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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, OCTOBER 31, 2017

9:45 a.m.

TRIAL VOLUME 5

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Chief Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

25 Reported by: Susanne Bergling, RMR-CRR-CLR

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C O N T E N T S

|          |        |       |          |         |      |
|----------|--------|-------|----------|---------|------|
| WITNESS: | DIRECT | CROSS | REDIRECT | RECROSS | VOIR |
| CAMARGO  | 946    | 1003  | 1037     |         |      |
| GELTOSKY | 1039   | 1117  | 1183     | 1194    |      |
|          |        |       | 1196     |         |      |
| REASONS  | 1198   | 1225  | 1244     |         |      |

1 P R O C E E D I N G S

2 - - - - -

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

5 First of all, I noticed that I -- based on some  
6 email traffic, there were two motions to compel. Were  
7 those filed?

8 MR. LOUGHLIN: I believe they were filed, Your  
9 Honor, but we withdrew them.

10 JUDGE CHAPPELL: Both of them? Because the  
11 followup email referred to one name but not Bingol.

12 MR. LOUGHLIN: We withdrew both.

13 JUDGE CHAPPELL: Okay. I'll need you to --  
14 whoever filed them needs to file a notice of withdrawal,  
15 not a motion to withdraw, a notice of withdrawal,  
16 because motions to compel have their own set of  
17 deadlines and issues once they're in the system.

18 MR. LOUGHLIN: We will do that, Your Honor.

19 JUDGE CHAPPELL: And if you haven't done one in  
20 this case, you can look in the past. It's something  
21 that's commonly done, notice of withdrawal.

22 MR. LOUGHLIN: Okay. Thank you, Your Honor.

23 JUDGE CHAPPELL: I noticed late yesterday I got  
24 a request to possibly go late today. I'm still looking  
25 into that, on whether the support staff is available.

1 What I will do is trim lunch to 45 minutes today, if  
2 possible go -- we will go no later than 6:15. Those two  
3 things together would give you an extra hour of  
4 testimony, if that works out.

5 MR. LOUGHLIN: Thank you, Your Honor.

6 JUDGE CHAPPELL: I think we can go until 6:00  
7 either way if we need to.

8 MR. LOUGHLIN: Thank you, Your Honor.

9 JUDGE CHAPPELL: So schedule your witnesses  
10 accordingly.

11 MR. LOUGHLIN: Thank you.

12 JUDGE CHAPPELL: Next witness.

13 MR. HASSI: Your Honor, if I might, on  
14 scheduling, I did have one other -- I wanted to let Your  
15 Honor know where we are, having evaluated the case over  
16 the weekend.

17 JUDGE CHAPPELL: All right.

18 MR. HASSI: So Complaint Counsel has indicated  
19 that they expect to wrap up their case this Friday. We  
20 believe that our case would probably take four trial --  
21 roughly four trial days, and that's including time for  
22 cross, and so we're scheduled to start on Monday, the  
23 6th.

24 JUDGE CHAPPELL: Right. We are going Monday  
25 through Thursday of next week. There's a federal

1 holiday next Friday.

2           MR. HASSI: Yes, Your Honor. And I guess what  
3 I'm indicating is we have two fact witnesses that aren't  
4 available next week but would be the following week.  
5 One of them had to travel to Taiwan and can't be back in  
6 time.

7           What we would ask is we think we probably have  
8 Monday, Tuesday, Wednesday covered. We have offered to  
9 Complaint Counsel -- they have a rebuttal witness,  
10 Mr. Hoxie. They're willing to take him out of turn,  
11 subject to his availability, either late Wednesday or on  
12 Thursday. And then we would ask to reconvene on -- if  
13 at all possible, on Tuesday, the 14th, for those two  
14 final fact witnesses. That would be Mr. Nestor and  
15 Mr. Hsu, the CEO. He's the one who's in Taiwan and is  
16 unavailable.

17           JUDGE CHAPPELL: Complaint Counsel can also  
18 offer their rebuttal expert, if they intend to do so,  
19 out of turn. We don't need to wait until the end for  
20 that.

21           MR. LOUGHLIN: Yes, Your Honor.

22           JUDGE CHAPPELL: We have done that before and,  
23 if need be, we can do that.

24           MR. LOUGHLIN: And we are happy to do that, Your  
25 Honor.

1 JUDGE CHAPPELL: So you think we'll have  
2 somebody all four days next week?

3 MR. HASSI: I think we will have somebody all  
4 four days, depending on when the rebuttal witness goes  
5 on, either -- he may go on as early as Wednesday --

6 THE COURT: All right.

7 MR. HASSI: -- and may carry over into Thursday.  
8 It will depend on how long the crosses go. Then and we  
9 have two fact witnesses, both of them we think we can  
10 get done in a day, and for that reason -- and, frankly,  
11 for reasons of Mr. Hsu's return -- he lives on the West  
12 Coast, is traveling to Taiwan, and I want to give him  
13 one day to adjust before he takes the stand if that's  
14 possible; hence, my request for the 14th as opposed to  
15 Monday, the 13th.

16 JUDGE CHAPPELL: One day to adjust for the  
17 approximately 14-hour time difference?

18 MR. HASSI: Yes, Your Honor.

19 JUDGE CHAPPELL: And then knock three more off  
20 of that?

21 MR. HASSI: Yes, Your Honor.

22 JUDGE CHAPPELL: All right. So just let me know  
23 how it shakes out during the week.

24 MR. HASSI: Thank you, Your Honor.

25 JUDGE CHAPPELL: All right, thank you.



1 Next witness.

2 MR. LOUGHLIN: Your Honor, Complaint Counsel  
3 called Joseph Camargo, and my colleague Lauren Peay will  
4 conduct the examination.  
5 Whereupon--

6 JOSEPH A. CAMARGO  
7 a witness, called for examination, having been first  
8 duly sworn, was examined and testified as follows:

9 MS. PEAY: Good morning, Your Honor. May it  
10 please the Court. I am Lauren Peay on behalf of  
11 Complaint Counsel.

12 DIRECT EXAMINATION

13 BY MS. PEAY:

14 Q. Good morning, Mr. Camargo.

15 A. Good morning.

16 Q. Mr. Camargo, would you please introduce yourself  
17 to the Court by stating your full name.

18 A. Joseph Andrew Camargo.

19 Q. And, Mr. Camargo, we met previously in Menlo  
20 Park, California, in the summer, and -- when I took your  
21 deposition. How are you doing today?

22 A. I am doing fine, thank you.

23 Q. I will let you know that if we look at any  
24 documents this morning, there are paper copies in a  
25 binder placed on the table next to you, but I will let

1 you know if you need to take a look at those.

2 A. Okay.

3 MS. PEAY: Your Honor, Mr. Camargo is a former  
4 employee of Impax, the Respondent in this case, and  
5 under your order of October 18, 2017, Mr. Camargo is an  
6 adverse witness and subject to examination by leading  
7 questions.

8 JUDGE CHAPPELL: Okay, thank you.

9 MS. PEAY: Thank you, Your Honor.

10 BY MS. PEAY:

11 Q. Mr. Camargo, you were previously employed by  
12 Impax?

13 A. Yes.

14 Q. From March 2002 through December 2011?

15 A. That's correct.

16 Q. You currently have a consulting agreement with  
17 Impax. Is that right?

18 A. Yes.

19 Q. You are being compensated for certain services  
20 related to this litigation under that consulting  
21 agreement.

22 A. That's true.

23 Q. You are being compensated \$500 an hour for  
24 services performed under the consulting agreement?

25 A. Yes.

1 Q. Including reasonable and necessary time spent in  
2 travel?

3 A. Yes.

4 Q. You were deposed in this litigation in August of  
5 2017.

6 A. I believe that was correct.

7 Q. And you were compensated for the time you spent  
8 preparing for that deposition?

9 A. Yes.

10 Q. And the time you spent testifying during that  
11 deposition?

12 A. Yes.

13 Q. Are you being compensated for time spent  
14 preparing for your testimony in this trial?

15 A. Yes.

16 Q. Are you being compensated for your time  
17 testifying today?

18 A. Yes.

19 Q. You were represented by Mr. Hendricks of  
20 O'Melveny & Myers at your deposition in August. Is that  
21 right?

22 A. Yes.

23 Q. At the time of your deposition, Mr. Hendricks  
24 represented Impax, too.

25 A. That's my understanding.

1 Q. And you met with Mr. Hendricks to prepare for  
2 that deposition?

3 A. Yes.

4 JUDGE CHAPPELL: Let me ask a question. When  
5 you ask this witness if he's being compensated, do you  
6 mean above and beyond any salary? For example, you and  
7 I are also being compensated today. Is that correct?

8 MS. PEAY: I am being compensated today, and I  
9 understand you are being compensated today, too.

10 JUDGE CHAPPELL: I would hope you are. Yes,  
11 yes.

12 MS. PEAY: My question to Mr. Camargo is whether  
13 he's being compensated under the consulting agreement at  
14 \$500 per hour, but I can make that clear.

15 JUDGE CHAPPELL: Right, because that wasn't  
16 clear.

17 MS. PEAY: Thank you.

18 BY MS. PEAY:

19 Q. Mr. Camargo, are you being compensated \$500 an  
20 hour for your time spent testifying today?

21 A. Yes.

22 Q. And, Mr. Camargo, were you compensated \$500 per  
23 hour for your time spent preparing for your testimony  
24 today?

25 A. Yes.

1 Q. Is the compensation paid to you under the  
2 consulting agreement from Impax?

3 A. Yes.

4 Q. I'd like to now turn to your time at Impax. You  
5 started as senior director of supply chain in March of  
6 2002?

7 A. It was actually senior director of materials  
8 management, yes.

9 Q. You started as senior director of materials  
10 management in March 2002, correct?

11 A. That's correct.

12 Q. And you were eventually promoted to vice  
13 president of supply chain?

14 A. Eventually, yes.

15 Q. And you were the vice president of supply chain  
16 for your -- approximately your last five years with  
17 Impax?

18 A. That's correct.

19 Q. So that went through 2011?

20 A. Yes.

21 Q. You were the vice president of supply chain  
22 during the 2009 to 2011 time frame, correct?

23 A. That's correct.

24 Q. As vice president of supply chain, you led the  
25 supply chain group?

1 A. That's correct.

2 Q. At a high level -- I'm sorry, let me ask a  
3 better question.

4 What is supply chain, Mr. Camargo?

5 A. The Supply Chain Department's responsibilities  
6 were planning, purchasing, warehouse and inventory  
7 control, and logistics.

8 Q. Did you also have responsibility, as vice  
9 president of supply chain, for managing third-party  
10 partnerships?

11 A. Yes.

12 Q. What type of third-party partnerships?

13 A. There were various arrangements. We had  
14 contract manufacturers that we had make some of the  
15 products that we had developed. We also had partnership  
16 deals with companies who manufacture products and ship  
17 them to us for finishing and distribution. Those were  
18 the two main types of arrangements.

19 Q. I'd like to ask you more about some of the areas  
20 of your responsibility as vice president of supply  
21 chain.

22 JUDGE CHAPPELL: Hold on a second.

23 (Pause in the proceedings.)

24 JUDGE CHAPPELL: Go ahead.

25 MS. PEAY: Thank you, Your Honor.

1 BY MS. PEAY:

2 Q. Purchasing includes procuring all the  
3 ingredients necessary to make the finished drug product.  
4 Is that right?

5 A. That's correct.

6 Q. And that includes procuring or purchasing active  
7 ingredients?

8 A. That's correct.

9 Q. As well as purchasing excipients?

10 A. Yes.

11 Q. You also had responsibility for planning in your  
12 role as vice president of supply chain, correct?

13 A. Yes.

14 Q. Planning includes long-term capacity-related  
15 planning activities. Is that right?

16 A. Yes, right.

17 Q. The purpose of the long-term capacity planning  
18 was to make sure that Impax had the capacity to support  
19 the products it intended to make in the future?

20 A. That's correct.

21 Q. Planning also included a routine monthly  
22 process?

23 A. Yes.

24 Q. The monthly planning process typically uses  
25 about an 18-month planning horizon?

1 A. Yes.

2 Q. And an 18-month planning horizon includes the  
3 products that Impax expects manufacturing operations to  
4 produce to support the sales forecast over the next 18  
5 months.

6 A. That's correct.

7 Q. Planning also included scheduling of the  
8 manufacturing operation?

9 A. There -- that was part of it during a portion of  
10 my time there. At some point -- I don't recall exactly  
11 when -- that responsibility was moved over to the  
12 manufacturing group to schedule their own shop floor,  
13 which was like a two-week horizon.

14 Q. Was scheduling of the manufacturing operation  
15 one of your responsibilities in 2009?

16 A. I think at that point they were scheduling the  
17 shop floor themselves, but we provided the monthly  
18 schedule that you referred to earlier.

19 Q. And was planning for the scheduling and  
20 manufacturing operation, was that under your  
21 responsibilities in 2010?

22 A. No. Once it moved to manufacturing, they took  
23 care of it from that point forward.

24 Q. Part of the scheduling of the manufacturing  
25 operation is to make sure that the plan fits within



1 Impax's capacity. Is that right?

2 A. Yes.

3 Q. Impax's capacity is measured in terms of labor  
4 hours?

5 A. In part, yes.

6 Q. Is it also measured in terms of the machine  
7 constraints?

8 A. Yes, that is correct.

9 Q. You're familiar with the term "load"?

10 A. Yes.

11 Q. And load is how many hours it takes to make a  
12 product?

13 A. That would be a factor in calculating what the  
14 total load is.

15 Q. Are there other factors?

16 A. Sure.

17 Q. What are those factors?

18 A. The other factors that determine what the load  
19 is is how much of each product that you are going to  
20 make, multiplied by what it takes to make each of those  
21 products, and that is in terms of both the labor load  
22 that you were referring to but also the load on the  
23 machines that the products go through.

24 Q. There are some months when the load exceeds the  
25 capacity?

1 A. That happens, yes.

2 Q. So that means that there are some months in  
3 which the number of hours to make the products --  
4 necessary to make the products exceeds the number of  
5 labor hours available?

6 A. From the initial plan, yes, but our  
7 responsibility is to create an alternate plan that does  
8 fit.

9 Q. In those circumstances where the number of hours  
10 to make the products exceeds the number of labor hours  
11 available in the initial plan, the supply chain group  
12 first tries to increase the capacity?

13 A. If that's feasible, but most often it's not  
14 within that monthly planning process. If the load is  
15 immediate, there's not much you can do about the  
16 capacity at that point.

17 Q. If you can't increase the capacity, you figure  
18 out what to take out of the schedule to make the actual  
19 plan fit with the available capacity?

20 A. Yes.

21 Q. In your experience at Impax, there were months  
22 when you had to take products off the plan and push them  
23 to another month because of capacity constraints?

24 A. That's correct.

25 JUDGE CHAPPELL: I want to make sure the record

1 is clear, sir. You said that scheduling and  
2 manufacturing operation was part of your job, and then  
3 that responsibility was moved over to another group. Is  
4 that correct?

5           THE WITNESS: Yes, Your Honor. What I was  
6 referring to there was a very short-term schedule, in  
7 other words, what you do -- what manufacturing was going  
8 to do day by day for the next couple of weeks, versus  
9 establishing a monthly schedule, which was always my  
10 department's responsibility. And that's the schedule  
11 she's referring to where you're balancing the load  
12 against the capacities in the monthly schedule.

13           JUDGE CHAPPELL: So what you're telling us now  
14 is -- what you're telling us about is something that was  
15 still your job at the time you were there.

16           THE WITNESS: That's correct.

17           JUDGE CHAPPELL: All right, thank you. One  
18 other thing, does Impax or did Impax -- you are gone  
19 now, correct?

20           THE WITNESS: That's correct, yes.

21           JUDGE CHAPPELL: Did they ever farm out  
22 manufacturing or always make their own drugs?

23           THE WITNESS: Yes, Your Honor. We did have  
24 situations where capacity was less than what we wanted  
25 to have, and we chose to move out some of that to

1 contract manufacturers. That's a longer term  
2 requirement, takes time to make that happen, so we did  
3 do some of that, and as I responded earlier, we had  
4 contract manufacturers that took on some of that load.  
5 That's not something that we could do in the monthly  
6 cycle, though. We couldn't just decide, okay, let's  
7 move some of that to somebody else.

8 JUDGE CHAPPELL: Was the Opana drug ever farmed  
9 out for manufacture?

10 THE WITNESS: Not during the time that I was  
11 there.

12 JUDGE CHAPPELL: All right, thank you.

13 Go ahead.

14 MS. PEAY: Thank you, Your Honor.

15 BY MS. PEAY:

16 Q. Supply chain also coordinated with marketing in  
17 planning for products?

18 A. That's correct.

19 Q. Marketing provided sales projections for new and  
20 existing products?

21 A. Yes.

22 Q. And the sales -- and these sales projections  
23 included providing information about launch timing for  
24 new products?

25 A. That's correct.

1 Q. And providing projected sales volumes for new  
2 and existing products?

3 A. Yes.

4 Q. Your job -- one of your jobs as vice president  
5 of supply chain was to ensure that you could meet the  
6 launch dates supplied by marketing?

7 A. Yes.

8 Q. And to -- and one of your jobs as vice president  
9 of supply chain was to ensure that you could meet the  
10 sales volume requirements for new and existing products?

11 A. Yes.

12 Q. I'd now like to focus specifically on how the  
13 supply chain group prepares for the launch of a new  
14 product. Every month marketing provides the supply  
15 chain group with a forecast for the next 18 months?

16 A. That's correct.

17 Q. The supply chain group bases its launch planning  
18 off of the monthly -- these monthly forecasts?

19 A. Yes.

20 Q. And the supply chain group would generally kick  
21 off the actual prelaunch preparation activities when a  
22 product falls within the 18-month window?

23 A. When the first month of sales in the forecast  
24 falls within the 18-month window, yes.

25 Q. The supply chain group has responsibility for

1 the 18-month planning process, correct?

2 A. Yes.

3 Q. And as vice president of supply chain, you  
4 oversaw the 18-month planning process.

5 A. I'm sorry. Can you ask that again?

6 Q. Certainly.

7 And as vice president of supply chain, you  
8 oversaw the 18-month planning process.

9 A. Yes, I did.

10 Q. Once a generic product enters the 18-month  
11 planning window, the supply chain group enters  
12 information about the product into Impax's ERP system?

13 A. Yes.

14 Q. ERP stands for enterprise resource planning?

15 A. That's correct.

16 Q. What is an ERP system, Mr. Camargo?

17 A. It's a computer system that allows a company to  
18 plan many aspects, including the purchasing, the  
19 planning, execution of shop floor activities, financials  
20 associated with paying suppliers, distribution of the  
21 product, collection of revenue from customers, many  
22 aspects, depending on what you choose to use it for. We  
23 used it in the context of this as our system for  
24 planning and purchasing of products.

25 Q. Impax's ERP system was called PRMS during the

1 2009 to 2010 time frame?

2 A. Yes.

3 Q. Do you know what PRMS stands for?

4 A. I don't recall specifically. It was an acronym  
5 when it was first developed. I don't remember it.

6 Q. The supply chain group would enter information  
7 about how the products were made into the ERP system,  
8 correct?

9 A. That's correct.

10 Q. And the supply chain group would enter  
11 information regarding how large the batch sizes are  
12 going to be.

13 A. That's correct.

14 Q. And the supply chain group would enter  
15 information about what types of materials were required  
16 to make the product?

17 A. Yes.

18 Q. And the supply chain group would enter  
19 information about the intended launch date into the ERP  
20 system.

21 A. Yes.

22 Q. Based on this information, the supply chain  
23 group used the ERP system to plan for the materials  
24 needed to make the product?

25 A. The ERP system was a tool that we used, not the

1 only tool.

2 Q. The supply chain group used the ERP system to  
3 determine how much capacity Impax will need to make the  
4 product?

5 A. Yes, in part. Again, it was a tool for capacity  
6 planning, but not the only one.

7 Q. And the supply chain group used the ERP system  
8 to -- as a tool to determine all the other milestone  
9 dates that you would need to accomplish to be ready to  
10 launch on the intended launch date. Is that correct?

11 A. No, that's not correct.

12 Q. Did you use another tool to determine the  
13 milestone dates you would need to accomplish to be ready  
14 to launch?

15 A. Yes.

16 Q. What tool did you use?

17 A. We used an Excel spreadsheet that I managed  
18 called the Product Launch Checklist.

19 Q. The supply chain group was responsible for  
20 ensuring that it does all of the necessary preparatory  
21 activities to get to the point where Impax is  
22 launch-ready as targeted by the management.

23 A. The supply chain group wasn't responsible for  
24 executing all the tasks, but we were responsible for  
25 overseeing and coordinating the execution of those



1 tasks.

2 Q. I'd like to turn now to discuss the Product  
3 Launch Checklist that you just referred to a moment ago  
4 that you used to keep track of the status of launch  
5 preparations.

6 As vice president of supply chain, you  
7 maintained a checklist of significant activities that  
8 needed to be completed to ensure that Impax was  
9 launch-ready by the date provided by Impax management?

10 A. That's correct.

11 Q. And just so we're all clear, that was called the  
12 Product Launch Checklist?

13 A. Yes. That was the tool I used.

14 Q. You created the Product Launch Checklist?

15 A. I did.

16 Q. And maintained it?

17 A. I did.

18 Q. You included all new products that fell within  
19 the 18-month window on the Product Launch Checklist?

20 A. Yes.

21 Q. As VP of supply chain, you chaired a meeting on  
22 a regular basis to discuss the activities listed on the  
23 Product Launch Checklist.

24 A. I did.

25 Q. That meeting was referred to as the launch

1 coordination meeting?

2 A. That's correct.

3 Q. And the meeting was generally held monthly?

4 A. Yes.

5 Q. And representatives of all departments who had  
6 responsibilities related to planning for the product  
7 launches attended the meetings.

8 A. That's correct.

9 Q. And that included someone from marketing?

10 A. Yes.

11 Q. Someone from purchasing?

12 A. Yes.

13 Q. Someone from regulatory?

14 A. Yes.

15 Q. As well as other groups within Impax?

16 A. Correct.

17 Q. The purpose of the launch coordination meeting  
18 was to ascertain the status of the products listed on  
19 the Product Launch Checklist?

20 A. Yes, among other things.

21 Q. And one of the other purposes was to ensure that  
22 everybody had a common understanding of the planned  
23 launch-ready dates and what things needed to be done by  
24 when?

25 A. That's correct.

1 Q. I'd like to turn to some of the specific tasks  
2 that, once a new product has been uploaded into the ERP  
3 system, need to be completed to prepare to be ready to  
4 launch a product. One task that needs to be completed  
5 is to place a purchase order for API and unique  
6 materials?

7 A. Yes.

8 Q. API is active pharmaceutical ingredient?

9 A. Yes.

10 Q. For oxymorphone ER, the API is oxymorphone HCL?

11 A. I don't recall if there's a specific salt form  
12 of it, but, you know, there were different forms, and  
13 that could very well be one. I don't recall.

14 Q. The API for oxymorphone ER was some form of  
15 oxymorphone, correct?

16 A. That's correct.

17 Q. Purchasing was responsible for placing purchase  
18 orders for API?

19 A. Yes.

20 Q. And purchasing fell within the supply chain  
21 group.

22 A. Yes.

23 Q. The amount of API needed is driven first and  
24 foremost by the monthly forecast?

25 A. Yes.

1 Q. As well as the definition of what it takes to  
2 make the product?

3 A. That's correct.

4 Q. And whether any safety stocks are required?

5 A. Yes.

6 Q. What is a safety stock?

7 A. A safety stock is a predetermined amount of  
8 inventory that you want to have in place to guard  
9 against potential variability of either the demand for  
10 that product or that material or the -- delays in the  
11 supply of that product or material.

12 Q. I'd like to talk about the steps that must be  
13 taken before placing a purchase order for API for a  
14 controlled substance. A controlled substance is one  
15 that is regulated by the DEA?

16 A. That's correct.

17 Q. Oxymorphone is a controlled substance?

18 A. Yes, it is.

19 Q. And to acquire API for a controlled substance,  
20 you have to request quota from the DEA?

21 A. For that type of controlled substance, you do.

22 Q. And by "that type," you're referring to  
23 oxymorphone?

24 A. Yes.

25 Q. Quota is an amount of a controlled substance

1 that the DEA permits you to purchase in a particular  
2 year?

3 A. Yes, for a particular purpose as well.

4 Q. Quota can be granted for different purposes. Is  
5 that correct?

6 A. Yes.

7 Q. Including research and development?

8 A. Yes.

9 Q. Or commercial sale?

10 A. Yes.

11 Q. You can only purchase as much API as the amount  
12 of quota you've been granted in that given year. Is  
13 that correct?

14 A. That's correct.

15 Q. To prepare for a product launch of a controlled  
16 substance, the quota would need to be granted for  
17 commercial manufacturing -- commercial manufacturing and  
18 sale, correct?

19 A. Yes.

20 Q. We have just been talking about purchasing API  
21 and requesting quota from the DEA. I would like to  
22 discuss another task that needs to be completed before a  
23 product can be ready to launch. Are you familiar with  
24 process validation?

25 A. Yes.

1 Q. Process validation is an FDA requirement that  
2 you have to prove that your manufacturing process is  
3 repeatable and makes the product in a satisfactory  
4 manner?

5 A. That's correct.

6 Q. Process validation has to be complete before the  
7 product is launched?

8 A. Yes.

9 Q. The process validation batches have to be  
10 tested?

11 A. Yes.

12 Q. And you have to document that the product was  
13 successfully validated.

14 A. Yes.

15 Q. That documentation is -- may also be referred to  
16 as approving the manufacturing PV summary?

17 A. We referred to it as a PV summary report.

18 Q. During your time as Impax's VP of supply chain,  
19 Impax typically planned to sell the process validation  
20 batches commercially. Is that correct?

21 A. That's correct.

22 Q. But sometimes the process validation batches are  
23 not enough to meet the projected demand at launch?

24 A. That's true.

25 Q. So Impax would need to manufacture additional

1 product to have enough available to meet the expected  
2 needs when you launch the product.

3 A. Yes.

4 Q. This additional product is referred to as launch  
5 inventory or launch inventory build?

6 A. That's correct.

7 Q. The launch inventory build is the additional  
8 product manufactured when the process validation batches  
9 are not enough to meet your expected needs to launch the  
10 product, correct?

11 A. That's correct, and they would be manufactured  
12 after -- they would be manufactured after the PV summary  
13 report is signed off on.

14 Q. We have been discussing the process for planning  
15 for the launch of a product generally. I would like to  
16 now turn to the process the supply chain group followed  
17 to prepare to be launch-ready for Impax's oxymorphone ER  
18 product, okay?

19 A. Okay.

20 Q. During your time at Impax, Impax was planning  
21 for the launch of a generic oxymorphone ER product?

22 A. Yes.

23 Q. And as VP of supply chain, you oversaw the  
24 planning for the launch of a generic oxymorphone ER  
25 product.

1 A. Yes.

2 Q. And just so we're clear as we go along, within  
3 Impax, was oxymorphone ER sometimes referred to as just  
4 oxymorphone?

5 A. Yes.

6 Q. And sometimes by the abbreviation OXM?

7 A. Yes.

8 Q. So you'll know what I mean if I refer to either  
9 of those shorthands?

10 A. Yes.

11 Q. Thank you.

12 Oxymorphone ER is the generic name for Opana ER?

13 A. Yes.

14 Q. And Opana ER is a pharmaceutical product that  
15 was manufactured and marketed by Endo Pharmaceuticals.

16 A. That's correct.

17 Q. The supply chain group began planning for the  
18 launch of oxymorphone -- let me ask a better question.

19 In 2009, the supply chain group began planning  
20 for the launch of oxymorphone ER.

21 A. Yes.

22 Q. The supply chain group's planning for  
23 oxymorphone ER began when the product entered the  
24 18-month planning window, correct?

25 A. I believe so.



1 Q. And the supply chain group learns about which  
2 products are within the 18-month planning window because  
3 it receives forecasts from marketing on a monthly basis.

4 A. In part.

5 Q. A member of marketing emails the 18-month  
6 planning window forecast to the supply chain group each  
7 month?

8 A. Yes.

9 Q. In 2009 and 2010, Mr. Kevin Sica was responsible  
10 for sending those monthly forecasts to the supply chain  
11 group?

12 A. Yes.

13 Q. And Mr. Sica was in marketing?

14 A. Yes.

15 Q. Mr. Camargo, would you please pick up your  
16 binder and take a look at Exhibit CX 2891.

17 While you are doing that, I will state that this  
18 exhibit is included in JX 2 and has been admitted in  
19 evidence. The exhibit is not subject to Your Honor's in  
20 camera ruling.

21 You received this email from Mr. Sica?

22 A. I'm sure I did.

23 Q. Is the answer yes, that you received the email  
24 from Mr. Sica?

25 A. I'm sure I did. I can't recall the receipt of

1 it, but it was addressed to me and it was something I  
2 saw routinely.

3 Q. And the email is dated June 5th, 2009?

4 A. Yes.

5 Q. Ms. Wint, would you please put the first page of  
6 CX 2891 up on the screen.

7 Mr. Sica is sending the type of monthly forecast  
8 that the supply chain group puts into the ERP system?

9 A. Yes.

10 Q. The supply chain group plans for the launch of  
11 new generic products based on the information provided  
12 in this type of monthly forecast.

13 A. Yes.

14 Q. In his email, Mr. Sica wrote that oxymorphone,  
15 four strengths, entered the forecast horizon in June  
16 2010 with an assumed at-risk launch.

17 Do you see that?

18 A. I do.

19 Q. Mr. Camargo, an at-risk launch is a launch while  
20 there is outstanding, unsettled patent litigation?

21 A. Yes.

22 Q. Turning to page CX 2891-003, this is a worksheet  
23 labeled "June Forecast Bottles"?

24 Is this a forecast -- is this a worksheet  
25 labeled "June Forecast Bottles"?

1 A. Yes. I'm sorry, I didn't realize that was a  
2 question.

3 Q. "Bottles" refers to the number of bottles of a  
4 particular product that are forecast to be sold?

5 A. That's correct.

6 Q. Ms. Wint, can you please pull up the lines for  
7 oxymorphone ER.

8 And, Mr. Camargo, in this June 2009 forecast,  
9 there's a line for oxymorphone ER, 5 milligrams. Do you  
10 see that?

11 A. I do.

12 Q. And in this June 2009 forecast, sales for the  
13 oxymorphone ER 5-milligram begin in June 2010. Is that  
14 correct?

15 A. That's correct.

16 Q. In this forecast, there is also a line for  
17 oxymorphone ER 10 milligrams as well?

18 A. Yes.

19 Q. And 20 milligrams?

20 A. Yes.

21 Q. And 40 milligrams?

22 A. Yes.

23 Q. And this June -- in this June 2009 forecast, the  
24 sales begin in June 2010 for the -- for all of those  
25 strengths of oxymorphone ER?

1 A. Yes.

2 Q. You can set that exhibit aside.

3 Mr. Camargo, the supply chain group uploaded  
4 this June 2009 forecast into PRMS, correct?

5 A. I'm sure we did.

6 Q. It was the supply chain group's practice to  
7 upload these monthly forecasts into PRMS, correct?

8 A. That's correct.

9 Q. And the supply chain group began planning to be  
10 ready for the launch of these four strengths of  
11 oxymorphone ER in June 2010.

