IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.A.R.L., Plaintiffs, v ACTAVIS LABORATORIES FL, INC., Defendant.	:	CIVIL ACTION NO. 15-164-LPS
COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.A.R.L., Plaintiffs, v ALVOGEN PINE BROOK, LLC, Defendant.	:	CIVIL ACTION NO. 15-193-LPS

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Wilmington, Delaware
Tuesday, May 23, 2017
Bench Trial - Volume B

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BEFORE: HONORABLE LEONARD P. STARK, Chief Judge

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P R O C E E D I N G S

(REPORTER'S NOTE: The following bench trial was held in open court, beginning at 8:35 a.m.)

08:19:50

08:51:34 (Dr. Fassihi left the courtroom.)

08:51:34 MR. CONCA: Thank you, Your Honor.

08:51:36 THE COURT: Okay.

08:51:38 MR. CONCA: Your Honor, defendants' motion for judgment under 52(c) should be denied because it suffers from several fundamental flaws.

08:51:46 First, it ignores the extensive affirmative documentary evidence that the defendants' products are macroscopically homogeneous, which includes numerous ANDA product development documents reflecting the substantial efforts that defendants made to design their products and their manufacturing process for making them so that the blended excipients will be homogeneous throughout the manufacturing process, and so that the resulting tablets will likewise remain homogeneous. These documents, including defendants' own extensive use of internal active ingredient uniformity testing, including express admissions in these documents that the defendants themselves use active ingredient uniformity testing with results routinely close to a hundred percent as a surrogate to demonstrate excipient homogeneity in the product blend.

08:52:38 For example, PTX-230 at page 4 states, "In addition, the final blend was also found to be homogeneous based on the results of blend uniformity studies and had good compressibility."

PTX-228 at 193. "To assess homogeneity of the blend, blend uniformity sampling will still be performed."

Further, both defendants' documents establish that the tablet compression was designed to minimize segregation of the homogeneous product blends created during their respective manufacturing processes, during those mixing processes.

Alvogen's PTX-228 at 170, "The compression process must provide the desired dose in each tablet by avoiding segregation of the uniform blend." And Actavis' PTX-230. "This process of blending in a series of steps ensured homogeneous mixing of nine milligrams of active ingredient in 300 milligrams of blend as evidenced by blend uniformity data and content uniformity data from the core tablet."

These ANDA documents are legal representations to FDA and defendants can't deviate from them without amending their ANDAs.

THE COURT: Where is the documentary evidence that it is macroscopically homogeneous as viewed by the naked eye?

MR. CONCA: The documentary evidence includes defendants' witness testimony, but the documentary evidence itself is the photographs that the defendants' experts took

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