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September 27, 2010

By Federal Express

Jan Horbaly
Clerk of Court
U.S. Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

Re: Appeal No. 2009-1593

Dear Mr. Horbaly,

I write on behalf of appellant Teva Pharmaceuticals USA, Inc., through its GATE Pharmaceuticals division ("Appellant"), to inform the Court of two changes in the factual background underlying this appeal, which was argued on May 3, 2010. Appellant's Opening Brief noted at page 6 that the separate ANDA filed in the name of Teva Pharmaceuticals USA, Inc. had been finally approved by the FDA in April 2008. On September 17, 2010, however, the Food & Drug Administration revoked the final approval of the Teva ANDA and instead changed its status to tentatively approved. A copy of the FDA's September 17, 2010 letter is attached. In addition, Appellant's Opening Brief noted at page 33 that Teva was engaged in ongoing litigation challenging the enforceability of the donepezil compound. On July 19, 2010 a Stipulation was entered in the District Court staying activity in the underlying case challenging the compound patent covering donepezil until the case becomes moot after the patent expires on November 25, 2010. A Copy of the July 19, 2010 Stipulation is attached.

The issue presented in this appeal involves the separate ANDA filed in the name of GATE Pharmaceuticals. The change in the status of the Teva ANDA does not change the arguments advanced by Appellant as to why a declaratory judgment regarding the unasserted Orange Book patents was necessary to prevent Ranbaxy's 180-day exclusivity resulting from it being the first filer with regard to those patents from potentially indefinitely blocking generic competition. Indeed, as a result of the recent FDA action, the Teva ANDA is also subject to potentially indefinite blocking arising from Ranbaxy's 180-day exclusivity.

The change in status of the Teva ANDA does directly impact one argument raised by the Appellees. At pages 31-32 of the Appellees' brief, they argue that Teva can market donepezil under its first ANDA and then selectively waive Teva's 180-day exclusivity in favor of the GATE ANDA, providing an alternate route to the market for the GATE ANDA product. As a result of the change in status of the Teva ANDA, there is no such possibility.

The Stipulation staying litigation activity in the underlying case does not mean that the *Janssen* case controls the outcome of the appeal from the dismissal of the GATE declaratory judgment action. The Teva parties did not stipulate to the validity of the compound patent, as happened in the *Janssen* case. The Stipulation staying activity in the underlying compound patent case was a result of the patentee's statement that the case could not be tried and decided before expiration of the compound patent on November 25, 2010. As explained in Appellant's Reply Brief at pages 13-20, even if there is no judgment on the enforceability of the underlying compound patent, a declaratory judgment on the unasserted patents is still necessary because of the circumstances that create a risk that Ranbaxy will not launch promptly upon expiration of the compound patent in November.

Respectfully,

Francis C. Lynch

cc: Bruce Wexler, Esq.

LIBA/2117714.1

EXHIBIT 1

ANDA 077344

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-8474

FAX TRANSMISSION COVER SHEET

DATE: September 17, 2010

TO: APPLICANT: Teva Pharmaceuticals USA TEL: 215-591-3141

ATTN: Philip Erickson FAX: 215-591-8812

FROM: Bob Gaines PROJECT MANAGER: 240-276-8495

TOTAL NUMBER OF PAGES : 17
(EXCLUDING COVER SHEET)

Special Instructions: Good morning Mr. Erickson. Please see the attached fax regarding your ANDA 077344 for Donepezil.

Thank you

Bob

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077344

TEVA Pharmaceuticals USA
Attention: Philip Erickson
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454-1090

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 26, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act), for Donepezil Hydrochloride Tablets, 5 mg and 10 mg (donepezil). We also refer to the approval letter for that application issued by this office on April 28, 2008.

This letter notifies you that, for the reasons set forth in the attached letter, FDA has concluded that its April 28, 2008 approval letter for ANDA 077344 was issued in error and, effective immediately, the Agency is correcting its error by converting the status of ANDA 077344 from approved to tentatively approved.

Any Supplemental ANDAs (approved or unapproved) or Annual Report Changes filed to this ANDA since April 28, 2008 are considered WITHDRAWN and must be re-submitted; these should be re-submitted in full as either a "MINOR / MAJOR Amendment to the Original" or as a new Supplemental ANDA once final approval has been obtained again.

Final approval of this ANDA cannot be granted until the date that:

1. a. the court decides that the Patent 4,895,841 ("the '841 patent) is invalid or not infringed, or

   b. the '841 patent has expired; and

2. any applicable 180-day exclusivity period has expired; and

3. the application otherwise meets the applicable requirements for approval.

To request final approval, please submit a "MINOR AMENDMENT – FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should include a copy of a court decision, or a settlement or licensing agreement, if Teva relies on any such decision, settlement, or license as a basis for asserting that

its product is approvable. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, *i.e.*, updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the requested information. Failure to submit either, or if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practice (cGMP) are subject to Agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the act, and will not be listed in the Orange Book.

For further information regarding this issue, please contact Cecelia Parise, R.Ph., Regulatory Policy Advisor to the Director, Office of Generic Drugs, at (240) 276-9310.