12 A. I can't say we began in June 2010, but certainly  
13 by then we were, if not sooner.

14 Q. I can ask a better question.

15 Based on this June -- based on this June 2009  
16 forecast, the supply chain group began planning to be  
17 ready for the launch of four strengths of oxymorphone ER  
18 in June of 2010.

19 A. I can certainly say we would have started no  
20 later than that date. We may have started planning  
21 sooner than that date.

22 Q. And the date of launch that you were planning  
23 for would have been June 2010.

24 A. At that point in time of that June 2009 email,  
25 yes, that was the date.

1 Q. As part of the planning process for oxymorphone  
2 ER, Impax requested quota from the DEA for oxymorphone,  
3 correct?

4 A. Correct -- well, I mean, let me correct one  
5 aspect of it. The supply chain group did not directly  
6 submit the quota request to DEA. We requested the quota  
7 through our Regulatory Affairs Department who then, in  
8 turn, submitted the request to the DEA.

9 Q. And Mr. John Anthony from the Regulatory Affairs  
10 Department was Impax's designated DEA contact?

11 A. That's correct.

12 Q. And he was responsible for submitting quota  
13 requests?

14 A. Yes.

15 Q. And you, in the supply chain group, provided  
16 Mr. Anthony with information regarding how much  
17 oxymorphone API Impax needed for the planned launch,  
18 correct?

19 A. Correct.

20 Q. And Mr. Anthony used that information in the  
21 request he made to the DEA for quota?

22 A. Yes.

23 Q. Impax made several requests for oxymorphone  
24 quota for 2010, correct?

25 A. Yes.

1 Q. The first request was denied?

2 A. Yes.

3 Q. So Impax submitted another request for quota  
4 after that first request was denied.

5 A. Yes.

6 Q. And Mr. Anthony asked you for your input  
7 regarding how much oxymorphone API Impax needed to  
8 manufacture enough product for process validation,  
9 correct?

10 A. I know he at least asked for how much we needed  
11 for process validation. I'm not sure if he asked only  
12 for process validation quantities.

13 Q. Did he also ask for how much oxymorphone API  
14 Impax needed to manufacture enough product for a launch  
15 inventory build?

16 A. That would have been part of the requested  
17 information, yes.

18 Q. And you provided him with the information he  
19 requested?

20 A. Yes.

21 Q. Impax received additional oxymorphone quota,  
22 correct? To be clear, in 2010.

23 A. Yes, during 2010.

24 Q. And as of March 2010, Impax had received enough  
25 quota to complete -- to enable it to complete process

1 validation, correct?

2 A. Yes.

3 Q. And as of March 2010, Impax had enough quota to  
4 enable it to manufacture some of -- part of the launch  
5 inventory build, correct?

6 A. I don't recall the specific timing, but I know  
7 at some point we got enough quota to start the launch  
8 inventory build.

9 Q. At some point in time prior to June 2010, you  
10 got enough --

11 A. Yes.

12 Q. -- quota to do part of the launch inventory  
13 build?

14 A. Yes.

15 Q. Impax used the quota it received from the DEA  
16 for oxymorphone ER?

17 A. You would have to put a time frame around that  
18 question.

19 Q. I can ask a better question.

20 Impax used the quota that it received from the  
21 DEA as of March 2010, correct?

22 A. Yes. We purchased that material that was  
23 authorized.

24 Q. So Impax purchased all of the API it was  
25 authorized to purchase under the oxymorphone quota it

1 had received as of March 2010.

2 A. Yes, I believe so.

3 Q. Mr. Camargo, I'd like you to take a look -- if  
4 you could pick up your binder and take a look at  
5 CX 2898.

6 While you're doing that, I will state that this  
7 exhibit is included in JX 2 and has been admitted in  
8 evidence, and it's not subject to the in camera ruling.

9 Mr. Camargo, this is an email you sent to a  
10 Mr. Todd Engle, correct?

11 A. Correct.

12 Q. And you sent this email on May 12th, 2010?

13 A. Yes.

14 Q. Mr. Engle was director of sales and marketing?

15 A. He was a director in the sales and marketing  
16 group. I don't know his exact title.

17 Q. And this is -- this is an email you sent to  
18 Mr. Engle regarding input he had requested on some new  
19 products?

20 A. Yes.

21 Q. Including oxymorphone ER?

22 A. Yes.

23 Q. Ms. Wint, can you please put the first page of  
24 CX 2898 up on the screen.

25 Mr. Camargo, let me direct you to the section of



1 your email labeled "Oxymorphone." Do you see that?

2 A. I do.

3 Q. Sir, as of the date of this email, May 12th,  
4 2010, Impax had purchased all of its API quota for  
5 oxymorphone, correct?

6 A. Correct.

7 Q. And Impax had enough to make two lots of  
8 20-milligram and six lots of 40-milligram oxymorphone  
9 ER, correct?

10 A. Correct.

11 Q. And those two lots of 20-milligram and six lots  
12 of 40-milligram were intended to be part of the  
13 inventory build, correct?

14 A. Correct.

15 Q. So that's eight lots total of the inventory  
16 build.

17 A. Yes.

18 Q. As of the date of this email, May 12th, 2010,  
19 the process validation batches had been manufactured.

20 A. Yes.

21 Q. And you expected the PV summary report to be  
22 signed off by May 18th?

23 A. Yes.

24 Q. And once the PV summary report has been signed  
25 off on, the process validation is complete?

1 A. Yes.

2 Q. And the standard practice at Impax in 2010 was  
3 to hold off on beginning a launch inventory build until  
4 the PV summary report had been signed off on, correct?

5 A. Yes. We did not start them until after a PV  
6 summary report was signed off.

7 Q. So as of May 12th, 2010, you were waiting for  
8 the go-ahead from senior management?

9 A. For the oxymorphone ER, yes.

10 Q. And if you received the go-ahead from senior  
11 management for oxymorphone ER once the process  
12 validation summary report was signed off on, you were  
13 prepared from the supply chain standpoint to commence  
14 with the launch inventory build.

15 A. That's correct.

16 Q. Let me direct you to the third bullet under  
17 "Oxymorphone." John Anthony is the individual from  
18 regulatory affairs you were discussing earlier?

19 A. Right.

20 Q. So Impax made another request for oxymorphone  
21 quota in mid-April of 2010?

22 A. Yes.

23 Q. So as of the date of this email, May 12th, 2010,  
24 you had enough API to do an initial launch of  
25 oxymorphone ER.

1 A. Yes, with just a bit under our target amount of  
2 three months of inventory.

3 Q. But you needed additional quota to sustain the  
4 product after launch.

5 A. Correct.

6 Q. And as of the date of this email, May 12th, you  
7 had not heard back from the DEA regarding the mid-April  
8 request for additional quota.

9 A. Correct.

10 Q. You can set this exhibit aside.

11 Mr. Camargo, I'd like to turn now to the  
12 progress you made by May 2010 to prepare to be ready to  
13 launch oxymorphone ER. Earlier, you testified that you  
14 created and maintained a Product Launch Checklist,  
15 correct?

16 A. Yes.

17 Q. And you circulated the Product Launch Checklist  
18 in advance of product launch coordination meetings.

19 A. Yes.

20 Q. You tracked the progress of your preparations to  
21 be launch-ready for oxymorphone ER on the Product Launch  
22 Checklist, right?

23 A. Yes.

24 Q. Mr. Camargo, can you please take a look in your  
25 binder at CX 3078.

1           While you're doing that, I'll state that this  
2 exhibit is included in JX 2 and has been admitted in  
3 evidence. This exhibit is not subject to the in camera  
4 ruling.

5           Mr. Camargo, this is an email and an attachment  
6 that you sent on May 11th, 2010?

7       A. Yes.

8       Q. And the attachment is the May 11th, 2010,  
9 version of the Product Launch Checklist?

10      A. Yes.

11      Q. Ms. Wint, can you please put the first page of  
12 CX 3078 up on the screen.

13           You sent this checklist in advance of the May  
14 11th, 2010, product launch coordination meeting?

15      A. Yes.

16      Q. I would like to direct your attention to the  
17 attachment, page CX 3078-003. Ms. Wint, can you please  
18 call up the planned launch-ready date.

19           The planned launch-ready date is the date by  
20 which you were aiming to complete all the activities  
21 necessary so that Impax is launch-ready, correct?

22      A. That's correct.

23      Q. And the planned launch-ready date, as of this  
24 May 11th, 2010, Product Launch Checklist for oxymorphone  
25 5-, 10-, 20-, and 40-milligram strengths listed --

1 listed at the top of that column, was the end of May?

2 A. Correct.

3 Q. And the default planned launch-ready date is  
4 three months before the launch target date, correct?

5 A. Yes, typically.

6 Q. The launch target date is provided by marketing?

7 A. Yes, in part. They are not the only  
8 participants in deciding what that date should be, but  
9 they chair a meeting where that type of thing is  
10 discussed and agreed upon.

11 Q. And the launch target date is the date of the  
12 planned actual product launch?

13 A. Correct.

14 Q. Sometimes the launch target date is the  
15 anticipated date of FDA approval?

16 A. Yes.

17 Q. But the launch target is not always the  
18 anticipated FDA approval date.

19 A. That's correct.

20 Q. Also, in some circumstances, the planned  
21 launch-ready date is less than the default of three  
22 months before the launch target date.

23 A. That's correct.

24 Q. Ms. Wint, can you please call out the columns on  
25 oxymorphone ER.

1           Mr. Camargo, do you see the column that's  
2 labeled "Task Description"?

3       A.   Yes.

4       Q.   That's the column that identifies the  
5 significant tasks that generally need to be completed to  
6 be ready to launch a product?

7       A.   Yes.

8       Q.   There are 51 tasks listed here?

9       A.   Correct.

10      Q.   Do you also see the column for oxymorphone ER  
11 5-, 10-, 20-, and 40-milligram strengths?

12      A.   Yes.

13      Q.   That's the column that tracks the progress of  
14 your product launch preparations for those strengths of  
15 oxymorphone ER?

16      A.   Correct.

17      Q.   Now, if you look at that column under the -- for  
18 the 5, 10, 20, and 40 oxymorphone ER strengths, you see  
19 a lot of Xs.

20      A.   Yes.

21      Q.   And an X in Excel means that a task is  
22 completed?

23      A.   Correct.

24      Q.   So task 20 says "Place purchase order" -- or  
25 "Place PO for API and unique materials"?

1 A. Correct.

2 Q. And an X next to that means that task had been  
3 completed as of May 11, 2010?

4 A. Yes.

5 Q. And task 32, for example, says "Validation  
6 batches started."

7 A. Yes.

8 Q. And validation batches are -- can also be  
9 referred to as process validation batches?

10 A. Yes.

11 Q. And an X next to that task means that the  
12 process validation batches had been started as of May  
13 11, 2010.

14 A. Correct.

15 Q. Three question marks next to a task means that  
16 you do not have enough information to populate the field  
17 yet?

18 A. That's correct.

19 Q. And there are only a couple of tasks for  
20 oxymorphone ER 5-, 10-, 20-, and 40-milligram strengths  
21 for which there are three question marks, correct?

22 A. Yes.

23 Q. In your checklist, the designation of "TBD"  
24 means that the timing of the completion of that task is  
25 not yet defined?

1 A. That is correct.

2 Q. You don't see -- there aren't any TBDs for  
3 oxymorphone 5, 10, 20, and 40 milligrams as of the date  
4 of this version of the Product Launch Checklist, are  
5 there?

6 A. No, there are not.

7 Q. The dates that are listed on the Product Launch  
8 Checklist are typically the date by which you plan to  
9 complete the task?

10 A. Yes.

11 Q. And those dates may be based on your backwards  
12 planning from the launch date provided by marketing?

13 A. Yes.

14 Q. And they may be updated during a -- during a  
15 launch coordination meeting to be the date when you are  
16 now actually expecting to complete the task?

17 A. Yes.

18 Q. As of the -- according to this Product Launch  
19 Checklist, the validation batches had been manufactured  
20 by April 20th?

21 A. That's not correct. That was the target date  
22 for -- that I had on this checklist as of the  
23 publication of this premeeting status.

24 Q. As of May 11th, the target to manufacture the  
25 launch inventory was May 28th?



1       A. That's correct. The -- it would -- it might be  
2 illogical sounding since it's past that date, but we  
3 typically met once a month, so that was the last  
4 scheduled date, and when we met, we would update that  
5 based on the input from the different groups. So as of  
6 that date, it may have been completed already. I just  
7 hadn't had the meeting. This is a premeeting status.

8       Q. Mr. Camargo, I just want to make certain that  
9 your testimony is clear, because my question may not  
10 have been clear.

11           My question was focusing on task 40. As of this  
12 May 11th Product Launch Checklist, the target date to  
13 manufacture the launch inventory was May 28th. Is that  
14 correct?

15       A. Yes. I'm sorry, I thought you were talking  
16 about step 33.

17       Q. Thank you.

18           And as of the date of this Product Launch  
19 Checklist, you expected to complete testing of the  
20 launch inventory batches on June 11th, as reflected by  
21 task 41.

22       A. Yes.

23       Q. And as of the date of this Product Launch  
24 Checklist, the launch-ready date indicated under task 49  
25 was June 14th.

1 A. Yes.

2 Q. Mr. Camargo, you can set that exhibit aside.

3 Impax settled litigation with Endo on June 8th,  
4 2010.

5 A. I don't recall the date. I know there was a  
6 settlement with Endo.

7 Q. Do you recall that Impax settled with Endo in  
8 June of 2010?

9 A. Again, I don't recall a specific date, but in  
10 that time frame, yes.

11 MS. PEAY: Your Honor, the parties have  
12 stipulated to the date of the settlement between Impax  
13 and Endo in JX 001, fact stipulation number 19.

14 JUDGE CHAPPELL: Okay, but the witness has  
15 already told you he doesn't know the date.

16 BY MS. PEAY:

17 Q. So, Mr. Camargo --

18 JUDGE CHAPPELL: In fact, I don't know that he  
19 knows anything about the litigation or the settlement.

20 MS. PEAY: Thank you, Your Honor.

21 JUDGE CHAPPELL: That means I haven't heard a  
22 foundation.

23 MS. PEAY: Thank you, Your Honor.

24 BY MS. PEAY:

25 Q. Mr. Camargo, in your position as VP of supply

1 chain at Impax, were you aware of whether Impax was  
2 engaged in litigation with Endo regarding its  
3 oxymorphone ER product?

4 A. I do not believe I was aware of that prior to  
5 the settlement.

6 Q. You weren't aware that there was a litigation  
7 ongoing between Impax and Endo?

8 A. I was aware of the open litigation, yes.

9 Q. And -- and that litigation concerned Impax's  
10 oxymorphone ER product?

11 A. Yes.

12 Q. And that was a patent litigation?

13 A. That's my understanding, yes.

14 Q. And so --

15 JUDGE CHAPPELL: Let's stick to what you know,  
16 sir, not your understanding. Tell us what you know, not  
17 what you understand.

18 THE WITNESS: I -- I can't say I knew absolutely  
19 for certain. I wasn't privy to the actual lawsuit  
20 itself.

21 BY MS. PEAY:

22 Q. And, Mr. Camargo, are you -- did Impax settle  
23 the litigation with Endo?

24 A. Yes.

25 Q. And did Impax settle the litigation with Endo in

1 June of 2010?

2 A. In that time frame, yes. I don't know the exact  
3 date.

4 Q. As a result of Impax's settlement with Endo, you  
5 halted work on preparing to launch oxymorphone ER?

6 A. That's correct.

7 Q. In your role as VP of supply chain, you sent  
8 monthly reports to your boss, Mr. Charles Hildenbrand?

9 A. Yes.

10 Q. And in those reports, you reported on the key  
11 things associated with the prior month's activity?

12 A. Yes.

13 Q. Okay. Mr. Camargo, can you please take a look  
14 at CX 2905 in your binder.

15 This exhibit is included in JX 2, has been  
16 admitted in evidence, and is not subject to Your Honor's  
17 in camera ruling.

18 Mr. Camargo, you are a sender and a recipient in  
19 this email chain. Is that correct?

20 A. Yes.

21 Q. Dated June 8th through June 11th, 2010.

22 A. Yes.

23 Q. And in the last email on June 11th, 2010, you  
24 sent a monthly report to your boss, Mr. Hildenbrand?

25 A. Yes.

1 Q. And these are reports that you sent to  
2 Mr. Hildenbrand on a regular basis?

3 A. Yes.

4 Q. Ms. Wint, can you please put the first page of  
5 CX 2905 up on the screen.

6 This particular report that you were sending to  
7 Mr. Hildenbrand was for activities in May of 2010,  
8 correct?

9 A. Correct.

10 Q. If you would please turn to CX 2905-003. Let me  
11 direct you to number 2 under "Other Highlights."  
12 Mr. Camargo, you wrote this report?

13 A. Yes.

14 Q. Okay. And number 2, under "Other Highlights,"  
15 reads: "The Oxymorphone PV Summary report was  
16 approved." Do you see that?

17 A. Yes.

18 Q. And the approval of the PV summary report was  
19 the last step in process validation?

20 A. Correct.

21 Q. So process validation had been complete.

22 A. Yes.

23 Q. You go on to write: "The launch inventory build  
24 is ready to start should management give the go-ahead."

25 A. Yes.

1 Q. If Impax management had given you the go-ahead,  
2 you were ready to start the launch inventory build?

3 A. Yes.

4 Q. You continued to write: "With the Endo  
5 settlement in place, this project will be halted."

6 A. I did.

7 Q. The Endo settlement refers to the settlement of  
8 the patent litigation with Endo that we were just  
9 discussing earlier?

10 A. Yes.

11 Q. So Impax halted launch preparations for  
12 oxymorphone ER due to the settlement with Endo.

13 A. Yes.

14 Q. Thank you, Mr. Camargo. You can put that  
15 exhibit aside.

16 At the time of the settlement with Endo, Impax's  
17 mid-April request for oxymorphone quota was still  
18 pending with the DEA, correct?

19 A. I don't recall when the DEA responded to that  
20 mid-April request.

21 Q. At the time of the settlement with Endo, Impax  
22 had a request for oxymorphone quota that was still  
23 pending with the DEA.

24 A. Again, I don't know when the DEA responded.  
25 They could have responded before that date. They may

1 not have. I don't recall.

2 Q. Mr. Camargo, you do not remember?

3 A. I --

4 Q. Do you not remember whether Impax had a quota  
5 request pending with the DEA at the time of Impax's  
6 settlement with Endo?

7 A. No. I don't recall the status of that specific  
8 request at that time.

9 Q. Might it refresh your memory if -- your  
10 recollection if I showed you an email that you were a  
11 recipient of that addressed the subject?

12 A. That would certainly help my memory.

13 Q. Can you take a look in your binder at CX 3081.  
14 And, Mr. Camargo, if you can read this quietly to  
15 yourself and let me know when you're done.

16 A. (Document review.) Okay.

17 Q. Does that refresh your recollection?

18 A. Well, this tells me that as of June 9th, it was  
19 not yet -- the DEA had not yet responded to that quota  
20 request, and we were considering withdrawing it.

21 Q. Thank you. You can set that aside.

22 The DEA did actually grant Impax additional  
23 oxymorphone quota later in June of 2010, correct?

24 A. Yes, sometime subsequent to this June 9th email.

25 Q. But Impax had no intention of using that quota

1 to purchase oxymorphone API in 2010, correct?

2 A. Not once the Endo settlement was achieved.

3 Q. And is that because after the settlement in June  
4 2010, Impax had no plans for launching an oxymorphone  
5 product in the calendar year 2010?

6 A. That's correct.

7 Q. At the time of the settlement in June 2010,  
8 Impax had already manufactured some quantity of  
9 oxymorphone ER?

10 A. Yes.

11 Q. And you were asked by management to calculate  
12 the value of that manufactured oxymorphone product?

13 A. Yes.

14 Q. Mr. Camargo, if you would turn in your binder to  
15 Exhibit CX 3053.

16 This exhibit is included in JX 2 and has been  
17 admitted in evidence. It is not subject to the in  
18 camera ruling.

19 Mr. Camargo, you were a sender and recipient of  
20 emails in this email chain?

21 A. Yes.

22 Q. And this was dated June 4th, 2010?

23 A. Yes.

24 Q. Ms. Wint, can you please put the first page of  
25 CX 3053 up on the screen.



1           Mr. Camargo, who's Ray Smith?

2           A. Ray Smith was part of our finance team, and one  
3 of his responsibilities was cost accounting.

4           Q. If you can turn to CX 3053-002.

5           Mr. Hildenbrand asked you, "What is the value of  
6 the OXM PVs that we have produced so far?" Do you see  
7 that?

8           A. Yes.

9           Q. And he's referring to oxymorphone ER -- do you  
10 know if he's referring to oxymorphone ER process  
11 validation batches?

12          A. Yes.

13          JUDGE CHAPPELL: What did he mean by "value,"  
14 what it had cost the company? What did that mean  
15 when -- she asked about value and you said yes. What  
16 did you mean by "value"?

17          THE WITNESS: Your Honor, the inventory that we  
18 have in our ERP system is carried at what's called a  
19 standard cost, which includes the cost of all the  
20 materials that it took to make it and the cost of all  
21 the direct labor and a factor to account for overhead.  
22 So the standard cost times the number of units that we  
23 had in inventory would be the total cost.

24          JUDGE CHAPPELL: Anything to do with market  
25 value or profits?

1 THE WITNESS: No.

2 JUDGE CHAPPELL: Go ahead.

3 MS. PEAY: Thank you, Your Honor.

4 BY MS. PEAY:

5 Q. Back on CX 3053-001, you responded to  
6 Mr. Hildenbrand's request for the value of the  
7 oxymorphone ER process validation batches that had been  
8 manufactured as of June 4th?

9 A. Yes.

10 Q. And you informed Mr. Hildenbrand that the total  
11 value of the manufactured oxymorphone product as of June  
12 4th at standard cost was \$1,387,883?

13 A. Yes.

14 Q. Some of the manufactured product was in  
15 britestock?

16 A. Yes.

17 Q. That's product that has been manufactured and  
18 put in bottles but has not been labeled?

19 A. Correct.

20 Q. And some of the manufactured product was  
21 finished goods?

22 A. Yes.

23 Q. That's product that has been manufactured, put  
24 in bottles, and has a label?

25 A. Yes, I believe as well as all finished packaging

1 ready for distribution.

2 Q. Impax was not able to sell the manufactured  
3 oxymorphone product, correct?

4 A. That's correct -- well, we were able to from an  
5 FDA perspective but not per the settlement.

6 Q. Thank you. We're done with that exhibit.

7 Mr. Camargo, can you please turn to CX 2896 in  
8 your binder.

9 This exhibit is included in JX 2 and has been  
10 admitted in evidence and is not subject to the in camera  
11 ruling.

12 Mr. Camargo, you were the sender of this email  
13 and attachment?

14 A. Yes.

15 Q. Ms. Wint, can you please put CX 2896 up on the  
16 screen, the first page.

17 Mr. Camargo, you were sending an email to your  
18 boss, Mr. Hildenbrand, on August 10th, 2010?

19 A. Yes.

20 Q. And you attach a monthly report?

21 A. Yes.

22 Q. And this monthly report is for activities in  
23 July of 2010.

24 A. Yes.

25 Q. Can you please turn to, in the attachment,

1 CX 2896-002. Mr. Camargo, you -- you wrote this memo?

2 A. Yes.

3 Q. And I'd like to focus on the second chart on  
4 this page and the text below it. This chart or table is  
5 titled "YTD Rejects as Percentage of COGS (Target =  
6 2.5%)." Do you see that?

7 A. I do.

8 Q. "YTD" is year to date?

9 A. Yes.

10 Q. And what is "COGS"?

11 A. Cost of goods sold.

12 Q. What did you mean when you wrote, "Target =  
13 2.5%"?

14 A. Our target was that the dollar value of our  
15 rejects that we had an -- you know, actually experienced  
16 or anticipated would be 2.5 percent or less of the cost  
17 of goods sold for that month.

18 Q. What is a reject?

19 A. A reject can happen for a multitude of reasons.  
20 It would be inventory that we had on the financial books  
21 that we no longer expected to be usable for one reason  
22 or another.

23 Q. Under the table, you wrote, "Rejects as % of  
24 [Cost of Goods Sold]: We took a \$1.4M hit in June for  
25 materials which became obsolete by virtue of settlement

1 on Oxymorphone."

2 A. Yes.

3 Q. You had manufactured oxymorphone product for a  
4 potential launch?

5 A. Yes.

6 Q. But now that Impax had settled with Endo, it had  
7 to destroy this oxymorphone product because it could not  
8 be sold before its expiration date?

9 A. It had to be accounted for financially as likely  
10 to be rejected. We didn't -- we didn't have to destroy  
11 it immediately.

12 Q. And the materials at issue were worth about 1.4  
13 million?

14 A. Yes, that was the value.

15 Q. These -- the rejected oxymorphone product drove  
16 the increase of rejects, as a percentage of cost of  
17 goods sold, above 2.5 percent, correct?

18 A. Yes.

19 Q. Which means including the \$1.4 million hit from  
20 the rejected oxymorphone ER product, you were not  
21 meeting your goal?

22 A. That's correct.

23 Q. You can set that exhibit aside.

24 While at Impax, your performance was assessed  
25 against goals that were set for the year.

1 A. Yes.

2 Q. Part of the performance review process involved  
3 a self-review?

4 A. Self-assessment, yes.

5 Q. As part of a self-assessment, you would assess  
6 whether you had met the goals that had been set for you  
7 for the year?

8 A. That's correct.

9 Q. If you can take a look at CX 3069 in your  
10 binder.

11 This exhibit is included in JX 2 and has been  
12 admitted in evidence and is not subject to Your Honor's  
13 in camera ruling.

14 A. I'm sorry, which exhibit were you referring to?

15 Q. CX 3069. 3069.

16 Mr. Camargo, you wrote this email?

17 A. I did.

18 Q. And this attachment?

19 A. Yes.

20 Q. And you sent it to your boss, Mr. Hildenbrand?

21 A. Yes.

22 Q. Ms. Wint, can you please put the first page of  
23 CX 3069 up on the screen.

24 Focusing on the last-in-time email, it's dated  
25 January 17th, 2011, and you wrote: "I corrected this to

1 include Oxymorphone being ready to launch on time." Do  
2 you see that?

3 A. I do.

4 Q. Can you -- and "oxymorphone" refers to Impax's  
5 oxymorphone ER product?

6 A. Yes.

7 Q. The attachment to this email is the year-end  
8 self-assessment, looking at the goals you had for 2010  
9 and assessing your performance against those goals?

10 A. Yes.

11 Q. And you sent this self-assessment to your boss?

12 A. Yes.

13 Q. If you can turn to CX 3069-002, this is titled,  
14 "2010 MBOs."

15 A. Yes.

16 Q. MBOs are your goals for the year?

17 A. Yes.

18 Q. And "MBO" stands for management by objectives?

19 A. Yes.

20 Q. And in the table below, on the left, you list  
21 the objectives for the year?

22 A. Yes.

23 Q. And then on the right, you list your results in  
24 accomplishing those objectives?

25 A. Yes.

1 Q. You also have columns next to -- you have a  
2 column next to the accomplishments that's labeled "% of  
3 Salary (Obtained)"?

4 A. Yes.

5 Q. And what does that refer to?

6 A. The -- as you can see in the top, there was 10  
7 percent associated with individual MBOs. That 10  
8 percent was parsed out by the different objectives  
9 listed below for a target number on the left side, and  
10 then on the right side, my self-assessment of how much  
11 of that I felt I had achieved.

12 Q. And to be clear, 10 percent of your salary was  
13 tied to your achievement of your individual MBOs,  
14 correct?

15 A. A bonus up to 10 percent of my salary was what  
16 was tied to it, not my actual salary.

17 Q. Thank you.

18 Can you please turn to the next page,  
19 CX 3069-003. I'd like to look at the first bullet  
20 listed on this page. You wrote: "Achieve new product  
21 launch on the day of ANDA approval without putting  
22 Company into unnecessary financial or legal risks."

23 Do you see that?

24 A. Yes.

25 Q. And 2 percent of your bonus salary would be



1 impacted by your achievement of this goal?

2 A. Yes.

3 Q. Under "Accomplishments" for that goal, you  
4 listed oxymorphone as one of four products that were  
5 approved and intended for launch?

6 A. Yes.

7 Q. You wrote that oxymorphone was approved and  
8 ready to launch same day but settled, and then in  
9 parentheses, "achieved goal"?

10 A. Yes.

11 Q. You considered this goal to be accomplished with  
12 respect to oxymorphone ER?

13 A. Yes.

14 Q. Thank you, Mr. Camargo.

15 I have no further questions at this time.

16 JUDGE CHAPPELL: Any cross?

17 MR. MCINTYRE: Yes.

18 JUDGE CHAPPELL: You're on.

19 MR. MCINTYRE: Your Honor, may it please the  
20 Court. My name is Stephen McIntyre with O'Melveny &  
21 Myers for Impax Laboratories. May I have permission to  
22 approach the witness to give him a binder?

23 JUDGE CHAPPELL: I didn't hear you.

24 MR. MCINTYRE: Your Honor, may I approach the  
25 witness to give him a document binder?

1 JUDGE CHAPPELL: Yes, go ahead.

2 MR. MCINTYRE: Thank you.

3 MS. PEAY: Counsel, can we have a binder?

4 MR. MCINTYRE: Sorry about that.

5 MS. PEAY: Thank you.

6 CROSS EXAMINATION

7 BY MR. MCINTYRE:

8 Q. Good morning, Mr. Camargo.

9 A. Good morning.

10 Q. Mr. Camargo, do you have any degrees?

11 A. I do.

12 Q. What degrees do you have?

13 A. I have a bachelor of science degree.

14 Q. And where did you earn that degree?

15 A. The United States Military Academy, West Point.

16 Q. And I believe you went over this earlier, but  
17 when did you join Impax Laboratories?

18 A. In March of 2002.

19 Q. And when did you leave the company?

20 A. December 2011.

21 Q. And have you worked for any other pharmaceutical  
22 companies?

23 A. Yes, I have.

24 Q. What companies have you worked for?

25 A. I worked for Yale Laboratories; Gensia

1 Pharmaceuticals, which was a spinoff from Yale  
2 Laboratories. And I worked for Synergen, a brief  
3 biotech startup. And I worked for -- after that Geneva,  
4 which through merger became Sandoz. I then worked for  
5 Impax, Ivax, and Teva.

6 Q. Altogether, how many years of experience would  
7 you say you have in the pharmaceutical industry?

8 A. At least 27 years.

9 Q. I believe Complaint Counsel spoke with you about  
10 an 18-month planning horizon at Impax. Do you recall  
11 that?

12 A. Yes.

13 Q. What determined when a product entered the  
14 18-month planning horizon?

15 A. The first month of forecasted sales falling  
16 within an 18-month window of the date.

17 Q. And who provided that information?

18 A. The actual forecast file itself during this time  
19 frame came from Kevin Sica in the marketing group, but  
20 the establishment of a target launch date was through a  
21 different group, and Kevin just passed along the actual  
22 forecast.

23 Q. What group provided the target date you just  
24 mentioned?

25 A. Another person in the marketing group chaired a

1 group that included the CEO and a number of vice  
2 presidents and other people to discuss the product  
3 portfolio and come up with projected launch dates.

