UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

RANBAXY LABORATORIES, LTD., Plot 90, Sector 32 Gurgaon (Haryana), India 122 001 and RANBAXY, INC., 600 College Road East Princeton, NJ 08540 Plaintiffs, v. SYLVIA MATHEWS BURWELL in her official capacity as Secretary of Health and Human Services, 200 Independence Avenue S.W. Washington, D.C., 20201 MARGARET HAMBURG, M.D. in her official capacity as Commissioner of Food and Drugs, and UNITED STATES FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993 Defendants.	Case No. _____

RANBAXY LABORATORIES, LTD. AND RANBAXY, INC.'S COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Ranbaxy Laboratories, Ltd. and Ranbaxy, Inc. (collectively, "Ranbaxy") bring this civil action seeking declaratory and injunctive relief against defendants Sylvia Mathews Burwell, in her official capacity as Secretary of Health and Human Services; Margaret Hamburg, in her official capacity as Commissioner

of Food and Drugs; and the United States Food and Drug Administration (collectively "FDA"). In support thereof, Ranbaxy states the following:

NATURE OF THE ACTION

1. This lawsuit seeks immediate judicial review of a November 4, 2014 FDA decision (attached hereto as Exhibit C, the "Letter Decision"), that has the immediate effect of stripping Ranbaxy of its statutory rights under the federal Food, Drug, and Cosmetic Act (the "FDCA") and literally hundreds of millions of dollars in anticipated revenues for certain generic versions of the brand-name drugs Nexium® and Valcyte®.

2. The Agency issued its decision with ***no prior notice*** to Ranbaxy. The Agency gave Ranbaxy ***no opportunity to comment*** on the issues raised in that decision. And the Agency had ***no power*** to issue its decision—which not only rescinds decisions FDA made over six years ago after it carefully considered all of the relevant facts, but hinges on a putative interpretation of the FDCA that is impossible to square with the statute's plain text and structure.

3. As a result, and as set forth in greater detail below, FDA's Letter Decision violates Ranbaxy's constitutional rights, *see, e.g.*, U.S. Const. amend V; *see also* 5 U.S.C. § 706(2)(B); exceeds the Agency's statutory authority, *see* 5 U.S.C. § 706(2)(C); and is arbitrary, capricious, and otherwise contrary to law, *see id.* § 706(2)(A). It must immediately be vacated and the Agency enjoined from implementing it.

PARTIES

4. Plaintiff Ranbaxy Laboratories, Ltd. is a corporation organized under the laws of India with its principal place of business in Gurgaon, India. It is an industry leader in the development, manufacture, and marketing of generic pharmaceutical products, including products intended for commercial marketing in the United States.

5. Plaintiff Ranbaxy, Inc. is a Delaware corporation with its principal place of business in Princeton, New Jersey. Ranbaxy, Inc. is the U.S. parent company of Ranbaxy Pharmaceuticals Inc., which promotes, sells and distributes the finished pharmaceutical products of Ranbaxy Laboratories, Ltd. in the United States. Ranbaxy, Inc. also provides management support services (including prosecution of ANDAs and communications with the FDA) on behalf of Ranbaxy Laboratories, Ltd. and manages litigation services on behalf of both Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals Inc. in the United States.

6. Defendant Sylvia Mathews Burwell is the Secretary of Health and Human Services ("HHS") and is the official charged by law with administering the FDCA. Secretary Burwell is sued in her official capacity. She maintains offices at 200 Independence Ave., S.W., Washington, DC 20204.

7. Defendant Margaret Hamburg, M.D., the Commissioner of the FDA, has the delegated authority to administer the drug approval provisions of the FDCA. Commissioner Hamburg is sued in her official capacity. She maintains offices at 200 C St., S.W., Washington, DC 20204, and 5600 Fishers Lane, Rockville, Maryland 20857.

8. Defendant FDA is the agency within HHS charged with overseeing, *inter alia*, the human drug approval process, including the portions of that process relevant to this case.