Sincerely yours,

{See appended electronic signature page}

Keith O. Webber
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST
09/17/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

William B. Shultz, Esq.
Zuckerman Spaeder LLP
1800 M Street, NW
Suite 1000
Washington, DC 20036-5807

Robert A. Dormer, Esq.
Kurt R. Karst, Esq.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, NW
Suite 1200
Washington, DC 2005-5929

Dear Mr. Shultz, Mr. Dormer, and Mr. Karst:

This letter responds to correspondence submitted on behalf of your clients, Ranbaxy Laboratories Limited ("Ranbaxy") and TEVA Pharmaceutical USA (Teva), regarding TEVA Pharmaceutical USA's (Teva's) abbreviated new drug application for Donepezil Hydrochloride Tablets, 5 mg and 10 mg (donepezil). On May 15, 2008, Ranbaxy contacted FDA regarding the approval of Teva's ANDA on April 28, 2008, arguing that, as discussed in more detail below, the approval was inappropriate because Ranbaxy was eligible for 180-day exclusivity for its donepezil ANDA. Following FDA's receipt of this letter, Teva and Ranbaxy agreed to submit letters to FDA on this issue and to provide each other with a copy of each letter submitted to FDA. In accordance with an agreed-upon schedule, Ranbaxy submitted a letter on June 26, 2008, and Teva submitted a letter on June 2, 2008. In addition, Teva submitted letters on this issue dated August 28, 2008, October 14, 2008, and October 21, 2009, and Ranbaxy submitted letters dated July 2, 2008,[1] July 17, 2008, October 31, 2008, October 8, 2009, August 19, 2010, and September 13, 2010. On September 16, 2008, Teva representatives met with representatives from the Agency to further discuss the issue. Representatives from Ranbaxy met with the Agency on September 3, 2008, on this issue as well.[2]

After careful consideration of the information presented, as well as other information available to the Agency, as set forth below, FDA has concluded that approval for Teva's ANDA was issued in error for two reasons. As explained in detail below, had FDA been aware on April 28, 2008, that a court in patent litigation involving Teva's donepezil ANDA had issued a preliminary injunction prohibiting Teva from commercially marketing its donepezil product, the Agency would not have granted approval, pursuant to section 505(j)(5)(B)(iii)(III) or (IV) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act). Additionally, and independent of the foregoing, FDA should not have approved Teva's donepezil ANDA on April 28, 2008, because approval of Teva's application was blocked by Ranbaxy's 180-day exclusivity for its donepezil

[1] In later submissions, Ranbaxy also argued that approval of Teva's ANDA on April 28, 2008, was inappropriate because Teva was, at the time of approval, subject to a preliminary injunction issued in related patent litigation.

[2] We also note that there are currently two citizen petitions pending related to Teva's donepezil ANDA (Dockets No. FDA-2009-P-0326 and FDA-2010-P-0430), to which the Agency will respond separately.

ANDA. Accordingly, via separate correspondence, the Agency is converting the status of Teva's donepezil ANDA from final approval to tentative approval.

Background

The reference listed drug (RLD) upon which Teva and Ranbaxy based their donepezil ANDA, Eisai Inc.'s (Eisai's) Aricept (donepezil hydrochloride) Tablets, is subject to periods of patent protection. The following patents with their expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
4,895,841 (the '841 patent)	November 25, 2010
5,985,864 (the '864 patent)	December 30, 2016
6,140,321 (the '321 patent)	December 30, 2016
6,245,911 (the '911 patent)	December 1, 2018
6,372,760 (the '760 patent)	March 31, 2019

With respect to each of these patents, Teva's ANDA contains a certification submitted pursuant to section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of Donepezil Hydrochloride Tablets, 5 mg and 10 mg, under this ANDA ("paragraph IV certification"). Ranbaxy also included in its ANDA paragraph IV certifications to four of the patents listed above (*i.e.*, the '864, '321, '911, and '760 patents), as well as a certification pursuant to 505(j)(2)(A)(vii)(III) ("paragraph III certification")[3] to the '841 patent. According to the submissions by Teva and Ranbaxy, Teva was the first applicant to submit an ANDA containing a paragraph IV certification to the '841 patent, while Ranbaxy was the first applicant to submit an ANDA containing paragraph IV certifications to all of the other listed patents.[4]

Neither Ranbaxy nor Teva was sued by Eisai for infringement of the '864, '321, '911, and '760 patents. However, Eisai initiated litigation against Teva for infringement of the '841 patent in the United States District Court for the District of New Jersey, *Eisai Co., Ltd. v. Teva Pharm. USA, Inc.*, Civ. No. 05-5727 (D.N.J. filed Dec. 7, 2005), within 45 days of receipt of notice from Teva of its submission of a paragraph IV certification, thereby triggering a 30-month stay of approval of Teva's ANDA. *See* FDCA § 505(j)(5)(B)(iii). Unbeknownst to FDA at the time, on March 28, 2008, the court granted a preliminary injunction that "restrained and enjoined [Teva] from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product containing donepezil or a pharmaceutical acceptable salt thereof, as claimed in United States Patent No. 4,895,841." *Eisai*

[3] A paragraph III certification indicates that an ANDA applicant does not intend to market its product until the date on which the patent that is the subject of the certification expires.

[4] According to court filings, Teva submitted paragraph IV certifications to the '864, '321, '911 and '760 patents in December 2004, and amended its ANDA in October 2005 to include a paragraph IV certification to the '841 patent. Ranbaxy's ANDA, which was filed in June 2003, contained a paragraph III certification to the '841 patent, and paragraph IV certifications to all of the remaining patents.

Co., Ltd. v. Teva Pharm. USA Inc., No. 05-5727, 2008 U.S. Dist. LEXIS 33747, at *38-39 (D.N.J. Mar. 28, 2008).

