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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SMITHKLINE BEECHAM CORPORATION,	:	
SMITHKLINE BEECHAM P.L.C., and	:	CIVIL ACTION
BEECHAM GROUP, P.L.C.	:	NO. 99-CV-4304
v.	:	NO. 00-CV-4888
	:	NO. 01-CV-159
APOTEX CORPORATION, APOTEX, INC.,	:	NO. 01-CV-2169
and TORPHARM, INC.	:	

:Judge R. Barclay Surrick

SMITHKLINE BEECHAM CORPORATION, and	:	
BEECHAM GROUP, p.l.c.	:	CIVIL ACTION
v.	:	NO. 99-CV-2926
	:	NO. 00-CV-5953

GENEVA PHARMACEUTICALS, INC.

SMITHKLINE BEECHAM CORPORATION, and	:	
SMITHKLINE BEECHAM, P.L.C., and	:	CIVIL ACTION
BEECHAM GROUP, p.l.c.	:	NO. 00-CV-1393
v.	:	NO. 00-CV-6464
	:	NO. 01-CV-2602

ZENITH GOLDLINE PHARMACEUTICALS, INC. and
SUMIKA FINE CHEMICALS CO., LTD.

SMITHKLINE BEECHAM CORPORATION, and	:	
BEECHAM GROUP, P.L.C.	:	CIVIL ACTION
v.	:	NO. 01-CV-1027
	:	NO. 01-CV-3364

ALPHAPHARM PTY., LTD.

SMITHKLINE BEECHAM CORPORATION and	:	
BEECHAM GROUP, P.L.C.	:	CIVIL ACTION
v.	:	NO. 01-CV-2981

ANDRX PHARMACEUTICALS, INC.,
ANDRX PHARMACEUTICALS, L.L.C.,
BASF CORPORATION,
BASF PHARMACHEMIKALIEN GMBH & CO. KG and
KNOLL A.G.

**SB'S OBJECTIONS AND RESPONSES TO
APOTEX CORP., APOTEX, INC. AND TORPHARM, INC.'S
FIRST SET OF REQUESTS (Nos. 1-14) FOR ADMISSION**

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure, plaintiffs SmithKline Beecham Corporation, SmithKline Beecham p.l.c., and Beecham Group p.l.c. (collectively "SB") object and respond to the First Set of Requests (Nos. 1-14) for Admission of defendants Apotex Corp., Apotex, Inc., and Torpharm, Inc. (collectively "Apotex") as follows.

GENERAL OBJECTIONS

The General Objections set forth in SB's Responses and Objections to Apotex's First Set of Interrogatories (Nos. 1-11), dated April 7, 2000, are adopted and are incorporated herein by reference.

RESPONSES TO ADMISSION REQUESTS

Admission Request No. 1

The clinical trials disclosed in and submitted in support of SmithKline's NDA No. 20-031 for paroxetine hydrochloride did not use a product that is or that contains paroxetine mesylate or the mesylate salt of paroxetine.

Response

Admitted.

Admission Request No. 2

The clinical trials disclosed in and submitted in support of SmithKline's NDA No. 20-031 for paroxetine hydrochloride did not include any clinical trial test results in which the safety and efficacy, to FDA standards, of paroxetine mesylate or mesylate salt was determined.

Response

SB admits that the clinical trials disclosed in and submitted in support of SB's NDA No. 20-031 for paroxetine hydrochloride did not include any clinical trial test results in which the safety and efficacy of paroxetine mesylate or mesylate salt was determined.

SB objects to the remainder of Admission Request No. 2 as calling for an admission of law or a purely legal conclusion rather than "statements or opinions of fact or of the application of law to fact" as required by Rule 36(a) of the Federal Rules of Civil Procedure.

SB also objects to the remainder of Admission Request No. 2 as calling for expert opinion as to FDA standards.

Admission Request No. 3

Prior to January 1, 1998, SmithKline performed no FDA-sanctioned clinical investigations with paroxetine mesylate.

Response

Admitted.

Admission Request No. 4

Prior to January 1, 1999, SmithKline performed no FDA-sanctioned clinical investigations with paroxetine mesylate.

Response

Admitted.

Admission Request No. 5

Prior to January 1, 2000, SmithKline performed no FDA-sanctioned clinical investigations with paroxetine mesylate.

Response

Admitted.

Admission Request No. 6

Prior to January 1, 2001, SmithKline performed no FDA-sanctioned clinical investigations with paroxetine mesylate.

Response

Admitted.

Admission Request No. 7

Prior to January 1, 2002, SmithKline performed no FDA-sanctioned clinical investigations with paroxetine mesylate.

Response

Admitted.

Admission Request No. 8

Prior to January 1, 1998, SmithKline performed no double-blind clinical investigations with paroxetine mesylate and paroxetine hydrochloride.

Response

Admitted.

Admission Request No. 9

Prior to January 1, 1999, SmithKline performed no double-blind clinical investigations with paroxetine mesylate and paroxetine hydrochloride.

Response

Admitted.

Admission Request No. 10

Prior to January 1, 2000, SmithKline performed no double-blind clinical investigations with paroxetine mesylate and paroxetine hydrochloride.

Response

Admitted.

Admission Request No. 11

Prior to January 1, 2001, SmithKline performed no double-blind clinical investigations with paroxetine mesylate and paroxetine hydrochloride.

Response

Admitted.

Admission Request No. 12

Prior to January 1, 2002, SmithKline performed no double-blind clinical investigations with paroxetine mesylate and paroxetine hydrochloride.

Response

Admitted.

Admission Request No. 13

SmithKline has not granted Synthon Pharmaceuticals, Inc. the right to rely on any SmithKline proprietary data that is disclosed in SmithKline's NDA No. 20-031 in support of Synthon's NDA NO. 21-299.

Response

Admitted.

Admission Request No. 14

The clinical trials disclosed in and submitted in support of SmithKline's NDA No. 20-031 for paroxetine hydrochloride did not determine, to FDA's standards, that the salts of paroxetine hydrochloride and paroxetine mesylate are bioequivalent.

Response

SB admits that its clinical trial disclosed in and submitted in support of SB's NDA No. 20-031 did not use paroxetine mesylate. See Response to Admission Request No. 1.

SB objects to the remainder of Admission Request No. 14 as calling for an admission of law or a purely legal conclusion rather than "statements or opinions of fact or of the application of law to fact" as required by Rule 36(a) of the Federal Rules of Civil Procedure.

SB also objects to the remainder of Admission Request No. 14 as calling for expert opinion as to whether paroxetine hydrochloride and paroxetine mesylate are bioequivalent according to FDA standards.

Dated: September 17, 2003

By: 

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