UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RANBAXY LABORATORIES, LTD. and RANBAXY, INC., Plaintiffs, v. SYLVIA MATHEWS BURWELL, in her official capacity as Secretary of Health and Human Services; MARGARET HAMBURG, M.D., in her official capacity as Commissioner of Food and Drugs; and UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	Case No. _____

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR A TEMPORARY RESTRAINING ORDER AND EXPEDITED PRELIMINARY INJUNCTION

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INTRODUCTION

This case involves a historically unprecedented decision by defendant U.S. Food and Drug Administration ("FDA" or "the Agency") that has the immediate effect of stripping plaintiffs Ranbaxy Laboratories, Ltd. and Ranbaxy, Inc. (together, "Ranbaxy") of their 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®. The Agency issued that decision with ***no prior notice*** to Ranbaxy. It gave Ranbaxy ***no opportunity to comment*** on the issues it adddressed. And, as set forth in greater detail below, the Agency had ***no power to issue that decision***—which not only rescinds decisions the Agency made more than six years ago after carefully considering all the relevant facts, but hinges on an interpretation of the FDCA that directly conflicts with the statute's plain text and structure.

Given the background against which it was issued, the Agency's decision also is outrageous. In full and direct reliance on the prior decisions FDA now has rescinded, Ranbaxy previously agreed to pay some $500 million to resolve related criminal and civil charges arising from its past submission of certain false statements to the government and prior failure to operate certain of its Indian manufacturing facilities in compliance with the Agency's required Good Manufacturing Practices ("GMPs"). Ranbaxy also agreed to remediate the affected facilities and cooperate with a series of audits designed to determine whether the company may have made other false statements to FDA in connection with its

pending generic drug applications (called "Abbreviated New Drug Applications" or "ANDAs")—including its ANDAs for generic versions of Nexium® and Valcyte®.

It should come as no surprise that the parties bargained exhaustively over the terms of those agreements. And they eventually agreed that, beyond the already-specified penalties, fines, and forfeited sums, Ranbaxy also would be required to withdraw the ANDAs at issue here if, and only if, the planned audits of those ANDAs revealed that one of two carefully specified conditions were met: (1) the relevant ANDA contained an untrue statement of material fact, or (2) the relevant ANDA contained a pattern or practice of data irregularities that called into question its reliability. *See* Consent Decree (1/25/12), *United States v. Ranbaxy Labs. Ltd., et al.*, No. 12-cv-250, Dkt. No. 2 at ¶ XV ("Consent Decree").

It would be hard to overstate the significance of those provisions. Each of the ANDAs at issue in this case was the first-filed ANDA that included a challenge to the applicable brand manufacturer's patents, and each thereby became eligible for a period of marketing exclusivity that would bar FDA from approving any other ANDA referencing Valcyte® or Nexium® until 180 days after Ranbaxy begins selling its products. The government expressly acknowledged Ranbaxy's eligibility for exclusivity in the course of negotiating the Consent Decree, and such exclusivity rights are extraordinarily valuable: Because the respective brand manufacturers' combined annual U.S. sales for the pertinent versions of these products exceed $4 billion, Ranbaxy's rights to 180-day generic marketing exclusivity for these products would have generated hundreds of millions of dollars in first-year net sales for the

company. But Ranbaxy's exclusivity for these products could, of course, be maintained only if the underlying ANDAs remained on file at FDA. In effect, then, a forced withdrawal of these ANDAs following an adverse finding in the agreed-upon data audits would have dramatically increased the penalties Ranbaxy otherwise agreed to pay, by depriving Ranbaxy of its right to an exclusive sales window for generic versions these widely prescribed drugs.

Since Ranbaxy entered those agreements, it has cooperated fully with the teams of independent and Agency investigators auditing the company's generic Nexium® and Valcyte® ANDAs—making hundreds of thousands of pages of documents available for review; making scores of company employees available for interviews, both here and in India; and opening every one of the company's facilities for inspection, announced or unannounced, without a moment's hesitation. Ranbaxy simply had nothing to hide: The ANDAs at issue here are unimpeachable, and the company knew that full cooperation with the government's audit would validate these submissions.

It did. On August 10, 2012, FDA completed its audit of Ranbaxy's generic Valcyte® ANDA and issued a formal letter (attached as Exhibit A to the Complaint) concluding that the company's generic Valcyte® 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." Compl. Exh. A at 2 (emphasis added). Then, last Tuesday, the Agency issued another formal letter (attached as Exhibit B to the Complaint) in which it likewise concluded 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." Compl. Exh. B at 2 (emphasis added). Those findings should have been the beginning and end of this long saga: With the integrity of these ANDAs having been validated by FDA after an extensive and exacting review, Ranbaxy should have been looking forward to the eventual approval of those ANDAs and the substantial revenues that its 180-day exclusivity rights for those products were expected to generate.

Then the other shoe dropped. Within minutes of conceding that there was nothing wrong with Ranbaxy's generic Nexium® ANDA, FDA issued yet another decision (the "Letter Decision," attached as Exhibit C to the Complaint) that effectively strips Ranbaxy of its statutory rights to marketing exclusivity for these products anyway. To reiterate, the Agency had given Ranbaxy ***no notice*** that it was considering the issues addressed in that letter. It had given Ranbaxy ***no opportunity*** to comment on the novel legal theory FDA apparently began considering once it realized the facts would not allow it to strip Ranbaxy's exclusivity under the Consent Decree. And just moments after emailing that decision to Ranbaxy, the Agency approved two generic Valcyte® ANDAs submitted by Ranbaxy's competitors—thereby authorizing them to flood the market with product before Ranbaxy could finish reading the Agency's second letter, much less secure judicial review of the Agency's historically unprecedented decision.

There is, of course, a reason why FDA chose to act in secrecy, deprive Ranbaxy of its right to be heard, and attempt to thwart Ranbaxy's ability to secure judicial review: The arguments set forth in its decision conflict directly with the statute's plain text and structure. And even if those arguments could be squared with the statute—and they cannot—FDA would have no power to act on them.

FDA's basic theory is that Ranbaxy effectively "forfeited" its 180-day exclusivity because the company allegedly failed to obtain "tentative approval" ("TA") for those ANDAs within 30 months of filing them with the Agency. Compl. Exh. C at 13 (citing 21 U.S.C. § 355(j)(5)(D)(i)(IV)). But Ranbaxy's ANDAs unquestionably ***did*** receive TA within 30 months of their filing; true and correct copies of the Agency's letters awarding TA to Ranbaxy's generic Nexium® ANDA (submitted August 5, 2005, TA notification dated February 5, 2008) and to its generic Valcyte® ANDA (submitted December 27, 2005, TA notification dated June 20, 2008) are attached as Exhibits D and E to the Complaint, respectively.