Neither Eisai nor Teva informed FDA of the existence of the preliminary injunction.[5] Although there is no FDA regulation that explicitly requires an ANDA applicant to notify FDA of the entry of a preliminary injunction against it, FDA regulations make clear, and experienced ANDA applicants are well aware, that FDA does not monitor private patent litigation but, instead, depends on applicants to keep it apprised of pertinent developments in relevant patent litigation. *See, e.g.*, 21 C.F.R. § 314.107(e) (requiring an applicant to submit a copy of the order or judgment to FDA within 10 working days of a final judgment); 21 C.F.R. § 314.50(i)(6)(iii)(A); 314.94(a)(12)(viii)(C)(*1*) (requiring an applicant to amend its patent certification if, at any time before the approval of the application, the applicant learns the certification is no longer accurate).

On April 28, 2008, the Agency approved Teva's ANDA because: the 30-month period identified in section 505(j)(5)(B)(iii) of the Act had expired; FDA was unaware at the time of the preliminary injunction that had been issued in the patent litigation on the '841 patent; and Teva had not been sued within the statutory 45-day period with respect to the remaining listed patents.

On July 19, 2010, the New Jersey district court entered a Stipulation and Order of Stay and Dismissal, staying the litigation through November 25, 2010 (the date the '841 patent expires), and dismissing the litigation as moot as of November 26, 2010. *Eisai Co., Ltd. v Teva Pharms. USA Inc.*, Civ. No. 05-5727 (D.N.J. July 19, 2010) (stipulation and order of stay and dismissal). The Stipulation and Order clarifies that the March 28, 2008 preliminary injunction remains "in full effect until and including the date of expiration of U.S. Patent No. 4,895,841 on November 25, 2010." *Id.* at 2. Thus, according to the terms of the July 19, 2010 Stipulation and Order, a decision on the merits of Teva's unenforceability defense is not expected to be issued.[6]

Had FDA been aware, on April 28, 2008, of the March 28, 2008 preliminary injunction in the patent litigation, it would not have issued the final approval letter. Moreover, as explained below, in approving Teva's ANDA, FDA also failed to properly consider the 180-day exclusivity issues raised by these applications. Specifically, because there was no mutually blocking exclusivity with respect to Teva's and Ranbaxy's ANDAs, FDA's "shared exclusivity" policy, which would permit approval of the Teva ANDA, did not apply. Ranbaxy submitted a paragraph III, not a paragraph IV, certification to the '841 patent, and, thus Ranbaxy was barred from approval by its own decision not to seek approval before the '841 patent had expired, not by Teva's paragraph IV certification to the '841 patent. Upon more fully considering this matter, FDA has concluded that at the time of approval of Teva's ANDA's, Teva was barred from approval by Ranbaxy's exclusivity on the '864, '321, '921, and '760 patents. Because Ranbaxy

[5] Indeed, we note that Eisai did not contact the Agency regarding the approval status of Teva's donepezil ANDA until August 13, 2010, when the Agency received Eisai's citizen petition requesting, among other things, that final approval of Teva's ANDA be revoked. *See* Letter from David M. Fox (on behalf of Eisai) to FDA Division of Dockets Management, Docket No. FDA-2010-P-0430 (Aug. 12, 2010).

[6] In reference to this stipulation, counsel for Eisai represented to the court that the parties "have an agreement in principle...that the parties take no further action in the case, through November 25th, when the patent expires. And, that would essentially maintain the status quo until that date." *Eisai Co., Ltd v. Teva Pharms. USA, Inc.*, Civ. No. 05-5727 (D.N.J. July 7, 2010) (transcript of telephonic hearing).

was not barred from approval by Teva's exclusivity on the '841 patent, shared exclusivity should not have applied here. Therefore, the approval of Teva's ANDA for donepezil on April 28, 2008, was also in error because approval of Teva's ANDA is blocked by Ranbaxy's eligibility for 180-day exclusivity for that drug.[7]

We note that, when the issues in this matter were initially brought to the Agency by Teva and Ranbaxy in 2008, both parties acknowledged that a court decision on the merits of the patent claims might be forthcoming. If such a decision had been issued, it might have obviated the need for FDA to have resolved this dispute; however, it now appears that no such a decision will be issued.[8]

Indeed, recent developments in the underlying patent litigation emphasize that Teva has effectively abandoned its court challenge to the '841 patent,[9] and that a decision on this matter by FDA is necessary. It has come to FDA's attention that Teva and its co-defendants have moved the court to modify or clarify the preliminary injunction entered on March 28, 2008, with a motion date set for September 20, 2010. *See Eisai Co., Ltd. v Teva Pharms. USA Inc.*, Civ. No. 05-5727 (D.N.J. Aug. 13, 2010) (Defendants' Notice of Motion for Clarification or Modification of the Preliminary Injunction) (Aug. 13, 2010); *Eisai Co., Ltd. v Teva Pharms. USA Inc.*, Civ. No. 05-5727 (D.N.J. Aug. 19, 2010) (Consent Order). Although Teva's motion to clarify has been filed under seal, the Agency's determination regarding the approval status of Teva's donepezil ANDA may be relevant to the court's decision.

Discussion

Teva's ANDA was not Eligible for Final Approval Because Entry of the Preliminary Injunction Triggered an Extension of the 30-Month Stay

Under sections 505(j)(5)(B)(iii) of the Act, approval of an ANDA shall be effective upon

[7] The Agency generally makes determinations regarding 180-day exclusivity only when it is in the position to either approve an application that may be eligible for 180-day exclusivity, or to act on a subsequent applicant's ANDA as to which final approval may be delayed by another application's eligibility for exclusivity. As referenced above, Ranbaxy was the first applicant to submit an ANDA containing paragraph IV certifications to the '864, '321, '911, and '760 patents listed for Aricept. As of April 28, 2008, the date on which Teva's ANDA was approved, and as of the date of this letter, Ranbaxy is eligible for 180-day exclusivity for its donepezil ANDA, subject to applicable future events (*e.g.*, forfeiture, patent expiration).

