UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of:	)
IMPAX LABORATORIES, INC,	)
a corporation,	) Docket No. 9373
Respondent.	)

TUESDAY, NOVEMBER 14, 2017

10:45 a.m.

TRIAL VOLUME 12

PART 1, PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Chief Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR-CRR-CLR

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I N D E X

WITNESS:	DIRECT	CROSS	REDIRECT	RECROSS	VOIR
NESTOR	2926	3002	3052		

EXHIBITS	FOR ID	IN EVID
None		

P R O C E E D I N G S

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JUDGE CHAPPELL: Let's go back on the record.

Respondent, are you ready to call your next witness?

MR. HASSI: Yes, Your Honor. Respondents --

JUDGE CHAPPELL: Do you want to give us an update on the record regarding one of your fact witnesses?

MR. HASSI: Yes, Your Honor. For the record, Respondents will not be calling Mr. Hsu. He has not returned to the country yet. With the understanding that his deposition and investigational hearing transcript are in the record, we will forgo calling Mr. Hsu and, therefore, will call our last witness, Mr. Michael Nestor, to the stand.

JUDGE CHAPPELL: All right. I can't vouch for this understanding referred to. That's between you and Complaint Counsel, what's in the record. I'm not aware of it.

MR. HASSI: They are on JX 2, Your Honor, admitted in evidence. That's the reason I say that.

JUDGE CHAPPELL: All right. Go ahead.

MR. HASSI: My colleague Ms. Anna Fabish will do the examination of Mr. Nestor.

Whereupon--

MICHAEL NESTOR

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. FABISH:

Q. Good morning.

Would you please state your full name for the record.

A. My name is Michael Nestor.

Q. And who is your current employer?

A. My employer is Impax.

Q. And what is your current position at Impax?

A. My position is president of the Specialty Pharma Division or Brand Division.

Q. And how long have you been in that position?

A. Eight years.

Q. And who held that position before you?

A. There was no one in that position before me.

Q. And why is that?

A. At the time, the division was not fully formed, and at the time I joined the company, it was originally to launch a product called Vadova, which was a -- essentially a combination of an immediate-release carbidopa-levodopa tablet and controlled-release

carbidopa-levodopa tablet. The FDA refused to accept it shortly after I got there.

Q. I'd like to talk a little bit more about the dopa in a moment, but first, would you mind telling us what your responsibilities are as president of Impax's Specialty Pharma Division?

A. So my responsibilities are basically to set strategy for the division; to ensure that the commercialization of our products are executed effectively; to ensure that our marketing programs are compliant with FDA regulations and are effective and are, in fact, implemented by our sales force; to ensure that we're able to provide the kind of logistical support for the sales force, as well as ensuring that they are trained.

Q. And were those your responsibilities in 2010 as well?

A. They were.

Q. And who reports to you as the president of the division?

A. So I have a number of different groups. So I have the marketing group reports to me; sales group reports to me; sales operations reports to me; sales training reports to me. I now have business development reporting to me and -- yeah, I think that's

it.

Q. And to whom do you report?

A. I report to ^ Paul Bazzaro, who's the chief executive officer of Impax.

Q. How long have you been working in the pharmaceutical industry?

A. Since 1980, so 37 years.

Q. And on a general level, what other positions have you held while working in the pharmaceutical industry during those 37 years?

A. Well, I started as a sales representative. I've held sales training positions. I've held sales management positions. I've held marketing, marketing executive, management positions. I was vice president and general manager for a vaccine in a pediatric division; been president of both the Generic and our Brand Division; president -- excuse me, CEO of a biotech startup; chief operating officer for an animal health startup company; and for the last eight years, president of Impax.

Q. And have you ever worked in a business development role in that time?

A. I have not worked in business development, per se, but I've always had business development people that would either report directly to me or with whom I

have worked very closely.

Q. Thank you.

And you mentioned that Impax's Brand Division was fairly new when you joined the company. On a high level, what were the areas of focus for the Brand Division when you joined?

A. The area of focus was central nervous system, specifically neurology, and that's because the intent was to bring to market a product that would be a better treatment for Parkinson's disease.

Q. Okay. And can you tell me a little bit about that, that treatment that Impax had in mind at the time?

A. Sure. So the idea was to develop a product that was better than what was at that point in time -- and still is -- the gold standard treatment for Parkinson's disease, immediate-release carbidopa-levodopa.

The problem with immediate-release carbidopa-levodopa is that as the disease progresses, patients have to take immediate-release carbidopa-levodopa more and more and more frequently, and essentially what that does is causes a spike in the blood serum level, which causes dyskinesias, and this is -- if you have seen Michael J. Fox on television,

you have seen him moving and kind of squirming around. That's dyskinesia.

Likewise, it's kind of like what goes up must come down, so as the disease progresses, it spikes very quickly, and then the serum levels drop very quickly. So patients do not have control of their motor symptoms as you and I normally have and as we take for granted.

So what we were trying to do was to develop a product that would give a much smoother effect from the Vadova product.

Q. And was there any particular strategy behind focusing on an improved carbidopa-levodopa Parkinson's disease treatment?

A. Only that it was identified as an unmet need within the Parkinson's space for patients.

Q. Did Impax ultimately bring Vadova to market?

A. No, it did not.

Q. Did the Brand Division then change its focus when it stopped working on Vadova?

A. We kept our focus on Parkinson's disease, but we switched our attention to another formulation of carbidopa-levodopa that we had done a little bit of work on. This was a product that we called IPX-066, and this was an extended-release version of carbidopa-levodopa that had a unique formulation that

allowed the blood serum level for IPX-066 to be extended for between five and six hours.

Q. And has IPX-066 since been brought to market?

A. Yes. We launched what became Rytary into the U.S. market in February of 2015.

Q. Thank you.

And before Impax launched Rytary, what did the Brand Division focus its efforts on?

A. Well, when the Brand Division was pulled together -- and this was before I joined the company, because it was 2006 -- we were promoting other people's products to the neurology community, and we were promoting Carbitol, which is an epilepsy product, to the community, knowing that we wanted to begin the process of developing those relationships with the neurology physicians.

Q. Did Impax seek to market any other products?

A. Yes, we did. We were always looking to get away from the reliance on other people's products, so we were looking for additional products that would be able to be promoted to the same physician group that we were calling on, the neurologists. And we looked at everything from other epilepsy products to migraine products, pretty much anything that a neurologist used.

Q. And were you marketing only to neurologists or

did you mark to any non-neurologists?

A. At that point in time, we were promoting just to neurologists, because we were mostly at that point interested in epilepsy.

Q. Were you successful in in-licensing any products to market to those physicians?

A. Ultimately we were in 2012, and this was a migraine product that we in-licensed from AstraZeneca. AstraZeneca was not promoting this product -- this product was called Zomig. AstraZeneca was not promoting this product at all, and we needed a way to be able to fund our expenses, because we worked for a -- we were a brand division within a generic company, and so we had to, as quickly as possible, pay our own way. So we were finally able to execute a license agreement with AstraZeneca and began promoting that product.

Q. Did Impax ever approach Endo about marketing any of Endo's products?

A. Yes, we did. Even before we began discussions with AstraZeneca, we had approached Endo about a migraine product they had called Frova. It was in the triptan category of migraine products, just like Zomig was. Every time we would talk to Endo about licensing the product from them, they would turn us down.

Q. Do you recall when the first time was that you approached Endo about licensing Frova?

A. That I was involved with was probably late 2008, 2009.

Q. Do you recall whether Impax was in settlement negotiations with Endo around that time?

A. At that time, no.

Q. Without limiting the question to collaborations regarding Endo's products, has Impax entered into any collaborations with Endo?

A. In what time frame?

Q. At any point.

A. At any point? We did. We entered into a development agreement for what has become IPX-203.

Q. Do you recall when that was?

A. It was probably around 2010.

Q. Okay. And if I refer to that agreement as the development and co-promotion agreement for the DCA, will you understand what I'm referring to?

A. Yes, I will.

Q. Do you know whether Impax executed any other agreements with Endo around the same time that it entered the DCA?

A. Not on my side of the business, no, but we did relative to the generic side.

Q. Did you -- and what agreement was that?
A. I beg your pardon?
Q. What agreement was that?
A. That was a -- an agreement on the generic side of the business around oxymorphone.
Q. Did you have any involvement in negotiating or drafting that --
A. The oxymorphone?
Q. -- agreement? The oxymorphone --
A. No, no.
Q. -- agreement?
JUDGE CHAPPELL: Hold on a second. You were talking at the same time, so please wait for her to finish.
THE WITNESS: Yes.
MS. FABISH: Thank you.
BY MS. FABISH:
Q. I'd like to ask you some questions about Impax's product candidate, IPX-203, which you just testified was the subject of the DCA.
A. Sure.
Q. And before you answer, I would like to note that many of the details regarding IPX-203's formulation have been designated for in camera treatment, so please answer these initial questions on

a high level, and I will ask you for more details once we go into an in camera session a little later on, okay?

A. Okay.

Q. So speaking in very broad terms, what is IPX-203?

A. IPX-203 is an extended-release formulation of carbidopa-levodopa. The goal with IPX-203 is to be a follow-on product to the product that we currently have in the marketplace, Rytary, which was IPX-066.

We launched IPX-066 because we had a profile that it would last longer in a Parkinson's patient than immediate-release carbidopa-levodopa, so there's a clinical benefit increment over and above what immediate-release carbidopa-levodopa could bring.

IPX-203, the whole idea behind this product -- and, in fact, what we're seeing now playing out in our early studies -- is to be able to even extend more the effective time that a patient is on IPX-203, meaning that they have a longer period of time when their motor control symptoms are under control.

Q. And how did the general idea for IPX-203 arise at Impax?

A. As we were going through the clinical trial program for Rytary. As we were looking out into the

future and wanting to at least begin laying the foundation for our brand business over a long period of time, we started thinking about what else could we do. The thought occurred to us that we have Rytary going through the clinic. The results look pretty good with what we had seen to date. It occurred to us that we would then, with Rytary, be creating a -- if you will, a Parkinson's disease franchise or at least had the opportunity to do so.

And so the whole concept behind IPX-203 was to be a follow-on product to Rytary that would offer a clinically meaningful clinical benefit to Parkinson's disease patients over and above Rytary.

Q. Can you just explain a little bit more, briefly, what you mean by "follow-on product"?

A. A follow-on product would be an improvement -- in this particular case, it would be an improvement on our Rytary formulation of carbidopa-levodopa that would allow it to be a distinct product entity, in and of itself, that would offer a greater therapeutic benefit to patients.

Q. And what did Impax hope 203 would achieve for it commercially?

A. Well, commercially, to help further establish the business foundation that we had laid out for

ourselves with the neurology community in the Parkinson's space.

Q. Did you envision that IPX-203 would replace 066 or Rytary in the market?

A. When we originally conceived the idea, that was the -- our thought behind the product; however, as the marketplaces have evolved, if you bring out a new or an improved version of a product, you cannot just pull an existing product from the marketplace.