4 Q. Were you part of the Marketing Department?

5 A. No.

6 Q. What department did you belong to?

7 A. Operations.

8 Q. And was supply chain part of the Operations  
9 Department?

10 A. Yes.

11 Q. Was it Impax's practice to begin preparation  
12 planning for all products within the 18-month planning  
13 horizon?

14 A. That's when we would actually enter the forecast  
15 and more detailed planning in our ERP system, as well as  
16 that would trigger the initiation of the product launch  
17 coordination activities that we were discussing earlier.

18 JUDGE CHAPPELL: Sir, I'll need to ask you to  
19 listen to the question and answer the question. Your  
20 answer appeared to be a yes, but you never said yes or  
21 no.

22 Would you like her to read the question back?

23 THE WITNESS: Yes, please.

24 (The record was read as follows:)

25 "QUESTION: Was it Impax's practice to begin

1 preparation planning for all products within the  
2 18-month planning horizon?"

3 THE WITNESS: Yes.

4 BY MR. MCINTYRE:

5 Q. Following up on your last answer, Mr. Camargo,  
6 what happened once a product entered the 18-month  
7 planning horizon?

8 A. Two specific things happened. One, we created  
9 the necessary master data within the ERP system to  
10 facilitate the use of that tool for capacity and  
11 materials planning. And secondly, it would trigger the  
12 entry of that product onto the Product Launch Checklist  
13 so that we would then commence coordinating those  
14 activities that we discussed earlier.

15 Q. And did you follow this practice with respect to  
16 products that were still the subject of active  
17 litigation?

18 A. Yes.

19 MS. PEAY: Objection, Your Honor. I don't  
20 believe there's been a foundation laid that this witness  
21 is aware of whether the products that he's planning for  
22 are the subject of active litigation.

23 MR. MCINTYRE: If you would like, Your Honor, I  
24 can ask him further questions to attempt to establish  
25 the foundation.

1 JUDGE CHAPPELL: She would like it, and I think  
2 it's a good idea. Sustained. Go ahead.

3 MS. PEAY: Thank you, Your Honor.

4 BY MR. MCINTYRE:

5 Q. Mr. Camargo, were you generally aware of whether  
6 a product that was within the 18-month planning window  
7 was the subject of litigation?

8 A. Yes.

9 Q. And I believe you just testified -- but you can  
10 correct me if I'm wrong -- did Impax follow the  
11 practices that you just described with respect to the  
12 18-month launch planning window with respect to products  
13 that were the subject of active litigation?

14 A. Yes.

15 Q. Mr. Camargo, did you have any role in selecting  
16 the forecast date?

17 A. No.

18 Q. Mr. Camargo, do you recall when oxymorphone ER  
19 entered the 18-month planning horizon?

20 A. I don't recall when it first entered the  
21 planning horizon.

22 Q. I'd like to go ahead and take a look at Exhibit  
23 RX 181. This should be in the binder --

24 JUDGE CHAPPELL: Before you do that, you  
25 referred to a forecast date. What's a forecast date?

1 THE WITNESS: My understanding of the question  
2 was the date of the forecasted product launch.

3 MR. MCINTYRE: Thank you, Your Honor.

4 BY MR. MCINTYRE:

5 Q. Mr. Camargo, can you please turn to RX 181 in  
6 your binder.

7 This is an exhibit that appears in JX 2, it is  
8 admitted in evidence, and it is not subject to in camera  
9 treatment.

10 A. So it's tab 3 then?

11 Q. Yes, that's right.

12 And, Robert, why don't we go ahead and blow up  
13 the bottommost email as well as the topmost email.

14 Looking at the bottommost email of this chain,  
15 which actually appears at the top of the screen, are you  
16 the author of this email?

17 A. Yes.

18 Q. And who is Mr. Smolenski?

19 A. Ted Smolenski was a member of our marketing  
20 group, and he was involved in the -- developing and  
21 chairing the group that discussed the new product launch  
22 portfolio.

23 Q. Looking at the second paragraph that appears in  
24 your email, it begins: "We also need to figure out what  
25 we want to plan for re: Oxycodone."

1 Do you see that?

2 A. I do.

3 Q. I would like to pause here for a moment and look  
4 at your email that was sent subsequent to this that  
5 appears at the top of the page, where you write:  
6 "Sorry, yes, I did mean Oxymorphone."

7 Taking the email chain as a whole, do you  
8 understand that in the bottom paragraph in your June  
9 4th, 2009, email, you were referring to oxymorphone?

10 A. That's correct. I had made an error.

11 Q. You write in the next sentence in this bottom  
12 paragraph: "I understand that the odds of launching  
13 6/10 when the 30-month stay expires may be low, but like  
14 Tamsulosin, isn't the upside substantial and something  
15 we may want to plan for?"

16 Do you see that?

17 A. Yes.

18 Q. When you say "6/10," what were you referring to?

19 A. The month of June 2010.

20 Q. Why did you believe that the odds of launching  
21 in June 2010 when the 30-month stay expired were low?

22 A. Because with other product discussions where we  
23 had a situation that would lead to a decision for an  
24 adverse launch, we tended to shy away from such risk.  
25 So the -- given that this was one of those situations,



1 it didn't seem likely to me that we would actually  
2 launch at that point.

3 Q. And so if you thought the odds of launching in  
4 June 2010 were low, why did you think it was still worth  
5 planning for?

6 A. Because my understanding at that time of the  
7 potential sales that we could generate from that product  
8 if we did launch with an exclusive situation, which was  
9 meaning the only generic on the market, that that could  
10 be very lucrative for the company and something that we  
11 may want to prepare for even though the odds that we  
12 would do it were low.

13 JUDGE CHAPPELL: I have a question about the two  
14 emails on the screen. The one at the top says it was  
15 sent at 4:27 p.m. on June 4th, 2009, correct?

16 THE WITNESS: Yes, sir.

17 JUDGE CHAPPELL: And then the one below that  
18 supposedly corrects something in that top email.

19 MR. MCINTYRE: Robert, can you take down the  
20 two -- blow up --

21 JUDGE CHAPPELL: Is that a yes?

22 THE WITNESS: Yes, sir.

23 JUDGE CHAPPELL: If it's correcting it, the date  
24 on the one below is also June 4th, 2009, but the time is  
25 3:30 p.m., which is before the email above it at 4:27

1 p.m. How do you explain that?

2 THE WITNESS: I can't explain it just by looking  
3 at the -- what's in front of me, Your Honor.

4 MR. MCINTYRE: Robert, can we take --

5 THE WITNESS: My guess would be that we were  
6 working across a three-hour time difference, I being in  
7 California, Ted being in Philadelphia, and sometimes the  
8 emails captured the local time, not the -- the time that  
9 you sent it, so...

10 JUDGE CHAPPELL: Can we see the email that he's  
11 referring to, because he says, "Sorry, I meant oxy" --

12 MR. MCINTYRE: Robert, why don't we go ahead and  
13 blow up the entire chain.

14 JUDGE CHAPPELL: So they are in the same email  
15 chain.

16 THE WITNESS: Yes, sir. So you can see what is  
17 demonstrated here. Chris Mengler's response to me was  
18 dated before or -- the time is before the time I sent  
19 it, so that is reflective of the three-hour time  
20 difference. He actually responded probably two minutes  
21 later.

22 JUDGE CHAPPELL: East versus West Coast? That  
23 makes sense. Thank you.

24 BY MR. MCINTYRE:

25 Q. Mr. Camargo, I believe you testified that Impax

1 performed process validation for oxymorphone ER. Did I  
2 get that right?

3 A. Yes.

4 Q. Are you familiar with the matrix approach to  
5 process validation?

6 A. Yes, I am.

7 Q. Can you describe what that is?

8 A. The default plan for process validations is to  
9 make three batches of each strength of the product;  
10 however, depending on the manufacturing process and how  
11 similar it might be between different strengths, you can  
12 sometimes abbreviate the process validation by using a  
13 matrix approach to cover the overall manufacturing  
14 process in a sufficient manner to meet the FDA's  
15 requirements. That's where we would do a matrix.

16 Q. Are there any advantages associated with using a  
17 matrix approach?

18 A. Sure. You don't have to manufacture as much  
19 product, so it takes less time, makes it easier to do  
20 all the necessary testing and analysis on those batches,  
21 and it reduces the amount of product that you have to  
22 actually produce during a process validation.

23 Q. Are there any cost savings associated with the  
24 matrix approach?

25 A. The cost of the validation batches is going to

1 be lower, and, again, you know, if you -- depending on  
2 whether you need to do a launch inventory build or not,  
3 you know, you may be able to save some production there.  
4 Ultimately, you may have to make up for it with launch  
5 inventory build.

6 Q. Do you recall whether Impax used the matrix  
7 approach when doing process validation for oxymorphone?

8 A. Yes, we did.

9 Q. And I believe Complaint Counsel asked you  
10 questions about requesting quota from the DEA. Without  
11 quota from the DEA, can you buy the API that you need to  
12 manufacture the product?

13 A. No, you cannot.

14 Q. And if you can't buy the API, what implications  
15 does that have if Impax is trying to be launch-ready by  
16 a target date?

17 A. If you cannot buy the API, you cannot start the  
18 process validation batches, and you're at a standstill.

19 Q. And if you can't start the process validation  
20 batches, is there any way that you can launch the  
21 product?

22 A. No, there is not.

23 Q. I believe Complaint Counsel reviewed a document  
24 with you that was CX 3078.

25 This document is in evidence and is not subject

1 to in camera treatment.

2           This was a May 11th, 2010, Product Launch  
3 Checklist. Do you recall that, Mr. Camargo?

4       A. Yes.

5       Q. And I believe the checklist targeted a May 28th  
6 date by which you would -- you anticipated that you  
7 would complete the launch inventory build. Did I get  
8 that right?

9       A. I generated many of these. I would have to look  
10 at that specific version to make sure that that's  
11 accurate.

12       Q. Why don't we go ahead and look at task number  
13 40, and we can extend that over so it includes the  
14 oxymorphone column. This should be in your binder as  
15 well. Once again, this is Exhibit CX 3078.

16       A. Yes, I can say the date was May 28th at that  
17 point.

18       Q. And do you recall looking at this document with  
19 Complaint Counsel?

20       A. Yes.

21       Q. And once again, the date of the cover email is  
22 May 11th, 2010. Do I have that right?

23       A. Yes, I believe so.

24       Q. I'd like to take a look at a couple of other  
25 documents from this period in time. Let's go ahead and

1 pull up RX 186. This should be in your binder as well  
2 if you want to look at a hard-copy version.

3 RX 186, this document is in evidence, and it is  
4 not subject to in camera treatment. This is tab 14 in  
5 your binder.

6 Can you describe the cover email for me?

7 A. This is one of the monthly reports I sent to my  
8 boss that we discussed earlier.

9 Q. And can you see the date on which you sent this  
10 report?

11 A. Yes. May 7th, 2010.

12 Q. So this was four days prior to the May 11th  
13 email we just looked at.

14 A. Yes.

15 Q. Let's go ahead and turn to the attachment, and  
16 this is RX 186.0003. What is this document,  
17 Mr. Camargo?

18 A. It's a monthly report that I submitted to my  
19 boss.

20 Q. And let's turn the page to RX 186.0004, and,  
21 Robert, can we go ahead and blow up number 4, under  
22 "Other Highlights."

23 Can you describe what this paragraph is  
24 communicating?

25 A. I'm reporting to Mr. Hildenbrand that the

1 oxymorphone ER process validation lots were completed  
2 and that we're expecting the PV summary report to be  
3 approved very shortly. At that point, we need  
4 management decision and direction to proceed with the  
5 launch inventory build.

6 Q. So once the PV summary report was approved, were  
7 you going to await management decision before proceeding  
8 with the launch inventory build?

9 A. Yes. At that point, we needed management  
10 approval to proceed with that launch inventory build.

11 Q. Also, let's pull up Exhibit CX 2898, and I  
12 believe that this is one that you also reviewed with  
13 Complaint Counsel.

14 This document is in evidence and it is not  
15 subject to in camera treatment.

16 Mr. Camargo, what is the date of this email?

17 A. May 12th, 2010.

18 Q. And so this is one day after the May 11th  
19 Product Launch Checklist that we reviewed.

20 A. Yes.

21 Q. Looking at the bullet points that appear under  
22 the heading "Oxymorphone," the second one reads, "The PV  
23 Summary report is expected to be signed off by 5/18 and  
24 we will not commence the launch inventory build until we  
25 receive direction to do so from senior management."

1 Did I read that correctly?

2 A. Yes.

3 Q. And so as of May 12th, 2010, was the plan to  
4 still await direction from senior management before  
5 beginning the launch inventory build?

6 A. Yes, that's correct.

7 Q. Let's go ahead and take a look at Exhibit  
8 CX 2904. This should appear in tab 18 in your binder.

9 This exhibit is also in evidence, and it is not  
10 subject to in camera treatment.

11 Robert, can we go ahead and blow up the two  
12 topmost emails.

13 Looking at the bottom email that appears there,  
14 it's from Chuck Hildenbrand. Who was Chuck Hildenbrand  
15 again?

16 A. He was a senior director of operations and he  
17 was my direct-report.

18 Q. He was directing this email to you. He begins,  
19 "Joe, I don't see the OXM happening in June, let's  
20 replace it with more MDD."

21 Do you see that?

22 A. Yes.

23 Q. What does "OXM" refer to?

24 A. The oxymorphone ER product.

25 Q. And what about "MDD"?



1 A. It was a product called Midodrine.

2 Q. And what do you understand Mr. Hildenbrand to be  
3 communicating to you here?

4 A. He --

5 MS. PEAY: I'm sorry, Your Honor. I object.  
6 Lack of foundation.

7 MR. MCINTYRE: Well, Mr. Camargo is the  
8 recipient of the email, and I was asking for his  
9 understanding as the recipient of the email.

10 MS. PEAY: Your Honor, he's asking for his  
11 understanding regarding what Mr. Hildenbrand meant, and  
12 he hasn't laid a foundation that he knows what  
13 Mr. Hildenbrand meant.

14 MR. MCINTYRE: That actually was not the  
15 question I asked. I asked what his understanding was as  
16 the recipient of the email.

17 JUDGE CHAPPELL: Why don't you just ask him what  
18 MDD means. If he knows that, he can tell us.

19 BY MR. MCINTYRE:

20 Q. What does "MDD" mean?

21 A. It means Midodrine.

22 JUDGE CHAPPELL: That way, you don't have to  
23 worry about his understanding.

24 BY MR. MCINTYRE:

25 Q. As the recipient of this email, what was

1 Mr. Hildenbrand conveying to you?

2 A. He had --

3 MS. PEAY: Objection -- I'm sorry. Objection.  
4 Lacks foundation again.

5 MR. MCINTYRE: Mr. Camargo can testify as to --

6 JUDGE CHAPPELL: Well, this one is more  
7 problematic than the last version. What he thought it  
8 meant, he can tell us. What the other man was  
9 conveying, not so much.

10 MR. MCINTYRE: Understood, Your Honor.

11 JUDGE CHAPPELL: Rephrase.

12 BY MR. MCINTYRE:

13 Q. Mr. Camargo, as the recipient of this email,  
14 what did you think Mr. Hildenbrand meant when he -- with  
15 this sentence?

16 A. I understand that he had reviewed our June  
17 production plan and that he was telling us that the  
18 oxymorphone ER product was not likely to be produced  
19 during June for whatever reason and that we should look  
20 at replacing that product in our June plan with the  
21 Midodrine product.

22 Q. What was the date of this email?

23 A. May 24th, 2010, from him, and May 25th, 2010,  
24 from me.

25 Q. And as you just mentioned, on May 25th, you

1 respond to Mr. Hildenbrand, "Okay, I'll look into that.  
2 I had advised the team that it was unlikely that we  
3 would make the Oxymorphone, but I kept it in the plan  
4 just in case."

5           First of all, when you say "the team," who are  
6 you referring to?

7       A. Here, I believe I'm referring to the planning  
8 team that developed this monthly plan.

9       Q. And why did you think it was unlikely that you  
10 would make the oxymorphone as of the date of this email?

11      A. For the same reason I testified to earlier, that  
12 given the situation where it would have been an at-risk  
13 launch, and we had no history of launching products at  
14 risk due to the -- you know, the magnitude of the --  
15 what could happen if we were to lose in the litigation,  
16 so, you know, I had been given no direction at that  
17 point in time to actually execute the product launch,  
18 and it seemed unlikely to me that we would ever do that.

19      Q. In fact, did you ever complete the product --  
20 the launch inventory build?

21      A. No, we did not.

22      Q. Did you ever receive instruction from senior  
23 management to begin the launch inventory build?

24      A. No, we did not.

25      Q. Mr. Camargo, was it unusual for Impax to have to

1 discard products or material in inventory?

2 A. No. That happened as a matter of course pretty  
3 much every month.

4 Q. Can you estimate about how frequently it  
5 happened?

6 A. Well, we -- I would typically capture what  
7 happened during a given month, you know, in a monthly  
8 report to the finance group, as well as these monthly  
9 reports to Chuck Hildenbrand. There would typically be  
10 several things that happened during a month, so whether  
11 they all happened in one week or another week or  
12 something, that was obviously irregular and not  
13 something routine.

14 JUDGE CHAPPELL: You had told us that you had to  
15 get DEA approval for the active ingredient in the oxy  
16 product.

17 THE WITNESS: Yes, Your Honor.

18 JUDGE CHAPPELL: Then when you destroy that  
19 product, do you then notify them, or is there any other  
20 communication with DEA or FDA when it's destroyed --

21 THE WITNESS: Yes, Your Honor.

22 JUDGE CHAPPELL: -- since it's a controlled  
23 substance active ingredient, correct?

24 THE WITNESS: Yes, sir. It was a finished  
25 product at that point, and they are both controlled

1 substances, and we would have to report to DEA on a  
2 regular basis the consumption, which would include  
3 destruction of materials that contained those controlled  
4 substances.

5 JUDGE CHAPPELL: So someone at DEA is supposedly  
6 keeping track of where this active ingredient is and  
7 when it's been used and when it's been destroyed.

8 THE WITNESS: Yes, Your Honor. We would have to  
9 report that at least on an annual basis.

10 JUDGE CHAPPELL: Go ahead.

11 BY MR. MCINTYRE:

12 Q. Mr. Camargo, do you recall whether, in June  
13 2010, Impax had any oxymorphone API on hand that had not  
14 yet been incorporated into actual oxymorphone ER  
15 product?

16 A. Yes, we did.

17 Q. Do you recall what happened with that API?

18 A. I believe that API was eventually used. It has  
19 a longer shelf life than the finished product that was  
20 manufactured.

21 Q. So to your knowledge, the API was not discarded.

22 A. That's correct.

23 Q. You just mentioned your monthly reports to  
24 Mr. Hildenbrand. Why don't we go ahead and take a look  
25 at a monthly -- the Exhibit CX 2905. This is one that

1 you also reviewed with Complaint Counsel.

2           This document is in evidence and not subject to  
3 in camera treatment.

4           Do you recall seeing this email during --

5       A. Yes, I do.

6       Q. Okay. Why don't we go ahead and flip to the  
7 attachment, and we can go to the page CX 2905-003.

8           Robert, can we blow up the paragraph that  
9 appears at the very top of the page.

10          Mr. Camargo, once again, what is -- what does it  
11 mean when you write "Rejects as % of COGS"?

12       A. It's referring to the dollar value of what was  
13 either rejected or something that we expected to end up  
14 being inventory loss, even if it had not been rejected  
15 yet, and that dollar value is reflected as a percentage  
16 of the cost of goods sold for that month.

17       Q. And can you tell from this paragraph what the  
18 dollar value of the rejects were for the month of April  
19 2010?

20       A. Yes. It says April losses were \$1,008,000.

21       Q. Let's also take a look at Exhibit CX 2896. This  
22 is also one that I believe you reviewed with Complaint  
23 Counsel.

24          This document is in evidence and it is not  
25 subject to in camera treatment.

1           Do you recall reviewing this document with  
2 Complaint Counsel?

3       A.   Yes.

4       Q.   And let's turn to -- Robert, there's -- we are  
5 going to get the paragraph that begins at the bottom of  
6 CX 2896-002 and continues to the top of 003.

7           With Complaint Counsel, I believe you reviewed  
8 the first sentence of this paragraph, which describes  
9 the \$1.4 million associated with oxymorphone product.  
10 Do you recall that?

11      A.   Yes.

12      Q.   Can you tell from this paragraph, aside from the  
13 oxymorphone, what the dollar value of Impax's losses  
14 were for rejected product in June of 2010?

15      A.   Yes, \$560,000.

16      Q.   Let's go ahead and turn to Exhibit 29 --  
17 CX 2922.

18           This one is also in evidence and it is not  
19 subject to in camera treatment.

20           For this one, it may be easier to look at a  
21 paper version of it. That should be in tab 26 of your  
22 binder.

23           Mr. Camargo, do you see your name in the "To"  
24 field of this email?

25      A.   Yes.

1 Q. And --

2 A. Actually, the CC.

3 Q. I'm sorry, you're right. It also appears in the  
4 CC field.

5 And the sender of this email, Willi Huang, who  
6 was he?

7 A. He was in charge of planning.

8 Q. And the subject of this email is, "At Risk  
9 Inventory report for March 2011." Do you know what the  
10 at-risk inventory report is?

11 A. Yes.

12 Q. What is the at-risk inventory report?

13 A. It's a report that we provided primarily to the  
14 cost accounting team in finance to advise them of  
15 product that was either raw materials or work in process  
16 or finished goods that for one reason or another we felt  
17 was unlikely to ultimately be usable.

18 Q. And if it was unlikely to be usable, then what  
19 would happen to it?

20 A. Eventually, if that turned out to be accurate,  
21 that it was unusable, it would eventually be scrapped.

22 Q. Let's turn -- Robert, can we turn to the first  
23 page of the attachment. This is CX 2922-003. Let's go  
24 ahead and blow up the line at the top that shows the  
25 column headings.



1           Where it says "Description," what does that  
2 refer to, Mr. Camargo?

3       A.   Just a description that we put in our ERP system  
4 for the code number that's in the column to the left.

5       Q.   And what about the quantity, which appears in  
6 the column to the right?

7       A.   That would be the quantity that was considered  
8 to be at risk from the amount in our inventory.

9       Q.   And when you say "at risk," what do you mean?

10      A.   Just as I described earlier, meaning that we  
11 expected that it would ultimately not be usable for  
12 commercial purposes for one reason or another.

13      Q.   And in the next column to the right, "Std Cost,"  
14 what does that refer to?

15      A.   It's the standard cost that that product was  
16 carried at in our ERP system and our financial books.

17      Q.   And to the right, "Ext. Cost," what does that  
18 refer to?

19      A.   The extended cost, which would be the standard  
20 cost times the quantity.

21      Q.   Okay. So you arrive at the extended cost by  
22 multiplying the quantity by the standard cost. Is that  
23 right?

24      A.   That's correct.

25      Q.   Looking two columns over where it says "Risk,"

1 what does that refer to?

2       A. Just a categorization that we used to  
3 communicate to finance, whether it was a high, medium,  
4 or low risk that it would ultimately be rejected.

5       Q. And so, for example, looking at the column -- at  
6 the row number 1 that appears immediately below that, it  
7 appears that there's an "H" listed in the "Risk" column.  
8 Do you see that?

9       A. Yes, I do.

10      Q. And what does the "H" denote?

11      A. A high level of risk.

12      Q. A high level of risk that the product will have  
13 to be destroyed?

14      A. That's correct.

15      Q. And looking at the very top of this page, it  
16 says, "Raw Materials & Packaging." What does that refer  
17 to?

18      A. We just broke the report -- we sent this  
19 inventory report to different groups, and this  
20 particular report was for raw materials and packaging  
21 components.

22      Q. Looking at this page generally, can you  
23 determine what the total amount of adverse inventory  
24 value that Impax had for raw materials and packaging as  
25 of this point in time?

1       A. At the bottom of page 003, the Hayward total is  
2 a little over \$2 million.

3       Q. And what does the "Hayward total" refer to?

4       A. We had two main operational areas at this point  
5 in time. We had a Hayward and we had a Philadelphia  
6 operation where we did packaging and distribution.

7       Q. Okay. Let's go ahead and skip to 2922-007.

8 Looking at the top of the page, it says, "Bulk Inventory  
9 & Open Work Orders." Do you know what that refers to?

10      A. Yes.

11      Q. What does that refer to?

12      A. Bulk inventory would be product in the form of  
13 tablets or capsules that we had manufactured but not yet  
14 packaged, so they would typically be in fiber drums.  
15 And open work orders would be work in process where we  
16 had started working on them but had not yet finished  
17 them through manufacturing.

18      Q. Looking at this page, it appears that there are  
19 several rows that are highlighted in yellow. Do you  
20 know what the yellow highlighting denotes?

21      A. Yes. The yellow highlighting indicated that it  
22 was new to that -- that month.

23      Q. So these are materials that were added to the  
24 list in this particular month. Is that right?

25      A. Yes.

1 MS. PEAY: Objection, Your Honor. This is --  
2 seems to be beyond the scope of the direct. I don't see  
3 how this is connected to oxymorphone ER from my direct  
4 examination.

5 MR. MCINTYRE: Well, Complaint Counsel elicited  
6 testimony concerning the destruction of oxymorphone  
7 quantities, and actually in a minute we will see that  
8 the oxymorphone is listed here. I would like to provide  
9 some context for understanding when and under what  
10 circumstances Impax has to write off product.

11 JUDGE CHAPPELL: All right. I agree, it is  
12 within the scope, and another point is we have this  
13 problem occasionally when a witness is called who is on  
14 both witness lists, and if he wants to take this witness  
15 as his own at this time, he's allowed to go beyond the  
16 scope of direct in this limited circumstance.

17 MS. PEAY: I understand, Your Honor. My  
18 understanding is that Mr. Camargo is not on Respondent's  
19 witness list.

20 MR. MCINTYRE: That's correct.

21 JUDGE CHAPPELL: All right. Well, I overruled  
22 the objection in this case.

23 MS. PEAY: Okay, thank you.

24 MR. MCINTYRE: Thank you, Your Honor.

25 BY MR. MCINTYRE:

1 Q. Mr. Camargo, I believe you just testified that  
2 the yellow highlighted products here represent bulk  
3 inventory and open work orders that were added to this  
4 list in this particular month. Did I state that  
5 correctly?

6 A. That's correct.

7 Q. And can you determine the risk that's associated  
8 with these products? I'm sorry, let me rephrase that.

9 Can you determine from this document the risk  
10 that this inventory would have to ultimately be  
11 discarded?

12 A. Yes. In the "Risk" column, they're all  
13 indicated as "H," meaning high.

14 Q. Can you determine the total amount of new bulk  
15 inventory and work orders that were added to the list  
16 for this particular month?

17 A. For that month, it was approximately \$618,000.

18 THE COURT: You said earlier that the stock was  
19 in fiber drums. What kind of fiber?

20 THE WITNESS: Fiberboard containers basically,  
21 cylindrical containers made out of fiberboard, and we  
22 would have that product in tablet or capsule form  
23 double-bagged inside those containers. Those were  
24 facilitated -- that's how we packaged it to ship it to  
25 our Philadelphia packaging operation.

1 JUDGE CHAPPELL: So the product would be within  
2 plastic bags inside the fiber drum?

3 THE WITNESS: Correct.

4 BY MR. MCINTYRE:

5 Q. Let's go ahead and turn to CX 2922-009, and at  
6 the top of this page, it reads, "Finished Goods in  
7 Distribution." What does that mean, Mr. Camargo?

8 A. These were products that were completely  
9 packaged and ready for sale.

10 Q. How is this distinguished from bulk inventory?

11 A. The bulk inventory would be product that was  
12 still awaiting packaging. It was still in loose tablet  
13 and capsule form as it came out of manufacturing.

14 Q. Okay. And looking at the first few rows here,  
15 it lists oxymorphone HCL. Do you see that?

16 A. I do.

17 Q. And for -- in rows number 1, 2, and 3, it says  
18 britestock. What does britestock refer to?

19 A. Britestock product is packaged in the final  
20 container, but the labeling has not yet been applied to  
21 it, and, therefore, the full packaging is not yet  
22 completed.

23 Q. And so at this point in time, the oxymorphone  
24 product was at risk of having to be discarded?

25 A. I'm sorry. Can you repeat the question?

1 Q. I'm sorry.

2 At this point in time, was the oxymorphone  
3 product at risk of having to be discarded?

4 A. Yes.

5 Q. Let's look further down the page. Robert, can  
6 you pull up rows 10 through 21.

7 Mr. Camargo, what is Digoxin?

8 A. Digoxin was just another product that we had  
9 prepared for launch.

10 Q. I'm not going to ask you to do the math  
11 precisely, but looking at the "Extended Cost" column,  
12 can you give a guesstimate, a rough estimate, as to the  
13 total value of the Digoxin product that was listed here?

14 MS. PEAY: Your Honor, I object that this  
15 question is beyond the scope of direct.

16 JUDGE CHAPPELL: Right. Based on this  
17 objection, I'm sustaining it until you can lay a  
18 foundation and bring this within the scope of the  
19 questions he was asked by opposing counsel.

20 MR. MCINTYRE: Understood, Your Honor. I can  
21 withdraw that question.

22 MS. PEAY: Thank you, Your Honor.

23 BY MR. MCINTYRE:

24 Q. Mr. Camargo, can you determine the total amount  
25 of new -- I'm sorry, the total value of new listings of

1 finished goods in distribution for this month?

2 A. From this report, the total for that month was  
3 1.16 million.

4 Q. Okay. Given your 27 years of experience in the  
5 pharmaceutical industry, would you say that it is  
6 unusual to have to discard inventory?

7 A. No, it's not, unfortunately.

8 Q. I'm going to switch gears a bit. Let's go ahead  
9 and pull up CX 3069, and this is another exhibit that  
10 you reviewed with Complaint Counsel.

11 This exhibit is in evidence and it is not  
12 subject to in camera treatment.

13 Do you recall reviewing this document with  
14 Complaint Counsel?

15 A. Yes.

16 Q. Let's turn to -003, and can we go ahead and blow  
17 up this.

18 I believe you reviewed the line with Complaint  
19 Counsel where it says, "Oxymorphone: approved and ready  
20 to launch same day but settled (achieved goal)."

21 Do you recall that, Mr. Camargo?

22 A. Yes.

23 Q. When you said "approved and ready to launch,"  
24 what did you mean?

25 A. That we were -- well, approved means that the



1 process validation report was signed off and those  
2 batches were all ready to be released should management  
3 have given us the go-ahead to do it; and that we were  
4 also ready to execute the launch inventory build that we  
5 were ultimately told not to execute.

6 Q. And when you just -- you said "those batches" a  
7 minute ago, were you referring to the process validation  
8 batches?

9 A. Yes.

10 Q. And, Mr. Camargo, you reviewed some documents  
11 earlier, some of your monthly reports to -- that you  
12 would send to your boss, Mr. Hildenbrand. Do you recall  
13 those?

14 A. Yes.

15 Q. And do you recall that there was a line in those  
16 reports that would say "Percentage" -- I'm sorry,  
17 "Rejects as a % of COGS"?

