
DIPAK CHATTARJ - NOVEMBER 9, 2000

GLAXO GROUP v. RANBAXY PHARMACEUTICALS

Page 1 to Page 196

CONDENSED TRANSCRIPT AND CONCORDANCE
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JA 1311

EX. 24 PAGE 1

BSA

Page 1

(1) IN THE UNITED STATES DISTRICT COURT
 (2) FOR THE DISTRICT OF NEW JERSEY
 (3) CIVIL ACTION NO.

(4) GLAXO GROUP LIMITED :
 (5) and :
 (6) GLAXO WELLCOME, INC., :
 (7) Plaintiffs, : DEPOSITION UPON
 (8) -vs- : ORAL EXAMINATION
 (9) : OF
 (10) : DIPAK CHATTARJ
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 (12) :
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(12) TRANSCRIPT of the
 (13) stenographic notes of STANLEY B. RIZMAN, a Notary
 (14) Public and Certified Shorthand Reporter of the
 (15) State of New Jersey, Certificate No. X100304,
 (16) taken at the offices of Mathews, Collins,
 (17) Shepherd & Gould, P.A., 100 Thanet Circle,
 (18) Suite 306, Princeton, New Jersey, on Thursday,
 (19) November 9, 2000, commencing at 9:45 a.m.
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 (22)
 (23)
 (24)
 (25)

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(1)	I N D E X		
(2)	WITNESS		PAGE
(3)	DIPAK CHATTARJ		
(4)	Direct examination by Ms. Linn		5
(5)			
(6)			
(7)	EXHIBITS	DESCRIPTION	IDENT.
(8)	1	Notice of Deposition	10
(9)	2	U.S. Patent No. 4,516,181	40
(10)	3	U.S. Patent No. 4,897,270	45
(11)	4	Document entitled "Bayer to Pump \$5 million in Ranbaxy" from The Economic Times.	54
(12)	5	Volume 1 of Ranbaxy's ANDA for cefuroxime axetil tablets, 125 milligrams, 250 milligrams and 500 milligrams, Bates No. R 3734 through 3857	66
(13)			
(14)			
(15)			
(16)	6	Volume 8 of ANDA, Bates Nos. R 3911 to R 4263	78
(17)	7	Volume 9, Bates Nos. R 1922 to R 2477	130
(18)			
(19)	8	Document entitled "Drug Master File, Cefuroxime Axetil (Volume 1 of 2)"	141
(20)			
(21)	9	Document entitled "Drug Master File, Cefuroxime Axetil (Volume 2 of 2)"	141
(22)			
(23)	10	Document entitled "Drug Master File, Cefuroxime Axetil (Crystalline)"	156
(24)			
(25)			

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(1) Appearance:
 (2) HOPGOOD, CALIMAFDE, JUDLOWE & MONDOLINO, LLP,
 (3) Lincoln Building
 (4) 60 East 42nd Street
 (5) New York, New York 10165
 (6) BY: JANET R. LINN, ESQ., and
 (7) BRIAN W. NOLAN, ESQ.,
 (8) For the Plaintiffs.
 (9) MATHEWS, COLLINS, SHEPHERD & GOULD, P.A.
 (10) 100 Thanet Circle, Suite 306
 (11) Princeton, New Jersey 08540-3674
 (12) BY: RONALD GOULD, ESQ.,
 (13) and
 (14) KNOEBE, HARTENS, OLSON & BEAR, ESQS.,
 (15) 629 Newport Center Drive
 (16) Newport Beach, CA 92660
 (17) BY: WILLIAM R. ZIMMERMAN, ESQ.,
 (18) For the Defendants.
 (19)
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 (21)
 (22)
 (23)
 (24)
 (25)