[8] In its October 14, 2008 letter, Teva asserts that FDA's April 28, 2008 approval of Teva's ANDA "will have a practical effect only if Teva prevails in its patent case prior to the patent's expiration." If the court had decided that the '841 patent was valid and would be infringed by Teva's ANDA, and that no defenses to infringement applied, the court would have likely issued an order under 35 U.S.C. § 271(e)(4), ordering the approval of Teva's ANDA to be effective no earlier then the expiration of the '841 patent. Had such an order been issued, FDA would have converted the status of the Teva ANDA from approved to tentatively approved. Thus, such a decision by the court would have rendered moot any decision by FDA on the approval date of Teva's ANDA, Teva would no longer have any claim on eligibility to exclusivity, and its approval would be subject to Ranbaxy's exclusivity.

[9] Once the '841 patent expires, any issues of patent infringement or validity will become moot, and any claim to exclusivity by Teva as to the '841 patent would be extinguished. *See Mylan Labs., Inc. v. Leavitt*, 484 F. Supp.2d 109, 122-23 (D.D.C. 2007). Further, upon expiration of the '841 patent, there will no longer be any patent barrier to approval of Ranbaxy's donepezil ANDA. The timing of approval of other ANDAs for donepezil will be governed by, among other things, Ranbaxy's 180-day exclusivity.

expiration of the 30-month period except that--

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed--

(aa) if the judgment of the district court is appealed, the approval shall be made effective on--

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

On March 28, 2008, prior to the expiration of the 30-month stay of approval triggered by the initiation of patent litigation, the New Jersey district court granted a preliminary injunction prohibiting Teva from engaging in the commercial manufacture, use, offer to sell, or sale of any drug product containing donepezil. As contemplated by subsections 505(j)(5)(B)(iii)(III) and (IV), the injunction prohibits the applicant from engaging in commercial manufacture or sale of the drug "until the court decides the issues of patent validity and infringement." Although the court found in its assessment of the preliminary injunction factors that Teva was not likely to succeed in its sole remaining defense to infringement of the '841 patent, to date the court has not

decided and entered judgment on the remaining issues of patent validity and infringement.

As noted above, FDA was unaware of the preliminary injunction when it approved Teva's ANDA on April 28, 2008. FDA must now decide whether, given the existence of the preliminary injunction, its approval of that ANDA was in error. FDA's decision on this matter is governed by its interpretation of 505(j)(5)(B)(iii), which, in turn, is governed by the principles described in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). Under a *Chevron* analysis, the first question is whether section 505(j)(5)(B)(iii) of the Act unambiguously required FDA to approve Teva's ANDA on April 28, 2008 (at the end of the 30-month period), despite the entry of the March 28, 2008 preliminary injunction by the New Jersey district court. *Id.* at 842-43. FDA concludes that section 505(j)(5)(B)(iii) of the Act is ambiguous as to what happens at the end of the 30-month period when a preliminary injunction has issued before the end of the 30-month period, but a court decision on the merits of the patent infringement and validity claims has not been entered by that time. Where, as here, the plain language of the statute is ambiguous, the next inquiry must be whether the Agency's proposed interpretation "is based on a permissible construction of the statute." *Id.* at 843.

FDA interprets section 505(j)(5)(B)(iii) of the Act to conclude that the 2008 approval of Teva's ANDA was in error because entry of the preliminary injunction in the underlying patent litigation triggered an extension of the 30-month stay until a court decision on the merits was issued. Section 505(j)(5)(B)(iii) of the Act instructs FDA when to approve an ANDA that is subject to a 30-month stay, taking into account certain events that occur during the underlying patent litigation. Specifically, subsections 505(j)(5)(B)(iii)(I) and (II) address when the approval of an ANDA that is the subject of a 30-month stay becomes effective when a decision on the issues of patent validity and infringement is made and a judgment is entered reflecting that decision.[10] Subsections 505(j)(5)(B)(iii)(III) and (IV), on the other hand, describe the effect on the timing of approval of a preliminary injunction entered prior to expiration of the 30-month period. In our view, under the better interpretation of subsections (III) and (IV), if a preliminary injunction is entered before expiration of the 30-month stay, the stay on approval is extended until the court decides the issues of patent infringement and validity. Once such a decision is made, the references to sections 505(j)(5)(B)(iii)(I) and (II) provide for the timing of approval. *See* FDCA §§ 505(j)(5)(B)(iii)(III) & (IV).

[10] Section 505(j)(5)(B)(iii) clearly contemplates that the decision on the patent infringement and validity issues (and a corresponding judgment reflecting such a decision) and the entry of a preliminary injunction prohibiting commercial marketing of a generic product are two separate events. With reference to the former, the statutory language links a decision on the issues of patent invalidity and infringement with the entry of judgment reflecting such a decision. As Teva noted in its October 14, 2008 letter, "a district court's preliminary injunction is just that: *preliminary*." Courts have long recognized that preliminary injunctions are distinguishable from final judgments, and merely reflect a consideration of the plaintiff's likelihood of success on the merits rather than a decision on the merits. *See, e.g., West Va. Ass'n of Comm. Health Ctrs., Inc. v. Heckler*, 734 F.2d 1570, 1578 (D.C. Cir. 1984). This is reflected is subsections (III) and (IV) which refer to "a preliminary injunction...*until the court decides the issues of patent validity and infringement*" (emphasis added), making clear that both are separate events. Further, as discussed in *Sanofi-Aventis v. FDA*, the date a court "enters judgment" is a "specific, unambiguous event described in Federal Rule of Civil Procedure 58." *Sanofi-Aventis v. FDA*, slip op. at 9, Civ. Action No. 09-1495 (RMU) (D.D.C. July 26, 2010). A preliminary injunction is entered pursuant to Rule 65 of the Federal Rules of Civil Procedure and, therefore, a separate event from those described in subsections 505(j)(5)(B)(iii)(I) and (II).