Undeterred by the facts, FDA now claims it made a "mistake" when it issued those TAs some six years ago because of the adverse "compliance status of the facilities referenced in the ANDAs at the time the ANDAs were granted [TA]." Compl. Exh. C at 12. But FDA knew all about the compliance issues at the relevant facilities when it issued those TAs. It not only had issued a formal Warning Letter to Ranbaxy before granting TA, ***but the parties repeatedly discussed <u>both</u> the impact of Ranbaxy's compliance issues on the company's eligibility for TA <u>and</u> the impact that withholding TA at that time would have on the***

company's first-to-file exclusivity rights. After carefully considering those issues, the Agency issued the TAs precisely in order to preserve Ranbaxy's eligibility for 180-day exclusivity—despite Ranbaxy's known compliance issues, and with full institutional awareness and a thorough understanding of the very issues now raised in its Letter Decision. FDA didn't make a "mistake." It simply has buyer's remorse.

Notwithstanding its mischaracterization of the record, however, the Agency decision exceeds any authority it otherwise might have to revisit its alleged "mistake." To the extent federal agencies sometimes have been said to possess an inherent power to correct their mistakes, it is well-settled that any such power must be exercised in a timely fashion, and in no event where the relevant agency simply changes its mind about a prior decision. Indeed, courts routinely hold that gaps of ***less than one year*** between an agency's initial decision and the date it notifies the decision's beneficiary of its intent to reconsider that decision are too long. We have not located a single case that has allowed an agency to revisit a decision ***more than six years after it was issued***. And there is no basis for making history here, not least of all given FDA's failure to even notify Ranbaxy that these issues even were on the table (much less provide Ranbaxy with an opportunity to comment).

Finally, the position set forth in the Letter Decision is meritless on its own terms. As a threshold matter, the "forfeiture trigger" FDA invokes has no applicability here. That clause provides for a forfeiture of exclusivity where "[t]he first applicant fails to obtain [TA] of the application within 30 months after the date

on which the application is filed," 21 U.S.C. § 355(j)(5)(D)(i)(IV), and therefore hinges solely on a matter of historical fact: Did the ANDA receive TA within 30 months or not? Here, it is undisputed that FDA issued formal written notifications awarding TA to these ANDAs within the statutory deadline, and the Agency can no more change that fact than it can rewrite history.

Moreover, FDA's Letter Decision ignores a critical exception built into the applicable forfeiture trigger. Even when the first applicant fails to obtain TA within the 30-month deadline, it will not forfeit exclusivity where "the failure is caused by a change in or a review of the requirements for approval." *Id*. To the extent FDA has the power to rewrite history (it doesn't), the very act of doing so here—where FDA has reversed its prior decision to award these TAs based on a new (and in any event meritless) interpretation of the statutory requirements—is precisely the sort of "change in or review of the requirements" that forecloses application of the forfeiture trigger.

FDA's interpretation of the TA provision is equally meritless. Though the Agency now claims that Ranbaxy's ANDAs were not eligible for TA because the facilities referenced in those ANDAs did not comply with then-current GMPs, the plain language of the statutory provision governing the award of TA—***in marked contrast to the plain language of the provision governing the award of final approval***—does not require GMP compliance. FDA's Letter Decision ignores the clear textual differences in these distinct statutory provisions, conflating the legal standards for TA with those for final approval and violating the cardinal rule that

such textual differences must be respected. For these reasons, Ranbaxy has an overwhelming likelihood of success on the merits.

The equities likewise favor the entry of injunctive relief. Both this Court and the D.C. Circuit repeatedly have recognized that the loss of 180-day exclusivity is a classic irreparable harm that warrants the entry of interim injunctive relief: "[T]he exclusivity reward that Congress made available as an incentive for patent challenges is time-sensitive," and "'the loss of [that] officially sanctioned head start' [is] an injury that would not be remedied by … securing 180 days of exclusivity later on." *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1311 (D.C. Cir. 2010). For that reason, courts routinely enter injunctive relief in cases where an FDA decision vitiates the first generic applicant's exclusivity period by approving—or threatening to approve—subsequently filed generic applications.

The result should be no different here, and given Ranbaxy's strong likelihood of success on the merits and the harms it already has suffered by FDA's decision to vitiate its statutory right to 180-day exclusivity, this Court immediately should order Defendants to rescind the approval of any ANDA referencing Valcyte® or Nexium® and restrain Defendants from approving any ANDA referencing Valcyte® or Nexium® until the conclusion of Ranbaxy's 180-day exclusivity period.

BACKGROUND

A. The Hatch-Waxman Framework

The approval process for new drugs is set forth in the Food, Drug and Cosmetic Act ("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."

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)).

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).

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

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

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.

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); 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.

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

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"],

[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).

> (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).

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."). 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).

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).

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 previous application has been submitted under this subsection cont[ain]ing 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, brand manufacturer AstraZeneca's latest annual report indicates that it sold more than $3.8 billion worth of Nexium® in 2013.

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®

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.

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).

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®

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.

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).

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

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.

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

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.

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.

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.

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." Compl. Exh. A at 2 (emphasis added). Last Tuesday, 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." Compl. Exh. B at 2 (emphasis added).

Mere 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.

Compl. Exh. C at 12.

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. 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.

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).

LEGAL STANDARD

In order to secure temporary injunctive relief, a plaintiff must establish "[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Aamer v. Obama*, 742 F.3d 1023, 1038 (D.C. Cir. 2014) (citing *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011), in turn quoting *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 20 (2008)). Ranbaxy readily meets all four prongs of this standard.

ARGUMENT

I. RANBAXY IS LIKELY TO SUCCEED ON THE MERITS.

Ranbaxy is likely to succeed on the merits of its claims that FDA's Letter Decision violates the Administrative Procedure Act (APA). That statute governs judicial review of federal agency action and provides that the courts "***shall*** … hold unlawful and set aside agency action, findings, and conclusions" in an array of circumstances. 5 U.S.C. § 706(2) (emphasis added).

Two grounds for reversal of agency action under Section 706(2) are relevant here. First, subsection (C) requires courts to vacate agency actions that are "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Nat'l Min. Ass'n v. Fowler*, 324 F.3d 752, 758 (D.C. Cir. 2003); *see also Elec. Power Supply Ass'n v. FERC*, 753 F.3d 216, 220 (D.C. Cir. 2014) ("If [an agency] lacks

authority … to promulgate a rule, its action is 'plainly contrary to law and cannot stand.'"); *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014) ("Congress … undoubtedly can limit an agency's discretion to reverse itself") (quoting *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008)). Second, subsection (A) requires courts to invalidate agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Under that provision, "agency interpretations must fall to the extent they conflict with statutory language." *Pub. Employees Ret. Sys. v. Betts*, 492 U.S. 158, 171 (1989); *City of Mesa, Ariz. v. FERC*, 993 F.2d 888, 893 (D.C. Cir. 1993); *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider[.]").

