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SPEAR PHARMACEUTICALS, INC.

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION – SANTA ANA

VALEANT PHARMACEUTICALS INTERNATIONAL,

Plaintiff,

v.

KATHLEEN SEBELIUS, et al.,

Defendants.

and

SPEAR PHARMACEUTICALS, INC.

Intervenor Defendant.

Case No. SACV08-449 AG (AGRx)

The Honorable Andrew J. Guilford

MEMORANDUM OF POINTS AND AUTHORITIES OF SPEAR PHARMACEUTICALS, INC. IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Date: **July 20, 2009**
Time: **10:00 A.M.**
Court: **Room 10D**

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS (con'td)

Winston & Strawn LLP
333 South Grand Avenue
Los Angeles, CA 90071-1543

Winston & Strawn LLP
333 South Grand Avenue
Los Angeles, CA 90071-1543

TABLE OF AUTHORITIES

Page

Cases

Winston & Strawn LLP
333 South Grand Avenue
Los Angeles, CA 90071-1543

TABLE OF AUTHORITIES (con'td)

Page

Statutes and Regulations

Winston & Strawn LLP
333 South Grand Avenue
Los Angeles, CA 90071-1543

TABLE OF AUTHORITIES (con'td)

Page

Winston & Strawn LLP
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Los Angeles, CA 90071-1543

MEMORANDUM OF POINTS AND AUTHORITIES

Spear Pharmaceuticals, Inc. ("Spear") respectfully submits this memorandum of points and authorities in support of its motion for summary judgment.

Many of the factual and legal issues discussed below were resolved by this Court in its June 18, 2008, Order denying Valeant's motion for a preliminary injunction and extinguishing the temporary restraining order ("June 18 Order"). While this Court is free to revisit its factual and legal findings made in the context of the preliminary injunction motion, because this is an Administrative Procedure Act ("APA") case, the Court's final ruling on the merits will be based on the administrative record – not on, as in an ordinary civil litigation, depositions of the parties, documents produced by the parties, and expert reports submitted by the parties. *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44, 105 S. Ct. 1598, 84 L. Ed. 2d 643 (1985) ("The task of the reviewing court is to apply the appropriate Administrative Procedure Act ("APA") standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.") (citation omitted). Here, the factual record before this Court is identical to the one before this Court at the time it issued the June 18 Order.[1]

Moreover, all parties to this action agree – and have previously advised this Court, "that this action should be resolved upon Cross-Motions for Summary Judgment. . . ." (Feb. 9, 2009, Joint Stipulation Modifying Scheduling Order & Setting Briefing Schedule at 1.)

[1] At the August 11, 2008, Scheduling Conference, Valeant's counsel told the Court that Valeant planned to file a motion for leave to take discovery from the FDA (something that is not typically permitted in APA cases) and that it would complete any discovery that was ordered, and be prepared to file its summary judgment motion, by November 2008. (Bhatt Dec. Ex. 4, August 11, 2008 Tr. at 19-21.) In addition, Valeant, in the parties' Rule 26(f) report filed with this Court, represented to the Court that it would "file a motion for leave to take discovery no later than September 15, 2008." Valeant did not, however, file its motion by September 15, 2008. Instead, it waited almost seven more months, filing its motion on April 2, 2009. Although Valeant's discovery request is now fully briefed, because of Valeant's delay, there has been no ruling on the motion as of this time.

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For the reasons set forth below, and in this Court's June 18, 2008, Order, Spear respectfully submits that its motion for summary judgment should be granted and this action should be dismissed with prejudice.

INTRODUCTION AND SUMMARY OF ARGUMENT

Valeant's Amended Complaint asks this Court to order the United States Food and Drug Administration ("FDA") to reconsider the approval of Spear's Abbreviated New Drug Application ("ANDA"), the denial of Valeant's Citizen Petition, and the reaffirmation of Spear's ANDA because, according to Valeant: (1) the FDA failed to consider the opinions of the Division of Dermatology and Dental Products ("DDDP") in the Office of New Drugs ("DDDP"); and (2) the FDA considered, when it should not have, the opinion of Dr. Jonathan Wilkin, a former FDA employee, that was submitted in support of Spear's ANDA.

Valeant is not entitled to the relief it requests because under the APA, agency action can be set aside only if it is "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' or if the action failed to meet statutory, procedural, or constitutional requirements." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414, 91 S. Ct. 814, 28 L. Ed. 2d 136 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 97 S. Ct. 980, 51 L. Ed. 2d 192 (1977). As demonstrated below, Valeant cannot satisfy this standard because the FDA's "decision was based on a consideration of the relevant factors" and "there has [not] been a clear error of judgment." *Citizens to Preserve Overton Park*, 401 U.S. at 416.

First, with respect to the opinions of the DDDP, the Administrative Record reflects that over a 39-month period there was a spirited debate between the DDDP scientists in the Office of New Drugs and the scientists in the Office of Generic Drugs during which the opinions of the DDDP were considered and addressed, but not followed. (AR627-909.)[2] As this Court properly found in its June 18, 2008, Order,

[2] The designation "AR" refers to the Administrative Record. On June 2, 2008, the FDA filed the Administrative Record (Docket No. 79).