So our thought relative to IPX-203 at this point in time is that we would promote Rytary up to a certain point when IPX-203 was ready to come to market, and then we would pull all promotion, all sampling from Rytary, and we would devote all of our sales force attention, all of our marketing attention, all of our sampling attention to IPX-203, to build the demand for IPX-203 and allow Rytary to have its natural decline.

Our thought there is that we would have a number of patients whose Parkinson's disease was well controlled on Rytary, and we did not want to essentially pull the rug out from under those patients and the control that they have. The reason for that is, for Parkinson's disease, once you are able to establish a level of control, that's a very important thing for those patients.

Q. Are there any other branded carbidopa-levodopa products on the market for the treatment of Parkinson's disease?

A. The only product that is promoted is a -- an infusion product. It's called Duopa. It's administered basically through a pump that goes directly into the intestines, into the jejuni, and is usually reserved for the most severe patients.

Q. Are there any generic carbidopa-levodopa products on the market for the treatment of Parkinson's?

A. Yes. Yes, there is. I should say -- excuse me. The original brand immediate-release carbidopa-levodopa, Sinemet, is still on the market, but it stopped being promoted by its originator a long time ago.

Q. How did you envision the presence of carbidopa-levodopa generics on the market that you just referenced would affect the commercial outlook for IPX-203?

A. As we -- as we look at the kind of spectrum of treatment, we view IPX-203 as a product that would be used in a certain patient at a certain stage of Parkinson's disease. Immediate-release carbidopa-levodopa works quite well for patients who

are newly diagnosed. They have what we call a wide therapeutic window, and immediate-release carbidopa-levodopa, with its peaks in blood serum and then the subsequent bottoming out of that blood serum level until another dose is taken, fits quite well and works quite well.

However, as the disease progresses and the therapeutic window -- sorry -- the therapeutic window narrows, it becomes very difficult for an immediate-release carbidopa-levodopa to be able to provide a long period of control of symptoms. So we envision IPX-203 being a better product, a much better product than not only immediate-release carbidopa-levodopa but also Rytary, in offering a longer period of control.

Q. And was this improved version of Rytary important to you as the president of the Brand Division?

A. Oh, very important in terms of ensuring that we had a longer term business foundation established.

Q. Where does the project name IPX-203 come from?

A. R&D folks allocate numbers to different therapeutic products that they work on.

Q. Does it have any particular significance, the numbers chosen?

A. Only that that becomes the designation for a particular product.

Q. Okay. As of 2010, what were some of the hurdles that Impax was facing in pursuing the IPX-203 product concept?

A. Because it was still an early concept, we were internally facing some difficulty in terms of where would the funding come from to begin the development process for the product. I think in order to kind of understand that mind-set, you need to kind of step back a little bit and look at what we encountered as we were developing Rytary.

So I run a brand business inside of a generics company. Shareholders in a generics company are not accustomed to the kind of spending for research and development that you do with a brand product. In fact, I can distinctly remember one of our shareholders at one point telling me to my face, at an analyst meeting that we were at, why do we continue to sink money into this branded sinkhole, is what he referred to it as.

So this was pretty typical of the mind-set of the shareholders or investors that we had in our company as a publicly traded company, and so there was naturally reluctance internally, on top of clinical trials that we were already doing for Rytary, to begin,

on top of that, an additional R&D development program for IPX-203.

Q. So if Impax was having difficulty getting funding to support the 203 program internally, how else did it consider getting funding for the contract?

A. Well, we had talked about a number of different ways internally, possibly to the extent of even, just for our own business, talking to venture capital to see if we could get support there. The CEO at the time, Larry Hsu, didn't think that was a very good idea, but we were quite intent on being able to begin the work on IPX-203.

And then when the idea of a co-development program with Endo came up, my team and I were very excited about that.

Q. And around this same time, so 2010, was Impax looking for partners to assist in funding the further work on IPX-066 as well?

A. No. No, we weren't.

Q. And why was that?

A. We had basically done all of the heavy lifting. We had already assumed all the risk around Rytary at that point, taken it through the early clinical trial phases, and so from my perspective -- which was also shared by our president and CEO -- was that we've

already taken all the risk, then we should get all the rewards for the product. I don't need anyone to help me with Rytary.

Q. Was Impax interested in seeking a partner for Rytary outside of the U.S.?

A. Yes, we were.

Q. And why would Impax be interested in a partner outside the U.S. but not domestically?

A. So when we did the clinical trial program, the Phase III clinical trial for Rytary, we had a substantial number of patients come from Europe. So there was this interest within the European clinical trial community that we had fed, if you will, and it was always our intent to file Rytary not just for U.S. approval, but also for European approval.

And on that basis, then, we needed a partner who could help us launch Rytary outside of the U.S. That was a capability we did not have.

Q. But how did the -- the fact that Impax had done the heavy lifting, as you just referred to it, why did that not cause Impax to not be interested in a partner for outside the U.S.?

A. We were interested in a partner outside of the U.S., and ultimately we were able to get the interest of GlaxoSmithKline, which was a big multinational

pharmaceutical company.

Q. Thank you for correcting my question earlier.

Were there additional risks associated in launching -- associated with launching the products in Europe that would not apply in the United States?

A. The markets outside of the United States have their own unique characteristics. Since we have no presence outside of the United States, we would not be fully aware of what the idiosyncrasies were outside the United States, so a partner that had a full understanding of the different markets, that had required infrastructure to effect the commercialization process, as well as a regulatory structure that allowed them to navigate the different regulations with each of the countries outside the U.S.

Q. Thank you.

And who would have been involved in decisions regarding possible collaborations on Rytary in 2010?

A. I would have been. The CEO of our company would have been. As a general rule, that would have been the starting point, as well as our business development folks.

Q. Were you ultimately able to secure additional funding to support further development of IPX-203?

A. Yes, we were.

Q. And what was the source of that funding?
A. That came from Endo.
Q. Okay. Was that pursuant -- was that under the development and co-promotion agreement?
A. Yes, it was.
Q. And in 2010, when you executed that agreement, how much did you anticipate IPX-203's development was going to cost Impax?
A. Well, we knew that Rytary had cost us around about $100 million, or would cost $100 million to bring to market, so our estimate, depending on the clinical trial construct for 203, was anywhere between 80 and 100 million dollars.
Q. Okay. And why would you use IPX-066 to help calculate what you anticipated 203's development costs would be?
A. Because basically it's coming into exactly the same market. It's coming in with a similar premise -- that is, an improvement, clinical improvement, over immediate-release carbidopa-levodopa -- except in this case a much greater improvement. But the basic structure of the clinical trial programs would be the same.
Q. Did you do any formal analysis in 2010 to determine the anticipated development costs of IPX-203?

A. Not a formal analysis relative to IPX-203, but we had already done a very formal analysis around IPX-066, so we knew what the components of the costs would be, and it was a natural extrapolation.

Q. Sure.

What was your initial reaction to the idea of a collaboration with Endo regarding IPX-203?

A. Oh, I was very pleased. It was a -- potentially a way that we could get IPX-203 off the ground very quickly.

Q. If you could take a look at tab 5 in your binder. Robert, if we could put up RX 387.

I'll note that this document is in evidence, and it is not subject to Your Honor's in camera order.

You will see this is an email from yourself to Chris Mengler, copying various other individuals, with the subject line, "Today's Meeting," dated June 1st, 2010.

In your email here, the very beginning, you note, "066A is not a slam dunk."

First of all, what is "066A" referring to here?

A. That was the initial name or designation that we had for what became IPX-203.

Q. Okay. And do you recall why you felt that 066A was not a slam dunk?

A. At that time it was still conceptual. We hadn't landed on a final formulation for the product. We had what we thought were some very good ideas based on the literature that would lead us to a formulation, but as you see in the email, my chief scientific officer, Suneel Gupta, for whom I have a great deal of professional respect, he thought it would be doable, and that was good enough for me.

Q. Could you explain a little bit why you hold Dr. Gupta in such high esteem?

A. Dr. Gupta has, throughout his career, done a number of product developments where he has basically taken an existing chemical compound and improved it and then had those products come to market and been very successful commercial products.

Q. Were there any reasons besides the early stage of development that you referenced earlier that you felt 066A or 203 was not a slam dunk?

A. No. It was just the -- the early stage relative to the development of the formulation.

Q. And later on in your email, you go on to say that, "Anne Hsu thinks there will be some difficulty with developing the formulation (which is why it would be nice to have a partner). My view is that is part of the development process."

Who is Anne Hsu?

A. Anne Hsu was our vice president of pharmacology within the research and development group at the time.

Q. And what do you mean when you -- what did you mean when you said, in connection with her concerns, that developing the formulation is part of the development process?

A. Whenever you come up with an idea for a formulation, many times you will end up trying different formulations before you come across the right formulation that you end up going forward with. It's just part of the normal course of developing pharmaceutical products.

Q. And then, finally, later on in the email, you state, with respect to 066A, "I would hate to have to sell it."

Why would you not want to sell the asset?

A. Well, I think with that you have got to go back to the original concept behind IPX-203, and that is that this would be a product that would be an extension of the franchise that we expected to create with Rytary. So if I was going to further build out an entire foundation for my business for the longer term, to my mind, there is no point in selling it. Let's keep it as part of the family, so to speak.

Q. Okay. When you initially discussed the idea of a co-promote with Endo regarding IPX-203 internally at Impax, who did you envision Impax would be able to continue to promote -- excuse me, who did you envision IPX would be able to promote -- excuse me. Who did you envision Impax would be able to promote IPX-203 to?

A. So what we had envisioned was that we would promote IPX-203 to the neurology community because they're the largest prescribers of Parkinson's disease patients. We were also aware that there were maybe a couple of thousand physicians who were primary care physicians that prescribed Parkinson's patients, somewhat like a neurologist. So that was the audience that we had envisioned promoting IPX-203 to.

Q. But was it important to you that Impax try and keep the rights to market to those non-neurologists?

A. Initially, yes. Ultimately, no.

Q. And when you say "Ultimately, no," why not?

A. Because as we got into the discussions around the development agreement, Endo wanted to have a clean break between the specialties that both companies called on. They had a sales force of their own that was calling on the physician community and a lot of primary care physicians, so they wanted to ensure that all primary care physicians, they would promote IPX-203

to, and we would promote to the neurology community.

Q. Thank you.

Your Honor, at this point, I would like to request an in camera session to discuss various materials subject to the in camera order.

JUDGE CHAPPELL: All right. At this time, we are going to go into in camera session. I need to ask those of you who are not subject to the protective order in this case to vacate the courtroom. You will be notified when you can re-enter.

MR. LOUGHLIN: We're fine on our side, Your Honor.

JUDGE CHAPPELL: Thank you.

MR. HASSI: We're okay as well, Your Honor.