JURISDICTION AND VENUE

9. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331. This action arises under the FDCA, 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman") and the Medicare Modernization Act of 2003 ("MMA"), codified at, *inter alia*, 21 U.S.C. § 355; the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 555, 702, and 706; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

10. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

FACTUAL ALLEGATIONS

A. The Hatch-Waxman Framework

11. The approval process for new drugs is set forth in the FDCA, as modified by Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, and the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066. Over time, this statutory scheme has come to be known as the "Hatch-Waxman Act."

12. To obtain approval for a brand-name drug like Nexium® or Valcyte®, the FDCA requires its manufacturer to prepare and submit a complete New Drug Application ("NDA") that contains, among other things, clinical data demonstrating the proposed drug's safety and efficacy. *See id.* § 355(b)(1). It also requires the NDA's sponsor to "file with the application the patent number and the expiration

date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *Id.* § 355(b)(1); *see also* 21 C.F.R. § 314.50(h) (citing § 314.53(b)).

13. Prior to Hatch-Waxman, generic applicants generally had to complete a full NDA to obtain approval—even though generic drugs have the same active ingredients and provide the same therapeutic benefits as their branded equivalents. That made generic market entry cost-prohibitive, and patients lacked widespread access to generic medicines that typically are sold at far lower prices. In 1984, Congress enacted Hatch-Waxman to remove those barriers to entry, increase the availability of generic drugs, and thereby reduce overall prescription drug costs. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998).

14. To accomplish those goals, Hatch-Waxman authorizes generic approval so long as an applicant shows that a proposed generic drug is "the same as" a previously approved drug in all material respects—the chemical composition of its active ingredient; the rate at which that ingredient is released into the patient's body; the strength of the drug (*e.g.*, 50mg, 100mg, or 200mg of active ingredient); the drug's route of administration (*e.g.*, oral or injected); its dosage form (*e.g.*, tablet or capsule); and its labeling. 21 U.S.C. § 355(j)(2)(A). Generic applicants do so by submitting an Abbreviated New Drug Application ("ANDA") with data on those essential product characteristics; where the drug meets those criteria, the generic

applicant need not repeat the innovator's clinical studies. *Id.* § 355(j)(2)(A) ; *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). After all, two drugs that are materially identical will share a common safety and efficacy profile.

B. Tentative and Final Approval of an ANDA

15. The FDCA provides that ANDA evaluation generally is subject to two stages of approval, tentative approval ("TA") and final (or effective) approval. Different statutory subsections establish the varying requirements for these forms of approval.

16. With respect to TA, the statute provides that:

> The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection ***meets the requirements of paragraph (2)(A)***, but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA) (emphasis added). In turn, cross-referenced subsection (j)(2)(A) provides that ANDAs must contain sufficient information to demonstrate that the proposed generic drug's inherent characteristics satisfy the core standards for generic drug approval, *e.g.*, "***information to show*** that the active ingredient of the new drug is the same as that of the listed drug," 21 U.S.C. § 355(j)(2)(A)(ii)(I) (emphasis added); "***information to show*** that the route of administration, the dosage form, and the strength of the new drug are the same as those of the [reference] listed drug," *id.* § 355(j)(2)(A)(iii) (emphasis added); "***information to show*** that the new drug is bioequivalent to the [reference] listed

drug," *id.* § 355(j)(2)(A)(iv) (emphasis added); and "***information to show*** that the labeling proposed for the new drug is the same as the labeling approved for the [reference] listed drug." *Id.* § 355(j)(2)(A)(v) (emphasis added). Each of these provisions thus requires ANDA applicants ***to demonstrate*** that their products fully satisfy these criteria—again, the applicant must actually "***show***" that their proposed generic products meet the relevant standards.