18 A. Yes.

19 Q. And was that a goal that you attempted to  
20 achieve generally in the operations division?

21 A. Yes.

22 Q. Looking at your self-evaluation here in CX 3069,  
23 there's a column that says "Objectives," and I'm looking  
24 at -002. What does "Objectives" refer to?

25 A. The objectives were the goals that we set for

1 that year.

2 Q. Does the goal of achieving a -- of limiting  
3 rejects to a certain percentage of COGS, does that goal  
4 appear here?

5 A. Yes.

6 Q. It does? Can you point me to it?

7 A. In the second block on the left side. Oh, I'm  
8 sorry, I can't --

9 Q. Does that --

10 A. No, I'm sorry.

11 Q. I'm sorry, go ahead.

12 A. I was looking at the screen and couldn't read it  
13 all. Can you expand it?

14 Q. Yeah. Can we go ahead and --

15 A. I can't see the whole thing right now.

16 Q. Where it says "COGS at 50% or less of net  
17 sales."

18 A. No, it's -- the COGS at 50% or less of net sales  
19 has nothing to do with rejects.

20 Q. Okay. Do you see anything here concerning  
21 rejects as a percentage of COGS?

22 A. Not with what I can see on this screen right  
23 now.

24 Q. You can go ahead and look at the full document,  
25 if you like. This is at tab 24 of your binder.

1       A. Tab 24. (Document review.) No, it's not on  
2 this particular year's objectives statement.

3       Q. Mr. Camargo, do you have any responsibility for  
4 deciding ultimately whether to launch a product?

5       A. Do I have any responsibility for what? Excuse  
6 me?

7       Q. I can rephrase that.

8             Mr. Camargo, were you responsible for deciding  
9 whether to launch a product?

10      A. No, I was not.

11      Q. Who was responsible for that?

12      A. Ultimately, Larry Hsu would be responsible.

13      Q. And Larry Hsu was the CEO at this time?

14      A. Yes.

15      Q. Mr. Camargo, do you have any knowledge of when  
16 the settlement negotiations with Endo began?

17      A. No, I do not.

18      Q. When did you first hear about the settlement  
19 with Endo?

20      A. To the best of my recollection, I heard about it  
21 when the settlement was announced.

22      Q. So you were not part of the team that negotiated  
23 the settlement?

24      A. No, I was not.

25             MR. MCINTYRE: Your Honor, may I briefly confer

1 with counsel?

2 JUDGE CHAPPELL: Go ahead.

3 (Counsel conferring.)

4 MR. MCINTYRE: Thank you, Mr. Camargo. No  
5 further questions at this time.

6 JUDGE CHAPPELL: Any redirect?

7 MS. PEAY: Your Honor, may I have a moment to  
8 confer with counsel?

9 JUDGE CHAPPELL: Go ahead.

10 (Counsel conferring.)

11 MS. PEAY: Your Honor, I will have some  
12 redirect.

13 JUDGE CHAPPELL: Okay.

14 REDIRECT EXAMINATION

15 BY MS. PEAY:

16 Q. Hello again, Mr. Camargo.

17 A. Hello.

18 Q. Can you turn to the exhibit RX 181 that counsel  
19 for Respondent -- it's in Respondent's binder. I think  
20 it is tab 3.

21 A. Okay.

22 Q. And, Mr. Camargo, counsel for Respondent  
23 discussed this exhibit, RX 181, with you earlier today,  
24 just now?

25 A. Yes.

1 Q. And focusing on the first email that you sent at  
2 the bottom of the page, counsel asked you questions  
3 about your -- what you wrote here, where you said, "I  
4 understand that the odds of launching 6/10 when the  
5 30-month stay expires may be low..."

6 A. Yes.

7 Q. Do you recall that?

8 And, Mr. Camargo, your understanding of -- that  
9 the odds of launching the oxymorphone product in June  
10 2010 as being low was based upon your general experience  
11 at Impax and in the industry, correct?

12 A. In part, yes.

13 Q. It was not based upon an assessment of the  
14 oxymorphone ER product, in particular?

15 A. There was discussion in other meetings that I  
16 participated in where that particular product and its  
17 particular likelihood was logically discussed in. I  
18 don't have any specific recollection of that discussion.  
19 Clearly, from my experience, there may have been  
20 discussions about that product. I don't recall the  
21 details of them.

22 Q. So, sitting here today, you don't know -- you  
23 cannot recall of any other basis for your understanding  
24 that the odds of launching in June 2010 as being low,  
25 other than your general experience.

1 A. I can't recall any specifics. It is very  
2 possible that there were other discussions, but I don't  
3 recall any specifics.

4 Q. But you don't know of any?

5 A. No, I do not.

6 MS. PEAY: No further questions, Mr. Camargo.

7 Thank you, Your Honor.

8 JUDGE CHAPPELL: Anything further?

9 MR. MCINTYRE: None for us, Your Honor.

10 JUDGE CHAPPELL: Thank you. You may stand down.

11 We are going to take a short break and come back  
12 and start with our next witness. We will reconvene at  
13 12:05. We are in recess.

14 (A brief recess was taken.)

15 JUDGE CHAPPELL: We are back on the record.

16 Next witness.

17 MR. LOUGHLIN: Thank you, Your Honor. Complaint  
18 Counsel calls Dr. John Geltosky. My colleague Mr. Dan  
19 Butrymowicz will conduct the examination.

20 Whereupon--

21 JOHN E. GELTOSKY, Ph.D.

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

24 DIRECT EXAMINATION

25 MR. BUTRYMOWICZ: Good afternoon, Your Honor.

1 May it please the Court.

2 JUDGE CHAPPELL: Go ahead.

3 BY MR. BUTRYMOWICZ:

4 Q. I'm Dan Butrymowicz on behalf of Complaint  
5 Counsel.

6 Good afternoon, Dr. Geltosky.

7 A. Good afternoon.

8 Q. How are you?

9 A. Doing fine.

10 Q. Would you please introduce yourself by stating  
11 your full name.

12 A. I am John Edward Geltosky.

13 Q. Would you please also briefly describe your  
14 professional background.

15 A. I have a Ph.D. in biochemistry from Cal Tech.  
16 I've worked in the pharmaceutical biotech industry for  
17 roughly 37 years. I've worked both at large  
18 pharmaceutical companies, small pharmaceutical  
19 companies. I've also been involved in technology  
20 transfer, and I am currently a consultant to biotech,  
21 too, in licensing and business development.

22 Q. Thank you.

23 Dr. Geltosky, I've placed a binder next to your  
24 seat that contains several exhibits that we may  
25 reference during the direct examination. There is no

1 need to refer to it right now. There is also a bottle  
2 of water next to your seat if you need it.

3           Before we discuss your professional experience,  
4 let me first review the issue that you were asked to  
5 address in this case. What did the FTC ask you to  
6 assess in this matter?

7       A. They asked me to provide an opinion regarding  
8 the due diligence, the negotiation history, and the  
9 terms of the draft -- of the license -- development  
10 co-promotion agreement between Impax and Endo, and I was  
11 to weigh in on the consistency with what I saw there  
12 with the practices and norms of the pharmaceutical  
13 industry when they consider and enter into an agreement  
14 of this sort.

15       Q. Without saying what your opinion is, have you  
16 formed an opinion on that issue?

17       A. Yes, I have.

18       Q. Before we get to that opinion, I would like to  
19 ask you about your professional experience, your  
20 education, and your training. You said a moment ago  
21 that your background is in pharmaceutical business  
22 development. Generally speaking, what is pharmaceutical  
23 business development?

24       A. Well, inside of all pharmaceutical companies,  
25 large and small, there exists a function called business



1 development, and it is a goal of the business  
2 development agreement basically to fill the pipeline,  
3 where necessary, with projects or technologies that come  
4 from outside the four walls of that -- of the particular  
5 company.

6           A little known fact is that roughly half the  
7 drugs that a given pharmaceutical company markets come  
8 from outside those four walls of their company. So we  
9 have in business development the window on the rest of  
10 the world to go find assets that are strategic to fill  
11 the pipeline.

12       Q. You used the term "asset." What do you mean by  
13 that term?

14       A. Typically, in this case, I'm referring to drugs  
15 in development. In some cases we look at market --  
16 already marketed drugs that the originator wanted to  
17 license out, to get rid of, but typically it's drugs in  
18 development.

19       Q. When you introduced yourself, you mentioned that  
20 you had worked for major pharmaceutical companies in  
21 business development. Which companies were those?

22       A. In business development, I worked -- well, I  
23 actually did business development work at Johnson &  
24 Johnson, I did business development work at SmithKline  
25 Beecham, and I also did similar activity at

1 Bristol-Myers Squibb.

2 Q. Let's take those one at a time. Let me ask you  
3 first about your work at Bristol-Myers Squibb. What was  
4 your title at Bristol-Myers Squibb?

5 A. I was the vice president of external science,  
6 technology, and licensing.

7 Q. And what were your responsibilities as vice  
8 president of external science, technology, and  
9 licensing?

10 A. Myself and my group of 15 professionals were  
11 responsible for finding those assets on the outside that  
12 fit into the therapeutic areas that were of interest to  
13 Bristol at that time. So it was our responsibility to  
14 find those molecules, find those assets, evaluate them,  
15 do technical evaluation, and work with our Legal  
16 Department and our Commercial Department to basically  
17 develop a commercial model for the -- for the asset,  
18 which would then lead to negotiations.

19 Q. And how long were you vice president of external  
20 science, technology, and licensing at Bristol-Myers  
21 Squibb?

22 A. Five-plus years.

23 Q. You also mentioned SmithKline Beecham. What was  
24 your title at SmithKline Beecham?

25 A. I was vice president of scientific licensing in

1 the Worldwide Business Development Department.

2 Q. What were your responsibilities as vice  
3 president of scientific licensing and director of  
4 scientific licensing?

5 A. Very similar to what I had at Bristol.

6 Q. How long were you in that role?

7 A. Five years.

8 Q. In pharmaceutical business development, what is  
9 in-licensing versus out-licensing?

10 A. Well, in-licensing, you're a net buyer. That's  
11 what we typically -- what we were responsible for. So  
12 we would -- we were basically looking to acquire assets  
13 on the outside. So we were buyers in that role.

14 JUDGE CHAPPELL: You used the word "licensing"  
15 there. Are you talking about patents, patented drugs?

16 THE WITNESS: Typically, yes.

17 JUDGE CHAPPELL: Did you have anything to do  
18 with patents?

19 THE WITNESS: I, myself, am not a patent  
20 attorney. I always -- it was always important for us in  
21 evaluating a technology or a potential acquisition to  
22 understand -- have an opinion of the intellectual  
23 property bolstering that particular asset.

24 JUDGE CHAPPELL: Did you do your job based on  
25 assumptions or guidance that was given to you by the

1 Legal Department?

2 THE WITNESS: I'm sorry, I didn't hear you  
3 properly.

4 JUDGE CHAPPELL: Did you do your job based on  
5 assumptions of patent validity that was provided to you?

6 THE WITNESS: Yes. I mean, the patent -- our  
7 Patent Department would weigh in, and we would sometimes  
8 debate it, sometimes go a little bit back and forth, but  
9 we would rely on the Patent Department to provide that  
10 opinion for us.

11 MR. BUTRYMOWICZ: Thank you, Your Honor.

12 BY MR. BUTRYMOWICZ:

13 Q. I also want to clarify a little bit about  
14 licensing as you describe it. When you use the term  
15 "in-licensing," are you referring only to licensing  
16 development agreements?

17 A. No. I used that sort of euphemistically. I  
18 mean, that can also -- it includes co-development type  
19 of agreements, co-promotion agreements, but it's easy  
20 for me just to think about it as licensing, because that  
21 is the underlying basis of all these other activities.

22 Q. So when we discuss pharmaceutical licensing  
23 agreements, you generally understand that to mean any  
24 type of pharmaceutical development deal?

25 A. Yes, all-encompassing.

1 Q. In your experience at Bristol-Myers Squibb and  
2 SmithKline Beecham, were you responsible for reviewing  
3 potential pharmaceutical development opportunities?

4 A. Yes.

5 Q. Were you involved in selecting opportunities to  
6 pursue?

7 A. Yes.

8 Q. Were you responsible for performing due  
9 diligence on those opportunities?

10 A. Yes.

11 Q. Were you involved in negotiations for  
12 pharmaceutical development agreements?

13 A. I participated in a team format. Typically it's  
14 a fairly large -- well, not a large team, but there's a  
15 number of people that are involved in the negotiation.

16 Q. Does your more than ten years of experience at  
17 SmithKline Beecham and Bristol-Myers Squibb relate to  
18 the opinions that you intend to give in this case?

19 A. Yes.

20 Q. How does it relate?

21 A. Because during that period I participated in  
22 numerous -- which I'm sure we will get into -- numerous  
23 licensing and evaluation opportunities. So you -- one  
24 becomes -- and I certainly became -- very immersed in  
25 all the moving parts that go into a business development

1 licensing agreement. So, perforce, that has informed my  
2 opinion on this subject.

3 Q. In addition to your experience as an executive  
4 at Bristol-Myers Squibb and SmithKline Beecham, you also  
5 mentioned that you're currently a consultant. Is that  
6 correct?

7 A. That is correct.

8 Q. Where are you currently employed?

9 A. JEG & Associates.

10 Q. What is JEG & Associates?

11 A. Well, basically, it is an LLC that I formed to  
12 provide business development/licensing consulting  
13 practice -- consulting advice to typically a small -- to  
14 small biotech companies as they consider finding a  
15 partner for their asset.

16 Q. What are your responsibilities at JEG &  
17 Associates?

18 A. So working with a typical client, I will work  
19 with them in terms of formulating an overall strategy  
20 that relates to their R&D activities. So, in essence,  
21 what I advise these people on are the kinds of  
22 experiments, the kinds of data, the kinds of knowledge  
23 that must be brought to bear to entice a potential  
24 partner.

25 In this business, partnerships are -- rule

1 everything. A small biotech company is great at  
2 originating and discovering brand new drugs, but they  
3 need large pharmaceutical companies to help them with  
4 development and commercialization. So I enable them to  
5 entice potential partners for their assets.

6 I help them draft their presentations,  
7 nonconfidential. I help them put together their  
8 confidential data packages. I basically am the  
9 ombudsman for that whole process on behalf of my client,  
10 and I participate in negotiations and give advice as  
11 needed.

12 Q. So you mentioned that in your role at  
13 Bristol-Myers Squibb and SmithKline Beecham you were  
14 involved primarily in analyzing things, and I think you  
15 said you were a net buyer. In your role at JEG &  
16 Associates, are you primarily a net buyer or a net  
17 seller?

18 A. I'm a net seller.

19 Q. And how does that differ from being a net buyer  
20 or in-licenser?

21 A. Well, when you're a net seller, you're  
22 essentially a salesman, so you're trying to entice a  
23 particular -- a -- an interest in forming partnerships.  
24 So it's -- the rules of the game are basically  
25 identical, and what allows me to be a good seller, I

1 think, or to help my companies sell is I know from a  
2 buyer standpoint what a buyer, a potential buyer, is  
3 looking for. So it's just the same dynamic, just  
4 different sides of the street, if you will.

5 Q. Before JEG & Associates, where were you  
6 employed?

7 A. Prior to that -- to JEG & Associates, I was  
8 with -- I was employed at Arizona State University.

9 Q. What was your title there at Arizona State?

10 A. I was senior vice president of technology  
11 transfer for the life science activities there.

12 Q. What were your responsibilities in that role?

13 A. Very similar, actually, to what I'm doing with  
14 biotechs, and I should say that I still am a consultant  
15 to Arizona State. So I would work with the professors,  
16 the inventors at the university, putting together what I  
17 would hope -- what we hoped to be attractive packages,  
18 again, to entice a licensor, you know, for this  
19 technology, whether it be a small biotech, a large  
20 pharmaceutical company, or a venture.

21 Q. Did your work at Arizona State focus on products  
22 in any particular stage of development?

23 A. They were all very -- because of the university  
24 environment, very early-stage technologies.

25 Q. In your role at JEG & Associates and Arizona



1 State University, did you interact with other  
2 pharmaceutical companies?

3 A. Certainly.

4 Q. Roughly how many would you say you interacted  
5 with during those roles?

6 A. Just referring to the consulting -- to the JEG  
7 and the Arizona State? Dozens, many dozens.

8 Q. Did you get any -- any experience seeing how  
9 those companies approached pharmaceutical development?

10 A. Certainly.

11 Q. Does your experience at JEG & Associates and at  
12 Arizona State University inform any of the opinions you  
13 intend to give in this case?

14 A. Yes, they do.

15 Q. How do they inform them?

16 A. Well, again, this is just another sort of subset  
17 of the licensing business development arena, and this is  
18 particularly -- the -- the areas that you've just drawn  
19 my attention to are particularly applicable to this  
20 because the asset in question here for the -- in the  
21 agreement between Endo and Impax is defined as very  
22 early stage.

23 Q. Do you currently hold any other positions, in  
24 addition to your employment at JEG & Associates?

25 A. Yeah, I'm the chairman of the Product

1 Development Review Committee for CPRIT, and CPRIT stands  
2 for Cancer Prevention Research Institute in Texas.

3 Q. What is CPRIT?

4 A. CPRIT is a funding agency put forth or put out  
5 by the State of Texas. When Rick Perry was the Governor  
6 of Texas, he was able to entice the taxpayers to  
7 basically invest \$3 billion over a ten-year period, so  
8 that's \$300 million a year, to invest in cancer  
9 research, both basic research in the universities in  
10 Texas and also, where I come into play here, small  
11 companies that are in -- you know, that are resident in  
12 the State of Texas or who are willing to move to Texas  
13 that are advancing novel therapies and diagnostics  
14 related to cancer.

15 Q. And what are your responsibilities as the chair  
16 of the Commercial Review Council for CPRIT?

17 A. So of that \$300 million, about a third of that  
18 is allocated to commercial aspects, which I am in charge  
19 of. So in my role, I have -- these are -- they are  
20 called grants, but, in fact, they're really business  
21 plans that we review. So I have roughly three to four  
22 dozen professionals that I use, that I can call on, to  
23 provide review.

24 These are peer-reviewed grants, if you will, and  
25 so I'm responsible for organizing all of those

1 functions, to assign people, and basically to come up  
2 ultimately with investment decisions that we are willing  
3 to fund, that we think have good technical sense and  
4 good business sense.

5 Q. Does your work as the chair of the Commercial  
6 Review Council for CPRIT relate to any of your opinions  
7 in this case?

8 A. Ah, yes. Even though we're not talking about an  
9 oncology drug here, we're talking about a Parkinson's  
10 drug, these are all very early-stage companies. So the  
11 dynamic, the meat and potatoes that goes into business  
12 plans, the analyses are very similar to what one would  
13 do in analyzing this particular project.

14 Q. Dr. Geltosky, are you on the board of directors  
15 of any pharmaceutical companies?

16 A. Yes.

17 Q. Which companies?

18 A. So I'm on the board of a company in LaJolla  
19 called Sophiris, and I'm also on the board of a company  
20 in Vancouver, Canada, called Sitka.

21 Q. In addition to the experience you've just  
22 described in pharmaceutical business development, do you  
23 also have experience working in pharmaceutical research  
24 and development?

25 A. Yes. That's how I started my career.

1 Q. And can you briefly describe that experience?

2 A. Well, I started my career in the laboratory at  
3 Dupont in 1980, and that was more -- that was really a  
4 diagnostics rather than therapeutics, but the mind-set  
5 that one applies in developing new products and  
6 diagnostics have a lot of overlap with pharmaceutical  
7 products. And, in fact, it's a very heavily regulated  
8 industry, just as therapeutics are, so that informs a  
9 lot of your activities in terms of how you do your job.

10 So when I switched over to the pharmaceutical  
11 area, I was basically involved in both research and  
12 development. I was involved in discovering new  
13 therapies across a variety of therapeutic areas. I  
14 collaborated closely with research scientists at Scripps  
15 and other institutions, Rockefeller being another  
16 example, and I also did a lot of what I would call  
17 straight development work.

18 So for a couple of years I was in charge of  
19 developing stable formulations and doing analytical  
20 methods development for a molecule called erythropoietin  
21 that Johnson & Johnson was selling through their  
22 relationship with Amgen.

23 Q. Approximately how long did you work in  
24 pharmaceutical research and development?

25 A. Approximately 15 years.

1 Q. And were you at Johnson & Johnson for the  
2 majority of that time?

3 A. Ten of those years, yes, roughly ten.

4 Q. Does your 15 years of experience in research and  
5 development relate to any of the opinions you intend to  
6 give in this case?

7 A. Certainly.

8 Q. How?

9 A. Well, in doing research, one is using a --  
10 doing -- applying the scientific rigor to the analysis  
11 of the asset, at least on the technical front, and so  
12 the science that one does in the laboratory, you bring  
13 that to bear to analyze other projects that somebody  
14 else might be doing, but you'll -- you review the data  
15 with the same degree of rigor that you would be  
16 reviewing your own data and of your group.

17 Q. Dr. Geltosky, all told, approximately how many  
18 years of experience do you have working in the  
19 pharmaceutical industry?

20 A. In toto, roughly 37.

21 Q. In your 37 years in the pharmaceutical industry,  
22 approximately how many pharmaceutical development  
23 opportunities have you been involved in?

24 A. Well, starting from just searching, you know,  
25 for projects that -- for assets that we would be --

1 SmithKline or Johnson & Johnson or BristolMeyers would  
2 be interested in, thousands, many thousands.

3 Q. And of those thousands, how many have you  
4 pursued to consider a potential development deal?

5 A. Well, back in 2006 -- I'll just take that  
6 snapshot -- when I was at BMS, a part of my job was to  
7 provide some metrics to management. So in that year,  
8 3 -- we reviewed -- myself and my group reviewed 3000  
9 potential asset acquisitions or licensing, however you  
10 want to define it. So of those 3000, we were serious  
11 enough, we were interested enough then to sign a CDA, a  
12 confidentiality agreement, on 300 of those.

13 We don't take the CDAs lightly because you put  
14 yourself at risk that you are now obligated to hold  
15 things in confidence for usually five to seven years, so  
16 that's an important sort of barrier for us. Of those  
17 300, 30 of them wound up being interesting enough to  
18 pursue further. And in that further pursuit, that  
19 involved intense technical due diligence, which meant  
20 going to visit the company with an army of scientists,  
21 usually taking a couple of days to go through all the  
22 data that the company has available to them, that they  
23 presented to us in summary form, so we were just  
24 confirming that what they were telling us was, in fact,  
25 true.

1           Of those 30 with due diligence -- and those,  
2 again, are very serious undertakings -- we did three  
3 deals in that particular year. So there was a  
4 logarithmic funneling.

5       Q. And that year, 2006, those three deals you  
6 described, was that representative of most years that  
7 you worked at Bristol-Myers Squibb or SmithKline  
8 Beecham?

9       A. Yeah. It was not an extraordinary year. I just  
10 happened to be taking account.

11      Q. Outside of your formal job responsibilities,  
12 what other experience do you have that's relevant to  
13 your opinion in this case?

14      A. Well, like I said, I have been in the industry  
15 for 37 years, and I have immersed myself in that  
16 industry. So especially in licensing business  
17 development for that last 15 years where I have been  
18 active, I've participated very actively in a number of  
19 industry-sponsored events. I was a speaker at a number  
20 of events, international events. I was on a panel where  
21 the topics we're discussing basically, best practices in  
22 licensing/business development. So I became -- I became  
23 a popular speaker. People wanted to invite me to come  
24 to do these presentations.

25           So I continue, even though I'm not working for

1 anybody else, per se, I don't have an employer, I still  
2 spend a lot of time just keeping abreast of what's going  
3 on in the industry, and there are two ways that I do --  
4 actually, there's a number of ways I do it, but most  
5 significantly, I rely on a daily bulletin that gets  
6 published that everybody in the industry knows about,  
7 it's called BioWorld, and BioWorld is sort of the trade  
8 sheet of the pharmaceutical biotech industry, but it  
9 focuses on business development deals.

10           There's a second source, similar in nature, not  
11 quite as extensive, called FierceBiotech. Where they  
12 came up with that name, I don't know. I read journals.  
13 I still subscribe to Science, where there is a lot of  
14 work in Science describing drug discovery. I read the  
15 Wall Street Journal, the New York Times, and The  
16 Financial Times with my eye on what's going on in the  
17 pharmaceutical industry. So I maintain an awareness of  
18 the trade.

19       Q.   What academic degrees do you hold?

20       A.   I have a Ph.D. in biochem from Cal Tech. I have  
21 completed a postdoctoral fellowship at Scripps Clinic in  
22 LaJolla. And I hold a bachelor's degree, magna cum  
23 laude, from University of Memphis.

24           MR. BUTRYMOWICZ: Your Honor, at this point, I  
25 tender Dr. Geltosky as an expert in pharmaceutical



1 business development agreements. I submit that he's  
2 qualified by reason of his 37 years of professional  
3 experience in the industry, his education, his training,  
4 to provide expert testimony on whether the overall  
5 strategic fit, negotiation history, due diligence  
6 efforts, and terms of the development and co-promotion  
7 agreement between Endo and Impax are consistent with the  
8 usual and expected practice in the pharmaceutical  
9 industry.

10 JUDGE CHAPPELL: Are you finished?

11 MR. BUTRYMOWICZ: Yes.

12 JUDGE CHAPPELL: That might be the longest one  
13 I've ever heard.

14 MR. BUTRYMOWICZ: I apologize, Your Honor.

15 JUDGE CHAPPELL: Any objection?

16 MS. FABISH: No objection.

17 JUDGE CHAPPELL: I can't hear you unless you  
18 stand up.

19 MS. FABISH: No objection, Your Honor.

20 JUDGE CHAPPELL: You don't want to start a bad  
21 habit there. Any opinions that meet the proper legal  
22 standards will be considered.

23 MR. BUTRYMOWICZ: Thank you, Your Honor.

24 BY MR. BUTRYMOWICZ:

25 Q. Dr. Geltosky, now that we have reviewed your

1 qualifications as an expert in the area of  
2 pharmaceutical development agreements, let's get to your  
3 actual opinions in this case.

4           In your opinion, was the overall strategic fit,  
5 negotiation history, due diligence efforts, and terms  
6 for the development and co-promotion agreement between  
7 Endo and Impax consistent with the usual and expected  
8 practice in the pharmaceutical industry?

9       A.   No.

10      Q.   Do you hold that opinion with a degree of  
11 certainty that's reasonable in your professional field?

12      A.   Yes.

13      Q.   In a moment, I'd like to go through the  
14 different parts of that opinion in more detail, but  
15 first, in general terms, can you describe how you came  
16 to arrive at your opinions in this case?

17      A.   Well, I was provided a whole raft of documents  
18 to review from the FTC that had quite a bit of  
19 information in those. I analyzed those through the lens  
20 of my experience of reviewing and participating and  
21 creating licensing/business development/co-promotion  
22 types of agreements. So I used that experience that  
23 informed my opinion of reviewing and analyzing the  
24 information provided by the Federal Trade Commission.

25      Q.   Before turning to anything specific about this

1 agreement, I'd like to get an understanding of the  
2 process that pharmaceutical companies, in your  
3 experience, typically follow for development agreements.

4           Can you explain in very general terms what a  
5 pharmaceutical development agreement is?

6       A. Well, basically, a -- it's a -- it's a legal  
7 contract between two companies who have agreed to work  
8 together to develop and possibly then commercialize an  
9 asset that is owned by one of the parties. There's a  
10 lot of meat in these agreements. They cover -- there is  
11 a roadmap of how this is going to -- how the project is  
12 going to be developed, a sense of timing of when events  
13 are going to occur.

14           There's a -- there's a description of how the  
15 product is going to be commercialized, who has  
16 responsibility. Actually, a licensing agreement spells  
17 out in great detail who is responsible for all the  
18 myriad activities that are -- that are necessary to  
19 advance a compound all the way through to  
20 commercialization.

21           There's a description of the committees, the  
22 decision-making process, and last, but not least, there  
23 is information about the compensation, the quid pro quo,  
24 how the money flows between the two parties.

25       Q. From a commercial perspective, are there

1 different forms that a pharmaceutical development  
2 agreement could take?

3       A. Yes. There -- as we've touched on before,  
4 there's licensing agreements, there's co-development  
5 agreements, there's co-promotion/co-development  
6 agreements.

7       Q. In terms of what you've described as the meat of  
8 the agreements, are there any significant differences  
9 between those different commercial forms?

10      A. They -- there are some differences. There are  
11 more similarities than there are differences, and the  
12 differences, say, in a co-promotion agreement is how the  
13 finances get cut and how the -- it's basically, in  
14 essence, a profit-sharing agreement, so it comes down to  
15 if Party A is putting in \$100, Party B is putting in  
16 \$50, the eventual profit split, in simple terms, is  
17 judged on those contributions, those investments.

18           Licensing agreements don't do that. They just  
19 talk about up-fronts, milestones, royalties, and there's  
20 often another mechanism by which development is funded,  
21 but it's not necessarily a co-development agreement.

22      Q. Over the course of your career, were the  
23 development agreements that you worked on limited to  
24 products in a specific stage of development?

25      A. No, they ran the gamut, from preclinical through

1 to -- practically to registration, to -- to sending in  
2 the NDA.

3 Q. In your experience, do pharmaceutical companies  
4 follow the same general process for evaluating and  
5 entering development deals?

6 A. Yes.

7 Q. On a very high level for now, what is that  
8 process?

9 A. Well, you find it. You do the technical  
10 evaluation. You do the intellectual property  
11 evaluation. You develop a commercial model. Then  
12 you -- if you're still interested, then there's  
13 diligence all along the way, and if you're still  
14 interested, you go into negotiations.

15 Q. In your experience, does this process vary based  
16 on the size of the company?

17 A. No.

18 Q. And why do pharmaceutical companies follow this  
19 type of process before entering a business development  
20 deal?

21 A. It's a very logical process, and basically what  
22 one is trying to do, whether it's a small company or a  
23 big company, is mitigate risk. And so you go through  
24 this set of analyses to understand the risks, to measure  
25 the risks, to quantitate the risks, and put a dollar

1 value on that risk. So it's a way -- you just -- you  
2 just manage risk.

3 Q. I'd now like to ask you more in-depth about your  
4 opinions, starting with your opinion about the  
5 negotiations for the Endo-Impax development and  
6 co-promotion agreement.

7 At a high level, what's the basis for your  
8 opinion that the negotiations for this agreement were  
9 not consistent with the usual practice in the  
10 pharmaceutical industry?

11 A. Well, there were two -- two -- two components.  
12 The first was it happened -- the speed at which the  
13 agreement was finalized was remarkable, very fast, a  
14 very short period.

15 The second thing that I found odd and very much  
16 out of place was that the focus of the agreement changed  
17 literally at the 11th hour. That was an unprecedented  
18 change in focus in these kinds of agreements.

19 Q. Let's take those one at a time. Turning first  
20 to your opinion that the negotiations were concluded  
21 very quickly, unusually quickly, what is your basis for  
22 that opinion?

23 A. It's based on my experience. I've never seen  
24 anything happen that fast.

25 Q. In your 37 years of experience in the

1 pharmaceutical industry, how long does it typically take  
2 to complete an early-stage pharmaceutical development  
3 deal from start to finish?

4 A. From the very start when you find the asset,  
5 when it crosses your desk or you find it, and to  
6 completing the agreement, the average is 12 months.