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"the opinions upon which Valeant relies were considered. However, it was ultimately determined by the experts in bioequivalence in the Office of Generic Drugs that an sBCC clinical study was not required." (June 18, 2008 Order, Conclusion of Law ¶ 33.) While Valeant wishes that the FDA had resolved the issue by siding with the scientists who supported the view that an sBCC clinical study was necessary rather than those who were of the opinion that the study was not necessary, such a determination is the job of the FDA, not of this Court.

Second, with respect to the opinion of Dr. Wilkin, the FDA has already done what Valeant asks this Court in its Amended Complaint to order it to do. When the FDA learned that Dr. Wilkin *might* have had a conflict of interest because he is a former FDA employee, four high-ranking FDA officials, including the Commissioner of the FDA, conducted a review and analysis of the 1,086 page Administrative Record that existed at the time of Spear's ANDA approval and denial of Valeant's Citizen Petition without regard to Dr. Wilkin's two-page letter and concluded that Spear's ANDA approval should be reaffirmed. (AR1088-225.) In its June 18, 2008 order, this Court approved the procedure utilized by the FDA. (Conclusions of Law ¶¶ 39-44.) In its Amended Complaint,[3] Valeant has not cited any evidence that was not before this Court when it issued its June 18 Order; therefore, nothing would be gained by asking the FDA to again reconsider its decision without regard to the opinion of a former employee who does not have a conflict of interest.[4]

Third, Valeant's Amended Complaint also ignores the fact that the FDA Office of Inspector General and Office of Internal Affairs investigated Dr. Wilkin's potential

[3] Valeant filed its Amended Complaint on September 23, 2008, and incorporated into that pleading the arguments that it had made, and the documents provided to the Court by the FDA in connection with, the preliminary injunction briefing and hearing.

[4] Even if Valeant could demonstrate that the FDA relied on Dr. Wilkin's letter, such reliance would not have been inappropriate in view of this Court's holding that "Valeant has not made a sufficient showing of an ethical violation," (Finding of Fact ¶ 78).

conflict of interest and determined that there was in fact no conflict of interest. (Bhatt Dec. Ex. 1, Vantrease Dec. ¶¶ 4-5; Bhatt Dec. Ex. 2, Doyle Dec. ¶ 5.)[5]

Fourth, the portion of Valeant's Amended Complaint relating to the conflict of interest issue is not legally cognizable for the additional reason that Valeant does not have standing to contest the FDA's determination that Dr. Wilkin did not have a conflict of interest. *See* Section III below.

Therefore, for each of these independently sufficient reasons Spear is entitled to judgment as a matter of law that Valeant cannot prove that the FDA's approval of Spear's ANDA, denial of Valeant's citizen petition, and reaffirmation of Spear's ANDA were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

FACTUAL BACKGROUND

On April 11, 2008, the FDA, after 39 months of review and consideration, approved Spear's ANDA for its 5-fluorouracil cream product. (AR1084-86.) On the same date, the FDA denied a Citizen Petition that Valeant had filed on December 21, 2004. (AR599-626.) In the Citizen Petition, Valeant asked the FDA to require ANDAs for 5-fluoruracil cream products to include clinical studies that demonstrated bioequivalence in both approved indications, actinic keratosis ("AK") and superficial basal cell carcinoma ("sBCC"). (AR1-138.) On April 25, 2008, Valeant challenged the FDA's approval of Spear's ANDA and denial of Valeant's Citizen Petition by filing a Complaint and an Application for a Temporary Restraining Order against the FDA. The Court granted Spear's Motion to Intervene.

While Valeant's Application for a Temporary Restraining Order was pending, the FDA determined that it needed to consider: (1) a possible conflict of interest of a former FDA employee, Dr. Wilkin, who had submitted a two-page letter in support of Spear's ANDA approval; and (2) a scientific issue. (AR1087.) On May 30, 2008, the

[5] References to "Bhatt Dec. Ex." refer to the exhibits attached to the Declaration of Minaksi Bhatt in Support of Spear's Motion for Summary Judgment.

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FDA reaffirmed Spear's ANDA approval. (AR1088-125.) On May 31, 2008, the Court granted Valeant's application for a temporary restraining order. On June 18, 2008, this Court denied Valeant's motion for a preliminary injunction and extinguished the temporary restraining order.

Having failed to prevail on its Motion for Preliminary Injunction, Valeant on September 23, 2008, filed an Amended Complaint in which it alleged two theories that, while they had not been present in Valeant's original Complaint had been vigorously argued by Valeant in its preliminary injunction motion papers and in the preliminary injunction hearing. Valeant alleged that the FDA's approval of Spear's ANDA, denial of Valeant's Citizen Petition, and reaffirmation of Spear's ANDA approval violated the APA because: (1) the FDA failed to consider the views of the DDDP; and (2) the FDA's process was tainted because it considered the views of Dr. Wilkin.