JUDGE CHAPPELL: All right. Go ahead.

(Whereupon, the proceedings were continued in in camera session.)

(The following proceedings were held in in camera session.)

(End of in camera session.)

(Public session.)

JUDGE CHAPPELL: Go ahead.

MS. FABISH: Thank you.

BY MS. FABISH:

Q. Mr. Nestor, I'd like to switch back to talking a little bit more about IPX-203.

What is the current status of Impax's work on IPX-203?

A. So we have just finished our Phase II-B clinical trial, having completed our Phase II-A program towards the end of last year.

Q. And what were the results of those Phase II studies?

A. So what we saw with IPX-203 in our Phase II-B study was a highly statistically significant difference in reduction in off time, which is the time when patients do not -- Parkinson's patients do not have control of their symptoms. So the shorter amount of time that a patient does not have that control is more desirable, but a highly statistically significant reduction in off time for IPX-203 relative to immediate-release carbidopa-levodopa. In fact, that would -- that time reduction was 2.3 hours, which is a lot.

Q. And what was your reaction to those results?

A. Wow.

Q. What, if anything, have you told Impax's investors about the results of these studies?

A. We actually notified our investors initially through our third quarter analyst call that we had last Thursday, and we had a slide in our presentation that summarized the results of that Phase II-B clinical trial.

Q. And you participated in this earnings call?

A. I did.

Q. Did you personally discuss the study results during the earnings call?

A. Yes, I did.

Q. If you would please turn to tab 17 in your binder.

JUDGE CHAPPELL: Lawman, did you check that side door?

BAILIFF: Not yet.

JUDGE CHAPPELL: The Judge might have accidentally locked it this morning. Thank you.

Go ahead.

MS. FABISH: Thank you.

BY MS. FABISH:

Q. Tab 17 is a document that I have premarked RX 576. This document is not on JX 2 and has not yet

been admitted into evidence.

Mr. Nestor, can you please flip through this document and tell me if you recognize it or -- it's tab 17 in your binder.

A. Yes. This was the slide deck that we used to take the analysts through our third quarter performance.

Q. And did you review this presentation before it was finalized?

A. I did.

Q. And when was this presentation prepared?

A. The presentation was prepared the week before the analyst call, but we were making finetuning touches until probably right up until the day before.

Q. Understood.

And was this presentation prepared by someone with knowledge of its contents?

A. It was. So the complete presentation was prepared either by our finance group, either by the generics group, or in the case of the slide on IPX-203, by my group.

Q. And does Impax regularly present its quarterly results to investors?

A. Yes, we do. As a publicly traded company, we are obligated to do so.

Q. Does Impax regularly prepare presentations in connection with that?

A. Yes, we do.

Q. And when you present to investors, do you try and be as accurate as possible?

A. Yes, we do.

Q. Does the information in these slides accurately reflect Impax's quarterly results for Q3-2017?

A. Yes, they do.

Q. Were these slides posted to Impax's website following that earnings call?

A. Yes, they were.

Q. And did you answer questions from your investors during the third quarter earnings call that we were just speaking about based, in part, on this presentation?

A. Yes.

Q. Okay.

Your Honor, at this time, I would like to offer RX 576 into evidence. It is admissible under Rule 3.43(b), as Mr. Nestor's testimony has established it's being relevant, reliable material. It was created by Impax to present to its investors who can and do rely on these types of investor presentations in making their investment decisions, and the information on the

slides goes to Impax's progress on IPX-203, the product of the DCA at issue here; in particular, the results of the Phase II tests that Mr. Nestor just testified about.

The FTC has suggested that Endo's decision to invest in IPX-203 was not justified; in particular, Dr. Geltosky argued that the new -- that a new carbidopa-levodopa product such as 203 would not present an attractive commercial opportunity because of the generics present on the market. These slides show that Impax continues to develop such a product and that it has achieved significant results in its testing over and above even Rytary, which is also on the market.

JUDGE CHAPPELL: Any objection?

MR. LEEFER: Yes, Your Honor. We have several objections, the first of which, this document does not appear to have been produced in discovery and it was not disclosed to us ahead of time. Furthermore --

JUDGE CHAPPELL: All right. Address that first.

MS. FABISH: Excuse me?

JUDGE CHAPPELL: Address that.

MS. FABISH: Yes, Your Honor. This document was only generated last week for -- as Mr. Nestor just testified, it was being finalized until the day of the

earnings call on November 9th, 2017, so we could not have produced it in discovery.

JUDGE CHAPPELL: Go ahead. Next?

MR. LEEFER: The next objection is that this appears to be a November 9th, 2017, presentation. Ms. Fabish has represented that this is relevant because it concerns the product subject to the development and co-promotion agreement, but I don't believe a foundation to that effect has been laid.

MS. FABISH: Your Honor, Mr. Nestor just testified that the presentation addresses the Phase II studies of IPX-203, which is the subject product of the DCA.

JUDGE CHAPPELL: Tell me again why it wasn't produced earlier.

MS. FABISH: Because it was only generated last week, Your Honor, in connection with preparing for this quarterly earnings call. It occurred on the date of the document.

JUDGE CHAPPELL: What's the RX number?

MS. FABISH: RX 576.

JUDGE CHAPPELL: I am going to hold off on ruling until after the break. You can re-urge it after the next break.

MS. FABISH: Okay. Thank you, Your Honor.

MR. LEEFER: Thank you, Your Honor.

MS. FABISH: May I continue to ask the witness questions about it if I don't publish it?

JUDGE CHAPPELL: Yes. If it's excluded, the testimony won't be considered. It depends on my ruling.

MS. FABISH: Okay. Thank you, Your Honor.

BY MS. FABISH:

Q. So, Mr. Nestor, just setting the document aside, first of all, you spoke previously about how the results of the Phase II-B studies were -- I believe you used the word "wow." Can you explain the specific results regarding off time that led you to make that comment?

A. Yes. So I had indicated earlier that the objective behind IPX-203 was to be able to provide a product that offered increased incremental clinical benefit over not only immediate-release carbidopa-levodopa, but also over our current product that we are promoting in the market, Rytary.

And so in addition to seeing 2.3-hour reduction in off time over immediate-release carbidopa-levodopa, we saw a -- what we saw in our Phase III clinical trial results with Rytary versus immediate-release carbidopa-levodopa -- so this is kind of from a

perspective standpoint -- what we saw was a one-hour improvement or further reduction in off time over immediate-release carbidopa-levodopa.

So the fact that not only were we two hours better than the immediate-release carbidopa, we were one hour better than Rytary, which is a clinically meaningful and relevant amount. That's a terrific result for us.

Q. Thank you.

Mr. Nestor, earlier today, you referenced needing to slow down on work on 203 as a result of a warning letter. What is a warning letter?

A. So a warning letter is a notification by the FDA that they are, shall we say, not pleased with what they see going on in, in our case, a manufacturing facility in Hayward, California. That warning letter was not that there were issues with the safety or efficacy of our product. It was to do with the processes that we were following in the manufacturing of our products.

And the reason we received the warning letter was, when the FDA did their last inspection, they noted a couple of items that they had also noted in the prior inspection that had not been completely fixed by us.

Q. And what effect did receiving this warning

letter have on Impax's business?

A. In terms of how we were running the business, it galvanized us to focus all of our efforts from our research and development teams to help the operations people, the technical operations people address not only specifically the issues that FDA had identified, but we actually brought in a third-party group to go through, really from soup to nuts, everything in the facility, and anything they found deficient, we fixed it. And a lot of that had to do with other products on the generic side that were in development, and so our R&D folks worked to help remediate those items.

Q. And what would happen if Impax did not remediate the deficiencies identified in the warning letter?

A. I think basically the FDA would have shut the facility down.

Q. And what would that mean for Impax?

A. We wouldn't be able to get any products out of the facility.

Q. Would the warning letter affect Impax's pending NDA regarding Rytary?

A. It did affect our pending FDA [sic].

Q. Do you recall when Impax received this warning letter?

A. I think originally in 2011.
Q. Okay. And did Impax ultimately address the issues raised in the warning letter?
A. Yes, we did.
Q. Could we put up RX 206, please. This is tab 10 in the binder. This document is in evidence. It is not subject to in camera treatment.
You'll see that this is an email chain between yourself, Mr. Nestor, and Suneel Gupta. Dr. Gupta asks you in his initial email, in the subject line, on January 15th, "Is 203 a go?"
And your response begins with the sentence, "It's a matter of when not if."
Can you explain what you meant by "It's a matter of when not if"?
A. So I think Suneel's concern was would IPX-203 be killed, and that first line addresses the -- basically is telling him it's not a case of it's not going to go forward; it's a matter of when we can go forward, and for the reasons that follow in the next -- the rest of that sentence.
Q. Can you explain those reasons to me?
A. All of our people were spending their time getting ready for a pre-approval inspection that we anticipated in the next 60 to 90 days, for the FDA to

come in and do their re-inspection, and all of our focus was ensuring that everything that we had identified, in addition to what FDA had identified, was fixed. So nothing was going to go forward until such time as we got over that hurdle.

Q. Okay. Let me draw your attention to the next sentence in the email, which reads, "Fred does not want any CMC R&D activities on anything but PAI for the next 60-90 days (or FDA come in) in order to prepare for next inspection."

A. Correct.

Q. Who is Fred that you're referring to here?

A. That was Fred Wilkinson, who was at that time our chief executive officer.

Q. Okay. And what are CMC R&D activities?

A. That's chemical manufacturing controls. Those are steps within the early stage of developing a formulation of a drug product.

Q. Would the work Impax was doing on 203 qualify as CMC R&D activities?

A. It was -- yes, it would be.

Q. At this time frame?

A. At that time.

Q. Thank you.

And what is PAI?

A. Preapproval inspection.
Q. Is that associated with the warning letter remediation?
A. Preapproval inspection was actually related to generic products that we were anticipating having an inspection of the facility in order for those products to be approved for sale.
Q. Is this sentence generally consistent with your recollection that there was a pause on research and development activity until the warning letter was addressed?
A. Totally.
Q. Okay.
JUDGE CHAPPELL: On the exhibit that you offered --
MS. FABISH: Yes.
JUDGE CHAPPELL: -- since it was not provided in discovery, you are going to need to demonstrate good cause for its admission. Are you prepared to do that or do you want to wait until the next break?
MS. FABISH: I would appreciate the opportunity to wait until after the next break, Your Honor.
JUDGE CHAPPELL: All right.
MS. FABISH: Thank you.
BY MS. FABISH:

Q. One additional question regarding this document, Mr. Nestor. Later on in the paragraph, you make reference to -- this is the second-to-last sentence -- "He" -- I believe referring to Fred Wilkinson -- "is aware the clock is ticking and that we have the Endo obligation."

What Endo obligation were you referring to here?

A. This was relative to the DCA and that we needed to update Endo as to what our status was relative to the IPX-203 formulation.