7 Q. Are there circumstances where you've seen a  
8 development deal completed in less than 12 months?

9 A. I believe -- yeah, I can't draw a precise  
10 recollection, but I am aware of, stumbling around, maybe  
11 something within nine months being done, not that we  
12 participated in, but I have heard through the industry,  
13 talking to other people, maybe less -- a little bit less  
14 than a year.

15 Q. Are there any circumstances, based on your  
16 experience, that might drive a deal to be completed in  
17 less than the usual time?

18 A. If there's competition for an asset, that could  
19 increase the speed.

20 Q. Did the development agreement between Endo and  
21 Impax involve any competition for the asset?

22 A. Not that I -- not that I could see.

23 Q. How long did the negotiations between Endo and  
24 Impax for the co-development and promotion agreement  
25 take?

1 A. Well, for the eventual product, IPX-203, they  
2 negotiated -- once that was divulged to Endo, they  
3 completed that agreement in four days.

4 Q. And putting aside the focus on the second  
5 product, which we'll discuss in a moment, how long did  
6 the overall negotiations for any form of the development  
7 and co-promotion agreement take?

8 A. I can't do the math. Here they started talking  
9 about another compound, another molecule, in May,  
10 mid-May, and they concluded the agreement on June 8th, I  
11 believe. So I think it was less than a month.

12 Q. In your experience, how unusual is it that  
13 negotiations for a development agreement would be  
14 concluded, from start to finish, in less than a month?

15 A. Extremely unusual.

16 Q. Based on your review of Endo's documents, did  
17 Endo have a documented approach to how it negotiated  
18 business development agreements?

19 A. Yes.

20 Q. I'd like to ask you to turn to CX 2784, which is  
21 in your binder.

22 Your Honor, CX 2784 is admitted in evidence,  
23 it's on JX 2, and it is not subject to Your Honor's in  
24 camera order.

25 And, Dr. Geltosky, I would specifically like to



1 direct your attention to CX 2784-20.

2 A. Yes, uh-huh.

3 Q. Do you recognize this document?

4 A. Yes.

5 Q. Did you review it in preparing your report?

6 A. Yes.

7 Q. Have you seen similar documents at  
8 pharmaceutical companies that you've worked with?

9 A. Yes.

10 JUDGE CHAPPELL: Hold on a second.

11 (Discussion off the record.)

12 JUDGE CHAPPELL: Go ahead.

13 BY MR. BUTRYMOWICZ:

14 Q. Based on your experience in the industry, what  
15 does CX 2784 represent?

16 A. The -- this whole document?

17 Q. Yes.

18 A. It's a roadmap of how one acquires an asset from  
19 the outside.

20 Q. I'd like to direct your attention specifically  
21 to CX 2784-54. Based on your experience in the  
22 industry, what does CX 2784-54 describe?

23 A. This is a version of a roadmap of how they -- of  
24 how Endo went about their normal business practices of  
25 evaluating and doing due diligence, going to various

1 committees for discussion and approval, all the way  
2 through to a close of the agreement.

3 Q. Is Endo's description of the pharmaceutical  
4 development deal negotiation process in this document  
5 consistent with your own experience in the industry?

6 A. Yes.

7 Q. At the bottom of this page, CX 2784-54, it  
8 states, "~ 6 months - 1 year from initial evaluation to  
9 deal close." Do you see that?

10 A. Yes.

11 Q. Is that timeline consistent with your experience  
12 working on pharmaceutical business development deals?

13 A. Yes.

14 Q. Dr. Geltosky, I'd like to change focus just  
15 slightly and ask you about something you mentioned a  
16 moment ago, which is the change in focus between two  
17 products during these negotiations.

18 Based on your 37 years of experience in the  
19 industry, why do you say it was unusual that the  
20 negotiations changed focus from one product to another?

21 A. Well, in this case, the originator, Impax, had  
22 disclosed or had -- well, the two parties were very  
23 obviously discussing an asset called IPX-066. They were  
24 discussing that asset as demonstrated in various emails.  
25 There was no other discussion. It was IPX-066 for a

1 couple weeks. So then, all of a sudden, it changed.

2 Q. And what did it change to?

3 A. It went to something -- the topic -- the focus  
4 became something called IPX-203.

5 Q. And, Dr. Geltosky, the Court has ordered some of  
6 the technical and scientific information about IPX-203  
7 in camera, and so we can't discuss it in a public  
8 session. I intend to request an in camera session  
9 toward the end of this examination to get into those  
10 details, and I want you to be careful in this public  
11 session not to provide any scientific or technical  
12 details about IPX-203.

13 With that in mind, from a practical standpoint,  
14 how was IPX-203 different from IPX-066?

15 A. It was at the very earliest stages of the drug  
16 development process, I'll call it discovery, and the  
17 lead molecule had not yet been identified.

18 Q. You said that IPX-203 was at the earliest stage  
19 of the development process. At the time that Endo and  
20 Impax were negotiating this agreement, where was IPX-066  
21 in the development process?

22 A. It was preparing to enter Phase III, the last  
23 stage of the drug development process.

24 Q. From a practical standpoint, based on your  
25 experience, what does it mean for a product to be in

1 Phase III of clinical development?

2       A. It means that a lot of risk has been taken out.  
3 It's been -- successfully gone through the endpoints of  
4 the preclinical, has an IND, has gone through Phase I,  
5 has gone through Phase II, they have defined a dose, and  
6 now they're preparing to do what are generally  
7 considered to be confirmation studies, but they are  
8 large, expensive studies in Phase III. That is the last  
9 step in the process.

10       Q. Based on your 37 years of experience in the  
11 pharmaceutical industry, is it unusual for companies to  
12 change from discussing a development deal for a product  
13 in Stage III of development to a product in discovery  
14 stage?

15       A. Well, in my 37 years, I personally have never  
16 experienced that, nor have I ever heard any of my peers  
17 at other companies say that it happened to them.

18       Q. Based on your experience, how would a  
19 pharmaceutical company like Endo typically react if its  
20 negotiating partner changed the product being discussed  
21 from a Stage III clinical product to an early-stage  
22 product over the course of the negotiations?

23       A. Well, I would have called time-out and said I  
24 needed to spend some time to do a proper valuation on  
25 this newly defined asset.

1 Q. And why would you have done that?

2 A. Because it's different -- it's a different  
3 chemical. I can't get into the details here. So one  
4 would want to do technical due diligence. Certainly one  
5 would want to do intellectual property due diligence,  
6 because a new asset is being defined. One would want to  
7 do other types of technical due diligence. And very  
8 importantly, one would have wanted to redo the entire  
9 commercial analysis of the asset.

10 Q. And why would a company want to do all those  
11 things?

12 A. Because it's a brand new -- I'm sorry. It's a  
13 brand new project. It's fresh territory. Throw  
14 everything away. Start a new analysis.

15 Q. Moving on from the negotiations, I'd like to  
16 briefly discuss your opinion that the Endo-Impax  
17 co-development deal was not a strategic fit with Endo's  
18 business. Can you start by explaining what the concept  
19 of "strategic fit" means in the pharmaceutical industry?

20 A. A strategic fit is that you have other  
21 activities going on, let's say, that this would be  
22 complementary to. So in a commercial sense, if you were  
23 in a given therapeutic area and selling a particular  
24 product there -- and let's say it's just one product --  
25 you would like to have a second product in that

1 therapeutic area, that the salespeople would be  
2 detailing to the same physician audience, and that  
3 basically cuts your sales cost in half.

4 Q. What are the bases for your conclusion that the  
5 Endo-Impax development deal was not a strategic fit with  
6 Endo's business?

7 A. Kind of twofold. One is, in my review of the  
8 information, the internal presentations and so forth at  
9 Endo that I saw, there was no mention of Parkinson's  
10 disease being an area of interest. There were plenty of  
11 other therapeutic areas, plenty of other diseases that  
12 they were interested in. So I didn't see any interest  
13 in Parkinson's.

14 Secondly, they also talked about only being  
15 interested in late-stage assets, things that were near  
16 term, say within a couple years of being on the market,  
17 near-term revenue generators. Those would be late-stage  
18 products.

19 IPX-203 is something that's still in the  
20 laboratory. In fact, at the time the agreement was  
21 signed, they weren't even in the laboratory. So that  
22 didn't seem to have a strategic fit either.

23 Q. Thank you, Dr. Geltosky.

24 I'd like to change topics now and ask you about  
25 your opinion that the terms of the development and

1 co-promotion agreement were not consistent with the  
2 usual practice in the pharmaceutical industry.

3           In your report you identify a number of unusual  
4 terms in the agreement, but I'd like to focus on the  
5 financial structure of the deal. Based on your 37 years  
6 of experience in the industry, is the structure of the  
7 Impax-Endo development and co-promotion deal consistent  
8 with what you would expect for a development deal of an  
9 early-stage pharmaceutical product?

10       A. No, because it's very front-loaded.

11       Q. What do you mean by "front-loaded"?

12       A. A lot of money is put at risk at the very  
13 earliest stages of the program. At the start of the  
14 program, the \$10 million up front. The second milestone  
15 is the same amount, \$10 million, and then they diminish  
16 over the course of time. That's the exact opposite of  
17 the way agreements like this are structured.

18           They -- the milestone payments actually, in  
19 every agreement that I've ever seen, increase as risk is  
20 taken out of the program. Value is created. The  
21 originator then is sort of rewarded with a larger  
22 milestone payment reflecting that increased value by  
23 taking risk out. So backload versus frontload.

24       Q. You mentioned both the up-front payments and  
25 milestone payments, and I'd like to take those one at a

1 time. In your opinion, was the \$10 million up-front  
2 payment in this agreement unusually large?

3 A. For an early-stage compound of this sort, in  
4 this therapeutic area, with the eventual fairly small  
5 market it was going to be addressing, it was very large.

6 Q. And why is it unusual to have a payment this  
7 large for, as you said, an early-stage product?

8 A. You're basically -- in this particular case,  
9 they were putting 25 percent down of a -- at least 25  
10 percent, maybe even more down on the up-front payment of  
11 the total precommercialization milestones. That's a  
12 very high percentage, especially for a molecule of this  
13 sort.

14 Q. Based on your experience, what percentage would  
15 you expect the up-front payment to be for an early-stage  
16 development deal like this?

17 A. I would say somewhere between 5 -- of the total  
18 deal, 5 to 10 percent.

19 Q. Dr. Geltosky, isn't \$10 million a very small  
20 amount of money for a company like Endo?

21 A. No.

22 Q. Why do you say that?

23 A. \$10 million is \$10 million. A company like Endo  
24 has a fairly small treasury from which to draw, so \$10  
25 million is -- actually, it's a meaningful amount for any



1 pharmaceutical company, large or small.

2           When I would bring in products where, you know,  
3 there was in the neighborhood of \$10 million or so being  
4 put at risk, I really had to justify that. That comes  
5 out of somebody's budget.

6           The important thing to consider is besides the  
7 \$10 million, that can buy you a lot of things, but in  
8 this case, it's an opportunity cost. So a company like  
9 Endo -- and any company -- you want to be able to put  
10 all your chips down where you think you're going to get  
11 a payback. So that -- that informs my -- my discussion  
12 on that.

13       Q. I'd also like to ask you about the milestone  
14 payments. I believe you mentioned that, in your  
15 experience, it's unusual for them to decrease over the  
16 course of the agreement, but let me first ask you, what  
17 is a contingency milestone payment?

18       A. Some event has to be successfully accomplished;  
19 that is, in this particular case, the first milestone  
20 was completion -- successful completion of a Phase II  
21 clinical trial.

22       Q. Why is it unusual that the milestone payments  
23 would decrease as the agreement progressed?

24       A. That's why I say, I don't understand why they  
25 decreased in this case, because in every agreement that

1 I've ever seen, they go in the reverse direction. They  
2 increase because value is being created during the  
3 course of the program. Less risk is taken. Risk is  
4 taken out. It's more likely that the project will  
5 eventually see the light of day.

6 Q. And, Dr. Geltosky, I just want to make sure that  
7 I understand your testimony correctly. You earlier  
8 mentioned that there was an opportunity cost associated  
9 with this \$10 million payment. Can you explain a little  
10 bit more what you meant by that?

11 A. Well, if you're spending \$10 million on this,  
12 then you're not spending \$10 million on that, and so  
13 they could apply that \$10 million in their case any  
14 number of ways. They could look to acquire another  
15 project. They can look to beef up their clinical trials  
16 or accelerate their clinical development of other  
17 projects that may be further along. They could invest  
18 that money in enhancing their sales force or increase  
19 their marketing budget, all of which would be aimed at  
20 increasing their -- eventually increasing their  
21 revenues. So there are any number of ways they could  
22 spend that money or invest it.

23 Q. Thank you.

24 Given the risks inherent in IPX-203 as an  
25 early-stage product, how would you have expected, based

1 on your experience, companies like Endo and Impax to  
2 structure a deal like this?

3 A. Well, I certainly would have -- for a deal like  
4 this, I would certainly have seen a more backloaded  
5 agreement if you're just looking at the traditional  
6 up-fronts and milestones and so forth. But a better way  
7 that -- of approaching this -- and this is a methodology  
8 that was familiar to both companies -- is to do an  
9 option agreement.

10 So in this case, looking at the two parties,  
11 Endo could have paid Impax a small amount of money to  
12 tell Impax, please do not shop this to anybody else.  
13 We're interested, but we're only interested if certain  
14 things are done in the laboratory or even in the clinic  
15 before we're willing to commit to larger dollars.

16 Q. In your experience, why do pharmaceutical  
17 companies use option agreements like you just described?

18 A. It's a great risk mitigator. You're not putting  
19 a lot of money at risk until you see something that  
20 convinces you it has a higher probability of success.

21 Q. In one of your answers a few minutes ago, you  
22 used the term "backloaded." Can you explain what you  
23 mean by that term?

24 A. "Backloaded" means that the payments, the  
25 success payments, the contingency payments increase in

1 amount.

2 Q. So the opposite of frontloaded?

3 A. It's the opposite of frontloaded, yes.

4 Q. Moving on from the terms of the agreements, I'd  
5 like to turn now to your opinion that Endo's due  
6 diligence for the Impax development and co-promotion  
7 agreement was not consistent with the usual process in  
8 the industry.

9 At a very high level, what is the basis for that  
10 opinion?

11 A. Well, they really did not appear, during that  
12 four-day period, to look at anything of a technical  
13 nature that would have convinced them that this project  
14 wasn't that risky and it had a decent chance of success.  
15 So a review of technical information for -- for  
16 starters.

17 Q. Before we get into detail on that, can you  
18 please explain generally what "due diligence" means in  
19 the pharmaceutical industry?

20 A. Well, basically, due diligence, as I referred to  
21 it before, is that when you're doing full technical due  
22 diligence, which would be at this point in this project,  
23 you would look at all the data that the other company  
24 had developed that would lead one to believe that the  
25 compound is going to be both safe and efficacious and

1 that it had a good chance of development success over  
2 the given period of time that the company said it would  
3 be on the market, and, importantly, that it would have a  
4 competitive label, because in this particular case, this  
5 drug was going to face lots of competition.

6 Q. Is there a standard process that pharmaceutical  
7 companies follow to conduct diligence for a development  
8 agreement?

9 A. Yes. You look at all the data that are  
10 available, and you bring in the experts in the  
11 particular area to render a judgment on the quality of  
12 the data.

13 Q. Based on your review of the record, did Endo  
14 follow the standard process for conducting diligence?

15 A. No.

16 Q. Dr. Geltosky, if I could direct you to -- I  
17 apologize, I think my question was unclear. Not  
18 referring to the process Endo followed for this  
19 agreement, but referring to Endo's general practices,  
20 did -- did your review of the record reveal that Endo  
21 had any general process for the way it conducted  
22 diligence?

23 A. Yes. Looking at some of their other work, yes,  
24 they had a -- they had a process.

25 Q. And directing your attention back to CX 2784,

1 which we discussed earlier and it's in your binder, in  
2 particular, CX 2784-50 --

3 A. Yes.

4 Q. -- based on your experience in the industry,  
5 what does this page represent?

6 A. Again, it's another process map for how one  
7 evaluates an opportunity all the way through to a  
8 transaction, and it has some timings on it, which is all  
9 very reasonable.

10 Q. Is this due diligence process that Endo  
11 describes here consistent with your own experience in  
12 the pharmaceutical industry?

13 A. Yes.

14 Q. In your experience, how long does it typically  
15 take to do due diligence for a development agreement?

16 A. It takes roughly -- to actually conduct the full  
17 due diligence, write the reports, have the discussions,  
18 around four months, three to four months.

19 Q. How long did Endo spend on due diligence for  
20 this agreement with Impax?

21 A. I'm sorry, which compound?

22 Q. I'm sorry. How long did Endo spend on due  
23 diligence in total for this agreement with Impax?

24 A. Well, for 203, they had four days to do their  
25 evaluation, both technical and commercial and

1 intellectual property.

2       Q. And you just mentioned intellectual property  
3 analysis. I'd like to turn now to that part of  
4 diligence. Generally speaking, what is an intellectual  
5 property analysis?

6       A. Basically one is evaluating the quality of the  
7 patents, and, again, as we've referred to before, I'm  
8 not a patent attorney, but you are really looking at two  
9 things. The first thing and I think the most important  
10 thing is the freedom to operate, the FTO, and basically  
11 that's a review of the available patent literature to  
12 see if, by exploiting this, your particular technology,  
13 are you going to be infringing somebody else's patent.

14           JUDGE CHAPPELL: Are you explaining an analysis  
15 that you actually do or someone else does?

16           THE WITNESS: Well, I'm relying on somebody else  
17 doing it, but I know what they're doing. I  
18 understand --

19           JUDGE CHAPPELL: Why don't we stick to what he  
20 does rather than what someone else does.

21           MR. BUTRYMOWICZ: Yes, Your Honor.

22           BY MR. BUTRYMOWICZ:

23       Q. Dr. Geltosky, if I could turn now to your  
24 opinion that Endo's financial analysis of the IPX-203  
25 opportunity was not consistent with the usual practice

1 in the industry. Let me start by asking, in your  
2 experience, what is a financial analysis conducted as  
3 part of a pharmaceutical development deal?

4 A. Well, a financial analysis basically tells you  
5 what you think -- based on some assumptions and  
6 calculations what you think that particular asset is  
7 going to be worth, and that informs you on a couple of  
8 levels --

9 JUDGE CHAPPELL: Again, is this an analysis that  
10 you do yourself?

11 THE WITNESS: Ah, I do.

12 JUDGE CHAPPELL: All right, go ahead.

13 THE WITNESS: I participate in that analysis,  
14 yes. I understand all the moving parts.

15 JUDGE CHAPPELL: Go ahead.

16 THE WITNESS: All right. So basically to do  
17 this analysis to -- to inform you of whether or not you  
18 want to do the deal at the end of the day, can I make  
19 enough money off of this. And secondly, relatedly,  
20 what -- what sort of milestones and so forth should I be  
21 paying to make this, you know, a -- you know, for --  
22 during my negotiations, because you definitely do not  
23 want to be overpaying.

24 BY MR. BUTRYMOWICZ:

25 Q. What is the output of a financial analysis in



1 your experience?

2 A. The output is so-called net present value or an  
3 NPV.

4 Q. And what is an NPV?

5 A. NPV is a financial tool that most businesses  
6 use, but the pharmaceutical industry relies on it very  
7 heavily. It looks at the cash flows discounted over  
8 time at a certain discount rate, a rate of return,  
9 versus the original investment that's put into it. So  
10 typically an NPV, if it's positive, that -- it means  
11 it's worthy of an investment.

12 Q. At a high level, what is the basis for your  
13 opinion that Endo's financial analysis of the IPX-203  
14 opportunity was not consistent with the usual practice  
15 in the industry?

16 A. Well, for one thing, they -- to go back to the  
17 NPV, there should be another initial put in front of the  
18 NPV, and it's an "r," a little "r," that means  
19 risk-adjusted NPV. An NPV, without taking into  
20 consideration the risk of failure in development, is  
21 really a number that doesn't have a lot of power, a lot  
22 of worth to it.

23 So in my review of the information provided to  
24 me, I did not see that Endo took risk at all into  
25 consideration, which is very important, especially for

1 an early-stage asset, and especially, too, for this  
2 particular molecule because it's going to face terrific  
3 competition if it ever did get to the market, so that,  
4 perforce, more risk is attached to it.

5           The second area of -- where I found that they  
6 were remiss in their financial analysis is the  
7 assumptions that they used to put into their model.

8       Q. Let's take those one at a time. Let me first  
9 ask about your opinion that the financial analysis did  
10 not adequately take into account the risks of IPX-203.  
11 How do financial evaluations typically account for risk  
12 and uncertainty?

13      A. Well, at every stage of development, there is  
14 a -- every year -- well, there's a sort of  
15 industry-accepted success rate for -- going from  
16 preclinical to Phase I, Phase I to Phase II, Phase II to  
17 Phase III, Phase III to the NDA, NDA to approval.  
18 There's risk, so those events don't always happen.

19           And so there are statistics, usually on an  
20 annual basis, and people rely on those factors to come  
21 up with an overall risk for the particular project.  
22 They -- you don't just generally rely on the particular  
23 published, say, risk of going from Phase II to Phase  
24 III. You look at and analyze the particular asset, see  
25 what endpoint it's going to have to meet, and judge

1 whether or not it has a higher or lower probability of  
2 success versus what is quoted in the industry.

3           And everybody relies on those industry numbers,  
4 and those are basically multiplied by the cash flow, so  
5 if it has a risk -- a probability of success of 70  
6 percent, you take the cash flow at that particular  
7 point -- and early in the process, it's a negative  
8 number -- so you multiply that by 0.7 to say that that's  
9 the money that is...

10       Q. Is it standard practice to include a risk  
11 adjustment in a financial analysis of a pharmaceutical  
12 development agreement?

13       A. Yes.

14       Q. Did Endo take any steps to account for the risks  
15 of IPX-203 in its financial analysis?

16       A. Not that -- not that I could see in the  
17 documents.

18       Q. Was this failure to account for the risks of  
19 IPX-203 consistent with industry standards?

20       A. Well, no. Everybody does do an rNPV eventually.

21       Q. What effect would this failure to account for  
22 the risks of IPX-203 have on the valuation?

23       A. You're flying blind.

24       Q. I'd like to ask you about the second opinion you  
25 mentioned, that many of the assumptions that Endo used

1 for its financial analysis of IPX-203 were improper.

2 And, again, we're still in a public session, so let me  
3 ask you first, generally, without getting into any  
4 specific assumptions that Endo used, what is your basis  
5 for the opinion that some of the assumptions were  
6 improper?

7 A. They were relying on work that was done for the  
8 predecessor molecule, so-called IPX-066. They had  
9 commissioned a market research firm to come up with  
10 basically a model, and so they relied on those numbers  
11 for that particular asset to come up with a valuation  
12 for the new asset, and I thought that was inappropriate.

13 Q. In your experience, where do pharmaceutical  
14 companies normally get the assumptions that they use in  
15 these financial analyses?

16 A. Doing -- there's a lot that goes into it, but  
17 the real driver is market research. They either do it  
18 themselves or they commission somebody to do it.

19 Q. I'd like to ask you in a little more detail --  
20 well, let me first ask, did Endo do any market research  
21 on IPX-203?

22 A. No.

23 Q. You mentioned that it was -- that it was unusual  
24 for Endo to use the assumptions that it had formulated  
25 for IPX-066 in its analysis of IPX-203. Can you explain

1 in a little more detail -- again, without getting into  
2 specifics about the chemical nature of IPX-203 -- why  
3 that was so unusual?

4       A. Well, a couple things. One is they were at  
5 vastly different stages of development, so the timelines  
6 and so forth were really skewed. A lot would happen in  
7 the marketplace between the time that IPX-066 was  
8 approved and on the market versus when IPX-203 would be  
9 on the market, so that -- that shift in the timeline  
10 would have a big effect on the quality of that market  
11 research.

12           And I don't know if we want to get into other  
13 details about --

14       Q. We will get into details --

15       A. Okay.

16       Q. -- but let's hold off for now.

17       A. Sure.

18           MR. BUTRYMOWICZ: Your Honor, at this point I  
19 would like to question Dr. Geltosky about areas that are  
20 subject to Your Honor's in camera order. I, therefore,  
21 request, Your Honor, a brief in camera session and to  
22 clear the courtroom.

23           JUDGE CHAPPELL: Okay. At this time, we are  
24 going to be discussing in camera information. Those of  
25 you not subject to the protective order in this case

1 need to leave the courtroom. The Bailiff will let you  
2 know when you may re-enter the courtroom.

3 MR. BUTRYMOWICZ: Thank you, Your Honor.

4 JUDGE CHAPPELL: I will need to -- I will need  
5 the attorneys at counsel table to look behind you and  
6 verify the people sitting behind you are subject to the  
7 protective order.

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

10 MS. FABISH: I'm sure -- I -- yes, Your Honor.

11 (Whereupon, the proceedings continued in  
12 in camera session.)

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

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(End of in camera session.)

1 (Public session.)

2 JUDGE CHAPPELL: Law Man, you can let the public  
3 know that we are going into public session, but we're  
4 breaking for lunch.

5 All right, I need the parties' assessment. Do  
6 we need to cut lunch shorter or does the full hour work  
7 for today? You can confer.

8 MR. HASSI: Your Honor, I think it's a close  
9 call whether we go past 5:30. I don't think from our  
10 collective estimates that we would go past 6:00 if we  
11 still took an hour lunch, but --

12 JUDGE CHAPPELL: All right, we will take 55  
13 minutes. We will reconvene at 3:00 p.m. We're in  
14 recess.

15 (Whereupon, at 2:05 p.m., a lunch recess was  
16 taken.)

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1 AFTERNOON SESSION

2 (3:05 p.m.)

3 JUDGE CHAPPELL: Okay, we are back on the  
4 record. Go ahead.

5 MS. FABISH: Thank you, Your Honor.

6 May I approach the witness to offer him a  
7 document binder?

8 JUDGE CHAPPELL: Go ahead.

9 MS. FABISH: Thank you.

10 BY MS. FABISH:

11 Q. Hello again, Dr. Geltosky.

12 A. Good afternoon.

13 Q. I have just handed you a binder of documents. I  
14 don't think we will need those for quite a while, but we  
15 will reference them later.

16 A. So I should hold them for now?

17 Q. You can set them to the side. Thank you.

18 I would like to start by clarifying what -- the  
19 scope of what it is you're opining on in this matter and  
20 confirm some of the opinions that you are not offering.

21 You do not have an opinion on whether Endo's  
22 profit-sharing rights under the DCA justified its  
23 payment obligations under the DCA, correct?

24 A. That's correct.

25 Q. So you don't have any opinion as to what the

1 market price for the profit-sharing rights that Endo  
2 acquired under the DCA would be, correct?

3 A. Correct. That was not part of my analysis.

4 Q. So you have no opinion?

5 A. Right.

6 Q. Okay. And earlier you criticized Endo's  
7 valuation analysis of the DCA and IPX-203 and the way it  
8 calculated a net present value, but you did not  
9 calculate a net present value for the DCA at the time it  
10 was executed, did you?

11 A. That is correct.

12 Q. What about a sensitivity analysis regarding the  
13 DCA?

14 A. I did not do that. I would know how to do it.  
15 I would actually be quite interested in doing one, but  
16 you need to have other information available to you to  
17 do it properly.

18 Q. In fact, you did not conduct any valuation  
19 analyses of the DCA at all. Is that correct?

20 A. In a strict sense, that's correct.

21 Q. So you don't have any opinion at all as to the  
22 actual value of the DCA to Endo at the time it was  
23 executed, correct?

24 A. That is correct.

25 Q. Okay. And you don't -- also don't have an

1 opinion on whether Endo should have entered into the  
2 DCA, correct?

3 A. That was not part of my assignment.

4 Q. So is that a no?

5 A. That is a no.

6 Q. Okay. And you don't have an opinion on whether  
7 Endo's decision to enter into the DCA reflects sound  
8 business judgment, do you?

9 A. That was not part of my assignment.

10 Q. So, I'm sorry, would you please just answer yes  
11 or no? Is that a no or a yes?

12 A. Well, I have my own opinions, but this was not  
13 part of the project that I undertook.

14 Q. So your opinions in this matter do not include  
15 an opinion as to whether or not Endo exercised sound  
16 business judgment in entering into the DCA.

17 A. That's not part of my opinion.

18 Q. Okay.

19 JUDGE CHAPPELL: So we're clear on the record,  
20 are you asking the witness if he has an opinion or  
21 formed an opinion or if he has an opinion that was  
22 included in his expert report in this case?

23 MS. FABISH: I'm asking him to confirm whether  
24 he's offering an opinion in this case on these topics.

25 JUDGE CHAPPELL: Do you understand that, sir?

1 THE WITNESS: Yes. I think it's obvious in my  
2 report that I did not offer an opinion.

3 BY MS. FABISH:

4 Q. Okay. So based on that --

5 JUDGE CHAPPELL: But the -- she has the right to  
6 question you about your opinion. That's what she's  
7 doing.

8 THE WITNESS: I'm sorry?

9 JUDGE CHAPPELL: She has the right to question  
10 you about your opinion.

11 THE WITNESS: Okay.

12 JUDGE CHAPPELL: And when she says did you  
13 express an opinion, it doesn't mean you did anything  
14 wrong. She's just looking for a yes or a no.

15 THE WITNESS: Well, no.

16 BY MS. FABISH:

17 Q. Thank you.

18 So based on that clarification, would you like  
19 to clarify any of your previous answers?

20 A. That is correct.

21 Q. Okay. And you also do not offer an opinion in  
22 this case as to -- about the termination of the DCA. Is  
23 that correct?

24 A. That's correct.

25 Q. And you have no opinion on whether the DCA was a

1 bona fide scientific collaboration. Is that correct?

2 A. Correct.

3 Q. And you don't have an opinion on whether Endo  
4 exercised good business judgment in its due diligence of  
5 the DCA. Is that correct?

6 A. That is correct.

7 JUDGE CHAPPELL: You need to be careful how  
8 you're phrasing that. The man said he's got 37 years'  
9 experience. He might have an opinion. The way you've  
10 phrased that, he could say, "Hell, yeah, I've got an  
11 opinion and here it is." So just be careful what you're  
12 asking the expert.

13 MS. FABISH: Okay. Thank you for that  
14 clarification. I'll rephrase.

15 BY MS. FABISH:

16 Q. Are you offering an opinion in this matter as to  
17 whether Endo exercised good business judgment in its due  
18 diligence under the DCA?

19 A. No.

20 Q. Okay, thank you.

21 I'd like to talk for a little bit about the  
22 basis for your opinions that you do offer in this  
23 matter, and you testified earlier that you base your  
24 opinions primarily on your experience in the industry.  
25 Is that correct?

1 A. Correct.

2 Q. Okay. You've never worked at Endo, right?

3 A. That is correct.

4 Q. You've also never worked at Impax?

5 A. Correct.

6 Q. And you've never done any consulting work  
7 regarding the DCA prior to your work as an expert on  
8 this matter?

9 A. That's correct.

10 Q. And all the information that you have about the  
11 DCA was gleaned from your review of documents and  
12 testimony in this matter. Is that correct?