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A. THE FDA'S APPROVAL OF SPEAR'S ANDA AND DENIAL OF VALEANT'S CITIZEN PETITION

The 1,125 page administrative record indicates that the FDA engaged in extensive deliberations in its consideration of Spear's ANDA and Valeant's Citizen Petition. (AR1-1125; June 18 Order, Finding of Fact ¶ 38.)

1. The FDA Considered the Views of the DDDP.

During the 39 months that Spear's ANDA was pending, the Administrative Record indicates that there was a spirited debate between the Office of Generic Drugs and certain scientists in the DDDP. (June 18 Order, Conclusion of Law ¶ 33.) The DDDP is a department in the Office of New Drugs. The Office of New Drugs is responsible for reviewing and approving applications for new drugs, which requires it to assess the safety and efficacy of the new drug. The Office of Generic Drugs is responsible for reviewing and approving applications for generic drugs, which requires it to determine whether the generic drug is bioequivalent to the referenced new drug. The Office of Generic Drugs – not dermatologists in the Office of New

Drugs – is the group chosen by the FDA to have the ultimate responsibility for reviewing and approving Spear's generic drug application.

The Office of Generic Drugs was of the view that Spear's demonstration of bioequivalence in AK was sufficient for FDA approval, while the DDDP thought that Spear should be required to demonstrate bioequivalence in both AK and sBCC. The Administrative Record reflects that the Office of Generic Drugs reviewed and considered the views of the DDDP in connection with both the approval of Spear's ANDA and the denial of Valeant's citizen petition. (AR636-56; AR727-39.)

Dr. Dena Hixon is the Associate Director of Medical Affairs in the Office of Generic Drugs and has a medical degree. (AR636.) In a February 20, 2007, 21-page memorandum, Dr. Hixon addressed, *inter alia*, the views of Dr. Markham Luke, a junior scientist in the DDDP. (AR636-56; June 18 Order, Finding of Fact ¶ 45.) Dr. Hixon provided a summary of each of Dr. Luke's opinions, and then provided the Office of Generic Drugs' detailed comments and responses to each opinion. (AR636-56; June 18 Order, Finding of Fact ¶ 45.) Dr. Hixon also noted that Dr. Luke based one of his arguments on a non-existent regulation. (AR653.)

Dr. Julie Beitz is the Director of the Office of Drug Evaluation III, in the Center for Drug Evaluation and Research, has a medical degree, and is an oncologist and internist. (AR727; Bhatt Dec. Ex. 3, June 10, 2008 Tr. at 84-86.) Dr. Beitz, who is the supervisor of the scientists in the DDDP, was specifically asked to review the scientific debate between the Office of Generic Drugs and the DDDP and provide her conclusions. (AR731.) In a December 3, 2007, twelve-page memorandum, Dr. Beitz described the respective views of the Office of Generic Drugs and the DDDP (AR730-36) and concluded that "a single study in AK would be sufficient to demonstrate bioequivalence of Efudex® 5-fluorouracil cream, 5% and Spear's 5-fluorouracil cream, 5% for both the AK and sBCC indications." (AR736; June 18 Order, Finding of Fact ¶ 48.)

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Dr. Beitz also stated, "[t]his memorandum documents my position regarding the issues raised by the petitioner and incorporates input received from Dr. John Jenkins, Director of New Drugs; Dr. Sandra Kweder, Deputy Director of the Office of New Drugs; and Dr. Robert Temple, Director of the Office of Medical Policy." (AR731.) The "petitioner" to whom Dr. Beitz refers is Valeant.

2. The Process Was Not "Tainted" by the Wilkin Letter.

On March 1, 2007, Spear submitted a two-page letter from Dr. Jonathan Wilkin in support of its ANDA. (AR1048-49.) Dr. Wilkin opined that a study in AK could demonstrate bioequivalence. This short letter did not contain any references or citations to the scientific literature. (June 18 Order, Finding of Fact ¶ 46; AR1048-49.)

Dr. Hixon's February 20, 2007, memorandum was written before Dr. Wilkin submitted his letter and therefore Valeant cannot argue that Dr. Wilkin's letter "tainted" Dr. Hixon's memorandum. (AR636-56.)

Dr. Beitz's twelve-page memorandum contains a detailed discussion of the scientific issues and extensively cites the scientific literature on the subject. (AR732-35.) The scientific literature cited by Dr. Beitz in support of her review comprises 170 pages in the Administrative Record. (AR740-909.) Dr. Beitz's memorandum also includes language that is almost identical to the language in Dr. Hixon's memorandum. (AR645.) The Beitz memorandum contains only the following reference to Dr. Wilkin in a footnote: "[o]n March 14, 2007, Spear Pharmaceuticals submitted to its ANDA the expert opinion of Jonathan Wilkin, MD, supporting the adequacy of Spear's AK study to support approval of their product. Dr. Wilkin was Director of the DDDP from 1994 to 2005. Dr. Wilkin does not appear to have been involved in this matter during his tenure at FDA." (AR730 at n.6.) The Beitz memorandum makes no other reference to Dr. Wilkin, does not state that Dr. Beitz relied on his opinion, and does not cite to, or rely on, the Wilkin letter in support of any of the conclusions in the memorandum. (AR727-39.)