Q. So did you feel you had a contractual obligation to do that?

A. We felt so, yes.

Q. And after you addressed the warning letter issues, did you resume work on 203?

A. Yes, we did.

JUDGE CHAPPELL: If you have a copy of this exhibit you're offering, provide it to my staff on my right side, please.

MS. FABISH: Yes, Your Honor.

BY MS. FABISH:

Q. So, Mr. Nestor, I just have a couple final questions regarding IPX-203. If you would turn back to tab 17, RX 576, the third quarter 2017 results and

business update presentation --

MR. HASSI: Your Honor, may I approach to give this to --

JUDGE CHAPPELL: Yes.

MR. LEEFER: Your Honor, just for the record, I want to make sure that our objection to this exhibit continues, and we understand that depending on the ruling, any testimony about this may later be stricken. Is that correct?

JUDGE CHAPPELL: It depends on my ruling, yes.

MR. LEEFER: Thank you, Your Honor.

BY MS. FABISH:

Q. Mr. Nestor, if you would turn to page 6 of this document.

JUDGE CHAPPELL: I would suggest Complaint Counsel review the document during the break. In the event it's admitted, you'll be allowed a lot of leeway in your cross exam, if it's admitted.

BY MS. FABISH:

Q. Mr. Nestor, this slide is entitled "IPX-203 Positive Outcome of Phase II-B Study." Is this the same Phase II-B study we were discussing earlier?

A. Yes, it is.

Q. Can you take a look at the information provided about the study here and let me know what you feel is

significant about it?

A. There are a couple of aspects here. The first is the chart on the left-hand side, under the "Patient Parkinson's Disease Diary." The first is the statistically significant number. You'll see it's 0.0001, and what you see is amount of off time, in hours, and you see for immediate-release carbidopa-levodopa, 5.5 hours; for IPX-203, it's 3.2, which is a difference of 2.3, so a highly statistically meaningful difference.

What's also important relative to this is the fact that we have received from the FDA a special protocol assessment -- also known as an SPA -- with the FDA on Phase III clinical trial program. Now, what that means is that we and the FDA have reached agreement as to exactly what the Phase III clinical trial program for IPX-203 will be, and if FDA has any questions about the final submission, the new drug application submission for IPX-203, no questions can arise as to the clinical trial design of the study.

The other aspect I will point you to is on the right-hand side of the page, and what you see here is the proportion of patients who achieved either a seven-point reduction in the Unified Parkinson's Disease Rating Scale, Part 3. This is -- measures

basically movement. And you'll see a highly statistically significant difference between patients on IPX-203 achieving a seven-point reduction. A seven-point reduction is -- that equates to about a 20 percent reduction in scores, which is clinically meaningful. But if you look to the right where it talks about a 13-point reduction, which is a 40 percent reduction, that is also very clinically meaningful as well.

Q. Thank you.

And with this Phase II-B study, has Impax completed Phase II of its development on IPX-203?

A. Yes, we have.

Q. And when did it complete Phase II?

A. We finished the Phase II-B program towards the end of last year.

Q. Mr. Nestor, earlier today we spoke a little bit about IPX-066, or Rytary, the predecessor to IPX-203, which you testified is now on the market. How has Rytary fared on the market?

A. I think within the neurology community, if I look at the movement disorder specialists who are the top tier of neurologists who treat Parkinson's disease, 80 percent of the physicians who started prescribing Rytary are still prescribing Rytary, and we're on track

for what we had anticipated to be the market share for that physician community.

The issue that we have with the neurology -- general neurologist community is that the dosing conversion from immediate-release carbidopa-levodopa to Rytary is not an intuitive one and requires a bit more calculation than it would seem the general neurologist wishes to spend. This is another benefit we anticipate with IPX-203, in that the dosing regimen that we would employ with IPX-203 would be much more simplified than Rytary.

Q. Mr. Nestor, thank you very much for your time. I have no further questions at this time.

JUDGE CHAPPELL: How much anticipated time do you think you need for cross?

MR. LEEFER: Without making any promises, Your Honor, I hope to be done within 60 to 90 minutes.

JUDGE CHAPPELL: All right. In that event, we will go ahead and take a lunch break now. As I said earlier, in the event that document's admitted, be prepared to cross on the document.

MR. LEEFER: Yes, Your Honor.

JUDGE CHAPPELL: We will take a little over an hour. We will reconvene at 1:40. We're in recess.

(Whereupon, at 12:32 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(1:40 p.m.)

JUDGE CHAPPELL: Okay, let's go back on the record.

Did you want to re-urge your admission of an exhibit?

MS. FABISH: Yes, Your Honor.

JUDGE CHAPPELL: What's the exhibit number?

MS. FABISH: 576, Your Honor.

JUDGE CHAPPELL: All right. And I had informed you that because it was not furnished during discovery, you are going to have to demonstrate good cause. So are you prepared to make your argument?

MS. FABISH: Yes, sir.

JUDGE CHAPPELL: Go ahead.

MS. FABISH: May I approach the podium?

JUDGE CHAPPELL: Yes.

MS. FABISH: So, Your Honor, as I mentioned previously, this document was only recently created, so we could not have produced it in discovery. It came to our attention yesterday in the course of preparing for Mr. Nestor's testimony.

I would also note that the document has been publicly available for several days, and we have provided a copy to Complaint Counsel at the outset of

the hearing today.

The FTC has implied that the DCA and, more specifically, IPX-203, the subject product of the DCA, are somehow a sham or not bona fide and thus --

JUDGE CHAPPELL: That doesn't go to good cause. You got anything else for good cause for lateness?

MS. FABISH: Well, I wanted to establish the relevance and materiality of --

JUDGE CHAPPELL: I have already heard that.

MS. FABISH: Okay.

JUDGE CHAPPELL: You don't need to repeat anything you've said already.

MS. FABISH: Understood, Your Honor.

May I offer some additional argument as to the relevance of the document or --

JUDGE CHAPPELL: Yes, anything I haven't heard yet.

MS. FABISH: Well, in terms of the relevance of the slide regarding IPX-203's Phase II-B studies, that reflects that this product in the real world is a real product that a company is actually pursuing and could be very lucrative, and had co-retained the profit-sharing rights that Complaint Counsel have implied were without value, so it would be potentially very valuable to Endo at this time.

In addition, slide 5, I believe it is, in the document speaks to the commercial success of Rytary, IPX-066, which is another carbidopa-levodopa Parkinson's disease treatment that is faring well in the Parkinson's disease market, despite the fact that there are numerous generics, which is another argument that the FTC has -- that Complaint Counsel has raised in terms of attacking the bona fides of the DCA.

And, finally, I would add that the additional detail provided in the slide is particularly helpful to supplement the testimony of Mr. Nestor, that Mr. Nestor offered separately based solely on his own knowledge.

JUDGE CHAPPELL: Is that it?

MS. FABISH: Thank you.

JUDGE CHAPPELL: Do you re-urge your objection?

MR. LEEFER: Yes, Your Honor, we do.

JUDGE CHAPPELL: Go ahead.

MR. LEEFER: For several reasons. First of all --

JUDGE CHAPPELL: Address good cause only.

MR. LEEFER: Yes. Respondent's counsel has not established good cause for the delay in showing this document and not producing it in discovery. As Ms. Fabish said, this document is from at least a week ago, and had they wanted to use this during the

hearing, they could have presented it to us at that point. Instead, they waited until the morning of Mr. Nestor's testimony to show it to us for the first time, and I believe I'm correct that we still do not have an electronic version of this document, only a hard copy today provided. This is litigation by ambush and should not be permitted.

Moreover, they haven't demonstrated any need to use this document and to offer it into evidence. Respondent's counsel could have and, in fact, did ask Mr. Nestor about the current status of the IPX-203 product without reference to this document.

JUDGE CHAPPELL: All right. Here's my ruling. You may sit down.

I don't need to reach relevance, materiality, reliability. My ruling is based on good cause, because under our scheduling order, you must demonstrate good cause to offer an exhibit at this point in trial. Based on what I've heard, having reviewed the document, Respondent has failed to establish good cause for admitting the document. I understand it was only recently generated and that that is an element of good cause, but that alone does not establish good cause.

In addition, given the extensive information in the document, there is simply insufficient notice to

enable Complaint Counsel to complete effective cross examination. In the interest of fairness, the document will not be admitted. And I want the record to be clear so we can follow this in the future, any testimony from the witness regarding the contents of the document will not be considered.

However, this ruling regarding the document does not affect the testimony from the witness' personal knowledge regarding anything in the document, because he's a fact witness.

First, I'm instructing you to remove any copy of this document from the witness or the witness stand. You can do that right now.

MS. FABISH: (Counsel complied.)

JUDGE CHAPPELL: So we're clear on how we're going to handle this fact witness' testimony, any question and answer in the record on direct regarding this document will not be considered; however, to be fair, I will give you a moment if you would like to look over your notes, and if you would like to continue your direct and inquire into the personal knowledge of this witness regarding these issues, I'll allow that.

Do you need a moment?

(Counsel conferring.)

JUDGE CHAPPELL: I don't know the format of

your examination notes, but any question that contained RX 576, that answer is out.

MS. FABISH: Understood, Your Honor. I would like a moment to ask just a couple brief additional questions to assure --

JUDGE CHAPPELL: Right. And to be fair, since you couldn't anticipate everything, if you want to take a moment to confer, go ahead. We'll wait.

MS. FABISH: Okay.

JUDGE CHAPPELL: And Complaint Counsel, I'll remind you that, based on my ruling, you don't need to inquire on cross about this document.

MR. LEEFER: Understood, Your Honor. Thank you.

JUDGE CHAPPELL: The subject that he might testify about, that's open, but not the document. The document's out.

MR. LEEFER: Thank you, Your Honor.

JUDGE CHAPPELL: Just so the record's clear, RX 576 will not be admitted. The motion to admit is denied.

(Counsel conferring.)

JUDGE CHAPPELL: Proceed when ready.

MS. FABISH: Thank you.

BY MS. FABISH:

Q. Mr. Nestor, what is a special protocol assessment?

A. A special protocol assessment is an agreement that a company will reach with the FDA as to what the trial design for a clinical trial will be, and under that agreement, basically, it means that when an NDA is submitted, the FDA will not question the trial -- the trial design if it has any questions regarding the overall Phase III clinical trial.

Q. And are there any special protocol assessments in place regarding IPX-203?

A. There is.

Q. And can you explain the relevance of that special protocol assessment to the Phase II studies of IPX-203 that we discussed earlier today?

A. Only that as a result of the Phase II clinical trials, we felt that we had very good results coming out of the Phase II-B clinical trial and that we wanted to go into a Phase III clinical trial, and that having a special protocol assessment, SPA, kind of takes an element of risk out of a new drug application review.

Q. Based on your -- on your many years of experience in the pharmaceutical industry, is it common to reach a special protocol assessment with the FDA?