17. Subsection (j)(2)(A) also references the applicant's methods, facilities, and controls for production of the proposed generic drug. But that requirement uses fundamentally different language than the other provisions in this subsection: Rather than requiring ANDA applicants to provide "***information to show***" that its methods, facilities, and controls are fully compliant, the TA subsection 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." 21 U.S.C. § 355(b)(1)(D) (emphasis added); 21 U.S.C. § 355(j)(2)(A)(vi) (requiring ANDAs to "contain ... the items specified in clauses (B) through (F) of subsection (b)(l) of this section"). Accordingly, the TA subsection merely requires applicants ***to disclose*** their ultimate plans for commercial production—not to prove that the facility proposed for ultimate commercial production is GMP-compliant at the time of the TA decision.

18. By further contrast, the statute conditions ***final approval*** on FDA finding actual compliance with generally applicable manufacturing, processing, and packing requirements, known in regulatory parlance as "GMPs." In particular, that

section of the statute provides that FDA "shall approve an [ANDA] unless the Secretary finds" that "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." *Id.* § 355(j)(4)(A).

C. The Statutory Right to 180-Day Generic Marketing Exclusivity

19. To balance the public interest in generic entry against the intellectual-property rights of NDA holders, Congress required each ANDA to include "a certification … with respect to each patent which claims the listed drug … or … a use for such listed drug." *Id.* § 355(j)(2)(A)(vii); *see also Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1350-51 (Fed. Cir. 2003).[1] Four certifications are available:

> (I) that patent information has not been filed with respect to the referenced NDA [a "Paragraph I certification"],
>
> (II) that the patent identified as claiming the referenced NDA has expired [a "Paragraph II certification"],
>
> (III) that the generic drug will not be marketed until the date on which the patent identified as claiming the referenced NDA will expire [a "Paragraph III certification"], or
>
> (IV) that the patent identified as claiming the referenced NDA is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug [a "Paragraph IV certification"].

21 U.S.C. § 355(j)(2)(A)(vii).

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[1] FDA publishes a list of relevant drug-claiming patents, which generally is referred to as the "Orange Book." *See Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004).

20. Paragraph IV certifications are critical to the statutory scheme. By design, such certifications challenge the NDA holder's exclusionary rights and thus create a possibility that generic competition might begin before patent expiry. *Teva Pharm. USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) (*Teva v. Leavitt*) ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier.").

21. But filing a Paragraph IV certification is risky. Paragraph IV challengers must make sizeable investments to develop either a non-infringing alternative formulation or legal defense based on patent invalidity or unenforceability. And where those efforts succeed, the very submission of a Paragraph IV certification an "artificial" act of patent infringement that can give rise to costly patent litigation. 35 U.S.C. § 271(e); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

22. To enable the prompt resolution of patent disputes, Paragraph IV challengers must provide both the NDA holder and any patentees with a formal notice of a Paragraph IV certification and detailed statement explaining its basis. 21 U.S.C. § 355(j)(2)(B)(i)-(ii). Where the NDA holder files suit within 45 days, FDA generally is barred from approving the ANDA for 30 months (while the litigation unfolds). 21 U.S.C. § 355(j)(5)(B)(iii). That is known as the "30-month stay." *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348-49 (Fed. Cir. 2009).

23. To encourage generic applicants to invest in the development of Paragraph IV challenges and accept the attendant risks of failure (on one hand) or high-stakes patent litigation (on the other), Hatch-Waxman rewards the first ANDA applicant who submits a Paragraph IV certification with a 180-day exclusivity period during which it is entitled to market its ANDA product without competition from other generic applicants. 21 U.S.C. § 355(j)(5)(B)(iv) (barring FDA from approving any ANDA that "contains a [Paragraph IV] certification … and is for a drug for which a first applicant has submitted an application [under this subsection] containing such a certification"). By providing that FDA can approve only the first Paragraph IV applicant's ANDA, the 180-day exclusivity period can be worth hundreds of millions of dollars to the first Paragraph IV challenger in cases involving drugs like Nexium® and Valcyte®. Indeed, Nexium® brand manufacturer AstraZeneca's latest annual report indicates that it sold more than $3.8 billion in 2013.

24. Finally, Hatch-Waxman now includes several "forfeiture triggers" under which the first applicant might lose its entitlement to 180-day exclusivity. As relevant here, one such trigger applies where the first generic applicant "fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure 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).