13 A. Excuse me. Correct.

14 Q. Okay. Have you ever met any of the individuals  
15 whose testimony you read?

16 A. No.

17 Q. Okay. Have you ever met any of the individuals  
18 whose emails you reviewed?

19 A. Never met them.

20 Q. Okay. Do you rely on any treatise or secondary  
21 sources in forming your opinion in this matter?

22 A. No.

23 Q. Does your expert report contain a complete list  
24 of the documents and testimony that you considered in  
25 reaching your opinions?



1 A. Yes.

2 Q. Okay. And as well as a complete statement of  
3 the bases for those opinions?

4 A. Yes.

5 Q. And it appears that the vast majority of the  
6 materials listed in your report -- if you would like to  
7 refer to it, you may, but you don't need to, it's tab 1  
8 in the binder that I've provided you -- the materials  
9 listed in Exhibit B as having been considered, by my  
10 count, only 14 of the 198 materials listed there are not  
11 Endo or Impax business documents. Does that sound about  
12 right to you?

13 A. I'm not sure what you're referring to right now.

14 Q. Okay. If you take a look at Exhibit B to your  
15 report, there's a list of materials --

16 A. In my -- wait a minute, in my -- not in this  
17 notebook?

18 Q. Exhibit B to your expert report, which is tab 1  
19 in the notebook that I've provided you.

20 A. Okay, tab 1 has my expert report, yes. Wait a  
21 minute, this is not the expert report. Yes, it is.  
22 Sorry.

23 Q. And your Exhibit F begins on page CX 5003-60.  
24 It's entitled "List of Materials Considered." Let me  
25 know when you get there.

1           And so looking at this list of -- of the  
2 materials that you considered, it seems to me that the  
3 vast majority, all but about 14 of them, are Endo or  
4 Impax business documents. Is that correct?

5           A. Yes.

6           Q. And the remaining 14 -- and I'm looking  
7 specifically, to help you answer this question, at the  
8 section entitled "Public Documents," right around page  
9 5003-65 -- are SEC filings or websites and a few things  
10 it looks like you pulled off the Internet. Is that  
11 correct?

12           JUDGE CHAPPELL: Wait until he's on the page.  
13 You changed pages, didn't you?

14           MS. FABISH: Of course. Thank you.

15           BY MS. FABISH:

16           Q. Page -065.

17           A. Yes, I am on that page. What's your question,  
18 please?

19           Q. So beyond the Impax and Endo business documents,  
20 it looks like you relied upon a few SEC filings,  
21 websites, and a few things that you pulled off the  
22 Internet. Is that correct?

23           A. That is correct.

24           Q. Thank you.

25           So in forming your opinions in this matter, it

1 looks like you compared the business documents provided  
2 to you by counsel against your experience in the  
3 industry. Is that fair to say?

4 A. Yes.

5 Q. Okay. Now, I think it's implied from your  
6 testimony a moment ago, but just to be clear, you did  
7 not perform any empirical analyses, such as valuation  
8 analyses, net present value calculations, things like  
9 that, in reaching your opinions that you offer in this  
10 matter, correct?

11 A. Well, I was able to look at the sheets provided  
12 in the OEW and based that on my conclusion. I actually  
13 started to do an NPV calculation, but if you look at  
14 that OEW, it basically doesn't have enough information  
15 there to properly perform one.

16 Also, so I could do that -- you know, actually,  
17 I can't do it, because it ends. The dates -- they refer  
18 to, I think, 2031 or something like that, but the --  
19 which they used to calculate their NPV, but they don't  
20 have data to support those outyears.

21 The other thing, why I decided I -- I should not  
22 even bother in calculating the NPV is I didn't trust the  
23 revenue lines at all. There is no market research, no  
24 sensitivity analyses. These are just random numbers as  
25 far as I was concerned. So I just didn't feel that it

1 was worth my time.

2 Q. So just to make sure the record's clear, you did  
3 not perform any empirical analyses, correct?

4 A. No. I used common sense, just looking at it,  
5 and came up with my conclusion.

6 Q. Thank you.

7 So you've read some documents and testimony by  
8 people you have never met, and you are telling us what  
9 you think about them based on your experience in the  
10 industry, right?

11 A. No. I'm not saying what -- your question,  
12 again, is what I think about those people --

13 Q. No.

14 A. -- without having met them?

15 Q. No, I'm sorry.

16 JUDGE CHAPPELL: Wait, wait, wait. Let him  
17 finish, and let her finish.

18 THE WITNESS: So as I understood your question,  
19 you're asking me, I formed an opinion on these people  
20 based on -- whom I've never met? I haven't formed any  
21 opinion on these people.

22 BY MS. FABISH:

23 Q. You're right. My question was unclear. I'll be  
24 happy to rephrase.

25 You've read documents drafted by people that

1 you've never met and you are telling us what you think  
2 about those documents based on your experience in the  
3 industry. Is that correct?

4 A. That's correct.

5 Q. Okay.

6 JUDGE CHAPPELL: That's better. The question  
7 you worded before, you said "what you think of them,"  
8 and it could have referred to the documents or the  
9 testimony of the people.

10 MS. FABISH: Indeed. No, I understand now.  
11 Thank you for clarifying.

12 BY MS. FABISH:

13 Q. I'd like to talk a little bit now -- switch  
14 gears and talk about risk, something that you discussed  
15 quite a bit with Complaint Counsel earlier today.

16 Do you agree that all pharmaceutical development  
17 has an inherent element of risk?

18 A. Yes.

19 Q. And that's true at all stages of development,  
20 just to varying degrees, correct?

21 A. That's correct.

22 Q. Okay. And earlier today you testified that  
23 co-promotion agreements involved risk and profit-sharing  
24 elements. Is that correct?

25 A. Well, they involve risk and, yes, there is a

1 profit-sharing component to the agreements, yes.

2 Q. And the DCA was a way for Impax and Endo to  
3 share the risks and costs associated with developing  
4 IPX-203, right?

5 A. Correct.

6 Q. Okay. Now, under the DCA, Endo did not agree to  
7 take on all of the development costs for 203. Is that  
8 right?

9 A. That's correct, yeah.

10 Q. Okay. And in terms of how much Endo was  
11 obligated to support the cost of 203 development under  
12 the DCA, that amount would be capped at the total amount  
13 of milestone payments listed in the agreement. Is that  
14 correct?

15 A. That's correct.

16 Q. Okay. But Impax remained responsible for  
17 performing all of the development work, right?

18 A. That's correct.

19 Q. Okay. So if Impax's development costs exceeded  
20 the amount that Endo contributed under the DCA, Impax  
21 would be responsible for covering all of those costs,  
22 correct?

23 A. Presumably. That was not articulated in the  
24 DCA. Sometimes agreements of that sort would have  
25 language that -- and this -- there's actually a real

1 peculiarity to this agreement. Most of these agreements  
2 are budget-based. There's no budget. They don't share  
3 a budget. Most agreements, we're going to fund --  
4 Company A will say I'll fund this much, Company B will  
5 say they'll fund that much, and they agree to that  
6 budget. This is a very unique way of paying -- for Endo  
7 to be paying their portion of the development. So it's  
8 left hanging, what happens if expenses get more than  
9 whatever.

10 Q. But to the extent that Impax's development costs  
11 exceeded the amount Endo contributed under the DCA, Endo  
12 would not have any responsibility for those additional  
13 costs.

14 A. Not as the contract is worded, as-is, yes.

15 Q. So just by way of illustration, if Impax  
16 succeeded in completing Phase II clinical trials with  
17 IPX-203, but development was unsuccessful beyond that,  
18 Endo would only pay Impax a total of 20 million,  
19 including the up-front payment, regardless of how much  
20 it cost Impax to reach that milestone. Is that right?

21 A. That's right. That is a very ambiguous  
22 statement in --

23 JUDGE CHAPPELL: Hold on there, sir. I let you  
24 ramble on in the last answer, where you said  
25 "Presumably," and then you went on for, like, 20 lines

1 after that. It seems like you are going to say the same  
2 thing here. So I don't want to be here until midnight.  
3 So please listen to the question, and when you've  
4 answered it, that's enough. "That's right," that's your  
5 answer. You didn't need to go further.

6 THE WITNESS: Could you rephrase -- restate your  
7 question, please?

8 BY MS. FABISH:

9 Q. Just by way of illustration, if Impax succeeded  
10 in completing Phase II clinical trials of IPX-203, the  
11 development was unsuccessful beyond that, Endo would  
12 only pay Impax a total of 20 million, including the  
13 up-front payment, regardless of how much it cost Impax  
14 to reach that milestone, correct?

15 A. That is correct. Sorry for misunderstanding  
16 your question.

17 Q. Thank you.

18 And just by way of illustration, again, if Impax  
19 were able to successfully bring 203 to market but it  
20 cost Impax \$100 million to get there, Endo's  
21 contribution would be limited to a maximum of 40 million  
22 of that -- maximum of 40 million of that cost, correct?

23 A. Correct.

24 Q. Okay. And regardless of the cost of development  
25 to Impax, Endo retains the same profit-sharing rights.



1 Is that right?

2 A. Yes.

3 Q. Do you recall what Impax estimated its costs to  
4 be of developing IPX-203?

5 A. There was a statement that I saw of roughly --  
6 between 80 and 100 million dollars.

7 Q. And --

8 A. That's only an estimate, though.

9 Q. Thank you.

10 And, Dr. Geltosky, you don't have an opinion  
11 on -- you don't offer an opinion in this case as to  
12 whether these risk- and profit-sharing provisions under  
13 the DCA favor Impax or Endo, do you?

14 A. That's correct.

15 Q. Okay. I'd like to shift gears a little bit now  
16 and speak to you about your opinions regarding the \$10  
17 million up-front payment portion of the DCA. In your  
18 report and prior testimony, you offered the opinion that  
19 the \$10 million milestone payment was unusually large  
20 for a development-stage drug product at the stage that  
21 203 was in.

22 To clarify, by "unusually large," you mean  
23 different than what you would expect based on your  
24 experience in the pharmaceutical industry, correct?

25 A. Correct.

1 Q. Okay. And I'm referring here specifically to  
2 the language that was in your report. You say  
3 "unusually large for a development-stage drug." I  
4 believe you've already clarified this in your earlier  
5 testimony, but just to make sure, you're referring there  
6 specifically to the fact that IPX-203 was in nonlead  
7 discovery stage, that no lead drug had yet been  
8 identified. Is that right?

9 A. That's right.

10 Q. Okay. And in reaching your conclusion that the  
11 \$10 million payment was different than what you would  
12 expect based on your experience in the pharmaceutical  
13 industry, did you review any pharmaceutical agreements  
14 besides the DCA?

15 A. Just relying on my experience and reading of --  
16 you know, constant reading of the literature, what deals  
17 go for.

18 Q. So is that a yes or a no?

19 A. Pardon me?

20 Q. Is that a yes or a no? Did you review other --  
21 other deals besides --

22 A. On an ongoing basis, I'm -- yes. So I did  
23 review other things on an ongoing basis which informed  
24 my opinion on this, my years of reading, every day, IO  
25 World, Fierce, et cetera.

1 JUDGE CHAPPELL: The question, sir, was any  
2 pharmaceutical agreements besides the DCA.

3 THE WITNESS: Just my recollections of the  
4 agreements that I was involved in.

5 BY MS. FABISH:

6 Q. Okay. But you did not actually review any  
7 agreements in the process of forming these opinions.

8 A. No.

9 Q. Thank you.

10 So I take it, then, you also did not compare the  
11 payment terms in any other agreements to the ones that  
12 are in the DCA, correct?

13 A. Correct.

14 Q. And, in fact, you don't consider such a  
15 comparative analysis to be necessary to reach your  
16 opinions on what is typical in a pharmaceutical  
17 collaboration agreement, correct?

18 A. I'm sorry? State it again.

19 Q. You don't consider such a comparative analysis  
20 between the DCA and other pharmaceutical agreements to  
21 be necessary to reach your opinions on what is typical  
22 in a pharmaceutical collaboration agreement, correct?

23 A. No. Again, I'm relying on my memory and  
24 knowledge of the agreements I was involved in, and I  
25 compare and contrast.

1 Q. And when we met last month and I deposed you, I  
2 believe you described reviewing such additional  
3 agreements and comparing them to the DCA as something  
4 that would have been a waste of your time in reaching  
5 your opinions in this matter. Is that correct?

6 A. I don't recall saying that.

7 Q. Would you like to review your transcript to  
8 determine is that -- well, strike that. I'll back up.

9 Do you agree with that statement now? Do you  
10 believe it would be a waste of your time to do that in  
11 reaching your opinions in this matter?

12 A. Yes. I'll stand by it.

13 Q. Now, when you were speaking earlier today with  
14 Complaint Counsel, you were discussing the different  
15 roles that you've played in your experience in various  
16 organizations and companies, and it sounds like the bulk  
17 of your experience assessing a pharmaceutical product or  
18 product candidate for potential investment comes from  
19 your time at Bristol-Myers Squibb and SmithKline  
20 Beecham. Is that correct?

21 A. The majority, yes.

22 Q. So you can't speak to whether the universe of  
23 companies smaller than big pharma companies like  
24 SmithKline Beecham and Bristol-Myers Squibb might take a  
25 different approach to assessing discovery-stage products

1 than do those larger companies.

2       A. No, because I've worked with smaller companies  
3 as a consultant, and I know what their processes are, I  
4 know what questions they ask, and they're just the same  
5 types of questions that, again, midsize pharma would ask  
6 and how they would go about their evaluation. So that  
7 is based on real, live experience as a consultant.

8           JUDGE CHAPPELL: Hold on a sec. Are you saying  
9 you've negotiated agreements like the one in this case?

10          THE WITNESS: Not exactly like this one, no.

11          JUDGE CHAPPELL: All right.

12          Go ahead.

13          BY MS. FABISH:

14       Q. Is that what you told me when I asked you a  
15 similar question at your deposition last month, do you  
16 recall?

17       A. You'll have to ask that question.

18       Q. Sure. If you could take a look at tab 2 in your  
19 binder, which is a copy of the transcript of your  
20 deposition, and I would direct you to page 167 of that  
21 deposition. You'll need to look at the little page  
22 numbers. You'll see there's four pages to a page. I'm  
23 referring to the...

24       A. Yes.

25       Q. And beginning on line 1:

1           "QUESTION: Might a company that is smaller than  
2 Glaxo, than SmithKline Beecham or Bristol-Myers Squibb,  
3 take a different approach to considering discovery-stage  
4 products?"

5           Then Mr. Butrymowicz objected.

6           "ANSWER: Yeah, I can't speak to the whole  
7 universe of those companies."

8           Do you see that?

9       A. Yes.

10       Q. Based on reviewing your prior testimony, as you  
11 sit here today, is it true that you cannot speak to  
12 whether the universe of companies smaller than big  
13 pharma companies like SmithKline Beecham or  
14 Bristol-Myers Squibb might take a different approach to  
15 assessing discovery-stage products than do those larger  
16 companies?

17       A. The universe is pretty large, so I can't  
18 possibly know everything in the universe of companies.

19       Q. So that's a yes?

20       A. And your question is?

21       Q. Saying it's -- is it true that you cannot speak  
22 to that universe of smaller companies?

23       A. Yes.

24       Q. Okay. Now, you testified earlier today as well  
25 that during your work at Arizona State, you did quite a

1 bit of work on early-stage development assets, and  
2 you've previously testified that you've only actually  
3 worked on one deal in which the potential subject  
4 product may not have had a lead drug identified. Is  
5 that correct?

6 A. At Arizona State?

7 Q. Just generally.

8 A. I'm sorry, say your question again, please.

9 Q. I'll just back up and rephrase. I think perhaps  
10 I can ask a better question.

11 You've only worked on one deal in your career in  
12 which the potential subject product may not have had a  
13 lead drug identified, correct?

14 A. There were probably more than one.

15 Q. Can you recall more than one as you sit here  
16 today?

17 A. I can't remember exact numbers, but there were a  
18 handful, a few.

19 Q. Do you recall what you told me during your  
20 deposition last month regarding your prior experience?

21 A. Yes, yes, um-hum.

22 Q. What do you recall about that?

23 A. I limited it, I believe, to one or -- yeah.

24 Q. But today you're saying you recall a handful?

25 A. A few more, right.

1 Q. A few more.

2 A. Right, yeah.

3 Q. Do you recall whether you calculated a net  
4 present value for the product involved in that one or  
5 potentially few deals involving a nonlead drug asset?

6 A. No.

7 Q. And in reaching your opinions that you offer in  
8 this matter, did you look into whether Endo has either  
9 invested in or collaborated on discovery-stage  
10 pharmaceutical products in the past?

11 A. I believe they -- I believe they have had a  
12 couple relationships with very early-stage technologies.  
13 I can't think of the concrete numbers, but I seem to  
14 recall, in reading the materials, that they had.

15 Q. Did you review any information as to how Endo  
16 structured such deals?

17 A. I seem to recall that the payments were quite a  
18 bit less, but this -- this is -- a lot -- I've reviewed  
19 a lot of information, so I'm a little bit uncertain.  
20 But that's my best recollection, that they were paying  
21 much smaller dollars.

22 Q. So sitting here today, what can you tell me  
23 about the information you recall about this  
24 discovery-stage product -- these discovery-stage  
25 products that Endo considered investing in?



1       A. They were -- there were only a few of them, and  
2 I believe they were roughly, you know, as early stage as  
3 this, maybe even earlier -- well, not earlier than this,  
4 nothing's earlier than this. And I believe the payments  
5 were actually pretty small, but I don't -- I don't have  
6 a great recollection.

7       Q. And you couldn't point me to where in the  
8 materials you reviewed you saw this information?

9       A. No.

10      Q. And you couldn't point me to a portion of your  
11 report that provides that information either?

12      A. That's correct.

13      Q. Is it your opinion that collaborations regarding  
14 discovery-stage pharmaceutical candidates are generally  
15 too risky for companies to enter into in any form?

16      A. No. People do it all the time.

17      Q. Okay. I'd like to shift gears again and focus  
18 again on the payment amount. Part of the basis for your  
19 opinion, you described earlier that the \$10 million  
20 payment was unusually large for a deal of that stage --  
21 a deal regarding an asset at that stage, was the amount  
22 of risk that you saw in the deal given IPX-203's stage  
23 of development. Is that correct?

24      A. That's correct.

25      Q. And we previously established that the lack of a

1 lead drug was the primary source of the risk that you  
2 saw, correct?

3 A. Yes, and I have had more time to think on that  
4 topic.

5 Q. I'm sorry? I didn't hear you.

6 A. I have had more time to think on that topic of  
7 risk related to 203, and I still keep my same  
8 conclusion, that it's a very risky project.

9 Q. Thank you.

10 But you haven't attempted to quantify that risk.  
11 Is that right?

12 A. I haven't -- no, I haven't tried to quantify it,  
13 no.

14 Q. You also didn't perform any actual calculations  
15 to determine what payment amount would, in your view,  
16 account for the risk that you perceived in the DCA,  
17 correct?

18 A. That's correct.

19 Q. And you discussed earlier today your criticisms  
20 of Endo's due diligence efforts in part because you felt  
21 that Endo did not adequately account for risk, but you  
22 agree there are different approaches to calculating a  
23 risk-adjusted value of a potential asset in a  
24 pharmaceutical collaboration, correct?

25 A. There are -- the benchmark is the -- is the

1 calculation of the -- of the rNPV, which is very  
2 straightforward.

3 Q. Are there -- do you agree that there are  
4 different ways to assess risk?

5 A. Yeah, there are a couple different ways. The --  
6 one of the ways that people do it, which is erroneous,  
7 is they don't -- what -- what needs to be done is to  
8 calculate the technical risk at each stage of  
9 development. Some people account for that by just  
10 fooling around with the discount rate, increasing it or  
11 decreasing the discount rate. If you know anything  
12 about this field, you can go onto the Internet, that's  
13 not a correct way of doing it. It doesn't properly  
14 account for all the technical risk.

15 There's another way that people calculate NPV  
16 using a so-called Monte Carlo analysis, which is very  
17 complex and most people don't use it.

18 Q. So if I can just remind you to please keep in  
19 mind His Honor's instruction to answer yes or no  
20 questions with just yes or no so we can move our  
21 examination along.

22 A. Well, I think that yes and no needs to be  
23 qualified sometimes.

24 Q. Okay. Do you agree there are different  
25 approaches to calculating a risk-adjusted net present

1 value?

2 A. Yes, as I just described.

3 Q. And do you agree there are different approaches  
4 to calculating a risk-adjusted internal rate of return?

5 A. Yes.

6 Q. Do you hold any degrees in accounting?

7 A. No.

8 Q. Any degrees in finance?

9 A. No.

10 Q. Any degrees in business?

11 A. Not a -- no, not a formal degree.

12 Q. In reviewing the materials -- strike that.

13 In forming your opinions that you offer in this  
14 matter, did you see any evidence suggesting that Endo  
15 asked for information from Impax during diligence and  
16 Impax refused to provide it?

17 A. No. Excuse me, no.

18 Q. Turning back to the payment size, you've  
19 testified that -- strike that.

20 You do not view anticipated R&D costs of a  
21 subject product as relevant to determining the  
22 appropriate payment amount in a pharmaceutical  
23 collaboration, correct?

24 A. Sorry, say that -- state it again.

25 Q. You do not view anticipated R&D costs of a

1 subject drug product as relevant to determining the  
2 appropriate payment amount in a pharmaceutical  
3 collaboration. Is that correct?

4 A. No, no.

5 Q. Okay. But in your report and in your prior  
6 testimony, you've offered no other metric for assessing  
7 the payment size under the DCA, other than comparing it  
8 generally with your experience in the industry. Is that  
9 correct?

10 A. That's correct.

11 Q. I'd like to talk a little bit about IPX -- the  
12 IPX-066 information that Endo reviewed in connection  
13 with its due diligence. You criticized the way that  
14 Endo worked with information about 066 in assessing  
15 IPX-203. I think that's fair to say, right?

16 A. Yes.

17 Q. But commercial market information about 066  
18 would be relevant in assessing 203, would it not?

19 A. Only in part.

20 Q. Okay. Commercial market information about 066  
21 would, in fact, address some of the key variables of  
22 performance for 203, would it not?

23 A. No.

24 Q. It would not?

25 A. No, because 203 is going to behave differently

1 from 066, so...

2 Q. When I deposed you in September, sir, do you  
3 recall me asking you a similar question?

4 A. No, I don't.

5 Q. Would you mind turning to tab 2 again, which is  
6 a copy of your deposition transcript, specifically the  
7 mini page 135. Let me know when you're there.

8 A. Okay. I'm there, yep.

9 Q. Looking at line 7.

10 A. Page 135, line 7? "With many degrees -- do you  
11 have many degrees" --

12 Q. I apologize. Hold on. My numbering is off  
13 here.

14 You know, I apologize, I have an incorrect cite,  
15 so we will just come back to that later.

16 My apologies for the delay. We may just need to  
17 come back to that later, so you can strike that question  
18 for now.

19 The disease -- so turning back, the information  
20 about IPX-066, the disease parameters and background of  
21 IPX-066 would be relevant in assessing 203, would they  
22 not?

23 A. That's true.

24 Q. Okay. And IPX-066 and IPX-203 were likely to  
25 follow a similar clinical development program. Is that

1 correct?

2 A. Yes.

3 Q. So information about the 066 clinical  
4 development program would also be relevant to assessing  
5 203, correct?

6 A. Not -- not really.

7 Q. So even though the two drugs were going to  
8 follow a similar clinical development program, you don't  
9 view information about the 066 clinical development  
10 program as relevant to assessing 203.

11 A. Right. The data that comes out of the 066  
12 clinical trial has no bearing at all on the data that  
13 would come out of the 203 clinical trial. Different  
14 drugs. Different responses in patients.

15 Q. Okay. I would like to turn back to my question  
16 from before when I had a technical difficulty, and I  
17 would like to ask you again whether -- I asked you  
18 whether commercial market information about IPX-066  
19 would be relevant to -- would address some of the key  
20 variables of performance for 203, and I'd like to refer  
21 you to page 133 of your deposition, which is located --

22 MR. BUTRYMOWICZ: Your Honor, I would object. I  
23 don't think that's the question that he was asked  
24 earlier.

25 MS. FABISH: I'm happy to read it back. I

1 didn't intentionally change the question. So maybe I  
2 will just ask a new question, and we'll start all over,  
3 to simplify things.

4 BY MS. FABISH:

5 Q. Dr. Geltosky, do you view commercial market  
6 information about 066 as addressing some of the key  
7 variables of performance for 203?

8 A. Well, in the sense of the uphill burden, et  
9 cetera, yes. So those are the -- they identify the  
10 parameters.

11 Q. Okay, thank you.

12 A. Yep.

13 Q. And you would acknowledge that Impax viewed  
14 IPX-203 as a potential franchise extender for the 066  
15 franchise, correct?

16 A. Correct.

17 Q. And Endo understood that it was intended as a  
18 line extension of 066 as well, correct?

19 A. I don't recall those words, but I think yes  
20 would be the answer.

21 Q. What do you understand a line extension to be  
22 referring to?

23 A. It would be basically a product in the same  
24 category that one would use because it had maybe patent  
25 protection, whereas the original didn't have any more



1 patent protection, or it had some superior performance  
2 to the original and it basically just kept the franchise  
3 going.

4 Q. And by "kept the franchise going," what do you  
5 mean?

6 A. Well, that they would still play a role in the  
7 treatment of Parkinson's disease; that they would have,  
8 you know, maybe more than one drug to be able to offer  
9 physicians.

10 Q. And so given that 203 was going to be a  
11 franchise extender for 066, in modeling how IPX-203  
12 might perform in the market, Impax and Endo would have  
13 used 066 as kind of a benchmark to try and improve upon.  
14 Is that correct?

15 A. Ah, yes.

16 Q. And, Dr. Geltosky, even assuming that the  
17 subject of the DCA negotiations changed in the way that  
18 you described in your testimony earlier today, from 066  
19 to 203, would at least some of the information about  
20 IPX-066 still be relevant for assessing IPX-203 in the  
21 ways we just discussed?

22 A. As it turns out, not really, because the  
23 performance -- you have to wait to see -- they -- there  
24 was not enough clinical data in my view at the time for  
25 Endo to have any degree of confidence that they -- that

1 203 would be able to be superior to it.

2 Q. So I want to make sure that I am making my  
3 question clear. So I asked you a series of questions  
4 just a moment ago about whether or not certain aspects  
5 of information about 066 would be relevant to assessing  
6 IPX-203, and in a few instances, at least, you agreed  
7 with me that, yes, that information would be relevant.  
8 Do you recall that?

9 A. Yes.

10 Q. And I am asking you now, even if at one point  
11 the parties were focused on 066 and then they changed to  
12 focusing on 203, even if that is true, would that  
13 information about 066 that we just discussed remain  
14 relevant to an assessment of 203?

15 A. Well, it would set a baseline, yeah, but I don't  
16 think there were enough data available to, you know,  
17 hang your hat on at that point. You need to do a Phase  
18 III, which they hadn't done yet.

19 Q. So is that a yes?

20 A. A partial yes.

21 Q. Okay, thank you.

22 And speaking more generally for a moment, in  
23 conducting due diligence on a candidate drug, it's  
24 useful to consider information about drugs with which  
25 the candidate would compete, correct?

1 A. Yes.

2 Q. Okay. And that's true for both potential  
3 competitors who might already be on the market as well  
4 as any potential competitors that you understand are in  
5 the pipeline of other companies, correct?

6 A. That's correct.

7 Q. And the kinds of information about those  
8 potential competitors that you might look at would  
9 include safety and efficacy information, correct?

10 A. Correct.

11 Q. Now, the IPX-203 product covered by the DCA  
12 would potentially compete with Impax's 066. Is that  
13 correct?

14 A. That's correct.

15 Q. Okay. And the information about 066 that Impax  
16 provided Endo included safety and efficacy data on 066,  
17 did it not?

18 A. It had -- yes, it had partial data sets, I would  
19 call it.

20 Q. Okay. Do you recall that Impax provided Endo  
21 access to a data room of information about IPX-066?

22 A. Yes.

23 Q. And you viewed that data room of information as  
24 pretty comprehensive, correct?

25 A. Yeah. The headline topics were correct, yeah.

1 Q. So, for example, that data room included -- we  
2 already established -- clinical information including  
3 safety and efficacy data, correct?

4 A. Correct.

5 Q. And information on the IP landscape?

6 A. I'm sorry? Say that again.

7 Q. Excuse me. Information on the IP landscape?

8 A. I don't recall that. It was a big list of -- of  
9 file folders to review. I don't recall that  
10 specifically.

11 Q. I'd like to turn to tab 5 of your binder.  
12 Perhaps I can help you. Turning -- this is RX 272, and  
13 turning to page RX 272.0005 --

14 A. Yes.

15 Q. -- do you see a portion entitled "Legal Folder"?  
16 Based on reviewing this document, do you recall whether  
17 the data room that Impax provided Endo access to  
18 included information about IP landscape?

19 A. There are two documents in there that would fall  
20 in that category.

21 Q. How about information on technical due  
22 diligence, did the data room include that type of  
23 information?

24 A. Yes.

25 Q. And information on financial analysis, did it

1 include that information?

2 A. Financial? Yes.

3 Q. All right, thank you. You can set that aside.

4 So I'd like to talk a little bit about your  
5 opinions regarding Endo specifically. You testified  
6 earlier that you've never worked or consulted for Endo,  
7 right?

8 A. That's correct.

9 Q. And, in fact, you do not have any information  
10 about Endo's business practices that you didn't glean  
11 from documents you received from counsel in this matter,  
12 correct?

13 A. I believe, as I testified during my deposition,  
14 I was aware of their shift in focus, which was going  
15 over to so-called men's health.

16 Q. And what was that -- that knowledge based on?

17 A. As I testified prior, I don't really recall. I  
18 mean, I live in a community that contains Endo. It  
19 could have been in the Philadelphia Inquirer, could have  
20 been places like that.

21 Q. Any other sources of information?

22 A. No.

23 Q. Okay. Yet you do offer an opinion as to whether  
24 Endo's diligence on the DCA was consistent with Endo's  
25 business development practices, correct?

1 A. Yes.

2 Q. Okay. And your understanding of Endo's process  
3 for diligence in deals comes from a review of Endo's  
4 documents describing that process, correct?

5 A. Correct.

6 Q. And, in fact, it's -- it's really just one  
7 document, isn't it?

8 A. There were a number of slides in that slide deck  
9 that I believe referred to -- it had -- they were -- I  
10 recall two what I would call process maps.

11 Q. Okay. But those were all slides in a single  
12 slide deck, correct?

13 A. That's correct.

14 Q. Okay. So to form your opinion that Endo did not  
15 follow its business development procedures, you  
16 basically read one Endo document from a group of Endo  
17 documents provided to you by Complaint Counsel and  
18 concluded that what was described in that document is  
19 different than what you understood Endo did with the  
20 DCA. Is that right?

21 A. That's correct.

22 Q. Okay. And you also offer an opinion that 203  
23 does not fit within Endo's strategic area of focus. Is  
24 that right?

25 A. That's correct.

1 Q. Okay. And you base that conclusion solely --  
2 you base that conclusion also solely on a review of  
3 certain Endo documents provided to you by counsel. Is  
4 that right?

5 A. That's correct.

6 Q. Okay. And specifically I believe you stated you  
7 base that conclusion on -- on two things. First, the  
8 fact that the words "Parkinson's disease" were absent  
9 from a set of slides or disease areas of interest. Is  
10 that one reason?

