UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

----------x

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES LTD., TEVA NEUROSCIENCE, INC. and YEDA RESEARCH AND DEVELOPMENT CO. LTD.,

Plaintiffs,

v. 08-CV-7611 (BSJ)

SANDOZ, INC., SANDOZ INTERNATIONAL GMBH, NOVARTIS AG, and MOMENTA PHARMACEUTICALS, INC.,

Defendants.

----------x

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES LTD., TEVA NEUROSCIENCE, INC. and YEDA RESEARCH AND DEVELOPMENT CO. LTD.,

Plaintiffs,

v. 09-CV-8824 (BSJ)

MYLAN PHARMACEUTICALS INC., MYLAN INC., NATCO PHARMA LTD.,

Defendants. Non-Jury Trial

----------x

New York, N.Y.
September 7, 2011
9:30 a.m.

Before:

HON. BARBARA S. JONES,

District Judge

APPEARANCES

KENYON & KENYON
Attorneys for Plaintiffs
BY: ELIZABETH J. HOLLAND, ESQ.
WILLIAM G. JAMES, II, ESQ.
CAROLYN A. BLESSING, ESQ.

GOODWIN PROCTER, LLP
Attorneys for Plaintiffs
BY: DAVID M. HASHMALL, ESQ.
JOHN T. BENNETT, ESQ.
NICHOLAS K. MITROKOSTAS, ESQ.

MORRISON & FOERSTER LLP
Attorneys for Defendants
BY: DAVID C. DOYLE, ESQ.
KAREN L. HAGBERG, ESQ.
ERIC M. ACKER, ESQ.

PERKINS COIE LLP
Attorneys for Defendants
BY: JOHN S. SKILTON, ESQ.
DAVID L. ANSTAETT, ESQ.
SHANNON M. BLOODWORTH, ESQ.
DAVID JONES, ESQ.

ALSO PRESENT: CORT CHASE, Litigation Support

MS. HAGBERG: As Teva tried to persuade the FDA even the most minor changes in manufacturing will produce a new molecular entity with a significantly different potency and safety and efficacy policy.

The evidence at this trial will prove conclusively that a person of skill in the art must know the SEC standards to have any confidence that it is producing co-polymer-1 having the same molecular weight as what Teva claims it invented. And that is the information that is missing from the patents. Without that entablement, each of the patents is rendered invalid.

Thank you for your time this morning, your Honor, and to allow me to emphasize an area of the evidence that Sandoz and Momenta believe will be very critical to this case

THE COURT: Thank you, Ms. Hagberg.

All right. I don't think -- do I have a list of witnesses yet?

MS. HOLLAND: Yes, your Honor I believe we did send one, a list of witnesses. Do we have one -- we can get you a copy of that, your Honor.

THE COURT: Okay, I'm sure it came in. We just didn't see it.

MS. HOLLAND: Yeah, we'll find one.

THE COURT: All right. Then are you ready to proceed?

MS. HOLLAND: Yes. Mr. Hashmall is going to be

presenting our first witness.

THE COURT: Mr. Hashmall.

MR. HASHMALL: Good morning, your Honor. Plaintiffs would call as our first witness Mr. John Congleton.

JOHN CONGLETON,

called as a witness by the plaintiff,

having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. HASHMALL:

THE COURT: Take your seat, and spell your last name -- state your full name and spell your last name for the record.

THE WITNESS: John Congleton, C-O-N-G-L-E-T-O-N.

MR. HASHMALL: May I proceed, your Honor?

THE COURT: You may proceed.

MR. HASHMALL: Thank you.

Q. Good morning.

A. Good morning.

Q. Mr. Congleton, could you please introduce yourself to the Court?

A. Yes. My name is John Congleton. I'm senior vice-president and general manager for Teva Neuroscience.

Q. Could you tell us a little bit about Teva Neuroscience, its business?

A. Yes. Teva Neuroscience is focused on the commercialization

of Copaxone, as well Azilect for Teva in the United States.
Q. Where is Teva Neuroscience located?
A. It's located in Kansas City, Missouri.
Q. Approximately, how many people does Teva Neuroscience currently employ?
A. Approximately 600.
Q. When was Teva Neuroscience founded?
A. Teva Neuroscience was founded in 1995.
Q. Now, what is the relationship between Teva Neuroscience and the plaintiff in this action, Teva Pharmaceutical Industries?
A. Teva Neuroscience is a subsidiary of Teva Pharmaceutical Industries.
Q. And you know when Teva Pharmaceutical Industries was founded?
A. In 1901.
Q. You mentioned that Teva Neuroscience is in the business of selling Teva's branded products, is that correct?
A. Yes.
Q. Does Teva also sell, Teva Pharmaceuticals also sell generic products?
A. Yes, it does.
Q. Do you know overall for Teva's business approximately how much of its sales derives from generic products and how much derives from branded products?
A. Approximately 70 percent is from generics, and

approximately 30 percent is from brand pharmaceuticals.

Q. Now, you testified that you currently, you are currently senior vice-president and general manager of Teva Neuroscience. Could you briefly describe for the Court what your responsibilities are in that position?

A. Yes. I'm accountable for the sales and profits of the products that Teva Neuroscience commercializes, Copaxone and Azilect.