Though it often is said that judicial review of agency decisionmaking under the APA is "deferential," that is only true in cases of statutory interpretation where the text of the statute is ambiguous:

> ***If the intent of Congress is clear, that is the end of the matter***; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. … The judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent. ***If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect***.

Chevron, U.S.A., Inc. v. Natural Res. Defense Council, Inc., 467 U.S. 837, 842-43 & n.9 (1984) (emphasis added). As a result, federal agencies are not entitled to any deference when either the basis for their actions or the substance of their decisions

conflict with the statute they purport to be interpreting. *Betts*, 492 U.S. at 171 ("No deference is due to agency interpretations at odds with the plain language of the statute itself."). Nor do agencies receive deference when seeking to exercise purported "inherent powers" outside the scope of a specific congressional grant of authority. *Ivy Sports Med.,* 767 F.3d at 86 (addressing agency's authority without deference).

A. The Letter Decision Exceeds FDA's Statutory Authority.

1. FDA Did Not Make A "Mistake," But Instead Seeks Retroactively To Change Administrative Policy.

The sole premise for FDA's rescission of Ranbaxy's TAs is its claim that the Agency made a "mistake" when it decided to grant those TAs six years ago. Compl. Exh. C at 12. That characterization of the events giving rise to this case might be colorable if the Agency had discovered new facts that fundamentally change the basis for its earlier decisions. But it is utterly frivolous here.

Though FDA now claims it should not have granted these TAs due to the "compliance status of the facilities referenced in the ANDAs," *id.*, FDA in fact was well aware of the relevant facilities' compliance issues at the time it decided to grant TA to Ranbaxy's ANDAs. The Agency had of course issued a Warning Letter to the Paonta facility before granting the TAs, and the parties specifically and repeatedly discussed the impact that Ranbaxy's compliance issues might have on the products' eligibility for TA in the weeks and months before FDA issued its TAs. Indeed, should this case proceed beyond the TRO stage, the evidence will show ***that three separate offices—the Office of Generic Drugs, the Office of***

Compliance, and the Office of Chief Counsel—were involved in establishing a line of precedent under which the Agency granted TAs for both of these ANDAs; that the relevant decisionmakers had full knowledge of the compliance status of Ranbaxy's facilities when the Agency issued these TA decisions; and that the Agency granted these TAs for the very purpose of maintaining Ranbaxy's first-to-file exclusivity rights.

This simply is not a case where FDA suddenly discovered previously unknown facts that would have required the Agency to reach a different result if they had been known at the time, which explains why the Letter Decision does not even attempt to base its decision on the discovery of new facts. Instead, the Agency both knew and carefully considered every single fact on which the Letter Decision is based, and now seeks retroactively to change the administrative policies on which its TA decisions were based.

That is impermissible. To the extent agencies have any authority to revisit prior decisions, *but see infra* at 25-33, the courts long have warned that such decisions must be based on genuine errors—like the discovery of previously unknown facts—not mere shifts in administrative policy. *See, e.g.*, *Chapman v. El Paso Natural Gas Co.*, 204 F.2d 46, 53-54 (D.C. Cir. 1953) (holding that an agency may not repudiate its earlier decision "for the sole purpose of applying some quirk or change in administrative policy"); *Upjohn Co. v. Pennsylvania R.R.*, 381 F.2d 4, 6 (6th Cir. 1967) ("[T]he power to correct inadvertent ministerial errors may not be used as a guise for changing previous decisions because the wisdom of those

decisions appears doubtful in the light of changing policies.") (quotations omitted); *NLRB v. Majestic Weaving Co.*, 355 F.2d 854, 860 (2d Cir. 1966) (rejecting agency's "decision branding as 'unfair' conduct stamped 'fair' at the time a party acted"). Again, however, FDA was well aware of the compliance issues at Ranbaxy's facilities when it issued TA for these two ANDAs, and it carefully considered both those issues and the impact that withholding TA would have on Ranbaxy's exclusivity rights before deciding to issue those TAs. The Agency obviously wants to reverse course as a policy matter, but the foregoing authorities make clear that is not a permissible basis for revisiting those decisions.

2. FDA Lacks Statutory Authority To Rescind A Previously Issued TA, And Its Actions Violate The Statutory Constraints Congress Otherwise Imposed On The Withdrawal Of Final Approval.

Even if it somehow could be said that FDA did make a "mistake" here—and, again, it cannot—the Agency would be powerless to correct it now. Because federal agencies are created by Congress, they possess only those powers Congress has granted them. *New York v. FERC*, 535 U.S. 1, 18 (2002) ("[A]n agency literally has no power to act … unless and until Congress confers power upon it.") (citing *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)); *see also Elec. Power Supply Ass'n*, 753 F.3d at 220 ("FERC is a creature of statute and thus has no power to act unless and until Congress confers power upon it.") (citations omitted); *North Carolina v. EPA*, 531 F.3d 896, 922 (D.C. Cir. 2008) ("Lest EPA forget, it is a creature of statute, and has only those authorities conferred upon it by

Congress; if there is no statute conferring authority, a federal agency has none.") (citation and internal quotation omitted).

In marked contrast to the statutory provisions authorizing FDA to rescind a final approval in various circumstances, the FDCA grants FDA no authority to reconsider or revoke a previously issued TA. *Cf.* 21 U.S.C. § 355(e) (enumerating the conditions under which FDA can rescind final approval). And even if those provisions could be stretched to cover a previously issued TA (as opposed to a final approval), their terms unambiguously foreclose the Agency's actions here. After all, this subsection not only begins by requiring the Agency to provide "due notice and opportunity for hearing to the applicant" before rescinding an approval—a critical procedural right necessitated by basic Due Process principles, yet blatantly violated by the Agency here—but authorizes the Agency to rescind an approval based on deficiencies in the applicant's "methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug" ***only*** if the Agency's decision is issued "on the basis of new information before [it], evaluated together with the evidence before [it] when the application was approved." *Id.*

FDA actions are impossible to square with this unambiguous statutory mandate. Again, the Agency's Letter Decision was issued without any notice to Ranbaxy, much less the required hearing. And it was not remotely based on "new information" that differs from "the evidence before [FDA]" at the time TA was issued. *Id.* Instead, FDA knew every single fact on which the Letter Decision is based at the time it granted the TAs at issue in this case. It should go without

saying that FDA cannot rewrite the statute to assume for itself powers that Congress has withheld. *See, e.g.*, *United States v. Seatrain Lines, Inc.*, 329 U.S. 424, 432-33 (1947) (rejecting agency attempt to reconsider the award of a license, because the "certificate, when finally granted, and the time fixed for rehearing has passed, is not subject to revocation in whole or in part except as specifically authorized by Congress"); *Civil Aeronautics Bd. v. Delta Air Lines, Inc.*, 367 U.S. 316, 333-34 (1961) ("[S]upervising agencies desiring to change [prior determinations] must follow the procedures specifically authorized by Congress and cannot rely on their own notions of implied powers in the enabling act"); *see also Ivy Sports Med.*, 767 F.3d at 86 ("Congress … undoubtedly can limit an agency's discretion to reverse itself.") (quoting *New Jersey*, 517 F.3d at 583)).