In its October 14, 2008 letter, Teva argues that subsections 505(j)(5)(B)(iii)(III) and (IV) of the Act "do not require the Agency to delay approval an ANDA upon the expiration of the 30-month stay," based on the entry of a preliminary injunction alone. Teva asserts that the exception to approval upon expiration of the 30-month stay contained in subsections (III) and (IV) (hereinafter, "30-month approval") is triggered only when both circumstances described in each subsection, *i.e.*, both the entry of the preliminary injunction and a judgment on the merits of the patent claim(s), occur before the 30-month stay expires. Under Teva's reading, at the end of the 30-month period, if a preliminary injunction has been issued, but a judgment on the merits of the patent claim(s) has not yet been entered, neither subsection 505(j)(5)(B)(iii)(III) nor subsection 505(j)(5)(B)(iii)(IV) is applicable and immediate approval of the ANDA is required under section 505(j)(5)(B)(iii). Teva argues that its interpretation is the only one that gives meaning to the clauses beginning with "and if" which refer to the substantive outcome of the patent litigation. As discussed in more detail below, we do not find Teva's interpretation of these statutory provisions persuasive.

Teva's reading of the statutory provisions is a strict grammatical interpretation of these provisions that fails to give due regard to companion provisions in subsections (I) and (II) or the place of subsections (III) and (IV) within an overall statutory scheme that reflects the realities of patent litigation. We do not adopt Teva's interpretation because we conclude that it is not reasonable in light of the statutory structure and established principles of statutory interpretation. If read as suggested, Teva's interpretation would render subsections (III) and (IV) superfluous and there would be no reason for Congress to have included these two subsections in the statute.

If subsections (III) and (IV) are only triggered by the entry of both a preliminary injunction and a decision (and corresponding judgment) on the issues of patent validity and infringement before the expiration of the 30-month period, the circumstances they address would be covered by subsections (I) and (II), which already govern applications in which a decision on the merits of the patent issues is made before expiration of the 30-month stay. Under this reading, a 30-month stay would only be extended if a decision on the merits is made prior to the expiration of the 30-month period, without regard to whether a preliminary injunction had been entered. Therefore, Teva's interpretation renders meaningless any references to a preliminary injunction in subsections (III) and (IV) and, indeed, causes these subsections to be subsumed within subsections (I) and (II).

However, if subsections (III) and (IV) are interpreted to be triggered by the entry of a preliminary injunction within the 30-month period when the court has not yet decided the merits of the patent infringement claims, these provisions instruct the Agency that the 30-month stay is extended upon entry of a preliminary injunction "until the court decides the issues of patent validity and infringement," and the language beginning with "and if" provide further instructions on the specific timing of final approval of the ANDA when the decision occurs after the 30-month period. *See* FDCA §§ 505(j)(5)(B)(iii)(III) & (IV). As Teva has noted, it is a cardinal rule of statutory construction that statutes must be interpreted to give effect to every clause and word. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001). Although it is possible that however the statute is interpreted, some of the words are unnecessary, only Teva's interpretation renders the entirety of both subsections (III) and (IV) superfluous.

In addition, there are sound policy grounds for interpreting subsections 505(j)(5)(B)(iii)(III) and (IV) to delay final approval of an ANDA when a preliminary injunction is entered during the 30-

month period. Consistent with the interim nature of a preliminary injunction, the Agency's interpretation of the statute would maintain the *status quo* until a final judgment is entered reflecting a decision on the merits of the patents claim(s). Under the Agency's approach, FDA would not be required to closely monitor patent litigation and make changes in approval status based on interim developments in the patent litigation. Instead, when a preliminary injunction is entered, the status quo would be maintained until FDA is notified of the entry of a final judgment, as required under 21 C.F.R. § 314.107(e). When a preliminary injunction has been entered, this outcome is preferable to changing the status of an ANDA's approval before a decision on the merits in the patent infringement litigation is made and a judgment reflecting such a decision is entered.[11]

Teva argues that the fact that FDA's regulation at 21 C.F.R. § 314.107(e) does not specifically require applicants to provide the Agency with notice of the entry of a preliminary injunction in the underlying patent litigation "strongly suggests that FDA always has understood that the entry of a PI during the 30-month stay does not preclude approval of an ANDA once the 30-month stay ends." Although Teva is correct that FDA's regulations are silent on this matter, this silence does not reflect a rejection of the interpretation the Agency describes here. Moreover, FDA's regulations addressing the timing of approval is consistent with the Agency's interpretation of subsections 505(j)(5)(B)(iii)(III) and (IV) of the Act.

FDA's regulation at 21 C.F.R. § 314.107(b)(3)(B)(iv) provides that "if before the expiration of the 30-month period...the court grants a preliminary injunction..., and if the court *later* decides that the patent is invalid, unenforceable, or not infringed, approval may be made effective on the date the court enters a final order or judgment that the patent is invalid, unenforceable, or not infringed." 21 C.F.R. § 314.107(b)(3)(B)(iv) (emphasis added). As with the parallel statutory provision at 505(j)(5)(B)(iii)(III), this regulatory provision would not be necessary if the entry of a preliminary injunction (without a decision on the merits of the patent claim) had no effect on the approval of the ANDA at the end of the 30-month stay; the regulation at 21 C.F.R. § 314.107(b)(3)(B)(ii) ("if before the expiration of the 30-month period...the court issues a final order that the patent is invalid, unenforceable, or not infringed, approval may be made effective on the date the court enters judgment") alone would be sufficient.

