharmaceutical products in the United States. That Act requires the manufacturer of a brand-name drug to submit a complete New Drug Application ("NDA") that contains, among other things, extensive scientific and clinical data demonstrating the safety and effectiveness of the proposed new drug. 21 U.S.C. § 355(b)(1). An NDA applicant also must submit information on any patent that claims the drug, or a method for using the drug, and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *Id.* §§ 355(b)(1), (c)(2). FDA publishes the patent information in what is known colloquially as the "Orange Book," but is formally the "Approved Drug Products with Therapeutic Evaluations." *Id.*; *see also* 21 C.F.R. § 314.53(e).

Before the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"), generic market entry was cost-prohibitive because manufacturers generally were required to submit a full NDA to obtain approval of a generic drug. As a result, patients were denied access to generic medicines, which are typically sold at much lower prices. The Hatch-Waxman Amendments were intended to balance innovation in the development of new drugs with accelerating the availability to consumers of lower cost alternatives to innovator drugs. *See* H.R. Rep. No. 98-857, 98th Cong., 2d Sess. at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647-48.

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http://www.nlm.nih.gov/medlineplus/druginfo/meds/a605021.html#overdose.

42 *See* Excellus at 2.

The Hatch-Waxman Amendments removed the barriers to entry by permitting generic manufacturers to submit ANDAs. 21 U.S.C. § 355(j). An ANDA relies on the previously approved drug (or Reference Listed Drug), and may not contain clinical data to demonstrate the safety or effectiveness of the generic drug product. *See id.* Rather, an ANDA must include data showing the generic drug product is bioequivalent to the brand-name drug. *Id.* § 355(j)(8)(B)(i). The ANDA also must contain specific information establishing the drug's stability:

- "full description of the drug substance including its physical and chemical characteristics and stability;"
- "the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability," among other things;
- "stability data with proposed expiration dating;" and
- information for each batch of the drug used to conduct a primary stability study, including the batch production record and the results of any test performed on the drug product.

21 C.F.R. § 314.50(d).

2. 180-Day Marketing Exclusivity

An ANDA also must contain one of four specified certifications for each patent that "claims the listed drug" or claims the use for the drug for which the ANDA seeks approval. 21 U.S.C. § 355(j)(2)(A)(vii). The certification must be one of the following:

(I) That such patent information has not been filed;
(II) That such patent has expired;
(III) That the generic drug will not be marketed until the date the patent will expire; or
(IV) That such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

Id. Only the Paragraph IV certification is relevant to this Citizen Petition. A Paragraph IV certification signals the generic applicant's intent to market its product prior to the expiration of the listed patent. It carries risks for the generic applicant; it is considered a technical act of infringement that enables the NDA holder and patent owner to sue the ANDA applicant, and thus subject the generic applicant to spend years defending its action in costly patent infringement litigation. 35 U.S.C. § 271(e)(2)(A). If the NDA or patent holder brings suit within 45 days of the date it receives notice of the Paragraph IV certification, FDA must stay approval of the ANDA for 30 months. If no action is brought within 45 days, FDA may approve the ANDA provided other conditions of approval are satisfied. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2).

Despite the inherent litigation risk, generic drug manufacturers are incentivized to be the first company to submit an ANDA containing a Paragraph IV certification because the statute grants, in certain circumstances, a 180-day period of marketing exclusivity to the first Paragraph IV challenger. 21 U.S.C. § 355(j)(5)(B)(iv). Exclusivity begins to run upon the applicant's first commercial sale of its generic drug. *Id.*

This 180-day exclusivity period can be subject to forfeiture, however, under provisions added to the FDC Act in 2003. *See* The Access to Affordable Pharmaceuticals provisions of the MMA, Pub. L. No. 108-173, 117 Stat. 2066. The MMA sets forth various types of forfeiture events in 21 U.S.C. § 355(j)(5)(D)(i), including where "the Secretary considers the application to have been withdrawn as the result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4)." *Id.* § 355(j)(5)(D)(i)(II).

3. Impact of Falsified Data in an ANDA

FDA is not authorized to approve an ANDA or to confer 180-day marketing exclusivity with respect to an ANDA that contains, or is tainted by, unreliable or falsified data or information. Under the plain language of the statute, FDA cannot approve an ANDA 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;"

- "the application contains an untrue statement of material fact;" or

- "the application does not meet any other requirement of [21 U.S.C. § 355(j)(2)(A)]."