3. FDA's Decision Is Untimely.

We of course acknowledge that courts occasionally have "assumed" that agencies might have certain "inherent authority" to reconsider prior decisions even absent statutory authority (though never, as here, in violation of the limits Congress has imposed on the exercise of statutory authority granted). *See Ivy Sports Medicine,* 767 F.3d at 86. But the U.S. Supreme Court has never embraced that assumption, which is at odds with the Court's repeated recognition that an agency's power to act necessarily is circumscribed by the powers conferred by its enabling legislation. *See, e.g.*, *New York*, 535 U.S. at 18. And even those lower courts that "assume" the existence of certain "inherent" agency authority to reconsider prior decisions have made clear that the scope of that authority is strictly circumscribed: To the extent such authority exists, it must be exercised ***"at least …***

in a timely fashion." *Ivy Sports Med.*, 767 F.3d at 86 (emphasis added); *Mazaleski v. Treusdell*, 562 F.2d 701, 720 (D.C. Cir. 1977) (reconsideration only appropriate where agency "does so within a reasonable period of time"); *see also Am. Methyl Corp. v. EPA*, 749 F.2d 826, 835 (D.C. Cir. 1984) (so-called implied authority, if legitimate, must be exercised within what would be the 30 or 60 day time to appeal an initial agency decision).

As the D.C. Circuit thus has warned, agencies can seek to reconsider a prior decision only if they act in matter of "weeks, not years." *Mazaleski*, 562 F.2d at 720 (citing *Gratehouse v. United States*, 512 F.2d 1104, 1109 (Ct. Cl. 1975), itself citing *Bookman v. United States*, 453 F.2d 1263, 1265-66 (Ct. Cl. 1972)); *see also Belville Mining Co. v. United States*, 999 F.2d 989, 1000 (6th Cir. 1993) (same) (citations omitted); *King v. Norton*, 160 F. Supp. 2d 755, 761 (E.D. Mich. 2001) (same); *Cabo Distr. Co. v. Brady*, 821 F. Supp. 601, 613 (N.D. Cal. 1992) (same).

FDA's Letter Decision does not remotely satisfy this well-settled standard. Far from acting in a "timely" fashion that can be measured in "weeks, not years," FDA's rescission of Ranbaxy's TAs for generic Nexium® and generic Valcyte® comes ***well over six years after*** it granted TA to Ranbaxy's generic Nexium® ANDA and ***nearly six years*** after it granted TA to the company's generic Valcyte® ANDA. Given the extraordinary passage of time since FDA granted the TAs at issue here, FDA's Letter Decision cannot possibly be considered a permissible exercise of any "inherent authority" the Agency conceivably could be thought to have.

Indeed, this Court repeatedly has rejected as untimely and therefore impermissible prior instances in which an agency purported to correct errors far more expeditiously than FDA has here. In *Prieto v. United States*, for example, this Court struck down an agency's attempt to reconsider a decision awarding trust status for the plaintiff's land that came ***nine months*** after the operative decision, holding "it completely clear that the Secretary exceeded his authority in reconsidering and in revoking the trust status of plaintiff's land" at that late date. 655 F. Supp. 1187, 1191-92 (D.D.C. 1987). And in *Gubisch v. Brady*, this Court likewise rejected an agency's attempt to reconsider its previous employment-related decision ***sixteen months after the original decision***, concluding that "the time period that elapsed in this case approaches the 'years' forbidden in *Mazaleski* rather than the 'weeks' permitted in that case," and holding that the government's "contention that there is no time limit on its ability to reopen its decisions is meritless." *Gubisch*, No. 88-cv-2031, 1989 WL 44083, at *10 (D.D.C. Apr. 20, 1989).

Other courts likewise have overturned agency reconsiderations made far faster than FDA's decision here. *See, e.g.*, *McAllister v. United States*, 3 Cl. Ct. 394, 396, 398 (1983) (holding agency powerless to act just ***thirty-two days*** after original decision); *Rosebud Sioux Tribe v. Gover*, 104 F. Supp. 2d 1194, 1202 (D.S.D. 2000) (holding ***five months*** unreasonable), *rev'd on other grounds sub nom. Rosebud Sioux Tribe v. McDivitt*, 286 F.3d 1031 (8th Cir. 2002); *C.J. Langenfelder & Son, Inc. v. United States*, 341 F.2d 600, 604-05 (Ct. Cl. 1965) (holding ***one year unreasonable***). Given that courts have rejected similar attempts to revisit past

decisions after mere weeks, months, and just over one year, there is no question that FDA lacks authority to revisit the six-year-old decisions at issue here.

4. FDA's Decision Impermissibly Abrogates Ranbaxy's Reliance Interests.

Finally, we note that the courts often have cautioned that it is particularly inappropriate for agencies to revisit past decisions—even if they act in a timely fashion—where reliance interests are at stake. *Confederated Tribes of Warm Springs Reservation of Oregon v. United States*, 177 Ct. Cl. 184, 191 (1966) (explaining that agency reconsideration "is especially dangerous if there has been reliance on the assumed finality of the decision"); *Prieto*, 655 F. Supp. at 1192 (refusing agency reconsideration where "plaintiff had built and contracted to lease storage facilities on the property, and had entered into a financing agreement for her billboard enterprise" and third-party that plaintiff contracted with expended over one-hundred thousand dollars relying upon original agency decision); *Rosebud Sioux Tribe*, 104 F. Supp. 2d at 1201 ("It sets an extremely dangerous precedent to act outside the bounds of established procedures and to internally reconsider an agency action within the context of litigation as the parties to the lease, who had already spent more than $5,000,000 in reliance on government action and approvals, 'watch from the sidelines.'"); *McAllister*, 3 Cl. Ct. at 398 (explaining agency reconsideration must be "timely" and regulated parties must "not [have] adversely changed their positions in reliance on [the original] decision.").