A. It does not happen all the time, but it is a

fairly frequent granting by the FDA.

MS. FABISH: Thank you very much.

JUDGE CHAPPELL: Cross?

MR. LEEFER: Yes, Your Honor.

CROSS EXAMINATION

BY MR. LEEFER:

Q. Good afternoon, Mr. Nestor. My name is Nicholas Leefer. How are you?

A. Good, thank you.

Q. Now, we're currently in open session, and so during this part of my examination, I just want to emphasize that I'm not intending to inquire about the scientific details of the IPX-203 product. So please don't volunteer that information until we go into in camera session, okay?

A. Okay.

Q. Now, you were just discussing Phase III clinical trials. Is that right?

A. Correct.

Q. In your experience, typically, once a company has acquired clinical data on a drug candidate, it can begin the process of looking for a development partner. Is that right?

A. It can be.

Q. In fact, in your experience, some companies

will wait until they have Phase III data to look for a development partner. Isn't that right?

A. That can be the case, yes.

Q. A Phase III trial is the last stage of development before filing a new drug application with the FDA, right?

A. Correct.

Q. And it's fair to say that for a branded drug, each step along the development process you get through, the probability of success increases, correct?

A. That would be correct.

Q. So early in development, the probability of success is much smaller than, say, when you finish a Phase III program, isn't it?

A. Typically.

Q. Okay. Now I'd like to talk a little bit about IPX-066, which is also called Rytary, correct?

A. Rytary.

Q. Rytary, thank you.

Now, other than Rytary -- I'm sorry, let me rephrase that question.

Rytary is a carbidopa-levodopa treatment for the symptoms of Parkinson's disease, correct?

A. That's correct.

Q. Other than Rytary, the market for

carbidopa-levodopa drugs is largely generic, right?

A. That is correct. For carbidopa-levodopa preparations, that's right.

Q. In fact, as you testified on direct, the levodopa compound is about 50 years old, right?

A. Correct.

Q. The planned follow-on drug to Rytary is IPX-203, right?

A. Yes.

Q. And to make sure that we have all the numbers straight, before that was called IPX-203, the follow-on drug was sometimes called IPX-066A, right?

A. That's correct.

Q. And you also sometimes call IPX-203 the second generation of IPX-066, right?

A. Rarely, but that has occurred.

Q. Now, Mr. Nestor, you are the president of the Specialty Pharma Division at Impax, right?

A. Correct.

Q. And Specialty Pharma is Impax's Branded Drug Division?

A. Yes.

Q. In 2009 and 2010, you would have been ultimately responsible for the general terms of an out-licensing agreement for a branded product, right?

A. Correct.
Q. And in 2010, Impax negotiated a development and co-promotion agreement with Endo, right?
A. Correct.
Q. And going forward, I will just abbreviate that as DCA, okay?
A. Fine.
Q. As the president of Impax's Branded Division, you had to sign off on the DCA deal with Endo, right?
A. Correct.
Q. And because you had to sign off on the deal, you think you probably would have had input on the milestone payments regarding IPX-203, right?
A. Correct.
Q. But sitting here today, you don't remember any specific input you had with respect to the milestone payments for IPX-203, right?
A. I don't have any specific memory, although I do remember we had discussions around what the -- I'm trying to think what would be the right word -- what might be the outlines of a structure for the DCA.
Q. So you remember those conversations, but you don't remember any general input you gave with respect to the milestone payments, correct?
A. Not specifically, but I would have given

general input into what we would be looking at from a parameters standpoint.

Q. Well, that was slightly different than my question. Let me ask it again.

You don't remember, sitting here today, the general input you gave with respect to milestone payments, correct?

A. Not specifically, no.

Q. Do you remember generally?

A. Generally, it would have been around the different phases we would have to take the product through, what we thought the cost would be moving through each of the phases.

Q. And you think that you would have had input into finalizing the development and co-promotion agreement, right?

A. Yes.

Q. But you can't remember specific types of input that you had, right?

A. That was seven years ago.

Q. You're familiar with Mr. Chris Mengler, right?

A. Correct.

Q. And he was the head of Impax's Generic Division in 2009 and 2010.

A. Correct.

Q. And you're also familiar with Robert Cabuzzi from Endo, correct?
A. As someone who was on the Endo side. I don't know him that well.
Q. He was the business development guy at Endo, right?
A. Okay.
Q. Do you know that to be true, or not?
A. I was reminded of that when I saw an email that had his name on it when we went through the deposition.
Q. So to the best of your knowledge, Robert Cobuzzi was a business development guy, correct?
A. Um-hum.
JUDGE CHAPPELL: You need to answer yes or no.
THE WITNESS: I'm sorry. Yes.
JUDGE CHAPPELL: The "um-hum" could be misconstrued on the record.
THE WITNESS: Okay.
MR. LEEFER: Thank you, Your Honor.
BY MR. LEEFER:
Q. You don't know why Mr. Mengler, who was the head of the Generics Division, was speaking with Robert Cabuzzi at Endo about IPX-066 in 2010, do you?
A. Well, Chris had --
MS. FABISH: Objection, Your Honor.

JUDGE CHAPPELL: Hold it. Sir, you are probably not an expert at this. When someone rises to object, stop your answer. Even if you're in midsentence, stop.

THE WITNESS: I did.

MS. FABISH: Your Honor, this is outside the scope of our direct examination of Mr. Nestor. We did not discuss the negotiations of the DCA or Mr. Mengler's role in those negotiations.

JUDGE CHAPPELL: Response?

MR. LEEFER: Mr. Nestor testified about the development and co-promotion agreement and, in particular, he testified, for example, that he would not have been interested in pursuing a deal with Endo related to IPX-066.

On cross examination, I'm entitled to explore that and see, for example, whether that was his position at the time the negotiations took place.

JUDGE CHAPPELL: Based on the objection --

MS. FABISH: Your Honor --

JUDGE CHAPPELL: -- you will need to lay a foundation that brings it within the scope of his direct, a foundation with the witness.

MR. LEEFER: Certainly, Your Honor.

JUDGE CHAPPELL: I will withhold my ruling for

now.

BY MR. LEEFER:

Q. Mr. Nestor, in your direct examination, you testified that your opinion was that you were not interested in partnering with Endo on IPX-066. Is that right?

A. That's correct.

JUDGE CHAPPELL: Ms. Fabish, were you going to add anything?

MS. FABISH: Yes. Thank you, Your Honor. I believe Mr. Nestor testified that he was not interested generally in a partnership regarding 066. He did not discuss whether he was specifically interested in a development and co-promotion agreement with Endo regarding 066.

THE COURT: All right. That wasn't helpful because the witness is sitting here and he just heard that. I don't allow coaching the witness.

Go ahead.

MR. LEEFER: Thank you, Your Honor.

BY MR. LEEFER:

Q. I understand that today you are saying that you were not interested in partnering with Endo on IPX-066, but in 2010, Mr. Mengler was discussing IPX-066 with Robert Cobuzzi from Endo, correct?

MS. FABISH: Object, Your Honor.

JUDGE CHAPPELL: Basis?

MS. FABISH: This is also beyond the scope of our direct examination.

JUDGE CHAPPELL: Are you asking him about negotiating?

MR. LEEFER: I am asking him what he recalls, if anything, about those negotiations.

JUDGE CHAPPELL: But if he didn't have anything to do with the negotiating, why are you asking him about negotiations? He's a fact witness. He's not here to tell us about negotiations if he wasn't a negotiator.

MR. LEEFER: Mr. Nestor just testified a few minutes ago that he would have been the person ultimately responsible for an out-licensing deal like this one with Endo, and he also testified that he would have signed off on that kind of deal.

MS. FABISH: Whether or not Mr. Nestor would have ultimately signed off on the terms of the deal does not bear on his involvement in the negotiations. As he just testified and as Your Honor noted, he was not involved in those negotiations.

And in addition, I do not believe that I asked Mr. Nestor any questions regarding the negotiations of

the DCA.

JUDGE CHAPPELL: The objection's sustained until you lay a proper foundation that this witness has any knowledge that he can provide to us about negotiations.

BY MR. LEEFER:

Q. Mr. Nestor, as the president of Impax's Brand Division, you were ultimately responsible for all branded products at Impax, correct?

A. Yes.

Q. And that would include signing off on any out-licensing deals with other companies, correct?

A. Yes.

Q. And that included signing off on the DCA agreement with Endo in 2010, correct?

A. Yes.

Q. And you have seen the DCA agreement with Endo from 2010, correct?

A. Yes.

Q. And you were involved in email exchanges with Endo regarding IPX-066 in May of 2010, correct?

A. Yes.

Q. Ms. Wint, can we please pull up CX --

JUDGE CHAPPELL: All right, before you go further, because I have had objections, you can ask him

about all these things he said yes to that he's involved in. He did not say negotiations, so negotiations are not allowed.

MR. LEEFER: Okay, Your Honor. I understand.

BY MR. LEEFER:

Q. Ms. Wint, please pull up CX 2625, and, Mr. Nestor, a copy of this is also in the white binder next to you.

Mr. Nestor, the top email here on CX 2625 was sent by --

JUDGE CHAPPELL: Do we have an objection?

MS. FABISH: Thank you, Your Honor. I would like to object to this document as outside the scope of direct as well. It appears to be bearing on due diligence, which is another topic that I did not discuss with Mr. Nestor.

JUDGE CHAPPELL: I haven't heard a foundation on due diligence. Pull the document off the screen until you lay a foundation. Sustained.

I heard him say he signed off on something. You can ask him about signing off on something. The things he said yes to you, those are allowed. Those are within his area of competence here.

MR. LEEFER: Yes.

JUDGE CHAPPELL: Other than that, no fishing,

unless it's for impeachment or credibility, because it is cross, but you can't turn him into a negotiator or a due diligence person. You can't do that.

MR. LEEFER: I am not trying to, Your Honor. I am trying to explore Mr. Nestor's direct testimony that he was not interested in partnering on IPX-066, and on cross, I want to explore whether that's consistent with the facts of which he has --

JUDGE CHAPPELL: So that's impeachment?

MR. LEEFER: -- personal knowledge.

JUDGE CHAPPELL: That's impeachment?

MR. LEEFER: Yes, Your Honor.

JUDGE CHAPPELL: That's allowed. Go ahead.

MR. LEEFER: Thank you.

BY MR. LEEFER:

Q. Again, Ms. Wint, can we please pull up CX 2625.

Mr. Nestor, you sent this top email here. Is that correct?

A. Correct.

Q. And you sent this email on May 22nd, 2010, correct?

A. Yes.

Q. The subject of this email is regarding IPX 066, correct?

A. Okay, yes.

Q. Now, the email below that, which was also sent on May 22nd, 2010, was an email to Endo indicating that it should have access to something called a data room, correct?

