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Attorneys for Defendant
Ranbaxy Pharmaceuticals Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

) Civil Action No. 00-5172 (MLC)
)
) DECLARATION OF SHIRLEY
) TERNYIK IN SUPPORT OF RANBAXY
GLAXO GROUP LIMITED and) PHARMACEUTICALS INC.'S
GLAXO WELLCOME, INC.,) OPPOSITION TO PLAINTIFFS'
) MOTION FOR A PRELIMINARY
Plaintiffs,) INJUNCTION
)
v.)
) JUDGE: Mary Little Cooper
RANBAXY PHARMACEUTICALS INC.,) DATE: December 12, 2000
) TIME: 11:00 A.M.
Defendant.)
)
) FILED UNDER SEAL
)
)

I, Shirley Temyik, declare as follows:

1. I am currently the Director of Regulatory Affairs for Ranbaxy Pharmaceuticals Inc. ("Ranbaxy"). I have personal knowledge of the matters set forth herein, and if I am called upon to testify, I could and would testify competently thereto.

2. On April 19, 1999, Ranbaxy Laboratories Limited ("Ranbaxy Laboratories") filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking approval to market an antibiotic containing cefuroxime axetil. I am the United States Agent to the FDA for Ranbaxy Laboratories with respect to this ANDA.

3. Ranbaxy cannot market its cefuroxime axetil antibiotic in the United States prior to the FDA approving Ranbaxy Laboratories' ANDA.

4. Under the ANDA approval process, a company seeking approval to market a drug product need not conduct clinical trials. Instead, the company must show that the drug product that is the subject of the ANDA is bioequivalent to a drug product that has already been approved by the FDA. "Bioequivalence" does not mean or require that the composition of the drug products be the same. Rather, the drug product that is the subject of the ANDA must deliver a comparable amount of active moiety to a patient as the already-approved drug product. Cefuroxime is the active moiety in the drug product that is the subject of Ranbaxy Laboratories' ANDA.

5. The cefuroxime axetil antibiotic that is the subject of Ranbaxy Laboratories' ANDA contains a mixture of 12% crystalline cefuroxime axetil and 88% amorphous cefuroxime axetil. The ANDA permits the content of crystalline cefuroxime axetil to range between 10-15%, but the crystalline content cannot deviate from this range. Ranbaxy specifically tests its drug product to ensure the presence of between 10-15% crystalline cefuroxime axetil. Any batch of drug product that fails to satisfy the crystalline cefuroxime axetil content requirement must be and will be rejected.

6. In Ranbaxy's cefuroxime axetil antibiotic, both the crystalline cefuroxime axetil and the amorphous cefuroxime axetil deliver the active moiety, cefuroxime, to the patient. The

crystalline cefuroxime axetil in Ranbaxy's cefuroxime axetil antibiotic is not an unavoidable impurity or a trace component, but is a necessary and active part of the drug product.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 29th day of November, 2000, in Princeton, New Jersey.

Shirley Ternyik

Shirley Ternyik