That rule has special force here. Ranbaxy relied heavily on the Agency's decisions granting TA to these ANDAs when it negotiated the terms of its Consent

Decree, and preserving its exclusivity on its important first-to-file products was Ranbaxy's principal objective during those negotiations. The company therefore made clear during the parties' negotiations that it would not voluntarily agree to give up its exclusivity rights in order to buy peace. In exchange for accepting what at the time was the most onerous set of restrictions ever written into an FDA consent decree, Ranbaxy instead insisted—and the government eventually agreed—that the company could maintain its right to exclusivity for these products unless the outside auditors or FDA concluded there was a fraud or disqualifying data integrity issue.

Put simply, the parties' eventual agreement depended on the Agency's prior decisions awarding TA and the company's resulting eligibility for 180-day exclusivity; that was the very predicate for the Consent Decree's terms. Had the government so much as hinted that FDA might one day rescind those TAs retroactively and thereby vitiate the company's exclusivity rights, the Consent Decree would have looked completely different than the one the parties signed. Years after the fact, it thus is particularly galling that FDA has unilaterally upended the parties' self-evident expectations. *See, e.g.*, *Branson v. Wirth*, 84 U.S. 32, 42 (1872) ("If one person is induced to do an act prejudicial to himself in consequence of the acts or declarations of another, on which he had a right to rely, equity will enjoin the latter from asserting his legal rights against the tenor of such acts or declarations."); *Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*, 467

U.S. 51, 61-62 (1984) ("When a private party is deprived of something to which it was entitled of right, it has surely suffered a detrimental change in its position.").

We also wish to emphasize that while Ranbaxy will bear the brunt of FDA's sudden reversal in this case, FDA's decision threatens ***every*** generic manufacturer. Upholding FDA's decision here would jeopardize the industry's reliance on the sanctity of the Agency's TA decisions, and raises the specter that ***any*** company now might lose one of its most valuable assets—in many cases, its single most valuable asset—at any time; without prior notice or opportunity to comment; and based not on newly discovered facts, but instead on retroactive changes in administrative policy.

Nor is this principle limited to generic drugs or cases involving FDA. The federal government makes thousands of decisions every day that profoundly affect the lives of individuals and businesses, from eligibility for Medicaid or veterans' benefits to the issuance government licenses or contracts. And the beneficiaries of those decisions necessarily organize their affairs based on their understanding that the government has spoken. Allowing the government to unilaterally reverse those decisions, with no notice, no opportunity to comment, in the absence of any new evidence, and years after the fact, is manifestly unfair and threatens to undermine every decision the government makes. *See, e.g.*, *Upjohn*, 381 F.2d at 5 ("The Commission's only basis for reversal of its prior decision is that, after some three years of elapsed time in a proceeding in another matter with the same factual situation, it has adopted a different policy, and therefore seeks to apply

retroactively its new policy. To permit such retroactive action would result in chaos and uncertainty of action for those who must rely on its findings.").

At bottom, FDA simply had no authority to correct its alleged "mistake" at this late date. Nothing in the FDCA authorizes the Agency to do what it did here, and its decision to wait over six years before attempting to revoke Ranbaxy's award of TA is leagues beyond what any court has ever contemplated. For these reasons, as well as those set forth below, Ranbaxy is likely to prevail on the merits.

B. The Letter Decision Conflicts With The Plain Language Of The Failure-To-Obtain TA Forfeiture Trigger.

Even if FDA did have the authority to revisit its earlier TA decisions, the Letter Decision still would be impossible to square with the statute. As set forth earlier, FDA's basic theory is that Ranbaxy forfeited its eligibility for 180-day exclusivity because it failed to obtain TA within 30 months of submitting those ANDAs to FDA for review. The record in this case and plain language of the statute foreclose that assertion.

The forfeiture trigger at issue in this case merely requires the first-filer to receive a TA letter from the Agency within the 30-month deadline. As relevant here, forfeiture occurs only if "[t]he first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed." 21 U.S.C. § 355(j)(5)(D)(i)(IV). 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 didn't, and FDA has no power to rewrite history. As a matter of text and logic, if FDA did provide notice of TA to an applicant within the statutory period, the forfeiture provision does not apply.

There is no dispute in this case that Ranbaxy's ANDAs obtained TA within the applicable statutory deadlines. Indeed, FDA's Letter Decision expressly confirms the historical fact that Ranbaxy's generic Nexium® and Valcyte® ANDAs received TA within 30 months of their respective filing dates. *See* Compl. Exh. C at 1 ("FDA … tentatively approv[ed] ANDA 077830 [esomeprazole] on February 5, 2008, and ANDA 078078 [valganciclovir] on June 20, 2008."). Under the applicable statutory definitions, those facts are true now and for all time. FDA's effort to undo TA and retroactively deprive Ranbaxy of its statutory right to 180-day exclusivity for these products is inconsistent with the statutory definition.

It also conflicts with the statute's conscious failure to authorize the withdrawal of TA once granted. As set forth above, the statute specifically authorizes FDA to withdraw a previously issued final approval but provides no such authorization to withdraw a previously issued TA. *Supra* at 25-27. The key point here, however, is slightly different than before: It is that the specific conditions under which Congress authorized FDA to withdraw a prior final approval illustrates the distinct character of final approval, on one hand, and TA, on the other. While TA is purely a matter of ***historical fact***, eligibility for final approval

is a matter of ***present status***. Just look at the triggers for withdrawing final approval, which authorize the Agency to constantly reconsider whether a given ANDA meets the requirements for approval on a continuing basis—for example, to reassess the drug's safety in light of "new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved," 21 U.S.C. § 355(e)(2), or reevaluate the drug's efficacy in light of "new information before him with respect to such drug." *Id*. at § 355(e)(3).

As these provisions illustrate, final approval is a continuing status: If its requirements cease to be met, such approval can and should be withdrawn; that's why the statute establishes a specific procedure for doing so. But once notice of TA has been provided, there is no way for FDA to undo it; that's why the statute lacks any provision for withdrawing it. The Agency's apparent belief that it can engineer a forfeiture of Ranbaxy's exclusivity by retroactively yanking the company's TAs for these two drug products thus fundamentally misconstrues the nature of TA. Once TA has been issued within the statutory window, that historical fact is established for all time; the forfeiture trigger simply does not apply.