D. Ranbaxy's ANDA for Generic Nexium®

25. Esomeprazole is a proton pump inhibitor used primarily to treat gastroesophageal reflux disease, erosive esophagitis, and certain types of ulcers. The drug originally was developed by AstraZeneca, which holds three approved NDAs and markets the drug under the brand-name Nexium® in various formulations. As relevant here, AstraZeneca's NDA No. 021153 covers delayed-release esomeprazole magnesium capsules, 20 mg and 40 mg, and the company ultimately listed twelve patents in the Orange Book. Together, those patents were scheduled to block generic competition for those products until November 3, 2019.

26. On August 5, 2005, Ranbaxy filed ANDA No. 077830 seeking FDA approval to market generic versions of those products. The company's ANDA included all information required by the statute, including information to show that its products would have the same active ingredient as Nexium®, be bioequivalent to Nexium®, and bear the same labeling approved for Nexium®. *See* 21 U.S.C. § 355(j)(2)(A)(ii)(I) (active ingredient); *id.* § 355(j)(2)(A)(iv) (bioequivalence); *id.* § 355(j)(2)(A)(v) (labeling). Ranbaxy's ANDA also contained a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of Ranbaxy's generic esomeprazole, including by disclosing Ranbaxy's intention to manufacture the product at the company's facility in Paonta Sahib, India ("Paonta"). *See id.* § 355(j)(2)(A)(vi).

27. Finally, Ranbaxy's ANDA contained several Paragraph IV certifications to the listed patents for Nexium®. As the first applicant whose generic Nexium® ANDA included Paragraph IV certifications to AstraZeneca's

patents, there is no dispute that Ranbaxy became eligible for 180-day generic marketing exclusivity. After extensive review of the company's submission, the Agency issued TA for Ranbaxy's generic Nexium® ANDA on February 5, 2008—within 30 months of the ANDA's filing date.

E. Ranbaxy's ANDA for Generic Valcyte®

28. Valganciclovir is an antiviral medication used primarily to treat cytomegalovirus infections. The drug originally was developed by F. Hoffmann-La Roche AG ("Roche"), which holds two approved NDAs and markets valganciclovir in various formulations under the brand-name Valcyte®. As relevant here, Roche's NDA No. 021304 covers 450 mg Valcyte® tablets. Roche listed U.S. Patent No. 6,083,953 ("the '953 patent") in the Orange Book, which was scheduled to block generic competition for that product until 2015.

29. On December 22, 2005, Ranbaxy filed its ANDA No. 078078 seeking FDA approval to market a generic version of that drug. The company's ANDA included all information required by the statute, including information to show that it would have the same active ingredient as Valcyte®, be bioequivalent to Valcyte®, and bear the same labeling approved for Valcyte®. *See* 21 U.S.C. § 355(j)(2)(A)(ii)(I); *id.* § 355(j)(2)(A)(iv); *id.* § 355(j)(2)(A)(v). Ranbaxy's ANDA also contained a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of Ranbaxy's generic valganciclovir, including by disclosing Ranbaxy's intention to manufacture the drug substance portion of the product at its Dewas, India ("Dewas") facility, and the

company's intention to produce its finished dosage form at the Paonta facility. *See id.* § 355(j)(2)(A)(vi).

30. Finally, Ranbaxy's ANDA contained a Paragraph IV certification to the '953 patent. As the first applicant whose generic Valcyte® ANDA included Paragraph IV certifications to that patent, there is no dispute that Ranbaxy became eligible for 180-day generic marketing exclusivity. After extensive review of the company's submission, the Agency issued TA for Ranbaxy's generic Valcyte® ANDA on June 20, 2008—within 30 months of the ANDA's filing date.