A. Correct.

Q. And this email was sent by David Paterson?

A. Yes.

Q. Mr. Paterson reported to you, correct?

A. That's correct.

Q. Mr. Paterson was responsible for out-licensing IPX-066, correct?

A. Mr. Paterson was responsible for all out-licensing activity at that point.

Q. That includes out-licensing IPX-066, correct?

A. Including IPX-066.

Q. This email exchange -- and you have a full copy of this exchange in your binder if you would like to look at it -- does not mention IPX-203, does it?

A. No, it does not.

Q. And at no point in this email chain did you indicate that Impax was not interested in partnering with Endo on IPX-066, correct?

A. Correct, and there's a reason for that.

Q. Let's take a look at page 3 of this email, CX 2625-3.

JUDGE CHAPPELL: Sir, thank you for cutting off your answer by just saying there's a reason for that. If that's something your counsel or someone on your side feels like is important, that will come out on redirect.

THE WITNESS: Okay.

JUDGE CHAPPELL: But thank you for keeping your answers to yes or no, if possible.

THE WITNESS: Sure.

BY MR. LEEFER:

Q. Let's, Ms. Wint, please zoom in on the bottom email here.

This is an email from Robert Cobuzzi to Chris Mengler, correct?

A. That is the case, yes.

Q. And in this email, the first line, Mr. Cobuzzi writes, "Thank you for taking the time to speak this evening about IPX-066."

Do you see that?

A. I see that.

Q. Now, you don't know why Mr. Mengler was speaking to Mr. Cobuzzi about IPX-066, do you?

A. Not specifically relative to this email, I don't.

Q. We can take that down. Thank you.

On May 26th, 2010, Endo sent a term sheet to Impax concerning a co-promotion deal. Is that right?

A. I don't have the specific date, so I can't verify that.

Q. Let's take a look at CX 2930, which, again, is in your binder, and we will pull up a copy here. Actually, let's look at CX 2930-2, and if we can zoom in on the top half there, please.

Mr. Nestor, this document is titled "Draft Term Sheet." Do you see that?

A. I see that.

Q. And it's dated May 26, 2010. Do you see that?

A. I see that.

Q. Let's go back to the first page, the cover email. Please zoom in on the top email, Ms. Wint.

You received a copy of this email on May 26, 2010, correct?

A. Yes.

Q. Now, this term sheet from Endo identified the product that would be the subject of this co-promotion agreement as IPX-066 and all improvements, modifications, derivatives, formulations, and line extensions thereof, correct?

A. I have no memory. I don't see it written down here.

Q. Would it refresh your recollection to look at the terms of the draft term sheet?

A. Yes.

Q. Okay, let's do that. Please zoom in on the chart there in the bottom half. Thank you.

And do you see where it says "Product," Mr. Nestor?

A. I do.

Q. Does reading this refresh your recollection as to the product that was the subject of this draft term sheet?

A. It says IPX-066.

Q. So is the answer yes, your recollection is refreshed?

A. Yes.

Q. Okay. Please take this off the screen.

So, Mr. Nestor, Endo's term sheet identified the product in this draft term sheet as IPX-066 and all improvements, modifications, derivatives, formulations, and line extensions thereof, correct?

A. In this draft, yes.

Q. In your experience, it's unusual for a company to send over an actual draft term sheet as an expression of interest in a product, isn't it?

A. Not necessarily, no.

Q. Let me be more specific.

In your experience working at Impax, it is unusual for a company to send over an actual draft term sheet as an expression of interest, correct?

A. No.

Q. Do you remember testifying at your deposition, Mr. Nestor, that it had never happened in your experience at Impax, that a company had sent over an actual draft term sheet as an expression of interest?

A. Well, I may have. Okay.

Q. So is it your experience at Impax that it's unusual for a company to send over an actual draft term sheet as an expression of interest?

A. Yes.

Q. Now, sitting here today, your testimony is that you were not interested in having Endo co-promote IPX-066. Is that correct?

A. Correct.

Q. But sitting here today, you can't recall explicitly sharing that opinion with anyone else at Impax, can you?

A. I can after that date.

Q. I'm sorry? I didn't catch that answer. Can you repeat it?

A. I said I can after receiving that draft.

Q. Again, Mr. Nestor, do you recall testifying at your deposition that you could not recall explicitly sharing that opinion with anyone else at Impax?

A. I -- could you read back to me what I just -- what I said earlier?

JUDGE CHAPPELL: Are you asking the witness whether he recalls testifying in a deposition or whether something's a fact or not? Let's just make sure it's clear.

MR. LEEFER: Currently I'm asking whether he recalls his deposition testimony. The next question will be to establish what that testimony was and how it compares to his testimony here today.

JUDGE CHAPPELL: Go ahead.

THE WITNESS: I don't remember the deposition testimony.

BY MR. LEEFER:

Q. Let's take a look at your deposition transcript, and if you could turn in your binder to the second tab, this is a copy of your deposition transcript.

A. Which --

MR. LEEFER: Your Honor, for the record, CX 4033 is a copy of Mr. Nestor's deposition transcript which is in evidence as part of JX 2. It is subject to

an in camera order. This version that I'm using right now is redacted to remove in camera information.

JUDGE CHAPPELL: All right.

THE WITNESS: So what am I looking for? What now?

BY MR. LEEFER:

Q. In the second tab, your redacted deposition transcript, Mr. Nestor, please find transcript page 65. There are four pages per page of the document.

A. What's the CX number?

Q. It's the second tab in the white binder. It's labeled "DEP_PUBLIC."

A. Okay. So what am I looking for, page 65?

Q. It's page 65. Please let me know when you're there.

A. Okay.

Q. I'd like to direct your attention to line 5 through line 9 of page 65.

A. Um-hum.

Q. And the question is:

"QUESTION: Did you share that -- that opinion with anyone else at Impax?

"ANSWER: I don't recall explicitly. I could speculate that I probably did, but I don't recall specifically doing that, if you're asking for a

specific instance."

Do you see that?

A. Yes.

Q. And if you turn back to the previous page, page 64, line 24, the question is:

"QUESTION: Did you tell anyone at Impax your opinion on not being interested in copromoting a product" -- excuse me, "copromoting IPX-066 with Endo at this point in May 2010?"

Do you see that?

A. Yes.

Q. So, Mr. Nestor, do you recall testifying that you can't recall explicitly sharing your opinion that you were not interested in copromoting IPX-066 with anyone at Impax?

A. Correct. It says, "I don't recall specifically. I would speculate that I probably did, but I don't explicitly remember it."

Q. And so your testimony that you would have shared that with other people at Impax, that would be speculation, correct?

A. Well, I'm limited to yes/no answers, right?

Q. I would appreciate a yes or no answer.

JUDGE CHAPPELL: Yes/no, if possible, and if you need to explain, let him know you would have to

explain the answer.

THE WITNESS: Okay. I need to explain my answer. So the --

BY MR. LEEFER:

Q. Okay. Let me rephrase the question a little bit.

In your deposition, you testified under oath, correct?

A. Yes.

Q. And the testimony you gave in your deposition was accurate and complete, to the best of your abilities?

A. To my best of abilities at that time, yes.

Q. After your deposition, you had a chance to review your transcript and correct any mistakes, correct?

A. Correct.

Q. And, in fact, you did that.

A. Correct.

Q. And you did not make any corrections to this portion of your transcript, did you?

A. No.

Q. So it was your testimony in your deposition that you could not recall explicitly sharing the opinion that you would not be interested in having Endo

co-promote IPX-066, correct?

A. I could not explicitly remember doing that. That is correct.

Q. But you could speculate that you probably did, correct?

A. Certainly.

Q. Now, that includes telling Mr. Mengler, the head of the Generics Division, right?

A. Yes.

Q. And you can't recall telling Mr. Mengler that you weren't interested in having Endo co-promote IPX-066.

A. Not specifically.

Q. And you can't specifically recall telling Dr. Hsu that you weren't interested in having Endo co-promote IPX-066, correct?

A. I cannot recall any specific instance where I said that. That was seven years ago.

Q. And you don't recall actually telling Mr. Paterson that either, do you?

A. Not specifically, explicitly.

Q. Thank you, Mr. Nestor.

I'd like to direct your attention to another document. This is RX 565, and this is the next tab, I believe, behind -- I'm sorry, that's not right. It is

another tab in your binder towards the back, RX 565. We can pull this up on the screen as well, the first page.

Now, Mr. Nestor, you were copied on this email from Chris Mengler. Is that correct?

A. Yes.

Q. And this email was sent on May 27, 2010, correct?

A. Yes.

Q. About halfway down this email, Mr. Mengler says, "R&D Collaboration: For a product I will designate as 066a. This is our next generation of 066."

Do you see that?

A. Yes.

Q. So as of May 27, 2010, the subject of the proposed DCA with Endo had changed from IPX-066 to 066A. Is that correct?

A. That's correct.

MS. FABISH: Objection, Your Honor. This is, again, outside the scope of the direct testimony. Mr. Leefer is no longer asking questions about an interest in collaboration on 066 but is discussing negotiations of the DCA regarding a different product.

MR. LEEFER: On direct examination, Mr. Nestor

testified at some length about IPX-203, the status of IPX-203 both at the time of the entry into the DCA and later. I am simply transitioning to now discuss IPX-203 now that I've finished discussing IPX-066.

JUDGE CHAPPELL: You need to lay a foundation.

BY MR. LEEFER:

Q. Mr. Nestor, you're familiar with the status of the development of IPX-203 at the time Impax entered into the DCA with Endo, correct?

A. Correct.

Q. And, in fact, in your direct examination, you testified about the status of IPX-203 at the time Impax entered into the development agreement with Endo, correct?

A. Correct.

Q. Now, at that time, in May or June of 2010, Impax didn't have significant data on IPX-203, correct?

A. We had what we thought was a formulation.

Q. Let me re-ask my question.

As of May or June 2010, Impax did not have significant data on IPX-203, correct?

A. That's the same question.

Q. It was the same question. You're right, Mr. Nestor. I was looking for an answer to that question. Did you understand the question?

A. You're asking did we have substantive data on IPX-203? And what would you mean by "substantive data"?

Q. Well, let me ask you about that, Mr. Nestor. In your definition, significant data would suggest that you had at least Phase II data, correct?

A. Correct. We did not have that.

Q. Thank you for anticipating my next question.

At the time Impax entered into the DCA with Endo, it did -- Impax did not have Phase II data on IPX-203, correct?

A. Correct.

Q. In fact, in May of 2010, there were no data on IPX-203, right?

A. There was lab data relative to the formulation.

Q. Do you recall testifying in your deposition, Mr. Nestor, that in May of 2010, there were no data on IPX-203?

A. There was no clinical data. All we had was formulation data.

Q. Well, let me ask you this question: IPX-203 is sometimes called IPX-066A, correct?

Can you please answer verbally?

A. Yes. I'm sorry.

Q. Thank you.

Now, let's take a look at your deposition again, the second tab, the redacted deposition, page 76, and please let me know when you're there.