Even if that trigger could apply ***in theory***, however, it would not apply ***here***. That is so because the trigger includes a critical exception where the applicant's failure to obtain TA is based on a subsequent "change in or a review of" the relevant approval requirements. *See* 21 U.S.C. § 355(j)(5)(D)(i)(IV). Prior precedent makes

clear that this is not a demanding standard: So long as "'***one*** of the causes of failure to get tentative approval by the 30-month forfeiture date was a change in or review of the requirements for approval imposed after the application was filed, an applicant will not forfeit eligibility even if there were other causes for failure to obtain tentative approval by the 30-month forfeiture date.'" *Mylan Labs. Ltd. v. FDA*, 910 F. Supp. 2d 299, 302 (D.D.C. 2012) (emphasis added) (quoting Mem. from Martin Shimer, Branch Chief, Regulatory Support Branch, Office of Generic Drugs ("OGD"), on 180-Day Exclusivity for Valsartan Tablets 1-2 (Sept. 28, 2012)).

Assuming *arguendo* that FDA could rescind Ranbaxy's TA's, its new insistence—six years after the fact—that Ranbaxy needed to satisfy then-current GMP requirements at the TA stage is precisely the sort of change in standards that triggers this critical exception. After all, FDA obviously did not consider GMP compliance a prerequisite to TA when it awarded TA to these ANDAs in 2008, after inspecting Ranbaxy's Paonta facility; documenting GMP deviations; and then issuing TAs following extensive discussion with Ranbaxy about the impact of the facilities' compliance status on both eligibility for TA and the relationship between TA and 180-day exclusivity. Should discovery in this case prove necessary, Ranbaxy further expects that a comprehensive review of FDA's records will reveal

prior instances in which the Agency has tentatively approved other ANDAs despite known compliance issues at the facilities from which those ANDAs originated.[2]

The plain language of the statute's forfeiture provision thus forecloses FDA's late-breaking assertion that Ranbaxy did not timely receive TA. As both a factual matter and legal matter, Ranbaxy did receive TA within the deadline—and even if it did not, the rationale FDA's Letter Decision hinges on brings Ranbaxy's ANDAs into the statutory exception. Again, Ranbaxy thus has a powerful likelihood of success on the merits.

C. The Letter Decision Impermissibly Conflates The Standards For Tentative Approval With Those For Final Approval.

Even if FDA could overcome the foregoing barriers, the entire premise of its decision—that the Agency made a "mistake" in granting TA because Ranbaxy's facilities were not GMP-compliant—rests on a fundamental misinterpretation of the statutory requirements for obtaining TA. Indeed, the Agency's decision ignores the statute's careful distinction between the requirements for obtaining TA and those necessary to receive a final, effective approval.

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[2] To the extent FDA claims that prior decisions support its position that GMP compliance always has been a prerequisite to TA, Compl. Exh. C at 4, nn. 16, 18, none of the purported Agency precedents FDA cites base the denial of TA on GMP noncompliance. Instead, those decisions reference current GMP status in the course of granting TA—just like the TA letters in this case. That hardly supports FDA's position that full compliance has always been considered a prerequisite to TA. Nor do the cases FDA cites. Not a single one arose from the denial of TA that resulted from the existence GMP issues; involved a dispute over whether the statute conditions TA on GMP compliance; or upheld the denial of TA in the face of a challenge to the newly announced standard applied in the Letter Decision.

Once again, the statute could not be more clear: It requires FDA to grant TA whenever the ANDA "meets the requirements of paragraph (2)(A)[.]" *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA). In turn, cross-referenced Section (j)(2)(A) provides that ANDAs must contain sufficient information to prove 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," *id.* § 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).

In contrast to these ***proof-based requirements***, Congress used fundamentally different language in addressing the TA-stage requirements that apply to the methods, facilities, or controls intended for use in the ultimate commercial production of a proposed ANDA product. By cross-reference to subsection (b)(1)(D) of the statute, Congress merely required the ANDA to include "***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(j)(2)(A)(vi) (requiring ANDAs to "contain … the items specified in clauses (B) through (F) of

subsection (b)(1) of this section"). Accordingly, and in sharp contrast to the proof-based prerequisites of subsection (j)(2)(A), the methods, facilities, and controls requirements applicable at the TA stage are satisfied by ***mere disclosure*** of the applicant's ultimate plans for commercial production.

FDA's inattention to the distinct language Congress used in this subsection of the statute is fatal to its position. After all, it is a cardinal rule of statutory interpretation that Congress acts deliberately when it chooses to use distinct words in different parts of the statute. *See, e.g.*, *Roberts v. Sea-Land Servs., Inc.*, 132 S. Ct. 1350, 1357 n.5 (2012) (invoking "'the usual rule that when the legislature uses certain language in one part of the statute and different language in another, the court assumes different meanings were intended'") (quoting *Sosa v. Alvarez-Machain*, 542 U.S. 692, 711, n.9 (2004) (additional internal quotation omitted)).

Indeed, Congress not only used different language to describe the various TA requirements ***within*** subsection (j)(2)(A), but ***between*** the TA requirements applicable to a given ANDA's methods, facilities, and controls and those required for final approval. Rather than replicate the TA subsection's requirement for a "full disclosure of" the applicant's methods, facilities, and controls, the final approval provisions set forth in subsection (j)(4) require FDA to "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***." *Id.* § 355(j)(4)(A) (emphasis added). In sharp contrast to the straightforward ***disclosure requirement*** incorporated by reference into the ***TA criteria*** set forth

in subsection (j)(2)(A)(vi), subsection (j)(4)(A) thus conditions ***final approval*** on ***proof that the applicant's methods, facilities, and controls are adequate***.

The upshot of these distinct statutory requirements—disclosure in subsection (j)(2)(A), on one hand, and acceptance in subsection (j)(4)(A)—is straightforward: Though ***final approval*** of an ANDA under subsection (j)(4)(A) is subject to FDA's acceptance of the proposed ANDA product's commercial production methods, facilities, and controls, ***TA*** under subsection (j)(2)(A) is not. Once again, FDA's decision cannot be squared with the clear distinctions Congress drew in the statute; it conflates the two standards entirely. *See, e.g.*, *Roberts*, 132 S. Ct. at 1357 n.5.

The Letter Decision barely grapples with the statutory language. Indeed, it studiously avoids it—simply paraphrasing the TA standard as requiring that a given ANDA must "***meet[] the substantive requirements for approval***." Compl. Exh. C at 3 (emphasis added). But that isn't what the statute says: The actual law Congress passed and the President signed instead requires the ANDA to "***meet[] the requirements of paragraph (2)(A)***." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA) (emphasis added). And when it comes to the adequacy of manufacturing facilities, the "requirements of paragraph (2)(A)" are not "substantive requirements for approval" at all; they are far more limited disclosure requirements. The Letter Decision impermissibly rewrites the statutory standard, time and again. *See, e.g.*, Compl. Exh. C at 7 ("If within 30 months after the date on which the [ANDA] is submitted, [it] has been determined by the agency to meet the statutory standards ***for approval*** … then an applicant will be given [TA] and will maintain eligibility

for 180-day exclusivity.") (emphasis added); *but see Utility Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2446 (2014) ("We reaffirm the core administrative-law principle that an agency may not rewrite clear statutory terms to suit is own sense of how the statute should operate.").