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As this Court has already held:

> Valeant's argument that Dr. Beitz must have relied on Dr. Wilkin's letter because of the similarity of the language in the two documents ignores the fact that Dr. Beitz's twelve page memorandum includes citations to the scientific literature and detailed analysis that do not appear anywhere in Dr. Wilkin's two page letter. It also ignores the fact that similar language is found in the pre-Wilkin Hixon memorandum.

(June 18 Order, Conclusion of Law ¶ 44.)

B. THE FDA REAFFIRMED APPROVAL OF SPEAR'S ANDA.

During a stay in this litigation requested by FDA so that it could review the potential conflict of interest and a scientific issue, the FDA reconsidered Spear's ANDA approval. That reconsideration resulted in the reaffirmation of Spear's approval on May 30, 2008. (AR1088-225.)

1. The FDA Considered the Views of the DDDP.

Dr. Douglas Throckmorton, the Deputy Director of the Center for Drug Evaluation and Research, participated in the reconsideration process. Dr. Throckmorton prepared a twelve-page memorandum that summarizes his role in the reconsideration. Dr. Throckmorton's memorandum describes in minute detail the history of the scientific debate between the Office of New Drugs and the DDDP. (AR1092-95; June 18 Order, Finding of Fact ¶ 72.) Dr. Throckmorton specifically addressed the DDDP's scientific arguments regarding the need for studies in sBCC patients. (AR1096-98.)

2. The FDA Reconsidered Spear's ANDA Approval Without Regard to the Wilkin Letter.

In connection with the reconsideration of Spear's approval, Dr. Beitz prepared her May 29, 2009, memorandum. In that memorandum, Dr. Beitz stated that at the time she wrote her December 3, 2007, memorandum she "was not aware that Dr.

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Wilkin had been involved in this matter during his tenure at FDA." (AR1107; June 18 Order, Finding of Fact ¶ 66.) Dr. Beitz was asked "whether [she] would have reached the same conclusion as stated in [her] December 3, 2007 decision, even if Dr. Wilkin had not made his March 14, 2007 submission in support of Spear's ANDA." (AR1107; June 18 Order, Finding of Fact ¶ 66.) Dr. Beitz stated that "[r]emoval of Dr. Wilkin's March 14, 2007, submission from consideration does not alter any of the conclusions that I reached in my December 3, 2007 memo regarding the adequacy of Spear's AK study to support approval of its product." (AR1107; June 18 Order, Finding of Fact ¶ 66.)

Dr. Beitz addressed Dr. Wilkin's statement that the stratum corneum was the greatest barrier to penetration. Dr. Beitz stated that her review of the literature indicated that this "observation is widely held" and cited numerous scientific references for this proposition. (AR1107 n.1; June 18 Order, Finding of Fact ¶ 67.) She also stated that the Office of Generic Drugs was aware of "this well-known fact" before Dr. Wilkin's letter, citing the Hixon memorandum. (AR1107; June 18 Order, Finding of Fact ¶ 67.) Dr. Beitz also stated that the thickness of the stratum corneum in AK and sBCC is described in the scientific literature cited in her December 3, 2007, memorandum and in the Williams reference submitted by Valeant in support of its Citizen Petition. (AR1107-08; June 18 Order, Finding of Fact ¶ 68.)

Dr. Throckmorton then reviewed Dr. Beitz's analysis. Dr. Throckmorton stated that "the statements made by Dr. Wilkin were based on information that is generally available and could reasonably have been derived from other submitted materials" and concluded that "omitting Dr. Wilkin's statement from the record does not change the conclusion regarding the approvability of the Spear ANDA." (AR1096; June 18 Order, Finding of Fact ¶ 73.)

Dr. Woodcock, the Director of the Center for Drug Evaluation & Research at the FDA, reviewed Dr. Throckmorton's memorandum and agreed "that the approval of ANDA 77-524 be affirmed as both scientifically and procedurally correct."

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(AR1089; June 18 Order, Finding of Fact ¶ 76.) She stated that the "statements made by Dr. Wilkin were based on information that is generally available and could reasonably have been derived from other submitted materials." (AR1090; June 18 Order, Finding of Fact ¶ 76.)

The Decision on Administrative Reconsideration of Dr. von Eschenbach, who was at that time the Commissioner of the FDA, states that he "reconsidered the approval of Spear's ANDA 77-524 for 5-fluorouracil cream, 5%, and based [on] Dr. Woodcock's recommendation, the approval of the ANDA 77-534 is hereby affirmed." (AR1088; June 18 Order, Finding of Fact ¶ 77.) Dr. von Eschenbach was not involved in the initial approval of the Spear ANDA. (AR938-1086; June 18 Order, Finding of Fact ¶ 77.)