A. Okay.

Q. I want to direct your attention to lines 9 through 15 of page 76.

"QUESTION: At this point in May, 2010, you had a formulation for 066A.

"ANSWER: Yeah. We thought we did.

"QUESTION: Was there any data on 066A at this point?"

Then there's an objection.

Your answer: "No."

Do you see that?

A. Yes.

Q. That was your sworn testimony in your deposition?

A. Um-hum.

Q. That was complete and accurate when you gave it?

A. Yes. We had no clinical data.

Q. The word "clinical" does not appear in that question or that answer, does it, Mr. Nestor?

A. No.

Are we done with this now?

Q. You can set that aside, yes, sir.
A. Thank you.
Q. Since there were no clinical data on 066A, you couldn't have sent any such data to Endo, right?
A. That's correct.
Q. In fact, all the data that Impax sent to Endo that related to the development and co-promotion agreement were sent through the electronic data room, correct?
A. That's correct.
Q. And the electronic data room was all about IPX-066, not 066A, right?
A. That's correct. And there was a reason for that.
Q. Now, on June 4th, 2010, before the DCA agreement with Endo was signed, Impax sent a forecast for IPX-066 to Endo, correct?
A. Yes.
Q. And you don't believe that Impax had sent Endo any forecasts relating to IPX-203, do you?
A. I don't recall.
Q. In fact, you don't know whether Impax sent Endo a forecast regarding IPX-203 by the execution date of the development and co-promotion agreement, correct?
A. I don't recall.

Q. Now, in your direct examination, Mr. Nestor, you testified that Impax was interested in finding a partner for IPX-066 outside the United States. Is that right?

A. Yes.

Q. But you don't remember whether Endo had expressed any interest in expanding outside U.S. borders, do you?

A. I do not recall.

Q. And you don't know why Endo -- sorry, let me withdraw that question.

You don't remember whether or not Endo had expressed any interest in promoting IPX-066 outside the United States, do you?

A. No.

Q. Mr. Nestor, in your direct examination, you testified that IPX-203 was originally envisioned as an improved formulation over IPX-066, correct?

A. Correct.

Q. You also testified that, in your experience, it's normal to try multiple or different formulations before arriving at the final formulation for a product, correct?

A. It usually happens in drug development.

Q. Now, I'd like to ask you a little bit more

about that process of bringing a branded product to market, okay?

Generally speaking, Impax does not develop new chemical entities, correct?

A. That's correct.

Q. In other words, Impax is not in the drug discovery business.

A. That's correct.

Q. So for Impax, step one of the process of bringing a branded product to market is developing a formulation for that product, right?

A. That's correct.

Q. And you have to come up with a -- the formulation before you can do any preclinical work, correct?

A. That's correct.

Q. That's because you've got to have a drug candidate first, right?

A. Correct.

Q. Now, as of June 4th, 2010, IPX-203 was in the formulation stage, correct?

A. That's correct.

Q. In fact, it was in the beginning stages of formulation, wasn't it?

A. It was early in the stage, yes.

Q. IPX-203 was early in the formulation stage? Is that right?
A. Yes.
Q. As of June 2010, IPX-203 was not a slam-dunk, was it?
A. No.
Q. I believe you testified about this exhibit during your direct exam, but I'd like you to take a look at CX 0506, and if we could please bring that up on the screen. Can we zoom in on the top two emails there? Thank you.
Do you recall testifying about this email that you sent during your direct examination?
A. Yes.
Q. Now, Anne Hsu worked for you at Impax, correct?
A. She worked for Suneel Gupta.
Q. Who, in turn, worked for you, correct?
A. That's correct.
Q. So Anne Hsu was within your group at Impax, right?
A. That's correct.
Q. And she was the VP of clinical pharmacology?
A. Correct.
Q. And she was very involved in working with the formulation of products, correct?

A. She was quite involved, yes.

JUDGE CHAPPELL: Hold on. Is everyone's realtime working?

MR. LEEFER: I believe mine is, Your Honor.

MS. FABISH: Yes, Your Honor.

(Pause in the proceedings.)

JUDGE CHAPPELL: Next question.

BY MR. LEEFER:

Q. Now, Anne Hsu thought there would be some difficulty with developing a formulation for IPX-203. Is that right?

A. Correct.

Q. Another one of your employees, Suneel Gupta, thought IPX-066 was doable, though, correct?

A. IPX-066A.

Q. Ah, thank you for the clarification.

And that's -- 066A is the same thing as IPX-203, correct?

A. Yes, it is.

Q. You don't remember what Mr. Gupta's conclusion that IPX-203 was doable was based on, do you?

A. He thought that the formulation would be doable.

Q. But you don't remember what Mr. Gupta's conclusion was based on, correct?

A. No.
Q. Ultimately, IPX-203 was not doable, correct?
A. Not in that particular formulation. It became another formulation.
Q. The formulation that existed at the time of this email was not doable, correct?
A. Correct.
Q. So Mr. Gupta was wrong?
A. He was wrong about the specific formulation we were looking at at that point.
Q. And Anne Hsu was ultimately correct, that the formulation being discussed here -- or there would be some difficulty in developing the formulation being discussed here, correct?
A. Only about that formulation specifically, yes.
Q. We'll get to the particular formulation when we go into in camera session in a little bit.
For now, I want to talk a little bit more about the progress that the development of IPX-203 went through, okay?
A. Um-hum.
Q. Now, when the -- let me restart that question.
The term "feasibility study stage" refers to a phase of development that is prior to actually locking in a final formulation, correct?

A. Correct.
Q. At the time the co-promotion agreement was signed, IPX-203 was in the feasibility study stage, correct?
A. Correct.
Q. And that was in June of 2010, correct?
A. Correct.
Q. Now, in July of 2012, IPX-203 was still in the feasibility study stage, correct?
A. Correct.
Q. So more than two years after the co-promotion agreement was signed, IPX-203 had not moved past feasibility studies. Is that right?
A. Correct.
Q. A PK study is part of the feasibility program, correct?
A. Yes.
Q. A PK study stands for a pharmacokinetic study?
A. Right.
Q. In April of 2013, Impax was still planning to do a PK study for IPX-203, correct?
A. Correct.
Q. So in April of 2013, IPX-203 was still in the feasibility study stage, right?
A. Correct.

Q. Now, the co-promotion agreement with Endo contained a term related to a joint development committee for IPX-203, right?
A. Correct.
Q. And you testified a little bit about the joint development committee on your direct examination. Do you remember that?
A. Yes.
Q. The joint development committee was supposed to include people from both Impax and Endo, right?
A. Correct.
Q. There was never a meeting of that joint development committee after the execution of the DCA with Endo, right?
A. Correct.
Q. That's because Impax didn't have anything for the joint development committee to discuss, right?
A. Correct.
Q. In fact, there had not been any members appointed to the joint development committee, correct?
A. Correct.
Q. I'd like to take a look at the actual DCA that we've been discussing here, and if we could please pull up RX 365. This is also available in your binder. I believe it's the third tab of your binder if you would

prefer to look at it in hard copy.

Mr. Nestor, you have seen the DCA with Endo, correct?

A. Yes.

Q. Is this a copy of that agreement?

A. It appears to be, yes.

Q. Let's look at page 16 of RX 365. Please zoom in on Sections 7 through 7.2.

Mr. Nestor, Section 7 is titled "Joint Development Committee." Do you see that?

A. Yes.

Q. And Section 7.1 is titled "Membership," correct?

A. Correct.

Q. Section 7.1 of the DCA, in the second sentence, says, "Promptly following the Effective Date, each Party shall appoint its initial representatives to the JDC."

Do you see that?

A. I see that.

Q. That never happened, did it?

A. Nope.

Q. Let's now look at Section 7.2. This says, "While Impax is Developing the Product, the JDC shall meet a minimum of four (4) times per year."

Do you see that?

A. I do.

Q. That never happened either, did it?

A. Nope.

Q. Now, Mr. Nestor, the parties have reached certain stipulations in this case, and for purposes of your testimony here today, you can assume that a stipulation that the parties have reached is a fact, okay?

A. Okay.

Q. And one of these stipulations -- and, Your Honor, this is on JX 001, Stipulation of Fact Number 43.

Mr. Nestor, this stipulation says: "Impax and Endo terminated the development and co-promotion agreement by mutual agreement effective December 23rd, 2015. At the time of termination, Impax had not received additional payments from Endo. At that point, the development had not met any of the milestones that would have required additional payment from Endo."

Mr. Nestor, you can treat that as an established fact for these purposes, okay?

A. Fine.

Q. December of 2015 is about 5 1/2 years after the DCA was signed by Impax and Endo, correct?

A. Correct.
Q. And at that point, about 5 1/2 years later, IPX-203 had not reached any milestones, correct?
A. Correct.
Q. And in that 5 1/2 years, there was never a meeting of the joint development committee, correct?
A. Correct.
Q. And in that 5 1/2 years, the joint development committee hadn't even been formed, correct?
A. Correct.
MR. LEEFER: Your Honor, at this point, I would like to request to go into in camera session. I have a few questions that will require going over information subject to your in camera order.
JUDGE CHAPPELL: Okay. At this time, we will go into in camera session. I will need to ask those of you who are not subject to the protective order to leave the courtroom. You will be advised by Lawman when we're open for public business.
MR. LOUGHLIN: We are fine on our side, Your Honor.
MS. FABISH: On ours as well, Your Honor.
(Whereupon, the proceedings were continued in in camera session.)

(The following proceedings were held in in camera session.)

(End of in camera session.)

(Public session.)

JUDGE CHAPPELL: You can invite them in but tell them we're going on a break, Lawman. You can take your seats. I don't know how long it will take them all to stream in.

All right. We will reconvene at 3:20. We're in recess.

(A brief recess was taken.)

JUDGE CHAPPELL: We are back on the record.

Redirect?

MS. FABISH: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MS. FABISH:

Q. Hello again, Mr. Nestor.

A. Hello.

Q. I just have a few additional questions for you following up on your discussions with Complaint Counsel.

You testified when you were discussing -- when you were speaking with Complaint Counsel that often pharmaceutical companies will wait to seek a partner until a drug is in Phase III studies.

Do you recall that?

A. Yes.

Q. Had Impax tried to wait until it was in Phase

III studies on IPX-203 to seek a partner, what would have happened?

A. It would never have happened.

Q. And why is that?

A. We didn't have the money to begin working on IPX-203, the clinical program. So I think I said this morning that our shareholders were not appreciative of us spending additional R&D money on developing a brand product.

Q. And why was that?

A. Because they didn't want to see large sums of money being spent over an extended time period on a single product. They were accustomed to R&D investments being made on many individual products that you bring to market as a generic to a brand product.

Q. You also testified in response to Complaint Counsel's questions about various discussions about IPX-066 with Endo around May and June of 2010. As the person at Impax who would ultimately have to sign off on any co-promotion agreement, did you ever agree to do a co-promotion agreement with Endo on IPX-066?