Beyond rewriting the statutory text, FDA's Letter Decision frustrates the statutory scheme in crucial ways. ANDA submissions often are based—indeed, most often are based—on development activities that take place at a different facility from the one where ultimate commercial production is planned, years before ultimate commercial production is slated to commence. The FDCA thus naturally contemplates that ANDAs can be entitled to TA long before they are ready for final approval and ultimate commercial production. Indeed, that is ***the very point*** of TA, which by design is granted before the statute otherwise would permit final approval, and which expressly presumes further Agency review prior to issuance of a final approval: "A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval ***until the Secretary issues an approval after any necessary additional review of the application***." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB) (emphasis added).

Against this backdrop, FDA's policy arguments hardly justify its position. Though the Agency's Letter Decision expresses concern that interpreting the statutory language to mean what it says "would require FDA to tentatively approve a product even when FDA knew that the product, if fully approved, would be deemed adulterated because it was made in a facility that did not comply with

CGMP," Compl. Exh. C at 4, that concern has no practical import: TA does not authorize an applicant to sell its product in the United States. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB) ("A drug that is granted tentative approval by the Secretary is not an approved drug and ***shall not have an effective approval until the Secretary issues an approval after any necessary additional review*** of the application") (emphasis added); *see also* 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."). Instead, TA simply recognizes that the applicant has satisfactorily proven that it has succeeded in developing a substantively equivalent product to the brand-name drug on which approval is based. Any manufacturing or compliance issues can be resolved before the company actually begins selling it.

Even so, FDA argues that following the statute's clear distinction between the standards for TA and final approval could undermine the "PEPFAR" program—a laudable administrative initiative intended to provide affordable HIV/AIDS drugs to impoverished countries. *See* Compl. Exh. C at 5. In particular, the Agency asserts that problems may result from granting TA to ANDA products developed at non-compliant facilities because PEPFAR authorizes applicants to begin marketing HIV/AIDS drugs outside the United States immediately upon receipt of TA. *Id.* That is no basis for rewriting the statute.

Whatever policies FDA has adopted with respect to those products—none of which are at issue in this case—the plain language of the statute makes clear that TA does ***not*** permit the introduction of a drug into interstate commerce: Again, a drug with TA is "***not*** an approved drug," *see* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB) (emphasis added), and so cannot be sold, *see id.* § 355(a). The fact that FDA apparently has exercised its enforcement discretion by refusing to enforce the statute as written for this narrow class of products hardly warrants a wholesale revision of the statute for all purposes. And there is no reason to construe PEPFAR as requiring FDA to exercise its enforcement discretion in the unlikely event that a manufacturer which has received TA despite known compliance issues begins marketing a given HIV/AIDS drug internationally. Suffice it to say, PEPFAR must yield to the statute, not vice versa. *See, e.g.*, *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (holding that FDA's general need to combat domestic shortages of medically necessary drugs does not justify its decision to allow the importation of misbranded or adulterated drugs for use in carrying out executions).

* * *

For the foregoing reasons, FDA's Letter Decision exceeds its statutory authority; is contrary to the FDCA; and cannot be sustained. Ranbaxy is thus likely to prevail against FDA on the merits.

II. RANBAXY WILL SUFFER IRREPARABLE HARM WITHOUT IMMEDIATE INJUNCTIVE RELIEF.

There is no serious question that immediate injunctive relief is necessary to prevent imminent and irreparable harm to Ranbaxy. FDA not only has determined

that Ranbaxy forfeited its statutory right to 180-day marketing exclusivity; it already has approved at least two competing ANDAs that could enter the market at any time. Barring injunctive relief, Ranbaxy not only will lose its statutory right to marketing exclusivity for all time—it will suffer hundreds of millions of dollars in losses that can never be recovered due to the government's sovereign immunity.

As this Court and the D.C. Circuit repeatedly have explained, the loss of a first applicant's 180-day exclusivity is a quintessential irreparable harm because it is impossible for the first ANDA challenger to obtain an effective judicial remedy after competing ANDA products enter the market. *Teva v. Sebelius*, 595 F.3d at 1311 (explaining that "the exclusivity reward that Congress made available as an incentive for patent challenges is time-sensitive" and that "'the loss of [the] officially sanctioned head start' [is] an injury that would not be remedied by [its] securing 180 days of exclusivity later on") (quoting *Mova*, 140 F.3d at 1066 n.6); *Mylan*, 910 F. Supp. 2d at 313 ("[C]ourts have held that a first applicant's loss of its statutory entitlement to the 180-day exclusivity period is irreparable because once lost 'it cannot be recaptured.'") (quoting *Apotex, Inc. v. FDA*, No. 06-cv-0627, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006), *summarily aff'd*, 449 F.3d 1249 (D.C. Cir. 2006)); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) ("Once the statutory entitlement has been lost, it cannot be recaptured.") (quotation omitted).

That is so because the Hatch-Waxman Act's 180-day exclusivity reward is a statutory right that it is immediately vitiated by the launch of competing products. And once the statutory right to an "'officially sanctioned head start'" is vitiated by

the launch of competing products, *Teva v. Sebelius*, 595 F.3d at 1311 (quoting *Mova*, 140 F.3d at 1066 n.6), the harms are extraordinary: In this case, where annual U.S. sales of the products at issues here easily exceed $4 billion, Ranbaxy stands to suffer hundreds of millions of dollars in lost sales.