Q. Approximately, how many people report to you currently, Mr. Congleton?

A. Approximately 450.

Q. And how long have you been employed by Teva Neuroscience?

A. A little over 15 years.

Q. Could you briefly describe your educational and professional background prior to you joining Teva Neuroscience?

A. Yes. I have a bachelors degree in marketing from Kansas State University, started off in field sales in pharmaceuticals developmental roles, field sales manager position prior to joining Teva Neuroscience.

Q. Could you tell us a little bit about your employment prior to joining Teva Neuroscience?

A. That's the pharmaceutical sales rep, developmental role, human resource in field base sales manager.

Q. Do you have any degree in chemistry or biology?

A. No, I do not.

Q. Now, since joining Teva Neuroscience, what positions have you held at the company?
A. I have been a field sales manager, a product manager and a marketing department, the product director for Copaxone, general manager for our Canadian Division of Teva Neuroscience, as well as my current position, general manager for the United States division.
Q. Prior to you taking on your current position, could you just generally describe what your responsibilities have been with respect to Copaxone?
A. Yes. I started off as a product manager prelaunch preparing that product, and moved into the director of marketing for Copaxone as well.
Q. And do you continue to have responsibilities currently with respect to Copaxone?
A. Yes. It's under my span of control.
Q. Could you just generally describe for the Court what those responsibilities include?
A. Generally it's around the development and approval of our work plan, the budget, the resources we apply against the product, as well as strategic oversight.
Q. Now, you mentioned that in addition to Copaxone, Teva Neuroscience also sells markets, a product known as Azilect? Could you just briefly describe for the Court what Azilect is?
A. Yes. Azilect is a medication indicated for the treatment

both early, as well as ajunctive for ideopathic Parkinson's disease.

Q. Now, do you have a binder in front of you, Mr. Congleton with some documents in it?

A. Yes, I do.

Q. If you could, sir, just turn to the first tab, it's labeled as PTX 697. Do you see that?

A. Yes, I do.

Q. And have you seen this document before?

A. Yes, I have.

Q. What is it?

A. It is the prescribing information for Copaxone.

Q. Is this sometimes referred to as a product insert?

A. Yes.

Q. Is it also known as a drug label?

A. Yes, it is.

Q. Now, was this drug label for Copaxone approved by the Food and Drug Administration?

A. Yes, it was.

Q. Is this a document that was created and maintained by Teva in the ordinary course of its business?

A. Yes, it was.

MR. HASHMALL: Your Honor, plaintiffs move PTX-697 into evidence.

MR. JONES: No objection, your Honor.

MR. DOYLE: No objection.

THE COURT: All right, admitted.

(Plaintiff's Exhibit PTX-697 received in evidence)

Q. Mr. Congleton, what is the purpose of the product insert, which is PTX-697?

A. It's to describe the use, the efficacy, safety, ability of the medicine.

Q. Now, if you could look at the top column on the first page of 697. There's a heading there called "indications and usage," do you see that?

A. Yes, I do.

Q. All right. What does this tell the person who is reading this label?

A. It would tell the physician how to use Copaxone and what patient it would be indicated for.

Q. And for what conditions is Copaxone indicated?

A. Copaxone is indicated for the reduction of frequent or -- reduction of the frequency of relapses in patients with relapsing-remitting form of Multiple Sclerosis, as well as for clinically isolated syndrome with one relapse and MRI indicative of MS.

Q. Now, below that there is a section entitled dosage forms "dosage form and strength," do you see that?

A. Yes, I do.

Q. Does this tell the physician in what form Copaxone is sold?

A. It does.
Q. And in what form is it sold?
A. It's sold in prefilled syringes with one milliliter of sterile water, as well as 20 milligrams of glatiramer acetate.
Q. Now, and just above that there's a section entitled "dosage and administration," do you see that?
A. Yes, I do.
Q. And does this tell the physician how Copaxone is to be administered?
A. It does.
Q. And how is Copaxone to be administered?
A. It's to be administered with a daily injection of the prefilled syringe with the 20 milligrams of Copaxone.
Q. Now, do you know, Mr. Congleton, when Copaxone was first approved for sale in the United States?
A. Copaxone was approved in December of 1996.
Q. And do you know, sir, when Copaxone was first offered for sale in the United States by Teva?
A. Yes, I do.
Q. And when was that?
A. April 2nd of 1997.
Q. Now, in April of 1997, you were employed by Teva Neuroscience?
A. That's correct.
Q. And how large was Teva Neuroscience marketing department in

April of 1997?

A. It was two people.

Q. And who were those two people, Mr. Congleton?

A. I was the product manager, and I had a boss who was the head of our marketing department named John Asler.

Q. And was there a sales force at Teva Neuroscience at that time?

A. Yes, there was.

Q. And how large was that sales farce in April of 1997?

A. In April of 1997, we had 32 sales associates.

Q. Now, at the time that Copaxone was launched in April of 1997, were there any other MS drugs on the market?

A. Yes, there were.

Q. And what were those drugs?

A. There was Avonex as well as Betaseron, both interferons.

Q. And Copaxone is not an interferon, correct?

A. That's correct.

Q. How are interferons, just generally, Mr. Congleton, how are interferons different from Copaxone?

A. They're a different class of drugs with a different mode of action. They have common traits, but Copaxone is in a different class onto itself with a different mode of action.