A. No.

Q. Would you have done a U.S. co-promotion agreement with Endo on IPX-066?

A. No.

MR. LEEFER: Objection, Your Honor. Calls for speculation.

JUDGE CHAPPELL: Sustained without further foundation.

BY MS. FABISH:

Q. Mr. Nestor, in your position as president of the Brand Division at Impax, would you need to sign off on any co-promotion agreement that Impax was going to enter into on the brand side?

A. Yes.

Q. And in -- and in 2010, when Impax was in discussions with Endo, did you provide input -- did you provide sign-off on the agreement with Endo regarding -- on the co-promotion agreement with Endo?

A. For IPX-203, I did.

Q. Yes.

You testified earlier that -- regarding a term sheet that you received -- that Impax received from Endo. Do you recall that?

A. Yes.

Q. And do you recall the description of the product that Endo provided in that term sheet?

A. It was IPX-066.

Q. Would you have agreed to a co-promotion agreement regarding -- on the terms set forth in that

term sheet?

A. No.

Q. Were you ever considering a co-promotion agreement with Endo regarding IPX-066?

A. Absolutely not.

Q. Thank you.

Complaint Counsel also asked you about information that you -- that various individuals at Impax provided to Endo in 2010 regarding IPX-066. Why did Impax send that information to Endo?

MR. LEEFER: Objection, Your Honor. Respondent's counsel has not laid a foundation that Mr. Nestor knows why the people engaged in the negotiations were sending information.

MS. FABISH: Your Honor, Complaint Counsel has asked similar questions as to why such information would have been sent to Endo in his questioning regarding Impax's interest in IPX-066. I'm merely following up to clarify his use of those emails.

JUDGE CHAPPELL: I'll allow it. Overruled.

BY MS. FABISH:

Q. Would you like me to repeat the question, Mr. Nestor?

A. Please.

Q. So earlier Complaint Counsel asked you about

information that various individuals at Impax provided to Endo in 2010 regarding IPX-066. Why did Impax send that information to Endo?

A. We sent that information, A, because we had already had -- already had established an electronic data room for out-licensing IPX-066 ex-U.S., and because we envisioned IPX-203 as a product beyond IPX-066 or Rytary, the foundational aspects of what was in the data room about IPX-066 were relative to the kind of product that we envisioned IPX-203 ultimately to be, which is an extended-release carbidopa-levodopa formulation that would offer clinically meaningful benefit over and above what the current standard of care was.

Q. Thank you.

You also discussed with Complaint Counsel the new formulation of IPX-203 and spoke at some length about the definition of the subject product of the DCA. Whether or not the current formulation is covered by the DCA as a legal matter, was Impax prepared to go forward under the DCA with Endo on the new formulation?

A. Oh, absolutely.

Q. And why was that?

A. We needed to because we couldn't fund it internally, and our perspective relative to the DCA we

had was that the current formulation of IPX-203, wording notwithstanding in the DCA, would potentially give us an avenue through which we could continue the development of IPX-203.

Q. And did you offer to Endo to continue to develop the new formulation of IPX-203 under the DCA?

A. We did in the teleconference that we had with them.

Q. Thank you.

I have no further questions. Thank you, Mr. Nestor.

A. Thank you.

JUDGE CHAPPELL: Any recross?

MR. LEEFER: May I have just a moment to confer with co-counsel?

JUDGE CHAPPELL: Go ahead.

(Counsel conferring.)

MR. LEEFER: No, Your Honor. No further questions.

JUDGE CHAPPELL: Thank you. You may stand down.

THE WITNESS: Thank you.

JUDGE CHAPPELL: Next witness?

MR. HASSI: Your Honor, Respondent, Impax Labs, rests.

JUDGE CHAPPELL: All right, thank you. I have some items I am going to go over, some administrative issues and other items.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: A number of items I am going to go over have to do with making sure the record's complete and exhibits, et cetera. Regarding exhibits, the parties may enter into the record marked demonstratives that were referred to in testimony and only those referred to in testimony. Please review the record, make sure you have provided all admitted exhibits, including those demonstratives I just referred to, to the court reporter within seven days.

Fact stipulations. As you were advised during trial, I expect the parties to work together to produce an agreed-upon set of facts on certain matters. The parties should be able to agree as to what the record shows on a wide variety of matters.

How long do you think you will need to complete the stipulation?

MR. LOUGHLIN: Your Honor, we -- in addition to JX 1, we have been working with Respondent on JX 3, which will be the timeline the Court requested. I'm hopeful that we can get that in by the close of the record on -- which I believe is on Friday.

MR. HASSI: We agree, Your Honor. We have been exchanging -- have exchanged drafts and we think we can get it done by Friday.

JUDGE CHAPPELL: All right. In the last case, it turned out that the stipulated facts were a lot more useful because the parties weren't constrained with the three-day deadline, so if I said to you you could have until the time the briefs were due, and at that time, just file a joint stipulation with the Office of the Secretary, copying my office, would that help?

MR. HASSI: It's certainly possible.

MR. LOUGHLIN: It may, Your Honor.

JUDGE CHAPPELL: It doesn't need to be admitted because it's an agreed -- it's a joint stipulation, and that way you -- both sides can refer to this stipulation and I can refer to the stipulation. So we will do that.

MR. LOUGHLIN: All right, Your Honor.

MR. HASSI: Yes.

JUDGE CHAPPELL: Don't worry about the three-day deadline.

MR. HASSI: Thank you, Your Honor.

JUDGE CHAPPELL: Was JX 2 -- that was agreed to exhibits, correct?

MR. LOUGHLIN: Correct, Your Honor.

MR. HASSI: Yes.

JUDGE CHAPPELL: Okay. If that has changed, if anything has been withdrawn or added, confer and make sure that there is a correct copy of that in the record.

MR. HASSI: Yes, Your Honor.

MR. LOUGHLIN: We will, Your Honor.

JUDGE CHAPPELL: And I will at this time, since it's a joint exhibit, I will say whatever corrections you make, it's admitted.

MR. HASSI: Thank you.

JUDGE CHAPPELL: And closing the record under Rule 3.44, I have three days. That will be noon, November 17th. So if either party feels the record is not complete or it needs to be supplemented, I need to be notified by noon on November 17th.

MR. HASSI: Understood, Your Honor.

JUDGE CHAPPELL: Let's talk about post-trial briefs. Rule 3.46(a) states the parties' proposed findings of fact and post-trial briefs are due within 21 days, et cetera, et cetera. That rule allows me to extend these deadlines for good cause.

I require the parties to be very thorough and careful in your briefs and especially in replying, in your reply briefs. The reply briefs and findings are

very helpful to me in reviewing the extensive evidence and transcript. I also acknowledge the upcoming holidays may affect the parties' ability to comply with what I believe are the tight deadlines in the rule.

Therefore, based on the record, since I have sat here every minute we have been here, I have determined more time is needed for you to prepare and file post-trial briefs beyond that time allowed in the rule.

Have the parties discussed dates they think they would provide -- that would provide adequate time for briefing?

MR. LOUGHLIN: We have, Your Honor.

MR. HASSI: We have.

MR. LOUGHLIN: And I think we have agreed on dates that we would like to propose to the Court.

JUDGE CHAPPELL: All right, let me have those.

MR. LOUGHLIN: We would like initial findings and briefs due on December 20th.

JUDGE CHAPPELL: Okay.

MR. LOUGHLIN: And then reply findings and briefs due on January 26th, 2018.

JUDGE CHAPPELL: That's agreed to?

MR. HASSI: It is, Your Honor.

THE COURT: All right. I am going to look that

over. I am going to check my notes. I will be issuing an order with a lot of information in what I require and what I'm looking for in the briefs and the deadlines.

MR. HASSI: Thank you.

JUDGE CHAPPELL: Those -- I may accept those deadlines. I can tell you this. I won't choose any date earlier than these two.

MR. LOUGHLIN: Thank you, Your Honor.

JUDGE CHAPPELL: So you can rest easy.

MR. HASSI: Thank you, Your Honor.

JUDGE CHAPPELL: Regarding briefing, one item I want to call your attention to is remedy. I want to see -- I sat here and said the last thing in the last ten trials. I want to see legal support for and against any proposed remedy. This includes Complaint Counsel providing a proposed order for relief, together with supporting law, and Respondent specifically replying thereto.

In the last case, I had a proposed order, and I had a number of provisions in an order that were not even referred to by the Government's brief. I don't consider that to be providing me with supporting law or argument. Every provision in a proposed order shall be supported by argument and authority.

Can I make that any clearer?

MR. LOUGHLIN: No, Your Honor.

JUDGE CHAPPELL: I'm looking your way because the proposed order comes from your way.

MR. LOUGHLIN: Understood, Your Honor.

JUDGE CHAPPELL: You might have seen the comment in the last decision about the failure to support the proposed order. Did you notice that?

MR. LOUGHLIN: I did see that, Your Honor.

JUDGE CHAPPELL: So I probably didn't have to say this today, did I?

MR. LOUGHLIN: I appreciate the reminder, Your Honor. We will do so.

JUDGE CHAPPELL: All right. I'm not attributing any of that to you, of course.

MR. LOUGHLIN: Understood, Your Honor.

JUDGE CHAPPELL: Another item I want to see briefing on -- and if I decide any other issues, they will be in the order I'm going to issue, this is just something that crossed my mind. There could be nothing to it, who knows? But I'd like to see briefing on the issue of whether the legal standards adopted in the Actavis decision are properly applied to agreements entered into before Actavis was issued.

Let's talk about closing arguments. Under Rule

3.41(b)(6), closing arguments are allowed no later than five days after the last filed proposed findings. You may be surprised to learn that closing arguments are not required and that you can waive them if both sides agree. Do you need time to consider that?

MR. LOUGHLIN: No, Your Honor. We would like closing arguments.

MR. HASSI: We don't disagree. Sorry, Your Honor.

JUDGE CHAPPELL: You know, I -- sometimes I handle cases for MSPB. They don't allow closing arguments. I've never missed them, never missed them one time, so...

My office will contact you regarding possible dates for scheduling the closing since we are going to have it.

Anything further?

MR. LOUGHLIN: Not from Complaint Counsel, Your Honor.

MR. HASSI: Nor from Respondents, Your Honor.

JUDGE CHAPPELL: It's been a long, hard road. I thank you all for your attention, consideration, and efforts. At this time, I will say efforts, because there's no decision yet on successes. So I will say thank you for your efforts.

Hearing nothing further, until we meet again, we are adjourned.

(Whereupon, at 3:41 p.m., the trial was adjourned.)

CERTIFICATE OF REPORTER

I, Susanne Bergling, do hereby certify that the foregoing proceedings were recorded by me via stenotype and reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

s/Susanne Bergling

SUSANNE BERGLING, RMR-CRR-CLR