C. THE FDA OFFICE OF INTERNAL AFFAIRS AND OFFICE OF INSPECTOR GENERAL INVESTIGATED AND CONCLUDED THAT DR. WILKIN DID NOT HAVE A CONFLICT OF INTEREST.

After finding three documents in the Administrative Record that included some reference to Dr. Wilkin, the Office of the General Counsel for the Department of Health and Human Services, Food and Drug Division referred the potential conflict of interest issue to FDA's Office of Internal Affairs, Office of Criminal Investigations. (Bhatt Dec. Ex. 2, Doyle Dec. ¶ 1.) The Office of Internal Affairs referred the matter to the Office of Investigations for the Department of Health and Human Services, Office of the Inspector General. (Bhatt Dec. Ex. 2, Doyle Dec. ¶ 3.) The Office of the Inspector General determined that there was no conflict of interest. (Bhatt Dec. Ex. 1, Vantrease Dec. ¶¶ 4-5.) Mr. Vantrease in the Office of the Inspector General concluded that:

> the referral did not provide sufficient information to support that Dr. Wilkin knew that his letter would be presented to the agency, as required by 18 U.S.C. §207(a)(1). In addition (and even if he did know that the letter would be presented to FDA), I concluded

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> that the information showed that *Dr. Wilkin was two supervisory levels above the Medical Officer conducting the review, and that there was nothing else indicating that he was personally and substantially involved in the matter at hand, as required for the permanent restriction relating to former employees under 18 U.S.C. §207(a)(1)(B). The one-year restriction in 18 U.S.C. §207(c) on communicating to the government would not apply to Dr. Wilkin (regardless of whether he qualified as a senior personnel) because he left HHS in 2005, and his expert opinion was written on March 14, 2007.*

(Bhatt Dec. Ex. 1, Vantrease Dec. ¶ 4 (emphasis added).) Mr. Vantrease determined "that no further investigation of this matter was warranted." (Bhatt Dec. Ex. 1, Vantrease Dec. ¶ 5.) Mr. Doyle notified the Office of the General Counsel "that neither HHS/OIG nor the Office of Internal Affairs would take any action against Dr. Wilkin." (Bhatt Dec. Ex. 2, Doyle Dec. ¶ 5.)

This Court has already found that "Valeant has not made a sufficient showing of an ethical violation." (June 18 Order, Finding of Fact ¶ 78.) The Amended Complaint does not rely on any additional evidence that was not before this Court at the time it issued its June 18 Order.

ARGUMENT

I.

APPLICABLE LEGAL STANDARDS

A. Standard for Granting Summary Judgment

Summary judgment is appropriate if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). Summary judgment is an "integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.'"

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Celotex, 477 U.S. at 327 (quoting Fed. R. Civ. P. 1). In an APA case, "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985). "[S]ummary judgment is an appropriate mechanism for deciding the legal question of whether the agency could reasonably have found the facts as it did." *Occidental Eng'g*, 753 F.2d at 770**.**

In this case, the parties agree, and have previously advised this Court, "that this action should be resolved upon Cross-Motions for Summary Judgment." (Feb. 9, 2009, Joint Stip. Modifying Scheduling Order & Setting Briefing Schedule at 1.)

B. Standard of Review under the APA

The Supreme Court in *Citizens to Preserve Overton Park*, addressed the standard of review in APA cases: "agency action must be set aside if the action was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' or if the action failed to meet statutory, procedural, or constitutional requirements." 401 U.S. at 414. "To make this finding the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park*, 401 U.S. at 416. "[T]he ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park*, 401 U.S. at 416.

The Court of Appeals for the Ninth Circuit has similarly held that "[t]he standard of review is highly deferential." *Friends of the Earth v. Hintz*, 800 F.2d 822, 831 (9th Cir. 1986). "The court may not set aside agency as arbitrary and capricious unless there is no rational basis for the action." *Friends of the Earth*, 800 F.2d at 831.

> In its paradigmatic statement of this standard, the Supreme Court explained that an agency violates the APA if it has 'relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation

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> for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'

Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric., 499 F.3d 1108, 1115 (9th Cir. 2007) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Inc. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983)).

II.

THE ADMINISTRATIVE RECORD INDICATES THAT THE FDA CONSIDERED THE OPINIONS OF THE DDDP

The FDA considered the opinions of the scientists in the DDDP both during the 39 months during which Spear's ANDA was pending and during the reconsideration of Spear's ANDA approval. (AR636-56, 727-39, and 1091-225.)

A. The FDA Considered the Views of the DDDP and Was Within Its Discretion in Adopting the Views of the Office of Generic Drugs.

Valeant alleges that the FDA failed to consider the opinions of the DDDP and alleges that the FDA "cannot depart from relying on their own experts, however, and still benefit from deference by the courts." (Am. Compl. ¶ 44.)