Taking into account principles of statutory construction, how the applicable provisions fit into the statutory scheme, and policy considerations, we conclude that FDA's interpretation of the

[11] There are already situations in which FDA might approve an ANDA, only to be required by further developments in patent litigation to convert the ANDA's approval to a tentative approval. This can occur when there has been no decision on the merits of the patent claims (and no preliminary injunction has been entered) before the 30-month stay expires, FDA approves the ANDA pursuant to section 505(j)(5)(B)(iii), and the court subsequently decides that the patent is infringed. It can also occur when a district court decision of non-infringement or unenforceability is reversed by the court of appeals. Given these unavoidable occasions for uncertainty regarding approval status, it is preferable to avoid creating additional opportunities for uncertainty, particularly where, as here, the patent owner or NDA holder has met the requirements for a preliminary injunction. According to the March 28, 2008 Opinion and Order entering the preliminary injunction, Teva stipulated that its generic drug would infringe the relevant claims of the '841 patent unless Teva proved that the claims are invalid or unenforceable. *Eisai Co., Ltd. v. Teva Pharm. USA Inc.*, No. 05-5727, 2008 U.S. Dist. LEXIS 33747, at *3-4, 28, 37 (D.N.J. Mar. 28, 2008). The court found that of those defenses, the sole defense remaining was that the '841 patent is unenforceable due to inequitable conduct and, further, that Eisai had "demonstrated a reasonable likelihood of success on the merits by showing Teva's inequitable conduct defense to lack substantial merit." *Id.* at *3-4, 28, 37.

effect of the preliminary injunction described in subsections 505(j)(5)(B)(iii)(III) and (IV) on approval of Teva's ANDA is not only permissible, but is the most reasonable approach. [12]

Accordingly, Teva was not entitled to final approval in April 2008, because a preliminary injunction had been issued prohibiting the company from marketing its product, even though the court has not yet decided the issues of patent validity and infringement in the underlying patent litigation.

Teva's ANDA was not Entitled to Final Approval Because of Ranbaxy's Eligibility for 180-Day Exclusivity

Regardless of the outcome of the analysis above, approval of Teva's ANDA was also in error because such approval was blocked by Ranbaxy's eligibility for 180-day exclusivity. Teva argues that both Ranbaxy's and Teva's donepezil ANDAs are entitled to "shared exclusivity," and therefore that Teva's ANDA was entitled to final approval on April 28, 2008. However, the Agency has determined that the application of its shared exclusivity approach was not correct in this situation, and approval of Teva's ANDA in April 2008 was therefore in error.

180-Day Exclusivity

The 180-day exclusivity provisions of the Act give the first ANDA applicant to submit a paragraph IV certification challenging a patent an incentive in the form of the opportunity to be the only generic drug manufacturer to compete with the innovator for a 180-day period. [13] *See* FDCA § 505(j)(5)(B)(iv). The statute addresses the effect of an ANDA's exclusivity on *other* ANDAs; it delays the approval of an ANDA containing a paragraph IV certification for a drug "for which a previous [ANDA] has been submitted [containing a paragraph IV] certification." *Id.* Thus, two things are required for a 180-day exclusivity to delay the approval of a competitor's application: (1) the application eligible for the exclusivity must contain a paragraph IV certification to a patent and (2) the application delayed by the exclusivity must also contain a paragraph IV certification to that same patent. The 180-day exclusivity period begins to run on the earlier of the date on which "the [FDA] receives notice from the applicant...of the first commercial marketing of the drug" or "the date of a decision of a court [in a patent infringement action] holding the patent which is the subject of the certification to be invalid or not infringed." *Id.*; *see also* 21 C.F.R. § 314.107(c)(1).

[12] In discussing the effect of 30-month stays, federal courts have expressed just such an interpretation. *See, e.g., Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358, 1366 (Fed. Cir. 2008) (in describing what occurs at the end of the 30-month period, stated "the ANDA is automatically approved unless the court grants a preliminary injunction or finds infringement."); *Valley Drug Co v. Geneva Pharms. Inc.*, 344 F.3d 1294, 1297 (11th Cir. 2003) ("If the court grants the patent holder a preliminary injunction prior to the expiration of the 30-month stay, the application will be approved on the date on which the court later holds the patent invalid or not infringed.").

[13] Because Ranbaxy, the first applicant to submit an ANDA referencing Aricept, submitted its paragraph IV certification before December 8, 2003, the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA), Pub. L. 108-173, unless otherwise noted, reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. *See* MMA § 1102(b)(1).

Development of FDA's Shared 180-Day Exclusivity Approach

In an August 2, 1999 response to petitions from two generic drug firms addressing the exclusivity issue associated with the approval of ANDAs for cisplatin, FDA stated that, at least with respect to the situation presented in the citizen petitions, the regulations governing 180-day exclusivity should be interpreted to award such exclusivity on a patent-by-patent basis.[14] That is, eligibility for 180-day exclusivity would be based on which company submitted the first paragraph IV certification for each listed patent. Therefore, in cases where multiple patents are listed, multiple ANDA applicants may simultaneously be eligible for 180-day exclusivity.