Q. All right. And now you mentioned these two drugs, Avonex and Betaseron. How long had they been on the market?

A. Betaseron was launched in the United States in 1993, and

Avonex was launched in the United States in 1996.

Q. Now, are you familiar with the indicated uses for those two drugs?

A. Yes, I am.

Q. And what are they indicated for?

A. They're also indicated for the reduction of relapses in relapse-remitting Multiple sclerosis.

Q. And are you familiar with how those two drugs are to be administered?

A. Yes, I am.

Q. And how are those products administered?

A. Avonex is a once weekly intramuscular injection, and Betaseron is an every other day subcutaneous injection.

Q. Now, at the time that -- in April 1997 when Teva first started selling Copaxone, did Teva Neuroscience develop a launch plan for Copaxone?

A. Yes, we did.

Q. And could you just generally tell the court what a launch plan is?

A. A launch plan is your effort to really raise the awareness of your molecule, help physicians and patients understand how to initiate utilization of that, as well as maintain it. So it's a communication plan that introduces your product to the appropriate audiences.

Q. Were you involved in developing the launch plan for

Copaxone?

A. Yes, I was.

Q. So could you tell the Court, generally, what was that launch plan for Copaxone in April of 1997?

A. In April of 1997, it was still early in the treatment of MS, so our focus was on raising the importance of treating the disease, getting patients to begin that therapy, then to convey the benefits that Copaxone could provide patients from an efficacy and safety standpoint. We utilized our sales representatives, we utilized non-sales representative activity, such as direct mail, conventions, journal advertising.

Q. Now, you mention there were these two interferon drug products that are marketed at that time. How did Teva position itself with respect to those two interferon products?

A. Really as the non-interferon. We had a different mode of action. The efficacy we felt was comparable. A better safety tolerability standpoint due to what the experience had been with physicians with interferon. So as a different mode of action and a different clinical profile.

Q. Were there any challenges that Teva faced when it first started selling Copaxone?

A. Yes, there were.

Q. And could you just tell us, generally, what those challenges were?

A. There were several. The first would be, again MS therapies

were new to both physicians and patients, so it was the need for treating MS was a challenge.

The fact that the interferons were in the marketplace anywhere from four to about a year earlier than us, and had gained traction as an approach to treat MS. And then, frankly, the fact that we were a daily injectable versus less frequently administered medications.

Q. Do you recall, approximately, what the U.S. sales were for Copaxone in 1997?

A. Yes.

Q. And what were those sales?

A. $25 million dollars.

Q. Now, since Copaxone was launched in 1997, have other MS drugs come on to the market?

A. Yes.

Q. And what currently approved drugs does Teva consider to be competitors of Copaxone?

A. Current first line competitors would be Avonex and Betaseron, as well Extavia and Rebif, all four of those being interferons.

Q. Now, you mentioned first line treatment. What do you mean by "first line treatment"?

A. First line treatment would be a therapy that a physician would, in all likelihood, use for a newly diagnosed patient or a patient that is beginning to investigate the utilization of

therapy to manage their MS.

Q. Now, the four competitor drugs that you have identified, are those all administered by injection?

A. Yes, they are.

Q. And with what frequency are those four drugs administered?

A. The Avonex, as I've said, is a weekly intramuscular. The other interferons are either every other day or three times a week, subcutaneously.

Q. So Copaxone is still the only drug that requires administration daily?

A. That's correct.

Q. Now, just very generally, how has Teva's sales fared since it was -- its first year it was launched in 1997?

A. It's fared very well. We have, over the course of time, grown from the third entrant into the market place into the therapy of choice almost by a factor of two currently. It built over time. Copaxone has a unique profile, unique mode of action. The experience that physicians gain, they saw the benefit that their patients were deriving. As that knowledge accumulated, that experience accumulated, the utilization of Copaxone grew.

And then in 2005 with the introduction or the data from to head-to-head trials against interferons, it really continued to accelerate Copaxone's growth. Because those trials showed that Copaxone was of equal efficacacy to the

interferons, and that was contrary to the perception that was in the marketplace prior to that.

Q. Now, as part of your responsibilities with respect to the marketing and sales of Copaxone, do you keep track of patient loyalty?

A. Yes, we do.

Q. Just tell the Court, what is patient loyalty?

A. Loyalty in the context of pharmaceuticals really focuses on compliance, non-adherence. And compliance is over a given month, does patient take the drug as indicated, in Copaxone's case, are they injecting daily over those 30 days. Adherence is more of a longer term frame. It's over a given year how well the patient stayed on that therapy, so that they can derive the benefits intended.

Q. Do you know approximately what percentage of patients started on Copaxone stay with the drug?

A. Yeah, our adherence figures are approximately 85 percent at the end of the first year.

Q. Could you just give us a ballpark about how many patients are currently using Copaxone?

A. Approximately 100,000 at this point in time are benefiting from Copaxone.

Q. And as part of its services, does Teva Neuroscience offer any patients support programs with respect to Copaxone?

A. Yes, we do.

Q. Is there a name for that program?
A. Yes. It's called Shared Solutions.
Q. So, and could you describe for the Court what Shared Solutions is?
A. Shared Solutions is a free service that we offer to all people with MS.

