UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, Inc. Plaintiff, v. MICHAEL O. LEAVITT, in his official capacity as Secretary of Health and Human Services; ANDREW C. VON ESCHENBACH, M.D., in his official capacity as Commissioner of Food and Drugs; UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants, MYLAN PHARMACEUTICALS INC., Intervenor-Defendant.	Case No. 08-395-RML

TEVA PHARMACEUTICALS USA, INC.'S RESPONSE TO
MYLAN PHARMACEUTICALS' SUPPLEMENTAL MEMORANDUM

Mylan is trying to make this case into something it is not. Teva's complaint does not assert an estoppel claim, and Teva's reliance is not at issue. Instead, Teva's complaint raises the purely legal question of whether FDA violated the APA when it denied Teva's citizen petition. As *Chenery* makes clear, the validity of that decision rises or falls on the Agency's purely legal rationale: that its "electronic Orange Book Query" feature—but not the Orange Book and then-current Cumulative Supplement—provided the legally operative patent listings at the time Teva submitted its risperidone ANDA. That, of course, explains why FDA itself agrees that no discovery is necessary here. If the Query feature controlled, Teva's certification was improper and it is not entitled to exclusivity—regardless of what the Cumulative Supplement indicated. And if the current Cumulative Supplement controlled, then Teva's certification was not only

appropriate but legally required, and Teva is entitled to exclusivity—regardless of what the Query feature would have shown (and whether or not Teva consulted that tool of convenience).

Mylan's discovery requests thus have no bearing on the purely legal dispute before the Court, which is whether FDA's rationale is consistent with the statute, regulations, Orange Book, and monthly Cumulative Supplements. It is not. As each of those sources makes clear, the Orange Book and current Cumulative Supplement comprised the legally operative source of patent data required by Hatch-Waxman at the time Teva submitted its ANDA:

- The statute required FDA to "publish and make available to the public … a list" of all drug-claiming patents, and to update that list "every thirty days." 21 U.S.C. §§ 355(j)(7)(A)(i)-(iii).

- FDA's regulations defined "the list" as "*Approved Drug Products with Therapeutic Equivalence Evaluations* [*i.e.*, the Orange Book] and any current supplement to the publication," 21 C.F.R. § 314.3; provided that "[p]atent information submitted by the last working day of a month will be published in that month's supplement to the list," *id*. § 314.53(e); and required applicants "despite any disagreement as to the correctness of the patent information, [to submit] an appropriate certification for each listed patent." *Id*. § 314.53(f).

- And, most important, in 2001 (but not today) both the Orange Book and monthly Cumulative Supplements explicitly confirmed that those publications (but not the electronic Orange Book Query feature) provided the "drug patent … information required of the Agency by [Hatch-Waxman]," and instructed applicants that the annual Orange Book "must be used in conjunction with the most current Cumulative Supplement … [b]ecause all parts of the publication are subject to changes, additions, or deletions." *See, e.g.*, August 2001 Supplement at iii.

It thus makes no difference whether Teva consulted the electronic Orange Book Query feature before submitting its ANDA: that tool had no legal force. Instead, every source of law made clear that the annual Orange Book and current Cumulative Supplement controlled, and that applicants were required to submit a certification to any patent whose listing was reflected in those official sources. FDA cannot lawfully divest an applicant of its exclusivity when the applicant's certification conformed to the Agency's own legal directives—and that is so whether or not the applicant also happened to consult a website, a crystal ball, or a deck of Tarot cards.

As a result, and although Teva does not believe that any of its employees consulted the electronic Orange Book Query feature prior to the submission of Teva's risperidone ANDA, Teva has no objection to this Court assuming *arguendo*: (1) that Teva knew about the electronic Orange Book Query feature before August 28, 2001; (2) that someone at Teva searched for Risperdal® in the electronic Orange Book Query feature before August 28, 2001; and (3) that even though FDA cannot even identify the date on which it allegedly updated the electronic Orange Book Query feature, someone at Teva saw that only the '663 patent appeared in the electronic Orange Book Query feature's Risperdal® record before August 28, 2001. But none of that changes the fact that only legally operative records of official patent information—the annual Orange Book and latest Cumulative Supplement—reflected no change in the patent listings for Risperdal®, and that those legally operative sources controlled in the event of an apparent conflict. Whatever the electronic Orange Book Query feature said, and whatever Mylan speculates Teva saw, the '952 patent remained officially listed, and Teva was legally required to submit a Paragraph IV certification to that patent..

Teva thus requests that this Court deny Mylan's request for discovery, and proceed to decide this case on the merits pursuant to Rule 65(a)(2).

Dated: April 10, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2008, I caused a copy of TEVA PHARMACEUTICALS USA, INC.'S RESPONSE TO MYLAN PHARMACEUTICAL'S SUPPLEMENTAL MEMORANDUM to be served upon the following attorneys through the Court's ECF filing system:

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