The agency has recognized, however, that with eligibility for exclusivity determined on a patent-by-patent basis, the agency could be prevented from approving ANDAs referencing a particular drug product by multiple conflicting exclusivities ("mutually blocking exclusivity"). *See generally* 64 Fed. Reg. 42873, 42875-76 (Aug. 6, 1999), *withdrawn* 67 Fed. Reg. 66953 (Nov. 1, 2002). An exclusivity stand-off (*i.e.*, A's exclusivity blocks approval of B and B's exclusivity blocks approval of A) whereby each ANDA applicant's approval is delayed indefinitely would be so at odds with both the narrow purpose of the 180-day exclusivity provision, to reward the first ANDA applicant to challenge a listed patent,[15] and the broader purpose of the Drug Price Competition and Patent Term Restoration Act of 1984 (hereafter "Hatch-Waxman Act"), to encourage generic competition, as to defeat the purpose of the generic drug provisions.[16]

To avoid results that cannot be reconciled with the purposes of the 180-day exclusivity provisions, in particular, and the Hatch-Waxman Act, in general, the agency has sought an approach to "mutually blocking" 180-day exclusivities that both hews as closely as possible to statutory language and is consistent with congressional intent. When different applicants have submitted first paragraph IV certifications to different listed patents and thus become eligible for exclusivity as to different patents, but each applicant is blocked by a previous paragraph IV certification on a patent to which it did not have the first paragraph IV certification, FDA will approve the ANDA for either of the applicants that qualifies for exclusivity as soon as it is otherwise eligible for approval. That is, if two or more applicants are each eligible for exclusivity based upon paragraph IV certifications to different patents and each is blocked by previous paragraph IV certifications on another patent to which it was not first to certify, FDA will conclude that neither application blocks approval of the other. Exclusivity for all of the ANDAs eligible for 180-day exclusivity as to any patent at that time will be shared, and it will be triggered by the earlier of either first commercial marketing of any first applicant or a court decision on any one of the patents that qualified any applicant for exclusivity. During that "shared" exclusivity period, FDA may approve any ANDA eligible for exclusivity, but no other ANDAs.

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[14] *See* Letter from Janet Woodcock to Robert F. Green, Steven H. Sklar, and Kate C. Beardsley, FDA Docket No. 99P-1271/PSA1 and PSA2, at 4 (Aug. 2, 1999).

[15] *See, e.g., Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1075 (D.C. Cir. 1998).

[16] We note that this problem was, for ANDAs that are covered by the 2003 amendments to the statute, rectified by Congress when it altered the statute to award exclusivity only to an ANDA applicant that submitted the first paragraph IV certification for any patent listed for the drug product. The issue of shared exclusivity discussed in this letter, therefore, applies only to ANDAs not subject to the 2003 amendments.

FDA's Shared Exclusivity Approach Should Not Have Been Applied to Teva's ANDA

FDA has only applied "shared exclusivity" when two applicants each have submitted paragraph IV certifications to two different patents, and one applicant was first to file a paragraph IV certification on one patent and the other was first to file on a different patent. The Agency has not extended shared exclusivity to a situation like the one at hand, where one applicant (in this case, Ranbaxy) was the first to file a paragraph IV certification to one patent, and filed a paragraph III certification to another patent, to which another applicant (in this case, Teva) filed a paragraph IV certification. In the situation here, Teva has never had 180-day exclusivity that blocked approval of Ranbaxy's ANDA because the two conditions required for such exclusivity under the statute -- that Teva have a paragraph IV certification as to a patent and Ranbaxy have a later paragraph IV certification as to the same patent -- are not present. In its June 2, 2008, letter, Teva acknowledges that FDA has never applied its shared exclusivity approach to this type of situation, but urges FDA to extend its shared exclusivity approach to Teva's and Ranbaxy's ANDAs. For the reasons discussed below, we decline to do so.

Teva argues that FDA should "regulate directly from the statute" and apply its shared exclusivity approach to Teva's and Ranbaxy's donepezil ANDAs. However, the approach Teva suggests does not have a basis in the statutory language, and is not necessary to effectuate the purposes of the statute. Section 505(j)(5)(B)(iv) provides 180-day exclusivity *solely* with respect to applicants who have filed paragraph IV certifications; by its terms, it applies to an application that "contains a [paragraph IV certification] and is for a drug for a which a previous application has been submitted under this subsection containing [sic] such a certification." The statute does not provide that an applicant who challenges a patent would obtain 180-day exclusivity with respect to an applicant who chose to await the expiration of the patent and thus filed a paragraph III certification to the patent. Because shared exclusivity was created to avoid a situation where two or more applicants have filed paragraph IV certifications to multiple patents and have mutually blocking exclusivity, it does not apply here because Ranbaxy filed a paragraph III certification to the '841 patent. Approval of Ranbaxy's ANDA is blocked by the '841 patent, rather than by Teva's exclusivity as to that patent, and it is inconsistent with the statutory language, as well as unnecessary, to extend shared exclusivity to the situation at hand.