The problem, of course, is that there is no conceivable make-whole relief for a first applicant like Ranbaxy once its competitors enter the market. A prospective recall of competing products is no answer: Once a consumer's prescription is filled with a competitor's product, it is impossible to "make up" for that lost sale by filling his or her ***next*** prescription; each tablet is consumed only once. Declaration of Dan Schober ¶ 13. Nor is an award of monetary damages: Ranbaxy has no legal remedy against competitors who lawfully enter the market pursuant to an FDA approval, and the only parties whose conduct is unlawful—defendants, who already have vitiated Ranbaxy's statutory right to marketing exclusivity—enjoy sovereign immunity that would preclude Ranbaxy from recovering monetary damages from them in the event this Court later overturns the FDA's ruling. *See, e.g.*, *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) ("Where a plaintiff cannot recover damages from an agency because the agency has sovereign immunity, 'any loss of income suffered by [the] plaintiff is irreparable *per se*.'") (quoting *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (alteration in original)), *aff'd sub nom. Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010) ("The district court's finding that this loss would be irreparable absent an injunction appears entirely reasonable."); *Brendsel v. Office of Fed. Hous. Enter. Oversight*, 339

F. Supp. 2d 52, 66 (D.D.C. 2004) (injunctive relief warranted because "plaintiff will be unable to sue to recover any monetary damages against either Freddie Mac or OFHEO"); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997) (FDA's immunity from damages means that "there is no adequate compensatory or other corrective relief that can be provided at a later date") (internal quotation marks omitted); *see also Entergy Ark., Inc. v. Nebraska*, 210 F.3d 887, 899 (8th Cir. 2000) ("The importance of preliminary injunctive relief is heightened in this case by the likely unavailability of money damages should the Commission prevail on the merits of its claims. Relief in the form of money damages could well be barred by Nebraska's sovereign immunity."); *Rum Creek Coal Sales, Inc. v. Caperton*, 926 F.2d 353, 361-62 (4th Cir. 1991) (holding plaintiff "will be prevented from recovering monetary compensation from the State"), *overruled on other grounds by Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346-47 (4th Cir. 2009); *Donohue v. Paterson*, 715 F. Supp. 2d 306, 316 (N.D.N.Y. 2010) ("[W]here a federal remedy to recover pecuniary losses is barred under the Eleventh Amendment, irreparable harm is present.") (citing *United States v. New York*, 708 F.2d 92, 93 (2d Cir. 1983)).

Again, that is why both this Court and the D.C. Circuit repeatedly have recognized that injunctive relief is both necessary and appropriate to preclude FDA from improperly divesting the first applicant of its statutory right to 180-day exclusivity. *See, e.g.*, *Teva v. Sebelius*, 595 F.3d at 1312 ("Teva faces an imminent threat of the same harm that has sufficed for Article-III injury purposes in all of our past drug-approval cases: the impending prospect of allegedly unlawful competition

in the relevant market.") (citing *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1497 (D.C. Cir. 1996) & *Ranbaxy Labs., Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006); *see also Mova*, 140 F.3d at 1066 n.6; *Sandoz*, 439 F. Supp. 2d at 32; *Torpharm, Inc. v. Shalala*, No. 97-1925, 1997 WL 33472411, at *4 (D.D.C. Sept. 15, 1997). There thus is no question that immediate injunctive relief is necessary to prevent Ranbaxy from suffering imminent, irreparable harm.

III. THE BALANCE OF HARDSHIPS AND PUBLIC INTEREST FAVOR IMMEDIATE INJUNCTIVE RELIEF.

The final equitable factors—the balance of hardships and public interest—likewise favor granting immediate injunctive relief. With respect to the former, FDA is a federal agency and cannot seriously claim that it would be "harmed" by an injunction requiring it to apply Hatch-Waxman in a manner consistent with the statutory text. And while other ANDA applicants who seek to market their versions of generic Nexium® and/or Valcyte® will temporarily be unable to do so because of Ranbaxy's exclusivity right, they stand to be just "one of just a few generics in the … market" and "rewarding runners-up was not Congress's object." *Mylan*, 910 F. Supp. 2d at 313; *see also Mylan Pharms., Inc. v. Sebelius*, 856 F. Supp. 2d 196, 217 (D.D.C. 2012) (explaining that in contrast to the first applicant, subsequent filers "would lose a ***shared*** head start and a smaller share of profits because it would be one of potentially [several] generics in the … market") (emphasis in original); *Apotex*, 2006 WL 1030151, at *17 ("[U]nlike the harm that [subsequent Paragraph IV challenger] Apotex allegedly faces, the potential injury that the intervenor-defendants [including first Paragraph IV challenger Teva USA] face is not 'merely

economic.' Rather, [the first filers] stand to lose a statutory entitlement, which is a harm that has been recognized as sufficiently irreparable.") (citing *Mova*, 140 F.3d at 1067 n.6).

Finally, the public interest decisively favors granting injunctive relief. Congress determined that the public interest is best served by providing 180 days of exclusivity as a "reward for generics that stick out their necks (at the potential cost of a patent infringement suit)." *Teva v. Sebelius*, 595 F.3d at 1318. The Agency's decision fundamentally undermines the engine that drives Hatch-Waxman—and it does so in a historically unprecedented fashion. Again, Ranbaxy entered into a comprehensive settlement of civil and criminal charges arising from its past compliance issues in India by agreeing to the largest monetary penalty FDA had ever secured and the most onerous terms it had ever imposed—all in reliance on the government's agreement that the company could maintain its statutory right to exclusivity for these products so long as its ANDAs survived a comprehensive audit, as they did.

We also wish to underscore that the government's actions in this case have ramifications that extend well beyond the facts of this case, the parties to this case, or even the generic drug industry as a whole. Allowing the government to flout its commitments and reverse years-old decisions that formed the basis for a comprehensive Consent Decree without affording its counterparty any notice of its intentions (much less providing an opportunity to comment), would make it far more difficult for both the government and the public to resolve future disputes

outside of court. After all, settlements, consent decrees, and plea bargains necessarily are premised on joint and mutual representations that each side will faithfully abide by what they have agreed to do. If the government can renege on its bargains, eviscerate the factual predicate for the deals it reaches, and get away with imposing hundreds of millions of dollars in irremediable losses on the parties with whom it settled, then it is the public at large who loses—and loses large. *Moragne v. States Marine Lines, Inc.*, 398 U.S. 375, 403 (1970) ("The confidence of people in their ability to predict the legal consequences of their actions is vitally necessary to facilitate the planning of primary activity and to encourage the settlement of disputes without resort to the courts."); *see also Brandt v. Hickel*, 427 F.2d 53, 57 (9th Cir. 1970) ("To say to these [plaintiffs], 'The joke is on you. You shouldn't have trusted us,' is hardly worthy of our great government."). There is thus a powerful public interest in making clear that the government's actions in this case are unacceptable, unlawful, and must be enjoined.

CONCLUSION

For the foregoing reasons, Ranbaxy respectfully requests that this Court grant its motion for a temporary restraining order and expedited preliminary injunction.

Dated: November 14, 2014

Respectfully submitted,

By: /s/ Michael D. Shumsky

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 14th day of November, 2014, he caused the foregoing **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR A TEMPORARY RESTRAINING ORDER AND EXPEDITED PRELIMINARY INJUNCTION** to be served upon the following via messenger and/or electronic mail:

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