F. Investigation and Consent Decree

31. In 2006 and 2008, for reasons not specifically related to the drug products at issue in this case, FDA issued warning letters asserting that Ranbaxy had failed to observe current GMPs at its Dewas and Paonta facilities. FDA and the U.S. Department of Justice ("DOJ") also began investigating Ranbaxy. Ranbaxy thereafter entered into a Consent Decree and Permanent Injunction that resolved certain claims brought by DOJ against Ranbaxy.

32. Broadly speaking, the Consent Decree divided Ranbaxy's pending ANDAs into two categories: "Affected Applications," which were subject to an internal review, third-party audit, and corrective action operating plan; and "Excepted Applications," which Ranbaxy was allowed to maintain pending the results of an audit intended to determine whether those ANDAs contained fraudulent data. As noted previously, the Consent Decree further provided that Ranbaxy would be required to withdraw any Excepted Application—and thereby forfeit 180-day exclusivity—if, and only if, the audit revealed that the specific

ANDA "contains any untrue statements of material fact" or "contains a pattern or practice of data irregularities affecting approval." Consent Decree ¶ XV. Ranbaxy's ANDAs for generic Valcyte® and generic Nexium® were among the "Excepted" ANDAs governed by those provisions.

G. The Audit Results And Letter Decision

33. Ranbaxy engaged Quintiles Inc. ("Quintiles"), an independent consultant with expertise in auditing FDA submissions, to conduct audits of the ANDAs for both products at issue in this case. Quintiles drafted an audit plan that would be used for both audits and sent it to FDA for approval. FDA requested certain modifications to the audit plan and approved it in final form on January 17, 2012.

34. With respect to both ANDAs at issue here, Quintiles then reviewed all original source documentation on which the ANDAs were based and compared it to the information included in the ANDA. That source documentation included, among much other data, batch records, analytical testing data, ingredient sourcing records, and equipment logbooks. The audit results for Ranbaxy's generic Nexium® and generic Valcyte® ANDAs were submitted to FDA in 2012, with neither audit revealing any untrue statement of material fact or pattern or practice of data irregularities with respect to either ANDA.

35. As contemplated by the Consent Decree, FDA then conducted its own comprehensive review of the Quintiles audits for each of these ANDAs. In both cases, FDA asked that Quintiles include more data in the audits, which necessitated

additional Quintiles visits to Ranbaxy's manufacturing sites in India. FDA also posed additional follow-up questions, which Quintiles and Ranbaxy answered fully.

36. On August 10, 2012, the Agency completed its review of Ranbaxy's generic Valcyte® ANDA and issued a formal letter stating its conclusion, after thorough review of the audit, that Ranbaxy's generic Valcyte® application "does ***not*** appear to contain any untrue statements of material fact … ***nor*** does it appear to contain a pattern or practice of data irregularities affecting approval." Exhibit A at 2 (emphasis added).

37. On November 4, 2012, the Agency issued another formal letter in which it likewise concluded, after thorough review of the audit, that Ranbaxy's generic Nexium® ANDA "does ***not*** appear to contain any untrue statements of material fact … ***nor*** does it appear to contain a pattern or practice of data irregularities affecting approval." Exhibit B at 2 (emphasis added).

38. Minutes after dispatching the Nexium® letter, however, FDA issued the Letter Decision giving rise to this case. That decision formally rescinded the prior TAs FDA had granted to both of the ANDAs at issue here, on the ground that FDA's prior decisions to grant those ANDAs were "mistake[n]" due to the adverse compliance status of Ranbaxy's Paonta and Dewas facilities:

> [T]he Agency has determined that FDA erred in tentatively approving Ranbaxy's ANDAs for Esomeprazole Magnesium Delayed-release Capsules, 20 mg and 40 mg, and Valganciclovir Hydrochloride Tablets, 450 mg. Specifically, the compliance status of the facilities referenced in the ANDAs at the time the ANDAs were granted tentative approval was inadequate to support approval or tentative approval, as described

> above. As explained above, FDA may not tentatively approve an ANDA like Ranbaxy's ANDAs for which there is evidence of non-compliance with CGMP. Accordingly, with this letter, the Agency is correcting its mistake and rescinding the tentative approval letters issued regarding these ANDAs.