(11) Also Present:
 (12) Jay R. Deshmukh, Director, Intellectual Property
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 (24)
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(1)	I N D E X (Continued)		
(2)	EXHIBITS	DESCRIPTION	IDENT.
(3)	11	Volume 2 of the Drug Master File for Cefuroxime Axetil Crystalline, (Volume 2 of 2), Bates Nos. R 4534 through R 4907	157
(4)			
(5)	12	Document entitled "Cefuroxime Axetil DMF 14074 DMF Amendment"	163
(6)	13	U.S. Patent No. 5,013,833	176
(7)	14	Document Bates numberd R 2478 through R 2765	179
(8)			
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EX. 24 PAGE 2

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- (1) DIPAK CHATTARAJ, residing at
(2) Seven Bayberry Drive, Princeton, New
(3) Jersey, being first duly sworn, testifies
(4) as follows:
(5) DIRECT EXAMINATION
(6) BY MS. LINN:
(7) Q I'll call you "Dr. Chattarj."
(8) A Mister. I'm not a doctor.
(9) Q How do you pronounce your last name?
(10) A Chattarj.
(11) Q Mr. Chattarj, where are you employed?
(12) A I'm employed with Ranbaxy Pharmaceutical,
(13) Inc.
(14) Q Where is Ranbaxy Pharmaceuticals,
(15) Inc. located?
(16) A 600 College Road East, Princeton, New
(17) Jersey.
(18) Q What is your position with Ranbaxy
(19) Pharmaceuticals?
(20) A I'm the President.
(21) Q Do you also have a position with
(22) Ranbaxy Laboratories Limited?
(23) A It is a wholly-owned subsidiary.
(24) Q Do you have any position in Ranbaxy
(25) Laboratories Limited?

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- (1) A I'm a transfer here. I have a position
(2) there.
(3) Q Excuse me?
(4) A I'm a transfer here. I'm on a posting
(5) here.
(6) Q So you have a position there?
(7) A Yes.
(8) Q What is your position with Ranbaxy
(9) Laboratories, Inc.?
(10) A I would be called a Regional Director.
(11) MR ZIMMERMAN: Janet, one quick
(12) point. Are we going to maintain the deposition
(13) outside counsel only for this litigation?
(14) MS. LINN: Yes. Until we have a
(15) protective order.
(16) Q Who do you report to as Regional
(17) Director?
(18) A I report to the President of the company.
(19) Q Who is the President of the company?
(20) A Doctor Brian Tempest.
(21) Q Can you spell that name?
(22) A Brian, B-r-i-a-n. Tempest, T-e-m-p-e-s-t.
(23) Q Where is Dr. Tempest employed?
(24) A In New Delhi.
(25) Q Dr. Tempest is the President of

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- (1) Ranbaxy Limited?
(2) A He's the President of Pharmaceuticals.
(3) He's the President, Pharmaceuticals.
(4) There are other sides -- he's not the
(5) President of R&D, for example. He's the President
(6) of Pharmaceuticals. Pharmaceuticals business in
(7) Ranbaxy.
(8) Q I thought you said Ranbaxy?
(9) A No.
(10) Q He's the President of the
(11) pharmaceutical business in Ranbaxy Laboratories
(12) Limited?
(13) A Yes.
(14) Q You mentioned that Ranbaxy, Inc. is a
(15) wholly-owned subsidiary of Ranbaxy Laboratories
(16) Limited?
(17) A That's right.
(18) Q Is Ranbaxy Limited a public company?
(19) A Yes.
(20) Q Is it traded on New York Stock
(21) Exchange?
(22) A No.
(23) Q Where is it traded?
(24) A It is traded in the National Stock Exchange
(25) in India. Bombay Stock Exchange and the Dehli

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- (1) Stock Exchange.
(2) It is also traded as a GDR. I think
(3) GDR is traded in Luxembourg.
(4) Q What is GDR?
(5) A Global Depository Receipt.
(6) Q Have you ever been deposed before?
(7) A Once before.
(8) Q When was that?
(9) A That was in the year '98.
(10) Q In 1998?
(11) A Yes.
(12) Q What case was that in?
(13) A It was '97, I think. That was Ranadine
(14) Form 1.
(15) Q For those of us who were not involved
(16) in that, was Glaxo Wellcome against Ranbaxy?
(17) A That's right.
(18) Q Relating to the patents on Ranadine?
(19) A Yes.
(20) Q Who was the defendant in that
(21) litigation? Was it Ranbaxy Pharmaceuticals or
(22) Ranbaxy Laboratories?
(23) A It was Ranbaxy Laboratories Limited.
(24) Ranbaxy Pharmaceuticals. Schein, S-c-h-e-i-n,
(25) Pharmaceuticals.