11 A. Yes.

12 Q. Okay. And I believe the other reason was that  
13 you saw a handful of Endo corporate documents that state  
14 that Endo was interested in near-term revenue  
15 generators, correct?

16 A. That's correct.

17 Q. Nothing else informed your opinion that 203 was  
18 not a strategic fit for Endo's business?

19 A. That's correct.

20 Q. Okay. And in reaching that opinion, you didn't  
21 consider any other deals completed by Endo. Is that  
22 right?

23 A. That's correct.

24 Q. Did you consider any deals Endo contemplated but  
25 didn't complete?

1 A. No.

2 Q. If you would turn to tab 9 of your binder,  
3 please. This is a document listed in your materials  
4 relied upon, the Bates number EPI001448440. Oh, I'm  
5 sorry -- oh, yeah, this is correct.

6 This is CX 1209 that you were discussing earlier  
7 with Complaint Counsel, and you'll recall the vast  
8 majority of this document has been designated for in  
9 camera treatment, so I am going to ask you solely about  
10 the cover email portion.

11 A. Um-hum.

12 Q. And I would ask you to please take care to  
13 respond only with respect to those -- those questions --

14 A. Sure.

15 Q. -- since we are in open session.

16 This is a June 8th, 2010, email from Robert  
17 Cobuzzi, who was Endo's senior VP of corporate  
18 development at the time the DCA was executed, to the  
19 Endo board of directors, announcing that the DCA with  
20 Impax had been executed.

21 I'd like to draw your attention -- actually,  
22 could we -- could we put that up on the screen, please,  
23 just the cover email? It's Exhibit Number 1209.

24 I'd like to draw your attention to the second  
25 paragraph that begins with, "This is..."



1 A. Um-hum.

2 Q. It says, "This is an exciting opportunity for  
3 Endo as it further builds our product pipeline for the  
4 future with a drug candidate that fits with our  
5 commercial footprint."

6 Do you see that?

7 A. Yes.

8 Q. Based on this document, does it appear that  
9 Endo's senior VP of corporate development in 2010 viewed  
10 203 as a good strategic fit with Endo's commercial  
11 goals?

12 A. I mean, the use of the term "commercial  
13 footprint" is pretty vague.

14 Q. Is that a yes or a no?

15 A. Well, he doesn't really address strategy here.  
16 So I guess I would say no.

17 Q. You don't believe that the statement saying that  
18 this project fits with our commercial footprint  
19 indicates that he views 203 as a --

20 A. Well, he does, but, I mean, it's -- yes.

21 Q. Okay. All right, fine. Do you think you're  
22 more qualified to assess the fit of the DCA with Endo's  
23 strategic business goals as of 2010 than is the VP of  
24 Endo in 2010?

25 A. I'm sorry?

1 Q. Do you feel that you are more qualified to  
2 assess the strategic fit of the DCA with Endo's  
3 strategic business goals as of 2010 than was the VP of  
4 corporate development at Endo in 2010?

5 A. No.

6 Q. In preparing your report more generally -- you  
7 can set that aside. Thank you.

8 In preparing your report more generally, you  
9 considered -- did you consider various other opportunity  
10 evaluation worksheets for products Endo was considering  
11 collaborating on?

12 A. Yes, I did.

13 Q. Okay. And you viewed those documents as  
14 consistent with your opinions that you offer in this  
15 matter, correct?

16 A. I don't understand that question.

17 Q. I'll rephrase.

18 Did you see anything in those documents that was  
19 inconsistent with the opinions that you offer in this  
20 case?

21 A. Well, the other OEWs that I looked at were  
22 definitely -- at least on the ones that were more  
23 advanced in their consideration, had more flesh on the  
24 bone than the one described here for OEW -- I'm sorry,  
25 for 203. They were more thorough.

1 Q. And earlier you noted that part of the basis for  
2 your opinion that 203 was not a good strategic fit for  
3 Endo was that the words "Parkinson's disease" did not  
4 appear in Endo's strategic documents that you reviewed.

5 Did you see the word "neurology" appear anywhere  
6 in Endo's strategic documents that you reviewed?

7 A. I don't recall.

8 Q. How about the phrase "CNS"?

9 A. I don't recall.

10 Q. Do you have an understanding of what "CNS"  
11 stands for?

12 A. Of course.

13 Q. Would you mind telling me?

14 A. Central nervous system.

15 Q. Thank you.

16 Would you consider Parkinson's disease  
17 treatments to be generally within the category of  
18 neurology and CNS treatments?

19 A. Yes.

20 Q. Okay. If you would turn to tab 3 of your  
21 binder, please, and this is a 2008 Endo opportunity  
22 evaluation worksheet which is listed in your materials  
23 considered. It's branded only with a Bates number  
24 because this has not been admitted into evidence, and it  
25 does contain some Endo confidential information, so

1 please do not read it aloud and please confine your  
2 answers to my questions.

3           Do you recall --

4           MR. BUTRYMOWICZ: Your Honor, excuse me. I have  
5 to object. I don't see this document on the list of  
6 Dr. Geltosky's materials considered, and I don't know  
7 that there's otherwise a foundation for it.

8           JUDGE CHAPPELL: Take a moment and talk about  
9 it.

10           (Counsel conferring.)

11           MS. FABISH: Just give me a moment to confirm  
12 while I'm looking on this list.

13           This is a fairly long list, and I don't know  
14 that I have time to confirm for certain that it is not  
15 on there, but I do think that it's properly within the  
16 scope of cross examination. Dr. Geltosky has stated he  
17 looked at several other opportunity evaluation  
18 worksheets and compared the way that they approached  
19 diligence and deals at Endo to the way that was done in  
20 the opportunity evaluation worksheet at Endo. These  
21 documents also speak to Endo's strategic goals.

22           MR. BUTRYMOWICZ: Your Honor, the list is long,  
23 but it's in numerical order, and I -- comparing this  
24 document's Bates number to where it would appear on the  
25 list, it appears to be absent.

1           Additionally, I don't see that there's been any  
2 foundation for this document as to what it is, whether  
3 it's final. I don't see a date on it. I -- I don't  
4 know that really there's any foundation for this.

5           JUDGE CHAPPELL: She's no longer saying that  
6 it's on the list. She's saying it's within the scope of  
7 fair cross. What's your response to that?

8           MR. BUTRYMOWICZ: Your Honor, I don't believe  
9 it's within the scope of fair cross given that  
10 Dr. Geltosky didn't testify about it, there's no  
11 indication that he's reviewed it, and after looking at  
12 the face of the document, it's not clear -- there is no  
13 date, there's -- there appears to be some missing --  
14 missing information. It's also not on JX 2. It is not  
15 in evidence, and I don't know that there's a foundation  
16 for it.

17          MS. FABISH: And to be clear, Your Honor, I am  
18 not attempting to offer it into evidence. I would  
19 solely like to use it for the purposes of cross  
20 examining Dr. Geltosky on his opinions regarding the  
21 strategic business fit, which is addressed squarely in  
22 this Endo document.

23          JUDGE CHAPPELL: All right. Let's start again.  
24 Rephrase your question with a proper foundation and see  
25 if we get an objection.

1 BY MS. FABISH:

2 Q. So, Dr. Geltosky, we established earlier that  
3 you reviewed various opportunity evaluation worksheets  
4 prepared at -- various Endo opportunity evaluation  
5 worksheet documents in forming your opinions in this  
6 matter, correct?

7 A. Well, they really didn't help me -- yes, it --  
8 yes, they did, in my review of -- I was looking for  
9 specific information in those OEWs. I wasn't really  
10 digging for anything else in terms of qualifying -- I  
11 was looking for whether they were doing sensitivity  
12 analyses and market research on their other projects.  
13 That's why I was looking at them.

14 Q. Okay. But you reviewed those documents in full,  
15 correct?

16 A. I wouldn't say I read them in full. I was  
17 searching for key words.

18 Q. Okay. Do you recall whether any of those  
19 documents spoke to Endo's strategic business goals?

20 A. I wasn't -- that's not what I was looking for.

21 MS. FABISH: Your Honor, may I have a moment to  
22 confer with counsel?

23 JUDGE CHAPPELL: Go ahead.

24 (Counsel conferring.)

25 BY MS. FABISH:

1 Q. So if you could take a look at tab 3, you'll see  
2 there is a section with the heading "Fit." Do you see  
3 that?

4 MR. BUTRYMOWICZ: Your Honor, I have to object  
5 again to the use of this document. I -- looking at it  
6 further, it doesn't appear to be dated. There is no  
7 indication that Endo entered this agreement. For  
8 example, I -- I'm sensitive to counsel's representation  
9 that this is -- that this is partially in camera, so I  
10 won't read from the document, but there are indications  
11 in it that Endo is still in a fairly early stage of  
12 considering whether or not to go forward with this. I  
13 just don't think that counsel has established really any  
14 foundation for what this is or what it represents.

15 JUDGE CHAPPELL: The current question is, do you  
16 see it? If you're objecting to that, it's overruled.  
17 Go ahead.

18 BY MS. FABISH:

19 Q. Do you see where it says "Fit" in the second  
20 paragraph?

21 A. Yes.

22 Q. And do you see that under that heading, there's  
23 a reference to "CNS targeted product" in the second  
24 line?

25 A. Yes.

1 Q. And you -- do you see that there is a reference  
2 in the second-to-last line to the asset at issue  
3 overlapping with neurology call points?

4 A. Yeah.

5 MR. BUTRYMOWICZ: Your Honor, I'm sorry, I have  
6 to object again to this line of questioning. I don't  
7 see how having Dr. Geltosky read from this document  
8 that's not in evidence -- I'm not sure where counsel's  
9 going with this, but it's hard to see how she's going  
10 anywhere other than to try to ask questions about this  
11 document that I think would be improper or to have him  
12 read parts of it into evidence.

13 MS. FABISH: Your Honor, if I may?

14 JUDGE CHAPPELL: I don't think we've heard the  
15 question yet. Go ahead.

16 MS. FABISH: Thank you.

17 BY MS. FABISH:

18 Q. You testified earlier that you had not seen the  
19 word "Parkinson's disease" or the word "CNS" in any Endo  
20 documents --

21 A. No, that's not what I testified. I did not see  
22 the word "neurology," and I don't remember whether I saw  
23 the letters "CNS."

24 Q. Okay. You can set that aside for now.

25 Now, I do know that you included the



1 investigational hearing testimony of Dr. Robert Cobuzzi  
2 in your materials considered list, correct?

3 A. Yes.

4 Q. Okay. Did you read -- I'd like you to turn, if  
5 you would, to tab 10, which is the transcript of that  
6 proceeding, and turn to page -- mini page 23, lines 19  
7 to 22. In considering this transcript --

8 THE COURT: Wait until he says he's there.

9 THE WITNESS: I'm sorry. I see it.

10 BY MS. FABISH:

11 Q. Do you see it?

12 A. Yes.

13 Q. In considering this transcript in forming your  
14 opinions, did you consider the portion of his testimony  
15 at page 23, starting at line 19, where he identifies  
16 pain and neurology as two of the key areas of focus for  
17 Endo's pharmaceutical products?

18 A. Yeah. I mean, at this time or at some point  
19 they were selling a migraine drug, which is in the pain  
20 franchise, and one of the rationales was that that was  
21 their -- I believe their only pain product at the time,  
22 and they were looking to add other neurology products,  
23 and they used -- they were using terminology like  
24 "adjacency," so Parkinson's is adjacent to pain and we  
25 can use our same sales reps to detail both products.

1 The problem there is Frova would go off patent long  
2 before 20 -- I'm sorry, 2003, would never see the light  
3 of day, so that rationale was not appropriate.

4 Q. I'm sorry, I don't see any discussion of  
5 adjacent fields or Frova on this page. I'll read you  
6 the portion I'm referring to just to make sure that  
7 we're clear.

8 On line 14:

9 "QUESTION: What was the corporate strategy when  
10 you started in that position?

11 "ANSWER: Pharmaceutical products in general.

12 "QUESTION: That sounds very broad.

13 "ANSWER: Yes.

14 "QUESTION: Was there any focus on certain areas  
15 of pharmaceutical products?

16 "ANSWER: Pain, neurology were the two key  
17 areas."

18 Did you consider this testimony, that pain and  
19 neurology were two of the key areas of focus for  
20 pharmaceutical products at Endo, in reaching your  
21 opinions about the strategic fit of 203 with Endo's  
22 business goals?

23 A. That didn't really -- well, I mean...

24 Q. Okay. Now, when we spoke last month --

25 JUDGE CHAPPELL: I don't think you got an

1 answer --

2 MS. FABISH: Oh, I thought he said no.

3 JUDGE CHAPPELL: Did you answer that?

4 THE WITNESS: I would answer no.

5 MS. FABISH: Okay, thank you.

6 Thank you, Your Honor.

7 BY MS. FABISH:

8 Q. When we spoke last month about your opinions on  
9 Endo, you mentioned that in the course of your work as a  
10 consultant, you had approached Endo about investing in  
11 two of your consulting clients' products. Do you recall  
12 that?

13 A. Yes.

14 Q. Okay. And you told me that it was your opinion  
15 that one of the assets you brought to Endo was -- and  
16 I'm quoting -- "very strategic for Endo" and was in  
17 Endo's "sweet spot." Do you recall that?

18 A. Yes.

19 Q. And did Endo ultimately decline to invest in  
20 those products?

21 A. Ah, yes.

22 Q. So would it be fair to say, based on that  
23 response, that you were incorrect about that asset being  
24 very strategic for Endo or it being in Endo's sweet  
25 spot?

1       A. Well, the area is very strategic. They wound up  
2 buying a company called Auxilium with a more advanced  
3 product. So it was strategic. It was just too early  
4 for them.

5       Q. So that's a no?

6       A. The question is? It is -- it is --

7       Q. Would you say --

8       A. -- they turned it down not because it was not  
9 strategic. It, in fact, was strategic. That's not --  
10 that's not the only criterion by which to execute an  
11 agreement. They were very -- this was a testosterone  
12 replacement product. This was in men's health, their  
13 new area of focus, and they wound up buying a company  
14 called Auxilium, which I believe had a marketed product.  
15 So they jumped over what I had to offer, which was a  
16 development compound.

17      Q. I see. But you initially thought they might be  
18 interested in that compound that your client had  
19 developed, correct?

20      A. Yes.

21      Q. And it turns out they were not, correct?

22      A. They were not interested enough to execute an  
23 agreement.

24      Q. Okay, thank you.

25           Now, I wanted to follow up on just -- this has

1 no relation to what we were just speaking about -- to  
2 something that you said when you were speaking with  
3 Complaint Counsel about just the general process for  
4 diligence. You mentioned that one step in the process  
5 of diligence is executing a confidentiality -- a CDA,  
6 and you testified, I believe, that that's something that  
7 you wouldn't take lightly. Do you recall that?

8 A. Yes.

9 Q. Do you recall when the CDA that the parties used  
10 for the diligence at issue here was executed in this --

11 A. No, I don't.

12 Q. I'd like to speak briefly about reasonable  
13 commercial efforts. You don't have an opinion on  
14 whether Impax exercised reasonable commercial efforts to  
15 develop the subject product under the DCA, do you?

16 A. I do.

17 Q. You do have an opinion as to whether Impax  
18 exercised --

19 A. Yes, as evidenced by the fact --

20 Q. Before you answer, sir -- and I apologize for  
21 interrupting -- but do you recall when I asked you that  
22 question at your deposition?

23 MR. BUTRYMOWICZ: Your Honor, I would like to  
24 object. I think this is outside the scope of the direct  
25 examination. I don't recall discussing whether Impax

1 used reasonable commercial efforts.

2 MS. FABISH: Well, Your Honor, he did speak to  
3 the efforts that Impax made to develop the product  
4 after, and I wanted to clarify whether he was attempting  
5 to offer an opinion which would be outside the scope of  
6 his expert report regarding whether or not those efforts  
7 met the reasonable commercial efforts standard. In  
8 addition, he does discuss reasonable commercial efforts  
9 generally in his report.

10 JUDGE CHAPPELL: Are you saying you're  
11 attempting to impeach his report?

12 MS. FABISH: I'm not attempting to impeach his  
13 report. I'm trying to clarify the scope of the opinions  
14 that he is offering with respect to reasonable  
15 commercial efforts.

16 JUDGE CHAPPELL: That's allowed. Overruled.

17 BY MS. FABISH:

18 Q. Do you have an opinion as to whether Impax  
19 exercised reasonable commercial efforts to develop the  
20 subject drug product under the DCA?

21 A. Today, I would say they -- I have an opinion.  
22 They did not.

23 Q. And are you offering an opinion in this matter  
24 as to whether or not that's the case?

25 A. Yes.

1 Q. Can you point me to the portion of your report  
2 that includes that opinion, sir?

3 A. I don't believe it's in there.

4 Q. It is not in your report?

5 A. Right.

6 MS. FABISH: Your Honor, I would like to move to  
7 strike Dr. Geltosky's testimony on that subject as he  
8 has acknowledged that it is not within the scope of his  
9 report.

10 MR. BUTRYMOWICZ: Your Honor, Respondent's  
11 counsel directly asked him about that, and I don't think  
12 that's warranted.

13 JUDGE CHAPPELL: The rule here is that opinions  
14 outside the reports are not allowed. If you're moving  
15 to strike, it's granted.

16 MS. FABISH: Thank you, Your Honor.

17 JUDGE CHAPPELL: Neither side can expound the  
18 opinions -- can expand on the opinions that have been  
19 submitted. One thing about these proceedings, the  
20 experts' opinions are locked in. That's the way it  
21 works.

22 Go ahead.

23 MS. FABISH: Thank you, Your Honor.

24 BY MS. FABISH:

25 Q. Dr. Geltosky, I'd like to speak briefly to

1 follow up on a few things about your background and  
2 experience that you discussed with Complaint Counsel  
3 earlier today.

4           You described how you began your career in  
5 research and diagnostics and research and development  
6 around 1980. Is that correct?

7       A. Correct.

8       Q. And based on your CV, it appears to me that from  
9 1980 to about 1994, you did not have any positions with  
10 business development responsibilities. Is that correct?

11      A. Formally speaking, that's correct.

12      Q. Okay. And you also noted earlier today that --  
13 fast-forwarding quite a bit to your work now with JEG  
14 Consulting, that your typical client at JEG is a small  
15 biotech company. Do you recall that?

16      A. Yes.

17      Q. And you also testified that these companies are  
18 net sellers in the potential collaborations that are the  
19 subject of your consulting work, correct?

20      A. Correct.

21      Q. Okay. So working on behalf of those clients,  
22 you were trying to get other companies to invest in a  
23 product that the client had developed or was developing,  
24 correct?

25      A. That's correct.



1 Q. And under those circumstances, the other company  
2 was doing diligence on your client's asset, correct?

3 A. That's correct.

4 Q. Okay. And isn't it true that the bulk of the  
5 experience that you have assessing a pharmaceutical  
6 product for a potential investment on behalf of the  
7 company potentially investing, so on behalf of a net  
8 buyer, came from your time at Bristol-Myers Squibb and  
9 SmithKline Beecham?

10 A. Yeah. The majority of the experience, yeah.

11 Q. And both Bristol-Myers Squibb and SmithKline  
12 Beecham were multimillion dollar companies when you  
13 worked for them, correct?

14 A. Correct.

15 Q. And their R&D budgets would have also been in  
16 the millions. Is that correct?

17 A. That's correct.

18 Q. So beyond your work on in-licensing deals at  
19 Bristol-Myers Squibb and SmithKline Beecham, in terms of  
20 assessing a pharmaceutical product for potential  
21 investment, on behalf of a company potentially  
22 investing, you also played this role while consulting on  
23 two deals with clients of JEG, correct?

24 A. Yes.

25 Q. And you played that role while consulting on one

1 deal while working with an outfit called C14 Consulting,  
2 correct?

3 A. Yeah. That's correct, yeah.

4 Q. And I understand you see yourself as playing a  
5 similar role in reviewing the various grant applications  
6 in connection with your role with CPRIT. Is that  
7 correct?

8 A. That's correct.

9 Q. And that's all in terms of work assessing a  
10 pharmaceutical product for potential investment on  
11 behalf of the company potentially investing on behalf of  
12 the net buyer, correct?

13 A. Yes.

14 Q. Okay. We've also spoken to varying extents  
15 throughout the day about financial analyses, and you  
16 testified that you had provided input into financial  
17 valuations of potential pharmaceutical collaborations  
18 over the course of your career, correct?

19 A. Correct.

20 Q. Okay. And this took the form of you providing  
21 technical input to someone else who was preparing a  
22 valuation analysis, correct?

23 A. Correct.

24 Q. Okay. But you, yourself, never actually  
25 performed such a valuation, correct?

1 A. Correct. It was always a team effort.

2 Q. Okay. You view the diligence process at all  
3 pharmaceutical companies as very, very similar. Is that  
4 fair to say?

5 A. Yes.

6 Q. And you view your knowledge of this process as  
7 one of the primary reasons clients hire you as a  
8 consultant. Is that right?

9 A. I'm sorry? I'm having a hard time hearing you.

10 Q. No problem.

11 You view your knowledge of that process as one  
12 of the primary reasons your clients hire you as a  
13 consultant. Is that right?

14 A. Well, my knowledge of the industry in general,  
15 the people on the other side, what they're looking for,  
16 how to properly prepare a package to make it attractive  
17 to a potential buyer, that's why they hire me.

18 Q. But how to prepare -- properly prepare a package  
19 to make it attractive, that would include knowledge  
20 about how that potential partner is diligencing a deal,  
21 correct?

22 A. Well, they were all diligencing it the same way.  
23 I knew what they were looking for. They were looking  
24 for the same things I would look for if I were sitting  
25 back at BristolMeyers. So that's why they hire me.

1 Q. Okay, that answered my question.

2 You've been -- how long have you been doing  
3 consulting work for your own consulting firm, JEG  
4 Consulting?

5 A. Golly, approximately ten years now.

6 Q. Okay. And during the course of those ten years,  
7 how many potential deals have you been involved in?

8 A. Probably roughly a dozen or so.

9 Q. And in how many instances over those ten years  
10 and in those dozen deals has your work for the client  
11 resulted in an executed agreement?

12 A. Well, none. I was extremely close to getting  
13 two of them done, and the companies decided they wanted  
14 to be bought rather than to effect a business  
15 development transaction. So I' teed everything up for  
16 them, and they brought in bankers to effect a  
17 merger/acquisition.

18 Q. Okay.

19 A. And I was involved, you know, as a consultant  
20 with JSB, who we talked about before, and there we  
21 concluded two transactions.

22 Q. So just to clarify, over the ten years that  
23 you've been working with JEG Consulting, there have been  
24 no executed deals as a result of your work.

25 A. Incorrect. Again, under the umbrella of JEG,

1 there was a company that we talked about before called  
2 JSB for whom I consulted, and in that -- in that  
3 two-year period that I was associated with them, we  
4 executed two deals.

5 Q. Okay. So that two-year period that you were  
6 associated with JSB, did that overlap with the ten years  
7 that you were associated with JEG?

8 A. It was included in that time period, yes.

9 Q. So over the course of those ten years, your  
10 consulting work has resulted in two completed deals?

11 A. That is correct.

12 Q. Okay.

13 A. And I have done work for other clients who wound  
14 up doing fairly major transactions, but I wasn't  
15 involved in them. I teed up a lot of the work for them  
16 in terms of putting the packages together. They weren't  
17 ready yet, and they wound up actually having some very  
18 nice transactions and companies being bought.

19 Q. So I'm not sure I understand the relationship  
20 between that to my question, so I will ask you my  
21 question again, and I will ask you, to the extent  
22 possible, to please just respond yes or no.

23 In the -- did the consulting work that you  
24 performed while associated with JEG and JSB over the  
25 past ten years result in two deals?

1 A. That's correct, yes.

2 Q. Thank you.

3 Just one last question. You spoke quite a bit  
4 about Endo's diligence efforts -- due diligence that it  
5 performed regarding the DCA and disagreed with various  
6 aspects of the way that it approached that. Do you --  
7 none of those criticisms apply to anything that Impax  
8 did, correct?

9 A. That is correct.

10 MS. FABISH: I have no further questions. Thank  
11 you, Your Honor. Thank you, Dr. Geltosky.

12 JUDGE CHAPPELL: Redirect?

13 MR. BUTRYMOWICZ: Yes, Your Honor.

14 REDIRECT EXAMINATION

15 BY MR. BUTRYMOWICZ:

16 Q. Good afternoon, Dr. Geltosky.

17 Respondent's counsel asked you how many deals  
18 you had completed in your ten years as a pharmaceutical  
19 consultant, and I believe that you responded that over a  
20 ten-year period, out of about a dozen deals, two were  
21 executed. Is that correct?

22 A. Ah, yeah. Those dozen were clients basically.  
23 So, yes, and so each one we tried, and so there were two  
24 that I was actively engaged in concluding.

25 Q. Based on your experience in the pharmaceutical

1 industry, is completing two out of 12 deals a low  
2 success rate?

3 A. No, it's -- it's like drug discovery. I mean,  
4 it's many -- I have no -- yeah, I think it's a  
5 reasonable hit rate.

6 Q. Respondent's counsel also asked you about your  
7 role as a consultant acting as a net seller. When you  
8 were in that role, did you gain experience seeing how  
9 the companies that you interacted with approached  
10 development agreements?

11 A. Yes.

12 Q. As a buyer?

13 A. Yes.

14 Q. Did you gain experience with how those companies  
15 conducted diligence?

16 A. Yes.

17 Q. In that role, did you have experience with  
18 companies that were similar in size to Endo  
19 Pharmaceuticals?

20 A. Yes.

21 Q. And in your experience as a buyer and a seller,  
22 have all these companies approached development  
23 agreements using the same general process that you've  
24 outlined?

25 A. Yes.

1 Q. Respondent's counsel also asked if you relied on  
2 documents from Endo that were provided by Complaint  
3 Counsel. Did you have access to any internal Endo  
4 business documents other than what Complaint Counsel  
5 could provide to you?

6 A. No.

7 Q. Were there any documents that you ever requested  
8 that Complaint Counsel did not give you access to?

9 A. No.

10 Q. Complaint Counsel -- sorry, excuse me.

11 Respondent's counsel also asked you some  
12 questions about data related to IPX-066, and I believe  
13 you said that data relevant to IPX-066 could be useful  
14 as a baseline to evaluate IPX-203. Is that correct?

15 A. That's correct.

16 Q. Why wouldn't this information be sufficient to  
17 determine whether Endo should go forward with a  
18 development deal for IPX-203?

19 A. It really wasn't relevant. I mean, that would  
20 establish a baseline for which then 203 would have to  
21 exceed in many ways to be a successful product, and  
22 there was no way of knowing that at the time of the  
23 agreement because there were no studies done on 203. So  
24 it was just a benchmark, something to aspire to years  
25 out when they finally got to the clinic.



1 Q. Respondent's counsel also asked you about the  
2 information that was contained in the data room for  
3 IPX-066. Do you recall that?

4 A. Yes.

5 Q. And you had reviewed that information as part of  
6 preparing your report?

7 A. That's correct.

8 Q. Was there any information in that data room that  
9 related specifically to IPX-203?

10 A. No.

11 Q. I'd like to ask you a few questions about  
12 strategic fit, which Respondent's counsel asked about at  
13 some length.

14 I apologize. Let me go back. I have one more  
15 question on the data room. Respondent's counsel asked  
16 you if the data room contained intellectual property  
17 information about IPX-066. Do you recall that?

18 A. Yes.

19 Q. And do you know from your experience in the  
20 pharmaceutical industry whether pharmaceutical companies  
21 do independent IP analyses before they enter development  
22 agreements?

23 A. They do.

24 Q. Did Endo do any independent analysis of the  
25 intellectual property for IPX-203 before entering this

1 agreement?

2       A. Not that I could see from the documents  
3 provided.

4       Q. All right. I'd now like to move on to strategic  
5 fit. Respondent's counsel showed you a document from  
6 Robert Cobuzzi, an executive at Endo, referencing, I  
7 believe, "a good commercial fit." Do you recall that?

8       A. Yes.

9       Q. In preparing your report and coming to your  
10 opinion, did you see any documents indicating that  
11 IPX-203 was a good commercial fit that were dated before  
12 Endo signed the co-development deal?

13      A. No.

14      Q. I would also like to ask you about some of the  
15 testimony that Respondent's counsel reviewed with you.  
16 Bear with me for a second as I try to find this.

17           If you could turn to tab 10 in the binder that  
18 Respondent's counsel provided, which is the  
19 investigational hearing transcript of Robert Cobuzzi,  
20 and particularly to Minuscript page 23. Let me know  
21 when you're there.

22      A. There.

23      Q. Do you recall discussing this page with  
24 Respondent's counsel?

25      A. Yes.

1 Q. And Respondent's counsel asked you about lines  
2 19 through 22, which state:

3 "QUESTION: Was there any focus on certain areas  
4 of pharmaceutical products?

5 "ANSWER: Pain, neurology were the two key  
6 areas."

7 Do you see that?

8 A. Yes.

9 Q. I would like to direct your attention to a few  
10 lines up, line 14, which says:

11 "QUESTION: What was the corporate strategy when  
12 you started in that position?"

13 Do you see that?

14 A. Yes.

15 Q. When Mr. Cobuzzi was saying that pain and  
16 neurology were two key areas, was he referring to when  
17 he started in his position at Endo?

18 A. Yes.

19 Q. Do you know when Mr. Cobuzzi started at Endo?

20 A. No.

21 Q. If I could direct you to page 12 of this same  
22 transcript, line 9. Let me know when you're there.

23 A. Yes.

24 Q. Line 9 says:

25 "QUESTION: How long have you been with Endo in

1 total?

2 "ANSWER: Since May 2nd, 2005."

3 Do you see that?

4 A. Yes.

5 Q. Does that provide any context for Mr. Cobuzzi's  
6 testimony that pain and neurology were two key areas for  
7 Endo?

8 A. No.

9 Q. Let me ask it differently.

10 Mr. Cobuzzi started at Endo in 2005.

11 A. Right.

12 Q. In his testimony on page 23, he states that when  
13 he --

14 JUDGE CHAPPELL: Hold on a second.

15 MR. BUTRYMOWICZ: Yes, Your Honor?

16 JUDGE CHAPPELL: Why are you going into another  
17 witness' testimony in such detail on redirect?

18 MR. BUTRYMOWICZ: I apologize, Your Honor. I --

19 JUDGE CHAPPELL: Mr. Cobuzzi is not here.

20 MR. BUTRYMOWICZ: I understand, Your Honor. I  
21 am trying to provide context for the questions that  
22 Respondent's counsel asked about this set of testimony  
23 to allow -- I don't believe Dr. Geltosky was given a  
24 fair view of the context, and I'd like to get his  
25 response to these questions with that understanding in

1 mind.

2 JUDGE CHAPPELL: He's an expert witness. He's a  
3 hired gun. He should be able to handle it. You go  
4 ahead, but you don't have a whole lot of leeway left  
5 here. You need to wrap this up and move to another  
6 topic.

7 MR. BUTRYMOWICZ: All right, Your Honor. I'll  
8 withdraw the question.

9 JUDGE CHAPPELL: If a man in his position can't  
10 say when he thinks he's being trapped or needs more  
11 context -- he's certainly capable of that, don't you  
12 agree?