Exhibit C at 12.

39. Based on its conclusion that the Agency should not have issued TA for these ANDAs, the Agency then considered whether the rescission of those TAs had consequences for Ranbaxy's right to 180-day exclusivity. With respect to Ranbaxy's generic Valcyte® ANDA, the Agency expressly concluded that the retroactive withdrawal of TA for that file did cause Ranbaxy to forfeit exclusivity: "Ranbaxy has forfeited its eligibility for 180-day exclusivity because [the company] failed to obtain [TA] within 30 months" of filing its ANDA. *Id.* at 13.

40. As for Ranbaxy's generic Nexium® ANDA, the Letter Decision purported to withhold a formal decision on forfeiture because the Agency typically does not announce forfeiture decisions until a subsequent generic applicant is poised for approval. *Id.* at 1 n.3. Even so, there is no doubt regarding the impact of FDA's decision: Agencies must treat like cases alike, and FDA's conclusion that Ranbaxy forfeited its 180-day exclusivity for generic Valcyte® due to the retroactive rescission of TA for that ANDA controls the analysis as to Ranbaxy's generic Nexium® ANDA—where TA likewise has been rescinded retroactively.

41. On the same day FDA issued the Letter Decision, it granted final approval to generic Valcyte® ANDAs held by at least two of Ranbaxy's competitors, Dr. Reddy's Laboratories and Endo Pharmaceuticals, permitting them to market

450 mg generic Valcyte® tablets in interstate commerce. *See* Ltr. from R. West, OGD, to S. Rao, Dr. Reddy's Laboratories (11/4/14), *available at* http://tinyurl.com/Reddys-Valcyte-FA (last visited Nov. 13, 2014); Ltr from R. West, OGD, to C. Holdos, Endo Pharmaceuticals (11/4/14), *available at* http://tinyurl.com/Endo-Valcyte-FA (last visited Nov. 13, 2014).

FIRST CAUSE OF ACTION
(Violation of the the FDCA and the APA)

42. Ranbaxy repeats and incorporates by reference the allegations contained in paragraphs 1 through 41 above.

43. As noted above, FDA's Letter Decision violates Ranbaxy's constitutional rights, *see, e.g.*, U.S. Const. amend V; *see also* 5 U.S.C. § 706(2)(B); exceeds the Agency's statutory authority, *see* 5 U.S.C. § 706(2)(C); and is arbitrary, capricious, and otherwise contrary to law, *see id.* § 706(2)(A).

44. ***First***, FDA has no power to correct an alleged "mistake" it made six years ago. Nothing in the FDCA permits FDA to revoke the issuance of a TA, and even if the Agency did have such authority, it was not timely exercised here. Nor did the Agency make a mistake in any event: FDA not only was aware of the relevant facilities' compliance issues at the time it granted TA to Ranbaxy's ANDAs, but senior FDA officials—at the Agency's highest levels, in multiple offices of the Agency—specifically considered and determined that those products were eligible for TA despite the known compliance issues at the relevant facilities. As a result, the Agency's decision to rescind its prior decisions granting TA to Ranbaxy's ANDAs

exceeds the Agency's statutory and constitutional authority, in violation of 5 U.S.C. §§ 706(2)(B) and (C).

45. ***Second***, FDA's Letter Decision conflicts with the plain language of the statute's failure-to-obtain TA forfeiture trigger, which merely requires the first-filer to receive a TA letter from the Agency within the 30-month deadline. 21 U.S.C. § 355(j)(5)(D)(i)(IV) (forfeiture occurs only if "the first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed."). The statute in turn defines TA as "notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot [yet] receive effective approval." *Id.* § 355(j)(5)(B)(iv)(II)(dd)(AA). TA thus requires no more than an act of notice by FDA, and whether FDA provided that notice to the ANDA applicant within the 30-month deadline is purely a matter of historical fact: Either FDA did issue such a notice or it did not.