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- (1) A I decide. The whole selection not by me.
(2) Any business is a teamwork. But the decision is
(3) mine, yes.
(4) Q You have the ultimate decision. Is
(5) that what you say?
(6) A There is a committee called Pharmaceutical
(7) Business Committee of which I am a member. That
(8) is entire Ranbaxy Laboratories Business Committee.
(9) But, as I said, regional
(10) responsibility is mine. So it would be very
(11) unusual if my recommendations were not accepted.
(12) Q Does Ranbaxy the Business Committee
(13) have input on what ANDAs are going to be filed in
(14) the U.S.?
(15) A The Pharmaceutical Business Committee is a
(16) corporate thing. That is Ranbaxy Laboratories
(17) Limited. All the units locally, all the
(18) regionals. All the Regional Directors sit on this
(19) committee along with the President.
(20) Q Do they have input on filing ANDAs in
(21) the U.S.?
(22) A They receive our requests. Much of the R&D
(23) work is carried out in India. So I may have ten
(24) requests. They may be able to accommodate only
(25) eight. So they will ask me to choose eight

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- (1) because there are source constraints and I will
(2) choose those final eight.
(3) It is rare for the committee not to
(4) accept.
(5) Q Who is on that committee? The
(6) Regional Directors?
(7) A The regional directors and the President of
(8) Pharmaceuticals. But others represented are R&D
(9) Chief, the Chemical Manufacturing Chief, the
(10) Pharmaceutical Manufacturing Chief, and so on.
(11) Associated functions. Finances, also.
(12) Q They're also on the committee?
(13) A They're also on the committee.
(14) Q Were you the person to decide a final
(15) ANDA for Cefuroxime Axetil?
(16) A Yes.
(17) Q When did you make that decision?
(18) MR. ZIMMERMAN: I have to make that
(19) decision.
(20) We're way outside of the lines of the
(21) 30(b)(6) topics that were noticed.
(22) MS. LINN: I think this is part of
(23) it.
(24) Q You can answer that question.
(25) A Please repeat your question.

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- (1) Q When did you decide to file an ANDA
(2) for cefuroxime axetil?
(3) A We started looking into it in '95.
(4) Q That was prior to your coming to the
(5) United States?
(6) A That's right. Because I was in business
(7) development earlier.
(8) Q Was someone else heading up
(9) Pharmaceuticals at that time?
(10) MR. ZIMMERMAN: Can I have a standing
(11) objection to the line of questioning?
(12) MS. LINN: Sure.
(13) A Please repeat your question.
(14) Q Was anyone else heading up -- was
(15) someone else heading up Pharmaceuticals at this
(16) time?
(17) A You mean Ranbaxy Pharmaceuticals, Inc.?
(18) Q Yes, Ranbaxy Pharmaceuticals, Inc.
(19) A We had Jim Youmans, Y-o-u-m-a-n-s.
(20) Q But it was your decision to file an
(21) ANDA rather than Mr. Youmans for cefuroxime
(22) axetil?
(23) A The decision to file an ANDA comes after
(24) you have the product. When you get in vitro data
(25) which shows that you have a product.