Prior to launching the drug in 1997, we were obviously getting to know the MS marketplace, the needs of those patients. And it was clear that beyond just therapy, MS patients had emotional, psychological issues they needed to manage.

We felt it was important to create a program, our service that would help manage those barriers so the patient could go -- could be as successful as possible with the medication Copaxone. So we created the service. We made it available for all people with MS. They could have access to nurses, to educational materials. If the patient was going to begin Copaxone, then they -- a door opened to other service they had access to, such as reimbursement support, injection training, free auto-ject advice, access to the nurse, as well as other educational materials. And it has been a benefit to patients only not taking Copaxone, but obviously those taking Copaxone to help them be successful with the molecule.

Q. Patient does not have to be actually using Copaxone to have access to Teva's services?

A. That's correct.
Q. And I'm sorry, does Teva charge the patients for these services?
A. No, we do not.
Q. I'd like to just talk to you a little bit, Mr. Congleton, about the details regarding Teva's promotion of Copaxone. Could you describe for the Court what Teva's promotional strategy is for Copaxone?
A. It's really focused on, again, building the awareness of the need to treat MS, then convey the unique properties of Copaxone and the benefits that a physician's patient can derive from utilizing Copaxone to manage their Multiple sclerosis.
Q. And who is the principal audience for Teva's promotional efforts relating to Copaxone?
A. Predominantly physicians, neurologists specifically, as well as MS patients.
Q. And what methods does Teva use to promote Copaxone?
A. We utilize our sales force, as well as non-sales force activities, such as conferences, journal ads, the website, direct mail.
Q. Are you familiar with the term of "detailing"?
A. Yes, I am.
Q. Could you just explain to the court what detailing means?
A. Detailing is when our field base sales associates go into physicians' offices and talk to them about Copaxone and how it

can benefit their patients who have MS.

Q. All right. Does Teva do any direct consumer advertising such as TV ads or radio ads with respect to Copaxone?

A. No, we do not.

Q. Now, in your binder, Mr. Congleton, could you turn to the document that's labeled PTX 908? What is PTX -- 908?

A. Sorry. It's a copy of a sales aid that we would give to our sales associates.

Q. Do you know what year this document was created?

A. I believe it's 2007.

Q. And was 908 prepared under your supervision?

A. Yes, it was.

Q. And was this document prepared in the ordinary course of Teva's business?

A. Yes, it was.

MR. HASHMALL: Your Honor, plaintiffs offer PTX-908 in evidence.

MR. JONES: No objection, your Honor.

MR. DOYLE: Your Honor, Sandoz doesn't have an objection to the admission of the document for the purpose which I think it is being proffered, which is to indicate what Teva tells the MS community about Copaxone. But we do object to it being accepted for the truth of any matter asserted therein, because it's a sales aid, and there is no foundation, and there is no support for any of the actual information

contained in this document provided by this witness.

THE COURT: All right. I'll admit it.

(Plaintiff's Exhibit PTX-908 received in evidence)

MR. HASHMALL: Thank you, your Honor.

Q. And the next question, your Honor, is, for what purpose was PTX-908 created, Mr. Congleton?

A. It is the primary tool that our sales representatives utilize when detailing a physician to convey the benefits of Copaxone.

Q. And could you just tell us a bit how the sales representative uses this aid?

A. They would set up appointments with physicians, over the course of ten to 15 minute conversation use this as a supportive document to share with them data that has been published and generated on Copaxone, to talk about its efficacy, as well as safety.

Q. All right. If you could, Mr. Congleton, turn to the pages that is Bates numbers on the bottom, if you could turn to the page that has the last three digits of 909 and 910?

A. Okay.

Q. We have that up on the screen. This is a chart. What data is presented in this clarity, Mr. Congleton?

A. This is looking at the main efficacy end points that neurologists focus on when managing MS, and specifically it's looking at the effect that Copaxone has on these efficacy end

points over a sustained period of time.
Q. And so how would a salesperson at Teva use this information with the doctor when he's being, he or she is meeting with the doctor?
A. This is one of the most important points for physicians is how does your product affect the patient over the long term. So a sales representative would share with the physician what they can expect to see as a response in their patients to the use of Copaxone in managing the disease over time.
Q. And if you could, sir, turn to page with the last three digits of 912?
A. Okay.
Q. Do you have this, Mr. Congleton?
A. I do.
Q. All right. What is described on this page?
A. This is describing the pivotal trial, as well as the extended version of that trial. In this particular case it's through ten years. This is the -- one of the unique aspects about Copaxone is it is prospectively followed long term to ensure that the effect is not only immediate, but also sustained in offering benefit to a neurologist's patient.
Q. If you could turn, Mr. Congleton, to the page that has the last three digits 3915?
A. Okay.
Q. And what's described on this page, Mr. Congleton?

A. Again, this is additional efficacy information. It shows that not only is Copaxone effect sustained, but it also shows that it is immediate within the first three months you see a separation of the drug's effect to placebo.