Furthermore, Teva's June 2, 2008 letter suggests that awarding shared exclusivity to Teva and Ranbaxy would further one of the goals of the Hatch-Waxman Act, to encourage the availability of generic drugs in the market. It is not necessary to extend shared exclusivity to this situation to effectuate the goals of the Hatch-Waxman Act. As explained above, FDA created shared exclusivity to avoid the situation where the purpose of the statute is defeated because approval of multiple applications - each of which is eligible for 180-day exclusivity as to one or more different patents - would be delayed indefinitely by mutually blocking exclusivity. But, in the case of an ANDA applicant such as Ranbaxy that is eligible for 180-day exclusivity as to one patent but that has filed a paragraph III certification to an earlier expiring patent, approval of ANDAs would not be delayed indefinitely, but instead that applicant's ANDA (here, Ranbaxy's) would be eligible for approval upon expiration of the patent to which it filed a paragraph III certification. With a reasonable date certain when an applicant would be eligible for approval, it is not necessary to apply shared exclusivity.[17]

[17] Although Teva asserts in its June 2, 2008 letter that shared exclusivity is appropriate here because Ranbaxy "chose to sit on the sidelines while Teva accepted the risk (and reality) of patent infringement litigation," we note

In light of the statutory language and the policy considerations that underpin shared exclusivity, the Agency finds that Ranbaxy and Teva are not eligible for shared 180-day exclusivity. Instead, only Ranbaxy is eligible for exclusivity, as a result of being the first to file paragraph IV certifications to the '864, '321, '911, and '760 patents.[18] Accordingly, because approval of Teva's donepezil ANDA should have been delayed until the expiration of any 180-day exclusivity applicable to Ranbaxy's ANDA, we have concluded that FDA's approval of Teva's donepezil ANDA on April 28, 2008, was in error.

* * * * *

Therefore, for the reasons set forth above, FDA has concluded that the Agency's April 28, 2008 approval letter was issued in error. As Teva concedes in its letters of October 21, 2009, and October 14, 2008, FDA has the authority to correct its errors. Indeed, it is well-established that an administrative agency such as FDA has the inherent authority to reconsider and correct its errors. As explained in *Rutherford v. United States*, administrative agencies like FDA "have the inherent authority to reconsider their own decision, since the power to decide in the first instance carries with it the power to reconsider." 806 F.2d 1455, 1460 (10th Cir. 1986) (quoting *Trujillo v. Gen. Elec. Co.*, 621 F.2d 1084, 1086 (10th Cir. 1980)).[19] Specifically, in *American Therapeutics, Inc. v. Sullivan*, the District Court of the District of Columbia upheld FDA's decision to rescind approval of an ANDA where, as here, approval of an ANDA had been issued based on a mistake. *American Therapeutics, Inc. v. Sullivan*, 755 F. Supp. 1 (D.D.C. 1990). Further, FDA has a duty to correct errors if it learns its prior position was incorrect. *See, e.g., Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966); *United States v. 60 28-Capsule Bottles*, 211 F. Supp. 207, 215 (D.N.J. 1962) *aff'd* 325 F.2d 513 (3d Cir. 1963) ("FDA has a duty to change its position with reference to the efficacy of a drug if it subsequently learns that its original position was in error"); *see also Bentex Pharmaceuticals Inc. v. Richardson*, 463 F.2d 363, 368 n. 17 (4th Cir. 1972) *rev'd Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1979) (noting FDA not estopped from alleging product was a "new drug," even though the agency had given the opinion that similar drugs were not "new drugs").

Accordingly, the Agency is correcting its error and converting the status of ANDA 77-344 from approved to tentatively approved, effective immediately. As referenced above, the Agency has

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that Teva is in essentially the same position with respect to a patent challenge as it would have been had it, like Ranbaxy, filed a paragraph III certification to the patent and awaited its expiration on November 25, 2010.

[18] Because Ranbaxy was the first to file paragraph IV certifications with respect to these patents, and is not blocked by any other ANDA's exclusivity, it may be eligible for final approval on November 25, 2010, when the '841 patent expires.

[19] In *Rutherford*, the court dismissed an action alleging that FDA erred in determining that product was a "new drug," holding that the proper forum for consideration of the issue was FDA, not the district court.

provided Teva with extensive opportunities to bring its position before the Agency, and to respond to arguments raised by Ranbaxy, and has carefully considered this information in making its determination.

Sincerely yours,

{See appended electronic signature page}

Keith O. Webber
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST
09/17/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.

EXHIBIT 2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

EISAI CO. LTD. and EISAI INC. Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD. Defendants.	**CONSOLIDATED** Civil Action No. 05-5727 (GEB)(ES) (Lead)
EISAI CO. LTD. and EISAI INC. Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD. and GATE PHARMACEUTICALS (a division of Teva Pharmaceuticals USA, Inc.), Defendants.	Civil Action No. 07-5489 (GEB)(ES)

STIPULATION AND ORDER OF STAY AND DISMISSAL

Plaintiffs Eisai Co. Ltd. and Eisai Inc. (collectively "Eisai") and Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and GATE Pharmaceuticals (a division of Teva Pharmaceuticals USA, Inc.) (collectively "Teva") stipulate and agree as follows:

1. Subject to paragraph 2, the parties shall take no further action in these consolidated civil actions, and these consolidated civil actions, including all pending motions, shall be STAYED through and including November 25, 2010.

2. For clarity, the March 28, 2008 Order granting Eisai's motion for a preliminary injunction shall remain in full force and effect until and including the date of expiration of U.S. Patent No. 4,895,841 on November 25, 2010, and this injunction remains subject to the provisions of 35 U.S.C. § 271(e)(1) to the extent that § 271(e)(1) may otherwise apply. Both parties reserve the right to file a motion to seek relief regarding whether particular activity does or should violate the injunction.

3. These consolidated civil actions shall be DISMISSED as MOOT as of November 26, 2010.

4. The parties shall bear their own costs and fees, including attorneys' fees.

IT IS HEREBY STIPULATED this 19th day of July 2010.

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IT IS SO ORDERED this 19th day of July 2010.

Garrett E. Brown, Jr., Chief Judge
United States District Court

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