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- (1) Before that, any decision is not
(2) really a decision.
(3) Q When you have in vitro data -- is
(4) that what you said?
(5) A Yes.
(6) Q What I understand of in vitro data?
(7) A That means you are able to match the
(8) resolution off a product for which the branded
(9) product or the innovated product for which you
(10) want to prove bioequivalences.
(11) The second step is until you have
(12) bioequivalence, you have good inventory data. But
(13) we don't get it until we get bioequivalence.
(14) Q You got in vitro data you needed for
(15) cefuroxime axetil?
(16) A That's right.
(17) Q When were you able to match the
(18) dissolution profile of the branded product?
(19) A When? I would say in 1998. I do not have
(20) the exact development history with me.
(21) Q After that you did bioequivalency
(22) testing?
(23) A That's right.
(24) Q When did you determine that your
(25) generic product was bioequivalent to cefuroxime

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- (1) axetil?
(2) A After we do a pilot bio. That is followed
(3) up by a pivotal bio.
(4) So a pilot bio is carried on it
(5) first. Then you may do several pivotal bios if
(6) you want to be more sure. A pivotal bio is
(7) usually done in the U.S. or Canada, and that is
(8) expensive.
(9) Q Did you do more than one pilot
(10) biostudy for cefuroxime axetil?
(11) A We usually do.
(12) Q Did you do more than one for
(13) cefuroxime axetil?
(14) A Yes.
(15) Q How many did you do?
(16) A Could be three. Could be four.
(17) Q Were they all on the same
(18) formulation?
(19) A The percentage of crystallinity might have
(20) differed.
(21) Q Do you recall whether it did?
(22) A It did.
(23) Q How did it differ?
(24) A Within the range of 10 to 20 percent.
(25) Q So over the three or four pilot

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- (1) A Please repeat.
(2) MS. LINN: Can you read the question
(3) back, please?
(4) (Record read.)
(5) A I need elaboration.
(6) Q You said you were trying to set
(7) specifications and you were doing these studies
(8) out of awareness of the patents.
(9) What is the specification in the ANDA
(10) that you ultimately filed?
(11) A The specification in the ANDA is 10 to 15
(12) percent.
(13) Q You did studies that went 10 to 20
(14) percent?
(15) A That's right.
(16) Q Did the awareness of the patent
(17) affect your picking the crystallinity level?
(18) A Entirely.
(19) Q Was there some reason that you picked
(20) 10 to 20 -- how did that relate to the patent, as
(21) you understood it?
(22) A In a generic company, which hopes to market
(23) its product on the expiring of a certain patent,
(24) starts even before -- after deciding on a product,
(25) starts by studying the patents.

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- (1) biostudies, the crystallinity range change was
(2) within 10 to 20 percent?
(3) A That's right.
(4) Q Is there a reason that the
(5) crystallinity percent changed in those biostudies?
(6) A The reason is for pharmaceuticals we need
(7) to set specifications to get an FDA approval.
(8) Q Why did you do different studies on
(9) different crystallinity levels?
(10) MR. ZIMMERMAN: I'll restate my
(11) objection.
(12) This doesn't fall within the scope of
(13) any of the 30(b)(6) topics.
(14) MS. LINN: It is part of the ANDA.
(15) It has to do with the formulation in the ANDA.
(16) Q Can you answer my question?
(17) A Please repeat.
(18) MS. LINN: Can you read the question
(19) back, please?
(20) (Record read.)
(21) A To set the specifications, and out of our
(22) awareness of the patents which will last beyond
(23) the product patent, which expired in May of 2000.
(24) Q How did your awareness of the patents
(25) affect what formulations you were testing?

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- (1) Unless you know for sure that you are
(2) going for a product whose patent is not in the
(3) Orange book or, as in the case of antibiotics, not
(4) there.
(5) Q So in this case you started by
(6) studying Glaxo Wellcome patents relating to
(7) cefuroxime axetil?
(8) A That's right.
(9) Q What patents were those?
(10) A All the patents that have been mentioned in
(11) the response given to 3 -- point No. 3, here.
(12) Q Did you, personally, review the
(13) patents?
(14) A As President, I don't have to personally do
(15) everything. I run a team.
(16) Q Did somebody review the patents for
(17) you and report back to you?
(18) A Yes.
(19) Q Do you remember how many patents they
(20) reviewed?
(21) A I think seven.
(22) Q Excuse me?
(23) A I think seven. There could have been more
(24) in review, but seven were the ones that were of
(25) concern.