Q. Now, does Teva train its sales staff on how to use this document, PTX-908?

A. Yes, we do.

Q. Could you turn, sir, to the document that's labeled as PTX-909 in your binder.

A. Okay.

Q. Do you recognize this document?

A. I do.

Q. And what is this document?

A. This is a sales aid training tool. It's internal use only. We provide it to our sales representatives in conjunction with the sales aid we just reviewed.

Q. And do you know what year this document was created?

A. In 2007.

Q. And was this created under your supervision?

A. Yes it was.

Q. Was this in document created in the ordinary course of Teva's business?

A. Yes, it was.

MR. HASHMALL: Your Honor, we offer PTX-909 in evidence.

MR. JONES: No objection, your Honor.

MR. DOYLE: No objection for the purpose being --

THE COURT: Purpose understanding.

MR. DOYLE: Yes, your Honor.

THE COURT: All right, admitted.

(Plaintiff's Exhibit PTX-909 received in evidence)

MR. HASHMALL: Thank you, your Honor.

Q. If you could turn to the page that's has the last three digits of 350. Could you describe what type of information is on this page, Mr. Congleton?

A. This is background information for sales associates to help them understand the graphic within that sales aid.

Q. And is this document used to instruct them in how to use the document that we had previously looked at?

A. Yes. It's a teaching aid.

Q. All right. Now on the top of that page you see there is a paragraph that's labeled direction; see that?

A. Yes, I do.

Q. What is the purpose of this paragraph?

A. It's to give the sales representative a sense for what the intents of this graphic is, the point that needs to be conveyed to the physician.

Q. All right. And then to the left on that page there is a section there entitled message musts. Do you see that?

A. Yes, I do.

Q. What are message musts?
A. There is a lot of data obviously within this graphic, and this is a way that we help the sales representative highlight what are the key points that we'd like them to convey to the physicians.
Q. Now, PTX-908 and 909, are these typical of the types of sales aids and manuals that are distributed and used by Teva sales force?
A. Yes, they are.
Q. Now, you start -- Teva Neuroscience started selling in 1997, started selling Copaxone. Has the promotional message for Copaxone changed since its introduction in 1997 until today?
A. It's evolved over time, but the core message has remained relatively constant; and that is, a unique mode of action that elicits a unique clinical profile that provides a sustained long term efficacacy in a safe and tolerable manner.
Q. Do you know what the approximate sales in the United States of Copaxone were for Teva in 2010?
A. Yes. In the United States approximately 2.25 billion.
Q. And do you know approximately how much sales have been told for Teva since introduction of the product in 1997?
A. Lifetime it's been over $10 billion.
Q. Thank you, Mr. Congleton.
MR. HASHMALL: No further questions, your Honor.

THE COURT: Cross-examination?

MR. JONES: May I begin?

THE COURT: Yes.

CROSS EXAMINATION

BY MR. JONES:

Q. Thank you, your Honor. Good morning, Mr. Congleton.

A. Good morning.

Q. Now, I think I heard, as you ended your testimony, you talked about how your sales force has stressed this unique mode of action of Copaxone; is that accurate?

A. That's correct.

Q. That's been a consistent sales strategy for Teva to talk about this unique mode of action of Copaxone; is that correct?

A. That's correct.

Q. Now, it's true, though, right, that the mechanism by which Copaxone works is not fully understood, right?

A. That's correct.

Q. In fact, no one really knows how Copaxone works, right?

A. That's correct.

Q. Now, you talked about, you talked about sales figures. Let me try and put it on a per patient level, and we can use an exhibit to help us get there.

Could I please have up 1981, PTX-1981.

Showing you, sir, if you go -- you've got a witness binder, you can look in the screen or you can look in the

witness binder, for DTX-1981. I'll represent to you and you can tell by the -- if you have the document yourself, you can see there is a Teva Bates number on it, but I'll represent to you that DTX-1981 is an excerpt from a spread sheet produced by Teva in this action. Do you recognize the information in DTX-1981, sir?

A. I do.

Q. All right. And you see that this is reported sales information as of January 5, 2010, sir?

A. Yes.

MR. JONES: All right, move admission of DTX-1981, your Honor.

MR. HASHMALL: No objection, your Honor.

THE COURT: All right, admitted.

(Defendant's Exhibit DTX-981 received in evidence)

Q. Just again, I think you talked about other methods or medications used for treating Multiple sclerosis. And we see those other medications listed on DTX 1981, correct?

A. Yes, we do.

Q. All right. And then about the one, two, three, four, the fifth medication is listed as Copaxone, correct?

A. That's correct.

Q. And if you go over to average wholesale price, we see that the average wholesale price for Copaxone is listed as $3,303, correct?