Valeant characterizes the DDDP scientists as "experts" suggesting that they are the only experts. However, the issues with respect to ANDA approval and the Citizen Petition involved bioequivalence of a generic drug product, and OGD is expert with respect to bioequivalence. (June 18 Order, Conclusion of Law ¶ 33 ("experts in bioequivalence in the Office of Generic Drugs").) DDDP is expert with respect to safety and efficacy determinations with respect to new drug products, but not with respect to bioequivalence of generic drugs.

The Ninth Circuit has held that "[w]hen specialists express conflicting views, we defer to the informed discretion of the agency." *Envtl. Prot. Info. Center v. U.S. Forest Serv.*, 451 F.3d 1005, 1017 (9th Cir. 2006). The Court is not required to

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"decide whether [the decision] is based on the best scientific methodology available, nor" is the Court required "to resolve disagreements among various scientists as to methodology." *Friends of Endangered Species, Inc. v. Jantzen*, 760 F.2d 976, 986 (9th Cir. 1985). Moreover, "[w]hen examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 103, 103 S. Ct. 2246, 76 L. Ed. 2d 437 (1983).

Furthermore, Valeant incorrectly concludes that because the FDA did not adopt the opinions of the DDDP that means that they did not consider those opinions. "[T]he fact that such evidence did not persuade the FDA to act as the petition requested does not mean that the FDA did not consider the evidence, as it is required to do." *Henley v. FDA*, 873 F. Supp. 776, 784 (E.D.N.Y. 1995), *aff'd*, 77 F.3d 616 (2d Cir. 1996).

Valeant also ignores the fact that Dr. Beitz, who was involved in the approval and reaffirmation of the approval, is the supervisor of the scientists in the DDDP, was aware of their views, and considered them. (AR727-39; June 18 Order, Conclusion of Law ¶ 33 ("Valeant ignores the fact that Dr. Beitz, an oncologist and internist in the Office of New Drugs and the supervisor of the dermatologists in the Office of New Drugs (including the much more junior Dr. Luke), was of the opinion that an sBCC study was not needed.").)

B. The Hixon, Beitz, and Throckmorton Memoranda Address the Arguments Made by the DDDP and Explain Why Their View Was Not Followed.

Valeant alleges that "[t]he Administrative Record reflects that the FDA's administrators never articulated a reasonable rationale for having disregarded the unanimous conclusion of the FDA's own acknowledged dermatology experts that a clinical study in sBCC would be required in order to establish bioequivalence between Spear's cream and Valeant's Efudex 5% Cream. (Am. Compl. ¶ 45.)

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As this Court has already found, the Hixon, Beitz, and Throckmorton memoranda specifically address the arguments made by the DDDP. (June 18 Order, Finding of Fact ¶¶ 45, 48, 72; AR636-56, 727-39, and 1091-225.)

Valeant's allegations "are essentially an effort to rehash the multi-year scientific debate that culminated in" approval of Spear's ANDA, denial of Valeant's citizen petition, and reaffirmation of Spear's ANDA approval. *Aluminum Co. of Am. v. Adm'r, Bonneville Power Admin.*, 175 F.3d 1156, 1162 (9th Cir. 1999). "Far from disregarding relevant scientific information, however, [FDA] engaged in a detailed analysis of these issues and weighed the available data." *Aluminum Co. of Am.*, 175 F.3d at 1162. The existence of "different views among scientists . . . does not establish a lack of adequate foundation for the conclusions reached." *Aluminum Co. of Am.*, 175 F.3d at 1161-62.

The FDA "provided a rational and ample basis for its decision" and the FDA's decision should therefore "be upheld under the arbitrary and capricious standard." *Northwest Motorcycle Ass'n. v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1471 (9th Cir. 1994).

III.

VALEANT DOES NOT HAVE STANDING TO CHALLENGE THE FDA'S DETERMINATION THAT DR. WILKIN DID NOT HAVE A CONFLICT OF INTEREST

Valeant's allegation that the administrative process was tainted because Dr. Wilkin's opinion was considered is an indirect attack on the FDA's determination that Dr. Wilkin did not have a conflict of interest. Valeant implicitly acknowledges its lack of standing on this issue, by not including in its Amended Complaint a cause of action challenging the FDA's determination that Dr. Wilkin did not have a conflict of interest.

It is well established that: "a citizen lacks standing to contest the policies of the prosecuting authority when he himself is neither prosecuted nor threatened with

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prosecution." *Linda R.S. v. Richard D.*, 410 U.S. 614, 619, 93 S. Ct. 1146, 35 L. Ed. 2d 536 (1973). "[I]n American jurisprudence at least, a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another." *Linda R.S.*, 410 U.S. at 619.