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- (1) Q Were any of those in the Orange book?
(2) A Antibiotics are not there in the Orange
(3) book. That is antibiotics before 21st November
(4) 1997.
(5) Q So how did you determine that there
(6) were seven patents of concern?
(7) A I did not determine.
(8) Q Who did?
(9) A Those who looked at patents in our company
(10) and Ranbaxy Laboratories Limited decided that
(11) seven are of concern. I wouldn't say decided.
(12) They brought to my notice that seven
(13) were of concern.
(14) Q Who did that? Do you recall who
(15) brought the patents to you?
(16) A Our scientists.
(17) Q Can you give me the names?
(18) A I wouldn't be able to give the name of all
(19) the scientists because we have 450 of them.
(20) Q All of them brought you the patents?
(21) A No. The key person would be Rajiv Malak.
(22) Q This was before you began formulating
(23) the product?
(24) A There is something called simultaneity of
(25) action. So everything goes on at the same space.

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- (1) Q Was Mr. Malak the person who was
(2) working on the formulation?
(3) A He is my main interface. He is in charge
(4) of regulatory in India. He's in charge of all the
(5) submissions, India filings or any other product
(6) license in all the markets of the world.
(7) Q Do you recall when he told you about
(8) the seven patents?
(9) A No.
(10) Q Do you recall when somebody started
(11) working on the formulation?
(12) A I said it was probably '95 we started
(13) looking into it.
(14) Q So that is when somebody started
(15) doing the development work?
(16) A Yes. And looking into the patents and
(17) studying the patents. See whether we can
(18) manufacture the raw material. Everything goes
(19) together.
(20) Q You said that the specification of 10
(21) to 15 percent crystallinity was related to an
(22) awareness of the patents. Was that one patent or
(23) more than one patent?
(24) A I think that could have been more patents,
(25) but one was of importance.

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- (1) Q Why did you determine not to use 20
(2) percent and you tested 20 percent in a pilot bio?
(3) A What?
(4) Q You said you tested between ten and
(5) 20 percent. Was that study successful?
(6) A Yes.
(7) Q But you set the specification at 10
(8) to 15 percent instead of 10 to 20 percent or 20
(9) percent. Why was that?
(10) A Because FDA requires tighter specification.
(11) That seems better with FDA.
(12) Q So all of the pilot biostudies, the
(13) three or four of them, showed bioequivalency with
(14) the branded product, is that right?
(15) A I think so. Yes.
(16) Q How many people are in a pilot
(17) biostudy?
(18) A It varies. There are no rules.
(19) Q In these three or four, do you
(20) remember how many people?
(21) A I do not remember how many were there.
(22) Q Generally, about how many people?
(23) A Six to 12 is the usual average. But this
(24) is decided by biostudies and not by me.
(25) Q Then after that, you did at least one

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- (1) pivotal biostudy?
(2) A Yes.
(3) Q Did you do more than one?
(4) A No.
(5) Q What percent of crystallinity of the
(6) product you tested in the pivotal biostudy?
(7) A It was 12 percent.
(8) Q That is the batch that is in the
(9) ANDA?
(10) A That's right.
(11) Q How did you choose 12 percent as a
(12) specification for the ANDA batch?
(13) A These decisions are not taken by me. These
(14) are taken by our R&D scientists.
(15) Q It was the decision of the scientists
(16) to use 12 percent?
(17) A They must have sat in a group and decided
(18) on that.
(19) Q You weren't involved in that
(20) decision?
(21) A I am involved in the sense that they will
(22) consult me. "This is what we are going to do."
(23) But since it is beyond my
(24) understanding, I would - if they had the
(25) bioequivalent product, I would go by what they