21 U.S.C. § 355(j)(4).

As described earlier, under the AIP, when FDA determines that data in an application are unreliable, the agency will either "refuse to approve the application (in the case of appending application) or proceed to withdraw approval (in the case of an approved application), regardless of whether the applicant attempts to replace the unreliable data with a new submission in the form of an amendment or supplement." 56 Fed. Reg. at 46,200. Further, if a company under the AIP "wishes to replace the false data with a new submission, the new submission ***should be in the form of a new application***." *Id.* (emphasis added).

Thus, even if an ANDA applicant is the first-to-file its Paragraph IV certification, if that application is tainted, the applicant cannot simply amend or supplement the application with new data; it must submit a new application, which would not be back-dated to the date of the original application.

D. Legal Analysis

1. Ranbaxy is Not a First Applicant

Under the Hatch-Waxman Amendments, only a "first applicant" is eligible for 180-day exclusivity. In order to qualify as a "first applicant," the sponsor must "submit[] a substantially complete application." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). A "substantially complete application . . . means an application under this subsection that on its face is sufficiently complete to permit a substantive review" and contains all the information required for an ANDA. *Id.* § 355(j)(5)(B)(iv)(II)(cc).

All of the ANDAs that contain any data from Ranbaxy's Paonto Sahib site (for instance, the February 25, 2009 AIP determination) or Dewas (Consent Decree) submitted by Ranbaxy that are currently pending contain flawed data that does not permit a substantive review as determined by FDA. Correspondingly, if one cannot meet that statutory definition, one cannot be a first applicant and therefore is not eligible for 180-day exclusivity.

For example, Ranbaxy's ANDA for valsartan was received by FDA in December 2004.[43] Publicly available information regarding the pervasive nature of fraudulent activities at Ranbaxy in and around this time makes it implausible that the contents of the application submitted in December of 2004 permitted a substantive review—then, now, or anytime in between or in the future. Rather, that application, like every other Ranbaxy application, was thoroughly infected by the company's widespread fraud. Even assuming *arguendo* that FDA did not realize, in December of 2004, that the ANDA was not "on its face . . . sufficiently complete to permit a substantive review," after the FDA and the United States Department of Justice's long history of documenting Ranbaxy's pattern and practice of falsifying data, there can be no question that, at some point in the approval process, FDA should have realized that the December 2004 application was not sufficiently complete to permit a substantive review. At that time, FDA was compelled by the statute to assess Ranbaxy's "first applicant" status based on all the information that the agency had, and conclude that Ranbaxy was not a first applicant with respect to valsartan. Even if Ranbaxy has been able to receive certification from an independent third party that the information in the valsartan ANDA was somehow credible, and even if FDA were to suspend common sense, the ANDA would require a major amendment (data certification) to permit the ANDA to receive substantive review. Such an amendment is the equivalent of submission of a new ANDA that would not receive first applicant status.

The Consent Decree does not foreclose from FDA from taking the proper and legally compelled course on ***eligibility for exclusivity*** now. With respect to ***approval***, FDA inexplicably agreed that "[f]or all Excepted Applications found by FDA . . . to have been substantially complete at the time they were initially filed, FDA will . . . evaluate the data to determine whether such Excepted Application contains any untrue statements . . ."), and if those Excepted Applications, do contain "untrue statements" – FDA agreed that for certain applications Ranbaxy "shall not be required to withdraw any Excepted Application . . . for which . . . [Ranbaxy] had replaced all untrue statements . . . prior to February 25, 2009." Consent Decree ¶ XIV. Although contrary to its own AIP, public policy and common sense, FDA's decision to permit the application to remain on file does not foreclose FDA from concluding that the application – although still pending –is not substantially complete for purposes of determining eligibility for exclusivity. Rather, the statute compels, and the Consent Decree permits, FDA to determine that the application Ranbaxy submitted in December 2004 was, on its face, not substantially complete because

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[43] The legal analysis portion of this petition references valsartan as an example, but would apply equally to other similarly situated drugs.

it could not have substantively reviewed, and therefore, Ranbaxy is not a first applicant eligible for 180-day exclusivity. Indeed, the plain meaning of "first applicant" is reinforced by FDA's own regulations, which state that "the 'applicant submitting the first application' is the applicant that submits an application that is . . . substantially complete." 21 C.F.R. § 314.107(c)(2). As previously noted, Ranbaxy's own behavior rendered the applications incapable of substantive review by FDA. Any submission now needed to attest to the integrity of the submitted data is evidence that the original submission was and is incomplete.

The statutory language nowhere indicates that FDA's determination of substantial completeness is made only at the time an application is initially filed. Indeed, to the extent that FDA is considering adding the non-statutory words "at the time they were initially filed" to the analysis of substantial completeness for purposes of determining eligibility for exclusivity, such action would be contrary to the plain meaning of the statute and in violation of the law. *See, e.g., Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1070 (D.C. Cir. 1998).