This rule has specifically been followed in cases involving the criminal conflict of interest statutes in Title 18 that govern the activities of government employees such as Dr. Wilkin. *City and County of San Francisco v. United States*, 443 F. Supp. 1116, 1125 (N.D. Cal. 1977), *aff'd*, 615 F.2d 498 (9th Cir. 1980) ("Plaintiff does not fall within the zone of interests arguably protected by these criminal statutes."); *Saratoga Sav. & Loan Assoc. v. Fed. Home Loan Bank of San Francisco*, 724 F. Supp. 683, 690 (N.D. Cal. 1989) ("[P]laintiffs assert a private right of action under the federal criminal conflicts of interest statue. 18 U.S.C. § 208. However, that statute creates no private right of action."); *Scherer v. United States*, 241 F. Supp. 2d 1270, 1285 (D. Kan. 2003) ("[t]he only right of action under this provision, however, is reserved for the Attorney General. . . the federal conflict of interest statute provides no express or implied private right of action.") (citation omitted).

Therefore, Valeant does not have the right to bring a private cause of action to enforce the criminal conflict of interest statute. What Valeant cannot do directly, it also cannot do through an indirect attack on the FDA's determination that Dr. Wilkins did not have a conflict of interest.

IV.

THE APPROVAL OF SPEAR'S ANDA, DENIAL OF VALEANT'S CITIZEN PETITION, AND REAFFIRMATION OF THE ANDA APPROVAL WERE NOT TAINTED BY DR. WILKIN'S OPINION

As explained above, Dr. Wilkin's opinion did not taint Spear's ANDA approval, denial of Valeant's citizen petition, and the reaffirmation of Spear's ANDA approval because (1) the FDA determined that Dr. Wilkin did not have a conflict; (2) the FDA reconsidered Spear's ANDA approval without regard to Dr. Wilkin's

statement and reaffirmed the approval; and (3) this Court has found that "Valeant has not made a sufficient showing of an ethical violation." (Bhatt Dec. Ex. 1, Vantrease Dec. ¶¶ 4-5; Bhatt Dec. Ex. 2, Doyle Dec. ¶ 5; AR1088-225; June 18 Order, Finding of Fact ¶ 78.)

A. The DDDP Had Ample Opportunity to Address the Opinions in Dr. Wilkin's Letter.

Valeant alleges that "there is no evidence in the administrative record that the DDDP was given the opportunity to review and challenge the arguments put forth by Dr. Wilkin before Dr. Beitz drafted her December 3, 2007 memorandum." (Am. Compl. ¶ 49.)

Valeant ignores the fact that Dr. Wilkin's letter includes the same or similar statements as those that had been made by OGD and Spear. (AR1047-58, 631-32, 141-88, 450-70, 502-28.) The DDDP had ample opportunity to address the arguments of OGD and Spear before Dr. Beitz wrote her December 3, 2007 memorandum. (AR627-30, 631-32, and 633-35.) Valeant also ignores the fact that Dr. Beitz is the supervisor of the DDDP, was aware of the views of the DDDP scientists, and was responsible for addressing the arguments made by the DDDP and reconciling them with those of OGD. (AR727-909; June 18 Order, Finding of Fact ¶ 48, Conclusion of Law ¶ 33.)[6]

B. Dr. Wilkin's Letter Was Not Considered During the Reconsideration of Spear's ANDA Approval.

Valeant alleges that the FDA's reconsideration of Spear's ANDA "was flawed as a matter of law" because "Drs. von Eschenbach, Woodcock, Throckmorton and

[6] Valeant also alleges that it did not have an "opportunity to review or challenge Dr. Wilkin's statement because it was submitted in the ANDA, rather than the Citizen's Petition Docket." (Am. Compl. ¶ 49.) This allegation is irrelevant to Valeant's APA claim and is also not supported by the Administrative Record. Dr. Wilkin's letter includes the same or similar statements as those that had been made by Spear (AR1047-58, 141-88, 450-70, 502-28**),** and Valeant had ample opportunity to respond to those arguments in its voluminous submissions to the FDA in support of its citizen petition (AR1-138, 190-449, 472-88, 530-48, 549-71).

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Beitz re-affirmed the approval of Spear's ANDA by relying upon" Dr. Wilkin's statement, which Valeant characterizes as "tainted." (Am. Compl. ¶ 59.)

Drs. Beitz, Throckmorton, Woodcock, and von Eschenbach reconsidered Spear's ANDA approval in order to address a *potential* conflict of interest issue and a scientific issue. (AR1087.) In order to address the first issue, these physicians reviewed Spear's ANDA approval without regard to any of the information in Dr. Wilkin's letter. (AR1107-08, 1096, 1089-90, and 1088; June 18 Order, Findings of Fact ¶¶ 65-77.) The memoranda that were prepared by these physicians reflect the careful and thoughtful analysis of the scientific issues that was undertaken by the FDA. (AR1088-225; June 18 Order, Findings of Fact ¶¶ 65-77.) In addition, Valeant ignores the fact that Dr. von Eschenbach was not involved in the original ANDA approval. (June 18 Order, Findings of Fact ¶ 77, Conclusion of Law ¶ 40.)