A. That's correct.
Q. So per year when you put that up per year, a patient is going to be charged $40,187 at least as of January 5, 2010, is that correct?
A. That's presuming they take 365 injections in a given year yes.
Q. And that's how it's prescribed, correct, you take a daily injection?
A. It's how it's prescribed, yes.
Q. Right. And you assumed your patients are going to be in compliance with their there medication, correct?
A. We try to help them with that, but we know the realities are they are not completely 100 percent compliant.
Q. So assuming, though, a compliant patient, a patient who wants to control their MS, which I think you'd agree most patients want to do is controlling their MS, correct?
A. That's their goal.
Q. Then they're going to be as, at least as of January 5, 2010, they're looking at $40,187 over the course of a year, correct?
A. If a hundred percent compliant, yes.
Q. Right. And that in fact when you look at the other drugs, Copaxone for yearly cost to the patient is the most expensive of the MS treatments, correct?
MR. HASHMALL: Objection, your Honor. I think the box

is obscuring the number on the bottom.

Q. Okay.

MR. HASHMALL: So I think if you --

A. It would be secondary to Tysabri.

Q. But it's certainly more expensive than Avonex, correct?

A. Yes.

Q. Betaseron, correct?

A. Yes.

Q. Extavia, correct?

A. Yes.

Q. And Rebif, right?

A. Yes.

Q. All right. Now, we've been looking at prices for January 5, 2010. Let's go to an exhibit and look to see what's happened with prices. If I could have up DTX-2022.

DTX-2022 -- and again, sir, you have that in your binder. 2022 is the SEC form 20-F, the annual report submitted by Teva Pharmaceutical for the year ended 2010. Have you ever seen form 20-F before, sir?

A. Yes I have.

Q. Right?

MR. JONES: Move admission of DTX-2022, your Honor.

MR. HASHMALL: No objection, your Honor.

THE COURT: All right, admitted.

(Defendant's Exhibit DTX-2022 received in evidence)

Q. Thank you. Just so we can have some context about Copaxone. If you go to page six. Unfortunately, this is not Bates numbered, but we'll use the organic page number of the exhibits. Page six of DTX-2022. Here we go. If you look at the 4th paragraph, it's the paragraph under the italicized portion, if I could have that blown up. Then the second sentence of that paragraph. Thank you, Nick. If I could have the second sentence of the paragraph highlighted. No, one before that. There you go. Thank you.

Now, Teva's statement to the SEC indicates that Copaxone is -- contributes disproportionately to your profits and your cash flows; is that correct?

A. It has significant impact on Teva's cash flows, yes.

Q. Well, it contributes disproportionately. That's at least what Teva told the SEC, correct?

A. That's what that does say, yes.

Q. And that's as of 2010. But in fact Copaxone has contributed disproportionately to your profits and cash flows for more than just 2010, correct?

A. It has continued to grow and add value to Teva, yes.

Q. That's right.

If we could move on in DTX-2022, if you go to page 60, 60, and if you could pull out paragraph one, two, three, fourth paragraph, the one that begins U.S. and market Copaxone sales. Thank you.

What I'm trying to get a sense, sir, is what's happened to prices. Remember we saw that spread sheet showing prices as of January 2010. We're trying to get a sense of what's happened to prices from January 2010 until present, all right. Prices have increased, correct?

A. Yes, they have.

Q. In fact according to what Teva told the SEC, you had two price increases in 2010, correct? If you look at that second sentence?

A. That's correct.

Q. Each of 9.9 percent, right?

A. That's correct.

Q. And then you had a -- so that's a total of what, about almost 20 percent sales price increase?

A. 19.8, yes.

Q. Yeah. Any reason to doubt the accuracy of that price increase reported to the SEC?

A. No, there would be no reason.

Q. Now, it also -- this discloses a second price increase that occurred I think in January 2011, if you look at the next sentence. So on top of the nearly 20 percent increase that we -- that's reported that occurred in 2010, in January 2011 you had an additional 14.9 percent increase in the sales price for Copaxone, correct?

A. That's correct.

Q. So since January of 2010, Teva has increased prices for Copaxone by about 39 percent, right?
A. That's correct. We've also seen the volume continue to grow, as well as the share grow, as it is the leading choice in treating MS.
Q. There is not much competitive pressure on you, is there
A. There's constant competitive pressure.
Q. All right, there's constant competitive pressure. Let me understand something. The rate of inflation for 2010 was about 1.5 percent, right?
A. I don't have that handy.
Q. Well, did you get any push back on raising prices by 40 percent? Did you get push back from your management saying, don't increase prices by 40 percent, inflation is only running about 1.5, push back from your management, sir?
A. We factor a lot of different things as we analyze our pricing actions.
Q. Do you agree, though, that after analyzing all those factors, including any competition that you say is out there, you agree that price has increased significantly for patients just over the course of a year, correct; 40 percent?
A. Prices have changed over time, as well as pressures within the co-pay system, the reimbursement. Lot of factors go into that, yes.
Q. Teva turn a profit on Copaxone in 2010?