46. It is undisputed that Ranbaxy's ANDAs in fact obtained TA within the thirty-month deadline set forth in the failure-to-obtain TA forfeiture trigger. Indeed, the Letter Decision itself expressly confirms the historical fact that Ranbaxy's generic Nexium® and Valcyte® ANDAs received TA within 30 months of their respective filing dates. *See* Exh. C at 1 ("FDA … tentatively approv[ed] ANDA 077830 [esomeprazole] on February 5, 2008, and ANDA 078078 [valganciclovir] on June 20, 2008."). Because the Letter Decision conflicts with the plain language of

the relevant statutory provision, it is arbitrary, capricious, and otherwise contrary to law, in violation of 5 U.S.C. § 706(2)(A).

47. ***Third***, FDA's Letter Decision cannot be squared with the plain text and structure of the statutory provisions that set forth the exclusive requirements for obtaining TA, on one hand, and final approval, on the other. Indeed, the Letter Decision impermissibly conflates the statutory standard for obtaining final approval—which requires FDA's acceptance of the ANDA applicant's proposed commercial production methods, facilities, and controls, 21 U.S.C. § 355(j)(4)(A)—with the statutory standard for obtaining TA, which merely requires the ANDA applicant to have provided a "full disclosure of" its proposed commercial production methods, facilities, and controls. *Id.* § 355(j)(2)(A)(vi) (cross-referencing *id.* § 355(b)(1)(D)). Once again, because the Letter Decision conflicts with the plain language of the statute, it is arbitrary, capricious, and otherwise contrary to law, in violation of 5 U.S.C. § 706(2)(A).

48. The Letter Decision is final agency action subject to immediate judicial review. Indeed, the Agency not only has rescinded Ranbaxy's TAs for these ANDAs and announced its determination that Ranbaxy has forfeited its exclusivity for generic Valcyte®, but has issued final approval to two competing generic Valcyte® ANDAs despite Ranbaxy's statutory right to 180-day exclusivity.

49. Neither defendants nor any other entity will suffer cognizable harm if the relief requested herein is granted, and the public interest will be served by such relief. By contrast, Ranbaxy has suffered and will continue to suffer substantial

and irreparable harms—in the form of permanently divested statutory rights and severe hardship to its business—unless and until the requested relief is granted.

PRAYER FOR RELIEF

WHEREFORE, Ranbaxy prays that this Court:

A. Declare that the FDA's November 4, 2014 Letter Decision violates the plain language of the federal Food, Drug & Cosmetic Act, 21 U.S.C. § 355, *et seq.*; exceeds the Agency's statutory authority, 5 U.S.C. § 706(2)(C); violates Ranbaxy's constitutional rights, 5 U.S.C. § 706(2)(B); and is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, 5 U.S.C. § 706(2)(A);

B. Declare that FDA may not approve or otherwise permit the introduction into interstate commerce of any ANDA product that references NDA Nos. 021153 or 021304 other than Ranbaxy's ANDA Nos. 077830 and 078078 until the conclusion of Ranbaxy's 180-day exclusivity periods;

C. Enjoin FDA from approving or otherwise permitting the introduction into interstate commerce of any ANDA product that references NDA Nos. 021153 or 021304 other than Ranbaxy's ANDA Nos. 077830 and 078078 until the conclusion of Ranbaxy's 180-day exclusivity periods;

D. Compel FDA to rescind and declare null *nunc pro tunc* any action that interferes with Ranbaxy's statutory rights to 180-day exclusivity for ANDA products referencing NDA Nos. 021153 or 021304; refrain from taking any further action that might interfere with Ranbaxy's statutory rights to 180-day exclusivity for ANDA products referencing NDA Nos. 021153 or 021304; and to proceed on

Ranbaxy's ANDA Nos. 077830 and 078078 in a manner not inconsistent with this Court's ruling; and

E. Provide such further relief as the Court may deem just and proper.

Dated: November 14, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 14th day of November, 2014, he caused the foregoing **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** to be served upon the following via messenger and/or electronic mail:

William B. Schultz
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