Valeant, as this Court has already held, cannot overcome the presumption that the FDA acted correctly and in good faith. "[T]here is a presumption of legitimacy accorded to the Government's official conduct." *Nat'l Archives & Records Admin. v. Favish*, 541 U.S. 157, 174, 124 S. Ct. 1570, 158 L. Ed. 2d 319 (2004) (citing *U.S. Dep't of State v. Ray*, 502 U.S. 164, 178-79, 112 S. Ct. 541, 116 L. Ed. 2d 526 (1991)). In order to displace the presumption, clear evidence to the contrary must be present. *Id.* Moreover, "[g]overnment officials . . . are presumed to have acted in good faith." *Seattle Audubon Soc'y v. Lyons*, 871 F. Supp. 1291, 1318 (W.D. Wash. 1994) (citing *Hoffman v. United States*, 894 F.2d 380, 385 (Fed. Cir. 1990)).

Valeant also totally ignores the fact that the FDA Office of Internal Affairs and Office of Inspector General investigated whether Dr. Wilkin had a conflict and determined that he did not and that this Court has found that "Valeant has not made a sufficient showing of an ethical violation." (Bhatt Dec. Ex. 1, Vantrease Dec. ¶¶ 4-5; Bhatt Dec. Ex. 2, Doyle Dec. ¶ 5; June 18 Order, Finding of Fact ¶ 78.) Therefore, even if Valeant could prove that Dr. Wilkin's opinion was considered, which this

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Court has held it cannot do on the Administrative Record that is before the Court, no harm was done and nothing would be gained by remand to the FDA.

V.

THE FDA'S RECONSIDERATION OF SPEAR'S ANDA APPROVAL SATISFIED THE APPLICABLE REGULATORY REQUIREMENTS

Valeant alleges that the FDA "failed to reconsider its approval decision in a manner that effectively omitted Dr. Wilkin's statement." (Am. Compl. ¶ 60.) Valeant asks this Court to declare that review of Spear's ANDA approval, reaffirmation of Spear's ANDA Approval, and denial of Valeant's citizen petition "can only be lawfully conducted by . . . FDA officials who were not tainted by the approval or re-affirmation of ANDA No. 77-524, or the denial of Valeant's Citizen Petition." (Am. Compl., Prayer for Relief ¶ A(v)(a).)

Valeant's Amended Complaint ignores the fact that this Court has already rejected this argument, holding that "[f]our high-ranking FDA officials were involved in the review process (two of whom – Drs. Throckmorton and von Eschenbach – were not involved in the original approval)" and "there is no legal requirement that 'new' agency personnel must be involved in the reconsideration process." (June 18 Order, Conclusions of Law ¶¶ 40 and 41.)

The FDA satisfied the requirements of the applicable regulatory provisions. Administrative reconsideration of action is addressed in 21 C.F.R. § 10.33. Subsection (a) provides that the "[t]he Commission may at any time reconsider a matter, on the Commissioner's own initiative." In this case, the FDA on May 14, 2008 decided to reconsider Spear's approval in order to address a potential conflict of interest and a scientific issue. AR1087.

Subsection (h) provides that

> [t]he Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken. If review of the matter is pending in the courts, the Commissioner

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> may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding is to include all additional documents relating to such reconsideration.

Here, the FDA decided to reconsider Spear's approval after Valeant filed its TRO application, so the FDA asked the Court to enter a stay. As a result of the reconsideration, the FDA reaffirmed Spear's ANDA approval and submitted the Administrative Record, which included the documents relating to the reconsideration, to the Court. (AR1088-225.)

Subsection (i) provides that "[t]he Commissioner may reaffirm, modify, or overrule the prior decision, in whole or in part, and may grant such other relief or take such other action as is warranted." The FDA reaffirmed Spear's ANDA approval.

Subsection (k) provides that the contents of the record of the administrative proceeding includes "the Commissioner's decision" and "the administrative record relating to reconsideration." The Administrative Record includes the decision of Dr. von Eschenbach, the Commissioner of the FDA, and the memoranda prepared by Drs. Beitz, Throckmorton, and Woodcock, relating to the reconsideration. (AR1088-225.)

Administrative stay of action is addressed in 21 C.F.R. § 10.35. Subsection (a) provides that "[t]he Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter." In this case, the FDA stayed Spear's ANDA approval pending its reconsideration. (AR1087.) Thus, the FDA satisfied each and every requirement of the applicable regulations, and the law does not require more.

Valeant, however, is asking this Court to impose upon the FDA an additional requirement: FDA reconsideration of Spear's ANDA approval and denial of Valeant's citizen petition by persons who were not involved in the original process. The requirement that Valeant seeks to impose upon the FDA finds no basis in the applicable rules and is in direct conflict with the Supreme Court's admonition in

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Pension Benefit Guaranty Corp. v. LTV Corp., 496 U.S. 633, 654, 110 S. Ct. 2668, 110 L. Ed. 2d 579 (1990), that "courts are not free to impose upon agencies specific procedural requirements that have no basis in the APA."

CONCLUSION

For the foregoing reasons, Spear respectfully requests that the Court grant its motion for summary judgment.

Dated: June 8, 2009

Respectfully submitted,

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