A. Yes, we did.
Q. 2009 profit?
A. Yes, we did.
Q. When is the first year Copaxone became profitable for Teva?
A. I don't have that information.
Q. Well, you know about 2010, 2009. 2008, was it profitable?
A. 2008 was -- I -- honestly I focus on the U.S. portion of that, and I don't see the roll up on a global basis for Copaxone specifically.
Q. Now, you talked a little bit about marketing, and in fact you showed a label. I want to ask you some questions about the information that Teva supplies to doctors and patients in its marketing activities. Are you familiar with the term "informational marketing"?
A. Yes.
Q. Would you agree that Teva engage in informational marketing with regard to Copaxone?
A. Yes, I would.
Q. With informational marketing, what you're basically trying to do is you're doing your best to inform doctors and patients about the benefits of Copaxone, correct?
A. As well as the importance of therapy in general in managing MS.
Q. Right. So talking about the benefits, the importance of the therapy, and you're trying to give them your best

information about the risks of Copaxone, correct?
A. That's our responsibility both efficacacy and the safety of the product, yes.
Q. You take that responsibility seriously, correct?
A. Yes, we do.
Q. If you know about a risk that your product might pose to the public, you're going to tell them about it, right?
A. Within our mandate, yes.
Q. Now, starting -- you said that you've been with the -- with Copaxone since I think its launch back in 19 -- well, you said it got approval to launch in 1996 with Copaxone; is that correct?
A. Approved in '96, yes.
Q. And then but your sales were April of 1997 were first sales?
A. That's correct, in the United States.
Q. In the U.S., that's correct, sir.

Now, when you first had permission from the FDA to launch Copaxone, that was at an approved average molecular weight of 4.7 to 11 kilodalts, correct?
A. To be honest, I don't have that information right in front of me.
Q. Right. Well, let's pull up DTX-1073, then.

1073, sir, is a December 20, 1996 approval letter from the FDA to Teva; you agree?

A. Yes, I can.

MR. JONES: Move admission of DTX-1073, your Honor.

MR. HASHMALL: No objection, your Honor.

THE COURT: All right, admitted.

(Defendant's Exhibit DTX-1073 received in evidence)

Q. Thank you. If we look at DTX-1073 again, this would be the approval letter from the FDA to Teva saying that you folks had approval to market and sell Copaxone, correct?

A. That's correct.

Q. And this exhibit does have Bates numbers. If we go to TEV104078. Just look for the 78 at the bottom.

A. I'm there.

Q. Great. If you would -- thank you very much. Actually, if you just focus right on that first paragraph, great. Thank you.

So what we see here depicted on 104078 of DTX-1073 is actually the label approved by the FDA for Teva to use with Copaxone, correct?

A. That's correct.

Q. And if you look at -- this label tells us a couple of things, right? First it tells us what the average molar fraction is for Copaxone, correct?

A. It's says the average molecular weight of Copaxone, yes.

Q. Well, let's actually -- if you go right --

A. There's the fraction; yes, you're correct.

Q. Were you in the courtroom for the opening statements?
A. Yes, I was.
Q. So you have heard the discussion about molar fractions, correct?
A. I did hear.
Q. And it's your understanding, right, that Teva reports accurately it's average molar fraction when it includes that information on its Copaxone label, correct?
A. Yes.
Q. And then after that we were getting to this average molecular weight issue, if you highlight the next sentence, Nick.

This reports that Teva is authorized to sell Copaxone with an average molecular weight of 4.7 to 11 kilodaltons, correct?
A. According to the label, yes.
Q. Right. And what I've done is, I know it's 4,700 daltons, but my mouth gets tired, so I'm just going to talk about kilodaltons, you understand that 4,700 daltons is the same as 4.7 kilodaltons, right?
A. Correct. I'll refer to the dalton portion, though.
Q. Great. And, in fact, Teva went on the market when you made that first sale in April of 2007, and/or April of 1997, Teva went on the market with a Copaxone with an average molecular weight 4.7 to 11 kilodaltons, correct?

MR. HASHMALL: Objection, your Honor. What's in the label -- there was extensive testimony at the prior trial about what the manufacturing specifications and what the actually went to market with, and I don't think there is any foundation that this witness knows the answer to that question. It's going well beyond the scope of what he was testifying about on direct.

THE COURT: I can read the label. I don't know that this witness is able to testify to this.

Q. All right. Well, did you provide promotional information and labeling information to patients and doctors about the average molecular weight of Copaxone?

A. We provided prescribing information to physicians and patients, yes.

Q. Did you know the average molecular weight of Copaxone that you were selling to the public and to doctors?

A. I was aware of the label, but it's not my field of expertise. I focus on conveying the benefits of the product to physicians and patients.

Q. And you have no reason to believe that the Copaxone that you sold was outside the range of 4.7 to 11 kilodaltons, right? You have no reason to believe it was outside that average molecular weight?

A. I don't have any information about that.

Q. Okay. Now, I want to look at another label. Let's look at

Exhibit PTX-695, all right. I'm showing you PTX-695, a label for Copaxen. Go to the last page of the exhibit. You'll see that it has a revision date of January of 2002. So having looked at PTX 695, do you recognize this as a label for Copaxone as of January 2002, sir?

A. Yes.

MR. JONES: Move admission of PTX-695?

MR. HASHMALL: No objection, your Honor.

THE COURT: All right, it's admitted.

(Defendant's Exhibit PTX-695 received in evidence)

Q. Now, when we go to the first page of PTX-695, just that first paragraph -- thank you, Nick -- again we see a report and this is actually the label that patient and a doctor would see with their Copaxone that they purchased as of 2002, correct?

