

**ATTACHMENT D**

Oral Argument Scheduled September 12, 2006  
No. 06-5154

UNITED STATES COURT OF APPEALS FOR DISTRICT OF COLUMBIA CIRCUIT JUL 27 2006 RECEIVED	UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT RANBAXY LABORATORIES LIMITED, <i>et al.</i> , Plaintiffs-Appellees, and IVAX PHARMACEUTICALS, INC. FILED Plaintiff-Appellee, v. MICHAEL O. LEAVITT, Secretary of Health and Human Services, <i>et al.</i> , Defendants-Appellants.	UNITED STATES COURT OF APPEALS FOR DISTRICT OF COLUMBIA CIRCUIT JUL 27 2006 CLERK
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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

REPLY BRIEF FOR THE APPELLANTS

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FOR THE DISTRICT OF COLUMBIA CIRCUIT

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No. 06-5154

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RANBAXY LABORATORIES LIMITED, *et al.*,

Plaintiffs-Appellees,

and

IVAX PHARMACEUTICALS, INC.,

Plaintiff-Appellee,

v.

MICHAEL O. LEAVITT, Secretary of Health and Human Services, *et al.*,

Defendants-Appellants.

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REPLY BRIEF FOR THE APPELLANTS

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**Summary of Argument**

1. The question presented in this case is whether a paragraph IV certification remains the proper certification under 21 U.S.C. 355(j)(2)(A)(vii) when a patent has been delisted from the Orange Book. The statute is silent on delisting and its effect on patent certification and generic exclusivity, and thus does not answer the question. Because the statute does not answer the question, the agency looked to its delisting regulation, 21 C.F.R. 314.94(a)(12)(viii)(B), a

paragraph IV certification].” 59 Fed. Reg. at 50362. Ranbaxy’s reliance on this Federal Register notice is, therefore, clearly misplaced.

c. Ivax asserts that FDA’s post-*Mova* Guidance for Industry and November 1998 interim rule represent the agency’s position that exclusivity should be granted to the first ANDA applicant who files a paragraph IV certification without regard to whether there is a lawsuit. Ivax Br. 25 (citing Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (June 1998), *available at* [www.fda.gov/cder/guidance/2576fnl.pdf](http://www.fda.gov/cder/guidance/2576fnl.pdf); and 180-day Generic Drug Exclusivity for Abbreviated New Drug Applicants Interim Rule, 63 Fed. Reg. 59,710, 59,711 (1998)). Notably, in the portions of the documents that Ivax cites, there was no discussion of exclusivity when there has been a request to delist a patent. Rather, FDA was characterizing the holdings in the *Inwood Labs., Inc.*, *supra*, and *Mova* district court decisions, and addressed the “threshold question of whether an ANDA applicant that was not sued for patent infringement as a result of its paragraph IV certification would nonetheless be eligible for exclusivity.” Guidance at 5 (noting that “[t]here are many additional issues related to the application of the statutory provisions that have yet to be resolved”). In any event, this Court’s *Mova* decision expressly reserved judgment on the question of

whether FDA could impose a litigation requirement, and limited its decision to striking down FDA's "win first" version of the successful defense requirement.

*Mova*, 140 F.3d at 1069.

There is also no merit to Ivax's additional contention that the delisting regulation is invalid because it cross-references the pre-*Mova* version of 21 C.F.R. 314.107(c), which contained the now-deleted reference to the successful defense requirement, Ivax Br. 24-26. As demonstrated above, FDA has always interpreted the delisting regulation the way it does now, and Ivax's argument appears to conflate the agency's grant of exclusivity, at issue in *Mova*, with the agency's determination to delist patents in certain circumstances, at issue here. See also p. 14, *supra*.

Finally, Ivax argues that FDA has shifted its position on appeal as to the meaning of the delisting regulation, "now conceding that 'declaratory judgment litigation' would preclude delisting." Ivax Br. 32.<sup>21</sup> Our reference to declaratory judgment actions on page 32 of our opening brief was inadvertent. FDA's interpretation is the one in its citizen petition response, and it clearly states that

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<sup>21</sup> Ivax also cites page 8 of our opening brief, which, in discussing the statutory and regulatory background, addressed the kinds of court decisions that can be the basis for the court decision trigger in Section 355(j)(5)(B)(iv). See *Apotex, Inc. v. FDA*, *supra*, 449 F.3d at 1253 (discussing the court decision trigger).

“lawsuit under § 314.107(c) \* \* \* [i]s a lawsuit as a result of the first applicant’s paragraph IV certification \* \* \*, rather than a lawsuit arising from *any* ANDA applicant’s paragraph IV certification to the patent.” JA294 n.17 (emphasis added). Accord: GPhA Amicus Br. 9-10. This Court in any event should not rely on the substance of our inadvertent mistake because, in appeals involving agency decisions, the Court looks to the reasoning in the agency’s decision alone. *People’s Mojahedin Org. of Iran v. Dep’t of State*, 182 F.3d at 23 n.7.

More importantly, the meaning of “lawsuit” in the delisting regulation is not, and never has been, at issue in this case. When the agency referred to it in the response to the citizen petitions, it was only as explanatory background. See JA294 & n.17. For that reason, it had no effect on FDA’s decision here and, accordingly, should have no effect on the ultimate outcome of this case. For this reason, Ivax’s argument (Br. 32-34) that a distinction between patent litigation against a first-filer within 45 days of notice (on the one hand) and declaratory judgment actions (on the other) has no meaning for this case.

**C. The Case Law Supports FDA’s Approach to Patent Delisting.**

In our opening brief, we demonstrated that FDA’s approach to patent delisting and its effect on both patent certification and 180-day exclusivity was sustained in two cases that addressed extremely similar issues and resolved the

## Conclusion

For the foregoing reasons and the reasons stated in our opening brief, the district court's judgment should be reversed, and consistent with this Court's June 1, 2006 order granting expedition, we respectfully request the Court to do so as promptly as possible — *and to immediately issue its mandate* — in order to permit FDA to approve other ANDAs whose approvals have been delayed by the district court decision.

Respectfully submitted,

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