It is beyond dispute that Ranbaxy committed fraud, some of which may never be detected. It is equally clear that Congress did not intend for FDA to make exceptions to the requirements for submission of a substantially complete ANDA in order to obtain first applicant status that rewards applicants who knowingly submit false information. Because its ANDAs, including the ANDA for valsartan, are infected by fraud, Ranbaxy is not a first applicant and is not eligible for 180-day exclusivity – a fact that should be self-evident to the agency based on the plain meaning of the text of the FDC Act. FDA "must give effect to the unambiguously expressed intent of Congress," and revoke first applicant status for Ranbaxy ANDAs. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843, n.9 (1984).

2. Ranbaxy is Pursuing Approval of a Different "Application"

Assuming for the sake of this argument that Ranbaxy was a first applicant for a particular drug, Ranbaxy is no longer pursuing approval of the same application for which it had first applicant status, and therefore is not eligible for exclusivity in connection with the application for which it is seeking approval.

The plain meaning of "application" as defined by FDA shows that even if Ranbaxy were deemed by FDA to be a first applicant with respect to the "application" that it submitted in December 2004, any data now pending before the agency must be deemed a

new "application" by FDA. Under FDA's own regulations, an "[a]pplication means the application described under § 314.50, including all amendments and supplements to the application." 21 C.F.R. § 314.3. FDA's regulations also describe various types of supplements and resubmissions (as well as defining "original application"). None of FDA's interpretations of "application" permits an applicant to substitute non-fraudulent data for fraudulent data. Indeed, the only document to specifically address fraud is FDA's AIP, which FDA issued in furtherance of its statutory mandate that ANDA submissions contain reliable data and information, and which sets forth FDA's policy with regard to fraudulent data. *See* 56 Fed. Reg. 46,191. The AIP states that the old fraudulent application cannot be amended or supplemented, but rather that "the new submission should be in the form of a new application." *Id.* at 46,200. Thus, because a sponsor that is subject to the AIP may not simply amend a tainted ANDA, the filing date is not the date that Ranbaxy submitted its first application, but rather the date Ranbaxy submitted an application that contains reliable data that permits substantive review by FDA.

In the event the Consent Decree is contrary to the plain meaning of the statute and FDA's own AIP policy, FDA should adhere to Congress' mandate and those policies that FDA implemented to meet the law's requirements.

3. Under Both the Statute and FDA's Regulations, FDA Must Deem Ranbaxy's Eligibility for 180-Day Exclusivity to Have Been Forfeited

a. FDA Should Consider Ranbaxy's ANDAs to be Withdrawn

Under 21 U.S.C. § 355(j)(5)(D)(i)(II), a "forfeiture event" includes instances in which "the Secretary considers the application to have been withdrawn as the result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4)." Under paragraph (4), the Secretary cannot approve an application that "contains an untrue statement of material fact." *Id.* § 355(j)(4)(K). Given the widespread fraud that infected Ranbaxy's applications, and the allowances made in the Consent Decree to keep an application on file for approval purposes, by substituting non-fraudulent data for fraudulent data, it seems likely that the December 2004 application contained an untrue statement of material fact. The Secretary's determination that the original application could not be approved is demonstrated by the Consent Decree provisions that inexplicably appears to permit Ranbaxy to replace contents of that application without withdrawing the application.

Whatever the merits of the Consent Decree provisions, they establish incontrovertible evidence that FDA concluded that the application did not meet the requirements for approval. For purposes of the statute, a forfeiture event has occurred, and therefore, even assuming that Ranbaxy were at one point a "first applicant," and further assuming that it is still seeking approval of the "application" for which it has first applicant status – two propositions that are demonstrably false as shown above – the Secretary is compelled to determine that for purposes of 180-day exclusivity, the application has been "withdrawn" as not meeting the requirements of 21 U.S.C. § 355(j)(4). This is so even if, for approval purposes, FDA has permitted some applications to remain on file for potential eventual approval – albeit one for which no exclusivity could attach.

b. Ranbaxy is No Longer Pursuing ANDA Approval

Ranbaxy's exclusivity as to valsartan is also forfeited under FDA's regulations. Under 21 C.F.R. § 314.107(c)(3), "if FDA concludes that the applicant submitting the first application is not actively pursuing approval of its abbreviated application, FDA will make the approval of subsequent [ANDAs] immediately effective if they are otherwise eligible for an immediately effective approval."