A. That's correct.

Q. All right. So the patient would see again these molecular fractions, right?

A. That's correct.

Q. And they would see that the average molecular weight of the product is from 4.7 to 11 kilodaltons, right?

A. That's correct.

Q. Now, and I encourage you if you need to to go ahead and look at the binder version of 695, but if you need to -- but you would you agree that in this 2002 label, regarding the 4.7 to 11 KDA Copaxone, there is no discussion about that product

being toxic in the rat basophilic leukemia in vitro assay, right?

A. No, there's not.

Q. Okay. There's no mention of 4.7 to 11 KDA Copaxone being toxic in the in vivo mouse assay, right?

MR. HASHMALL: Your Honor, I would object to this. I think, unless there is some other purpose here, I'm not able to certain -- it seems like we're going back to issues that were tried fully in July, and this is obviously the wrong witness to be questioned about this.

THE COURT: Well, I mean if there's no objection to these documents going in, you can make these arguments. I don't think we need to labor through this with this witness.

MR. JONES: And I'll get right to the point with it then.

Q. If, to your knowledge, sir, the 4.7 to level KDA Copaxone, that Teva marketed, that drug is not toxic, correct?

MR. HASHMALL: Object.

THE COURT: I'm going to sustain the objection. This is the wrong witness.

Q. Did you --

THE COURT: I like you, don't get me wrong, but you're the wrong witness on this one.

Q. Right.

THE COURT: Okay.

Q. I'll ask --

THE COURT: Let's move along, Mr. Jones.

MR. JONES: Yes, your Honor.

Q. I'll simply ask, what you told doctors and patients?

THE COURT: That's not relevant.

MR. JONES: Just so that I'm clear, your Honor, is it your preference, because I don't want to try the Court's patience on this, you're right, this is something that we can develop in argument, I do -- I was going to plan on asking him what Teva told the public in regard to toxicity for various weight ranges of Copaxone?

THE COURT: I'm assuming you can -- it's all in here. Would there be any difference in the materials that they -- what was in the label, the materials? I doubt it. I think that's your point, right?

MR. JONES: Precisely, your Honor, just simply establishing that there was no mention of toxicity to the public of 4.7 to 11 or five to nine, no mention to the public that 5 to nine was any less toxic than 4.7 to 11. That's the point.

MR. HASHMALL: Your Honor, they can argue obviously what they want from the label, but --

THE COURT: Right, I'm just trying to shorten this up.

MR. HASHMALL: I know. But I have a concern that the issue -- I don't see how this goes to any issue, other than the

issue that we tried in July, but maybe we can have that discussion later. But I'm hoping we're not going to start getting the same argument that we heard in July about differences between what they told.

THE COURT: I'm not worried right now about who is arguing what. I just want to get our witness taken care of.

MR. JONES: With that, your Honor, thank you for your guidance. I'll excuse -- thank you.

THE COURT: All right, good enough.

THE WITNESS: Thank you.

MR. DOYLE: Your Honor, I have one question. Could I just ask it from here?

THE COURT: Please, that would be great.

MR. DOYLE: Yes, your Honor.

CROSS EXAMINATION

MR. DOYLE: I'd like to know, Mr. Congleton, in any of its Copaxone marketing materials, does Teva state that the side effect profile of co-polymer-1 is associated in any way with its molecular weight?

A. With it's what? I'm sorry.

Q. Its molecular weight?

A. We share in our communications with patients beyond the efficacy and how to utilize the drug is the adverse effects that are within our product insert that are most frequent and that physicians and patients need to be aware of.

Q. My question is a little more specific, which is in its marketing materials, is there any relationship drawn by Teva between that side effect profile and molecular weight of Copaxone?

A. There is not.

MR. DOYLE: Thank you.

THE COURT: Any redirect?

MR. HASHMALL: No, your Honor.

THE COURT: All right, thank you very much. You may step down. You're excused.

We'll take a ten minute break. And who is your next witness.

MR. HASHMALL: Next witness will be Dr. Lisak.

MS. HOLLAND: Your Honor, I have the list --

(Recess)

(In open court)

THE COURT: Please be seated everybody. Call your next witness.

MR. HASHMALL: Your Honor, Mr. John Bennett is going to be putting on our next witness.

THE COURT: All right, Mr. Bennett.

MR. BENNETT: Good morning. The plaintiffs call Dr. Robert P. Lisak.

ROBERT P. LISAK,

called as a witness by the plaintiff,

having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. BENNETT:

THE COURT: You can be seated, sir. Thank you.

THE WITNESS: Thank you.

MR. BENNETT: Your Honor, before we begin, Dr. Lisak is our practicing physician expert, and you may remember from the pretrial conference that the parties have agreed that the practicing physician experts may appear once to accommodate their patient schedules. So Dr. Lisak is going to be providing some testimony today related to the validity issues, specifically secondary considerations of non-obviousness called long felt need and the failure of others that typically would be rebuttal testimony in this type of case.

THE COURT: All right.

MS. HOLLAND: In addition to some infringement testimony.

THE COURT: So, I'm going to hear everything I'll ever need to hear from Dr. Lisak.

MR. BENNETT: That's right.

THE COURT: That's everybody's understanding? All right, then you're wide open. Go ahead.

MR. BENNETT: Thank you.

Q. Dr. Lisak, would you please introduce yourself to the Court?