In promulgating this rule, FDA stated that

> [f]or purposes of this rule, the phrase 'actively pursuing approval' is intended to encompass a drug sponsor's ***good faith effort*** to pursue marketing approval in a timely manner. In determining whether a sponsor is actively pursuing marketing approval, FDA will consider all relevant factors, such as the sponsor's compliance with regulations and the timeliness of its responses to FDA's questions or application deficiencies during the review period.

59 Fed. Reg. 50,338, 50,354 (Oct. 3, 1994) (emphasis added).

Ranbaxy has not pursued ANDA approval in good faith. There is an abundance of evidence of Ranbaxy's bad conduct and intent to defraud and mislead FDA.[44]

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[44] *See also* Press Release, A.G. Schneiderman Announces Settlement With Generic Pharmaceutical Companies for Entering into Anticompetitive Arrangement (Feb. 19, 2014), *available at* http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-generic-pharmaceutical-companies-entering. The New York settlement required Ranbaxy to abandon portions of an agreement with Teva Pharmaceuticals USA, Inc., pursuant to

Notwithstanding FDA's apparent tolerance for this criminal conduct, FDA's regulations plainly require forfeiture of exclusivity with respect to the implicated applications.

4. Ranbaxy's Pending Application is for a Different "Drug" Than the One for Which it First-Filed an ANDA

We understand that Ranbaxy has substituted data contained in the 2004 ANDA for valsartan with new data, including changing the manufacturing site that produced the test drug and test data for its valsartan product. Based on the statutory plain meaning and FDA's long-standing interpretation of "drug" and "drug product" as discussed below, such action created a new application for a new "drug." Accordingly, even if Ranbaxy were deemed to still be a first applicant for some "drug," it is not seeking approval of the application for the same "drug" for which it is the first applicant. Instead, Ranbaxy is seeking approval of another application for another "drug," for which it did not first-file an application.

The FDC Act exclusivity provision applies only to "a drug for which a first applicant has submitted an application." 21 U.S.C. § 355(j)(5)(B)(iv)(I). Whether Ranbaxy retains exclusivity depends on whether the company's valsartan is a "drug" for which it submitted the first application. It is not. Specifically, courts have held that the word "drug" in the context of Hatch-Waxman 180-day exclusivity means "drug product." *Apotex Inc. v. Shalala*, 53 F. Supp. 2d 454 (D.D.C. 1999), *aff'd*, 1999 WL 956686 (D.C. Cir. 1999) (exclusivity period for one drug product does not apply to a drug product with different dosage strength, since the two are different drug products). Further, FDA has long taken the position that drugs manufactured by different manufacturers are different drug "products" from each other. For example, in *United States v. Premo Pharm. Labs., Inc.*, 511 F. Supp. 958, 961-64 (D.N.J. 1981), in the context of determining whether a "drug" was generally recognized as safe, the court explained, "The United States contends . . . that, even if all ingredients are the same, differences in manufacturing practices can cause one manufacturer's product to differ substantially from another in safety and effectiveness." The court agreed, noting: "Even if the characteristics of a product's active ingredient are kept constant, and precisely the same excipients are used, the pharmacological properties of

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which the companies had agreed not to challenge each other's regulatory exclusivity rights for all of their drugs, which the State of New York alleged constituted an unlawful anticompetitive agreement.

a 'me-too' drug product may still differ substantially from those of the pioneer drug because of the manufacturing process itself."

If in fact Ranbaxy has substituted manufacturing sites for any drug including valsartan, the switch in manufacturing site has created a different drug product based on FDA's long held and accepted interpretation. On this basis Ranbaxy has ceased to pursue approval of the original drug application and has created a new filing date for the ANDA that should not result in first applicant status unless the amended ANDA was submitted to FDA before any other ANDAs containing a Paragraph IV certification.

E. Conclusion

Ranbaxy has admitted to submission of fraudulent data to FDA. FDA has recognized that data in Ranbaxy's ANDAs are so materially flawed that it invoked the AIP against Ranbaxy to assure that FDA could review applications that contained credible and reliable information. As discussed above, there are numerous bases for FDA to determine that Ranbaxy's status as a first applicant on any pending ANDA should be revoked. To not do so is to reward Ranbaxy for its illegal behavior at the cost of denying consumers low cost high quality generic drugs from other manufacturers. FDA should immediately approve any and all ANDAs that are being blocked by Ranbaxy's wrongfully obtained eligibility for marketing exclusivity.

III. ENVIRONMENTAL IMPACT

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

IV. ECONOMIC IMPACT

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

V. CERTIFICATION

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it

includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

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