13 MR. BUTRYMOWICZ: I understand, Your Honor.  
14 Yes, Your Honor.

15 BY MR. BUTRYMOWICZ:

16 Q. Let me just ask one final question on this  
17 topic, putting aside that testimony. Did you see  
18 anything in Mr. Cobuzzi's IH transcript that you  
19 reviewed in preparing your report indicating whether  
20 neurology was a key strategic area for Endo in 2010?

21 A. No.

22 MR. BUTRYMOWICZ: Your Honor, I would like to  
23 ask just a very few questions about the in camera  
24 document that Respondent's counsel discussed at the  
25 beginning of her cross examination, and so, regrettably,

1 I would ask that we go back into in camera session just  
2 for a few minutes to do those questions.

3 JUDGE CHAPPELL: At this time, we will go into  
4 in camera session. I need to ask those who are not  
5 subject to the protective order to vacate the courtroom.

6 Let me know if you see anyone in the courtroom  
7 who should not be here.

8 MR. LOUGHLIN: Fine on our side, Your Honor.

9 MS. FABISH: No, Your Honor.

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

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

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(End of in camera session.)

1 (Public session.)

2 JUDGE CHAPPELL: Thank you, you may stand down.

3 We are going to take a short break and then come  
4 back for our last witness. We will reconvene at 4:50.  
5 We're in recess.

6 (A brief recess was taken.)

7 JUDGE CHAPPELL: Okay, we're back on the record.

8 Next witness.

9 MR. LOUGHLIN: Your Honor, Complaint Counsel  
10 calls Bryan Reasons.

11 JUDGE CHAPPELL: Okay, and we expect to wrap  
12 this up no later than 6:00.

13 MR. LOUGHLIN: Thank you, Your Honor. My  
14 colleague Jamie Towe will conduct the examination.  
15 Whereupon--

16 BRYAN M. REASONS  
17 a witness, called for examination, having been first  
18 duly sworn, was examined and testified as follows:

19 JUDGE CHAPPELL: Go ahead.

20 MR. TOWEY: Good afternoon, Your Honor, and may  
21 it please the Court. I am Jamie Towe on behalf of  
22 Complaint Counsel.

23 DIRECT EXAMINATION

24 BY MR. TOWEY:

25 Q. Good afternoon, Mr. Reasons. How are you?

1 A. Good. How are you?

2 Q. Good, thank you. We have not met before. My  
3 name is Jamie Towey, and I will be asking you some  
4 questions today.

5 Why don't we start by having you please  
6 introduce yourself by stating your full name.

7 A. Brian Marlon Reasons.

8 Q. And is there anything that might affect your  
9 ability to give truthful, complete testimony here today?

10 A. No.

11 Q. Mr. Reasons, there should be a white binder next  
12 to your chair there. We may refer to that throughout  
13 the day. There's also a bottle of water if you need  
14 that at any point.

15 A. Thank you.

16 Q. Mr. Reasons, who is your current employer?

17 A. Impax Laboratories.

18 MR. TOWEY: Your Honor, pursuant to your order  
19 dated October 18th, 2017, and Rule 4.1(d) of the  
20 Commission rules, as a current employee of Impax,  
21 Mr. Reasons is an adverse witness and subject to  
22 examination by leading questions.

23 JUDGE CHAPPELL: Okay.

24 BY MR. TOWEY:

25 Q. Mr. Reasons, you started at Impax in January of

1 2012, correct?

2 A. Yes.

3 Q. And prior to working at Impax, you had other  
4 jobs in the pharmaceutical industry?

5 A. Yes.

6 Q. At Teva Pharmaceuticals?

7 A. Yes.

8 Q. And prior to that, at Cephalon?

9 A. Yes.

10 Q. In total, you have been employed in the  
11 pharmaceutical industry for 12 to 13 years?

12 A. Yes.

13 Q. And about six of those years have involved  
14 working at companies that produce generic products?

15 A. Yes.

16 Q. When you started at Impax, your position was  
17 vice president of finance, correct?

18 A. Yes.

19 Q. You later became chief financial officer for  
20 Impax, correct?

21 A. Yes.

22 Q. And that's your position today?

23 A. Yes.

24 Q. And you became chief financial officer around  
25 December of 2012?

1 A. Yes.

2 Q. As CFO, or chief financial officer, for Impax,  
3 you report directly to the chief executive officer,  
4 correct?

5 A. Yes.

6 Q. And as CFO, you have responsibility for  
7 accounting functions?

8 A. Yes.

9 Q. And for SEC reporting?

10 A. Yes.

11 Q. For budgeting and forecasting?

12 A. Yes.

13 Q. For tax?

14 A. Yes.

15 Q. For investor relations?

16 A. Yes.

17 Q. And for corporate communications?

18 A. Yes.

19 Q. As CFO at Impax, one of your responsibilities is  
20 to communicate with the investment community, correct?

21 A. Yes.

22 Q. And you participate in quarterly earnings  
23 conference calls?

24 A. Yes.

25 Q. And during those earnings conference calls, you



1 deliver prepared remarks?

2 A. Yes.

3 Q. And you also answer questions from analysts?

4 A. Yes.

5 Q. And during those earnings conference calls, you  
6 try to be accurate, correct?

7 A. Yes.

8 Q. And for those earnings conference calls, you try  
9 to be knowledgeable about the topics you'll present?

10 A. Yes.

11 Q. Now I want to ask you some questions about the  
12 Endo credit. You're familiar with that term, correct?

13 A. Yes.

14 Q. And the Endo credit is a cash payment received  
15 by Impax in 2013?

16 A. Yes.

17 Q. And the Endo credit was paid to Impax by Endo  
18 Pharmaceuticals?

19 A. Yes.

20 Q. And the Endo credit was paid to Impax by Endo  
21 because of provisions in a 2010 settlement agreement  
22 relating to generic Opana ER?

23 A. Yes.

24 Q. And the purpose of the Endo credit was to  
25 protect Impax from Endo destroying the oxymorphone ER

1 market?

2 A. Yes.

3 Q. And oxymorphone ER is the generic name for Opana  
4 ER?

5 A. Yes.

6 Q. Now, the Endo credit protected Impax by  
7 requiring Endo to make payment to Impax if the  
8 oxymorphone ER market declined before Impax could enter,  
9 correct?

10 A. Yes.

11 Q. And the market for oxymorphone extended release  
12 did decline before Impax could enter, correct?

13 A. Yes.

14 Q. And that's why Impax received a payment from  
15 Endo.

16 A. Yes.

17 Q. Within Impax, you were not responsible for  
18 running the calculations of the Endo credit, were you?

19 A. I'm sorry. Could you repeat that?

20 Q. Sure.

21 Within Impax, you were not responsible for  
22 running the calculations of the Endo credit, correct?

23 A. I was not.

24 Q. The people responsible for doing the calculation  
25 of the Endo credit were in the Legal Department?

1 A. Correct.

2 Q. But even though you weren't responsible for  
3 running the calculation, you looked at the calculation  
4 for mathematical accuracy, correct?

5 A. I did.

6 Q. And you were overall in charge of collecting the  
7 Endo credit?

8 A. Yes.

9 Q. And you were overall in charge of accounting for  
10 the Endo credit?

11 A. Yes.

12 Q. The payment that Impax received under the Endo  
13 credit was more than \$100 million, correct?

14 A. Yes.

15 Q. In fact, the payment that Impax received under  
16 the Endo credit was \$102,049,199.64?

17 A. I believe so.

18 Q. For ease, when I'm referencing that, would you  
19 be okay if I referenced that as 102 million?

20 A. Okay.

21 Q. Now, Impax received the \$102 million Endo credit  
22 payment on April 18th, 2013, correct?

23 A. I believe so.

24 Q. And even before Impax received the Endo credit  
25 payment, Impax was telling investors that it may receive

1 a \$110 million payment from Endo, correct?

2 A. Correct, based on Endo's public statements.

3 Q. And Impax told investors that because a  
4 potential payment of \$110 million would be material to  
5 the company?

6 A. Material to the cash flows, yes.

7 Q. When Impax received the Endo credit payment in  
8 2013, it had an impact on Impax's net income.

9 A. It did.

10 Q. In fact, the payment had a substantial impact on  
11 Impax's net income.

12 A. It did.

13 Q. The payment that Impax received increased its  
14 2013 net income by about \$65 million, correct?

15 A. GAAP income, approximately, yes.

16 Q. And approximately 65 million is the \$102 million  
17 Endo credit payment minus taxes?

18 A. Correct.

19 Q. That's how you got to 65 million?

20 A. Correct.

21 Q. As part of your job as CFO of Impax, you review  
22 Impax's filings required by the Securities and Exchange  
23 Commission, correct?

24 A. Yes.

25 Q. And you review them before they are filed?

1 A. Yes.

2 Q. And you try to be accurate in the SEC filings.

3 A. Yes.

4 Q. You sign SEC filings when they're filed?

5 A. Yes.

6 Q. I'd like to ask you some questions about Impax's  
7 10-K from the year in which it received the Endo credit  
8 payment. If you could take the binder next to you and  
9 turn to the tab marked CX 0425.

10 Your Honor, CX 0425 has been admitted into  
11 evidence under JX 002 and is not subject to Your Honor's  
12 in camera ruling.

13 I'd like to start, Mr. Reasons, on page  
14 CX 0425-007, and, Ms. Wint, if I could ask you to pull  
15 that page up on to the screen.

16 You're at that page?

17 A. Yes.

18 Q. Now, this is Impax's 10-K covering the fiscal  
19 year ending December 31st, 2013?

20 A. Yes.

21 Q. And that was the year that Impax received the  
22 Endo credit, correct?

23 A. Yes.

24 Q. Okay. If we could turn now to page CX 0425-155,  
25 and this is the signature block for the 10-K filing?

1 A. Yes.

2 Q. And in the column of signatures, that's yours  
3 below Larry Hsu's?

4 A. Yes.

5 Q. And did you review this document before filing  
6 it?

7 A. Yes.

8 Q. And you believed it was accurate when it was  
9 filed?

10 A. Yes.

11 Q. Okay. If I could have you turn to page  
12 CX 0425-069. Are you there?

13 A. Yes.

14 Q. Do you see the chart on that page?

15 A. Yes.

16 Q. And the chart on this page shows Impax's net  
17 income for 2012 and 2013.

18 A. Yes.

19 Q. And in 2013, the year that the Endo credit was  
20 paid, Impax's net income was approximately \$101.3  
21 million, correct?

22 A. Correct.

23 Q. And looking at the chart, the highlighted area,  
24 that's the 101,259?

25 A. Yes.

1 Q. And how can you tell if that's in millions?

2 A. At the front of the document, it says, "In  
3 millions unless otherwise stated."

4 Q. Okay. And does the parenthetical at the top of  
5 the chart also --

6 A. Yep.

7 Q. -- tell you?

8 A. True.

9 Q. Now, earlier you testified that net income from  
10 the Endo credit was about \$65 million. Do I have that  
11 right?

12 A. Yes.

13 Q. So to put that into perspective, the Endo credit  
14 represented almost two-thirds of Impax's net income for  
15 2013, correct?

16 A. Yes.

17 Q. And in the paragraph at the bottom of that page  
18 that starts, "Net income for the year ended December 31,  
19 2013" -- do you see that?

20 A. Yes.

21 Q. -- Impax said that the increase in net income  
22 between 2012 and 2013 was primarily attributable to two  
23 things, correct?

24 A. Correct.

25 Q. And the first of those things was the \$102

1 million Endo credit payment.

2 A. Correct.

3 Q. And the second of those was a \$48 million  
4 payment that Impax received from another litigation  
5 settlement, correct?

6 A. Correct.

7 Q. And both of those are pretax figures.

8 A. Correct.

9 Q. So according to the chart, Impax's net income in  
10 2012 was about 55.9 million?

11 A. Correct.

12 Q. So the \$65 million net income from the Endo  
13 credit payment was about \$10 million more than all of  
14 the net income from all of Impax in 2012.

15 A. Correct.

16 Q. You can put that document aside, and you can put  
17 the binder aside as well for now.

18 I'm now going to ask some questions about  
19 first-to-file exclusivity for generic Opana ER. You're  
20 familiar with the term "first-to-file exclusivity"?

21 A. Yes.

22 Q. And first-to-file exclusivity applies to a  
23 generic company if it's the first to file an ANDA under  
24 certain circumstances?

25 A. Correct.



1 Q. And that first-to-file generic company has a  
2 potential 180-day exclusivity period where no other ANDA  
3 generics would be on the market?

4 A. Correct.

5 Q. So if Impax has first-to-file exclusivity for a  
6 generic drug, typically other generic manufacturers  
7 cannot come onto the market during that 180-day period,  
8 right?

9 A. Correct.

10 Q. And being the only generic version of a branded  
11 product has value for Impax.

12 A. Yes.

13 Q. For generic Opana ER, Impax had first-filer  
14 exclusivity on five dosage strengths, correct?

15 A. I believe so.

16 Q. Do you know that that is a yes or you can't  
17 recall the exact number?

18 JUDGE CHAPPELL: Do you think he's the best  
19 person to ask about this? He's a CFO.

20 MR. TOWEY: And we are going to get into kind of  
21 the financial significance of the exclusivity period,  
22 Your Honor.

23 JUDGE CHAPPELL: He said "I believe so," so go  
24 ahead.

25 MR. TOWEY: Yes, Your Honor.

1 BY MR. TOWEY:

2 Q. I'll ask you a couple of questions now about  
3 authorized generics. You're familiar with the term  
4 "authorized generic"?

5 A. Yes.

6 Q. And that's sometimes abbreviated as "AG"?

7 A. Yes.

8 Q. And an authorized generic, or AG, is when the  
9 brand manufacturer either launches their own version or  
10 contracts another company to launch the generic version  
11 of a branded product?

12 A. Yes.

13 Q. And while you've been at Impax, the company has  
14 launched authorized generics of some of Impax's branded  
15 products.

16 A. Can you say that again?

17 Q. While you have been at Impax, the company has  
18 launched authorized generics of some of Impax's branded  
19 products.

20 A. Ah, yes.

21 Q. And those were launched in response to generic  
22 companies introducing generic versions of Impax's  
23 branded products?

24 A. Yes.

25 Q. And authorized generics sold by Impax partially

1 offset sales of the branded product that were lost to  
2 generic competition?

3 A. Yes.

4 Q. In fact, when Impax launched an authorized  
5 generic, you discussed Impax's authorized generic with  
6 analysts during earnings conference calls, correct?

7 A. Correct.

8 Q. Now, a branded manufacturer can compete with an  
9 authorized generic during the 180-day exclusivity  
10 period, correct?

11 A. Say that again.

12 Q. Sure.

13 A branded manufacturer can sell its authorized  
14 generic product during the 180-day exclusivity period of  
15 an ANDA generic, the first-to-file ANDA generic,  
16 correct?

17 A. I'm not -- I'm not sure if that's factual in  
18 every circumstance.

19 Q. In your -- do you recall being deposed in this  
20 matter in September of this year -- August of this year?

21 A. On this -- on this case or --

22 Q. Yes.

23 A. -- this specific question?

24 Q. In this case.

25 A. Yes.

1 Q. And do you recall testifying that there's  
2 nothing that prevents the brand name manufacturer from  
3 releasing an authorized generic during the 180-day  
4 period, typically?

5 A. I guess, yes.

6 Q. Do you agree with that statement?

7 A. If there's no other settlement, I do.

8 Q. And in general, an authorized generic is an  
9 additional competitor in the generic marketplace,  
10 correct?

11 A. Yes.

12 Q. Indeed, from Impax's perspective, there is no  
13 difference between competing against an authorized  
14 generic or a regular ANDA generic.

15 A. I agree.

16 Q. Except that an authorized generic can sell  
17 during the exclusivity period.

18 A. Correct.

19 Q. And the effect of having an additional generic  
20 competitor is usually a lower price, right?

21 A. A combination of either a lower price or lower  
22 volume.

23 Q. Are you ever aware of an additional generic  
24 competitor not resulting in a lower price?

25 A. No.

1 Q. And generally speaking, in your experience,  
2 adding a second generic will result in a price decrease  
3 of about 30 to 35 percent?

4 A. Generally.

5 Q. And in addition to decreasing the price,  
6 generally speaking, entry of a second generic product  
7 will reduce the first generic's market share?

8 A. Generally.

9 Q. So rather than the first generic having 100  
10 percent of generic sales, the two generic companies will  
11 split those sales.

12 A. Usually.

13 Q. Now, you're aware that the 2010 settlement  
14 agreement between Impax and Endo contained a clause  
15 relating to Endo's sales of an authorized generic,  
16 correct?

17 A. Yes.

18 Q. And under that clause, Endo would not introduce  
19 an authorized generic during Impax's 180-day exclusivity  
20 period for certain strengths of Opana ER?

21 A. Yes.

22 Q. For ease of reference, will you understand me if  
23 I call this provision the no-AG agreement or the no-AG  
24 provision?

25 A. Yes.

1 Q. And with the no-AG provision, there would be no  
2 second generic of Opana ER during Impax's exclusivity  
3 period, correct?

4 A. Correct.

5 Q. Having a no-AG provision, Impax could charge a  
6 higher price for generic Opana ER than compared to a  
7 marketplace that had two generics.

8 A. Repeat that, please.

9 Q. Sure.

10 Having a no-AG provision, Impax could charge a  
11 higher price for generic Opana ER than compared to a  
12 marketplace that had two generics selling generic  
13 products.

14 A. Ah, yes.

15 Q. And generally speaking, earlier you said that  
16 that higher price is about 30 to 35 percent.

17 A. Yes.

18 Q. Now, the products that could reduce the price of  
19 Impax's generic Opana ER were other generic versions of  
20 Opana ER, correct?

21 A. Yes.

22 Q. And it was other sellers of oxymorphone ER who  
23 you identified to analysts in earnings conference calls  
24 as the source of potential price erosion for Impax's  
25 generic Opana ER, correct?

1 A. Correct.

2 Q. I'd like you, again, to take the binder, and if  
3 you could turn to a tab marked CX 2656.

4 Your Honor, while he's looking that up, I will  
5 state that CX 2656 is included in JX 002 and has been  
6 admitted into evidence, and this is a public document  
7 and is not subject to your in camera ruling.

8 Are you there, Mr. Reasons?

9 A. Yes.

10 Q. And CX 2656 is a transcript from an earnings  
11 conference call from May 2013, correct?

12 A. Yes.

13 Q. And this is a final version of the transcript?

14 A. It looks like it, yes.

15 Q. If I could have you turn to page CX 2656-007.

16 Ms. Wint, if you could publish that.

17 I want to look at the middle of the page.

18 There's a line that says:

19 "Bryan Reasons: I guess I will clarify. You're  
20 talking about oxymorphone -- generic oxymorphone."

21 Do you see that?

22 A. Yes.

23 Q. And that was you speaking there?

24 A. Yes.

25 Q. And you're talking about generic Opana ER?

1 A. Yes.

2 Q. In your next paragraph, after Jason Gerberry  
3 says yes, you say in the middle of the paragraph:

4 "Obviously our exclusivity period ends in June  
5 so, end of June, so we expect some competition then and  
6 some price erosion."

7 Do you see that?

8 A. Yes, as it relates to our annual plan.

9 Q. And the exclusivity period you reference there  
10 is the first-to-file exclusivity for generic Opana ER?

11 A. Yes.

12 Q. And when you say "we expect some competition,"  
13 the competition was companies that would come out with  
14 generic versions of Opana ER?

15 A. It's what we put in our plan, our budget.

16 Q. But those companies were other generic companies  
17 selling generic versions of Opana ER.

18 A. As it relates to our plan, our annual plan, we  
19 put in that we expect additional competition.

20 Q. And what I -- I understand this is part of your  
21 plan. I'm just trying to understand who those -- that  
22 competition was. So was that competition generic  
23 companies selling generic versions of Opana ER?

24 A. Yes.

25 Q. And up until this point, rather than sharing the



1 generic marketplace, Impax had 100 percent share during  
2 its first-to-file exclusivity period, correct?

3 A. Of the ER market, yes.

4 Q. Yes.

5 A. Yes.

6 Q. And being the only generic version of this  
7 branded product had value to Impax.

8 A. Yes.

9 Q. And in general, being the only generic version  
10 is more valuable when sales of the branded product are  
11 higher rather than lower, correct?

12 A. Yes.

13 Q. Thinking about this, I'd like to revisit the  
14 no-AG agreement. A sharp decline in the sales of  
15 branded Opana ER before Impax's generic launch would  
16 decrease the value of the no-AG agreement, correct?

17 A. Yes.

18 Q. And the value of the no-AG agreement would  
19 decrease because the total market potential for generic  
20 Opana ER was decreasing.

21 A. Yes.

22 Q. And earlier we discussed, in the situation where  
23 the market for Opana ER declined sharply before Impax's  
24 launch, Impax might be eligible for payment of the Endo  
25 credit, correct?

1 A. Correct.

2 Q. So without a decline in the market for Opana ER,  
3 the value of the no-AG provision would be higher, but if  
4 the market did decline, then Impax could get a payment  
5 under the Endo credit.

6 A. It could decline and no payment would be paid as  
7 well.

8 Q. But it could -- it could decline and the Endo  
9 credit payment would be required.

10 A. If it declined enough, yes, based on the  
11 formula.

12 Q. I'd like to ask some questions now about how  
13 Impax values a generic opportunity. You're familiar  
14 with the term "automatic substitution"?

15 A. Yes.

16 Q. And under automatic substitution, if a pharmacy  
17 carries an Impax drug and the brand and the scrip is  
18 written for the branded product, a pharmacist could  
19 substitute the Impax AB rated generic for the brand.

20 A. Yes.

21 Q. So when Impax assesses the potential market  
22 opportunity for a new generic drug, it looks at the size  
23 of the corresponding brand's sales.

24 A. Correct.

25 Q. And it also looks to see if there's any existing

1 generics of that branded drug, correct?

2 A. Correct.

3 Q. In fact, the best way to estimate the size of a  
4 generic market opportunity is to look at the size of the  
5 brand plus the existing generic products.

6 A. Yes.

7 Q. And that's the most accurate way to estimate the  
8 potential market opportunity for a generic drug,  
9 correct?

10 A. Could you repeat that?

11 Q. Sure.

12 You just said that it was the best way to  
13 estimate the size of a generic market opportunity. It's  
14 also the most accurate way to estimate the potential  
15 market opportunity for a generic drug, correct?

16 A. Yes.

17 Q. Now I'd like to turn and ask some questions  
18 about Impax's patent litigation expenses. As CFO,  
19 you're responsible for the budgeting process at Impax.

20 A. Yes.

21 Q. And that includes budgeting for generic patent  
22 litigation?

23 A. Yes.

24 Q. And Impax reports its patent litigations in its  
25 public filings, correct?

1 A. Correct.

2 Q. And Impax reports its patent litigations as part  
3 of its generic R&D expenses?

4 A. Correct.

5 Q. Patent litigations are -- let me start that  
6 again.

7 Patent litigation expenses are largely comprised  
8 of expenses from outside counsel, right?

9 A. Yes.

10 Q. And those are hourly fees from attorneys?

11 A. Yes.

12 Q. And Impax might allocate a little bit for its  
13 internal Legal Department as well, correct?

14 A. A little bit.

15 Q. But it's just a little bit. Those are pretty  
16 minor?

17 A. Um-hum, yes.

18 Q. Is that a yes?

19 A. Yes.

20 Q. Now, the amount that Impax spends on a specific  
21 patent litigation can vary based on a variety of  
22 factors, correct?

23 A. Correct.

24 Q. And one of those factors could be the length of  
25 the litigation?

1 A. Correct.

2 Q. And another of those factors would be whether  
3 there's a settlement.

4 A. Correct.

5 Q. But for the budgeting process, you have to make  
6 the best estimate you can for litigation expenses in  
7 advance, correct?

8 A. Correct.

9 Q. And when you do that, the top end of the range  
10 that you use for a generic patent litigation is about 3  
11 to 4 million dollars?

12 A. Per -- per case?

13 Q. Per litigation, yes.

14 A. Yes.

15 Q. And the 3 to 4 million dollars, that's from the  
16 start of litigation to the finish?

17 A. Yes.

18 Q. Now, for budgeting purposes, Impax has a single  
19 line in its budget for patent litigation spending,  
20 correct?

21 A. Yes.

22 Q. And for 2013, the -- 2013 was the first year  
23 that you were the CFO and doing that process, correct?

24 A. As the CFO, yes.

25 Q. Yes. And do you recall that the total budgeted

1 patent litigation spending for 2013 was \$16.5 million?

2 A. That sounds right.

3 Q. Is that a yes or --

4 A. Yes. Yeah, yes.

5 Q. And the \$16.5 million was for all of Impax's  
6 litigations in 2013.

7 A. Yes.

8 Q. And that was \$6 million higher than Impax had  
9 originally planned for that year.

10 A. I -- I can't recall.

11 Q. If I could -- if I showed you a budget  
12 presentation that you made to the board of directors  
13 with financial results from 2013, might that refresh  
14 your recollection about the budgeted amount of patent  
15 litigation expenses that year?

16 A. It would.

17 Q. All right. Then I'll ask you again, in the  
18 binder, to turn to tab CX 3096.

19 Your Honor, this is in JX 002. It has been  
20 admitted into evidence. It is covered, in part, by Your  
21 Honor's in camera order, but I am using a redacted  
22 version and will not be inquiring about any of the in  
23 camera portions.

24 JUDGE CHAPPELL: Okay.

25 BY MR. TOWEY:

1 Q. Mr. Reasons, if I could have you, when you get  
2 there, to turn to page CX 3096-005. Ms. Wint, could I  
3 get you to put that on the screen.

4 Are you on page 005?

5 A. Yes.

6 Q. Okay. At the very bottom of the chart, there  
7 are three bullets. The bottom bullet says, "Patent Lit  
8 (YTD) exceeded Plan by \$6 million, offset by delayed R&D  
9 spending." Do you see that?

10 A. Yes.

11 Q. And does that refresh your recollection as to  
12 whether patent litigations were \$6 million higher in  
13 2013 than Impax originally planned?

14 A. Yes.

15 Q. And if I could have you put that document aside,  
16 and I just asked if it refreshed your recollection, so  
17 now I'll ask the original question again.

18 So were Impax's patent litigation expenses \$6  
19 million higher in 2013 than Impax originally planned?

20 A. Yes.

21 Q. And even with that additional 6 million,  
22 totaling 16.5 million in the budget for all of Impax's  
23 litigation, that's a lot less than the \$102 million Endo  
24 credit, correct?

25 A. Yes.

1 Q. And that's a lot less than the \$65 million in  
2 net income for the Endo credit.

3 A. Yes.

4 MR. TOWEY: Your Honor, may I confer with  
5 counsel?

6 JUDGE CHAPPELL: I couldn't understand you.

7 MR. TOWEY: May I confer with counsel, please?

8 JUDGE CHAPPELL: Yes, go ahead.

9 (Counsel conferring.)

10 MR. TOWEY: I have no more questions for direct  
11 examination.

12 JUDGE CHAPPELL: Any cross?

13 MR. ANTALICS: Yes, Your Honor.

14 JUDGE CHAPPELL: Go ahead.

15 CROSS EXAMINATION

16 BY MR. ANTALICS:

17 Q. Mr. Reasons, you spoke about the settlement  
18 agreement at some length with counsel. Do you recall  
19 that?

20 A. Yes.

21 Q. Okay. And you talked a little bit about the  
22 Endo credit provision.

23 A. Yes.

24 Q. Okay. Now, was there also a possibility under  
25 the settlement agreement with Endo that a payment would



1 go in the other direction, from Impax to Endo?

2       A. Yes. The settlement agreement was designed so  
3 that if Endo was able to grow the market, Impax would  
4 pay them a royalty.

5       Q. Okay. Well, between paying a royalty to Endo  
6 and, on the other hand, receiving a payment from Endo  
7 under the Endo credit, which is better from Impax's  
8 financial perspective?

9       A. We would prefer to launch the generic into a  
10 robust, large market and pay a royalty and have larger  
11 ongoing revenue streams than have a one-time cash  
12 payment that we would pull out of our GAAP results when  
13 we report to the investors.

14       Q. In your experience, does the investment  
15 community respond better to a one-time payment or a  
16 stream of income into the future?

17       A. They tend to exclude the one-time payment and  
18 are much more forward-looking and prefer forward-looking  
19 revenues.

20       Q. Okay. Now, could Endo have moved the market to  
21 a new formulation and at the same time have avoided  
22 making a payment under the terms of the agreement?

23       A. Yes.

24           MR. TOWEY: Objection, Your Honor. Speculation.

25           THE WITNESS: Yes --

1 JUDGE CHAPPELL: Hold it. Hold it.

2 THE WITNESS: Oh, sorry.

3 JUDGE CHAPPELL: He objected to speculation.  
4 What's your response?

5 MR. ANTALICS: Your Honor, Complaint Counsel  
6 went on at length saying, well, if -- if sales went down  
7 in the future, you know, would you receive a payment  
8 under the Endo credit. I'm just trying to complete the  
9 record here to get the witness' perspective on what  
10 would result in a payment under the agreement and what  
11 would not.

12 JUDGE CHAPPELL: Well, the way it's worded, I'm  
13 not sure it's speculation. It's asking a direct  
14 question. Could Endo have done this at that time?

15 MR. TOWEY: Right, but he has laid no foundation  
16 that he knows what Endo could have or would have done.

17 JUDGE CHAPPELL: That's a different objection.  
18 Are you objecting on foundation?

19 MR. TOWEY: Yes, Your Honor.

20 JUDGE CHAPPELL: That's sustained. Speculation  
21 is overruled. The answer will be disregarded.

22 MR. ANTALICS: May I rephrase it, Your Honor?

23 JUDGE CHAPPELL: Yes.

24 BY MR. ANTALICS:

25 Q. Based on your reading of the agreement, is there

1 a way for -- was there a way for Endo to move the market  
2 to a new formulation and at the same time avoid making a  
3 payment under the agreement?

4 A. Yes.

5 MR. TOWEY: Objection, Your Honor. He's asking  
6 for a legal conclusion. He's asking him to apply a  
7 formula, and there is no foundation that he has applied  
8 that formula.

9 JUDGE CHAPPELL: Do you want to rephrase and  
10 make sure it's not legal?

11 BY MR. ANTALICS:

12 Q. Having read the agreement, did you as a  
13 businessman expect that a business strategy could have  
14 been to move the market in a way that would avoid making  
15 a payment under the Endo credit?

16 A. Yes. They could have moved the market down so  
17 in the last quarter it would be down less than 50  
18 percent and they would not have had to pay the credit.

19 Q. Okay. When was the first time that you heard a  
20 payment would be due under the Endo credit provision?

21 A. Probably May of 2012 when Endo reported their  
22 first quarter results and they publicly disclosed that  
23 they accrued -- they had accrued for that credit.

24 Q. Okay. Did you have an understanding as to what  
25 triggered Endo's disclosure at that point?

1 JUDGE CHAPPELL: You mean does he know?

2 MR. ANTALICS: I think he'll testify to what  
3 he's read.

4 JUDGE CHAPPELL: Let's find out what he knows  
5 rather than what he understood.

6 BY MR. ANTALICS:

7 Q. Okay. Did you read anything -- any statements  
8 from Endo describing the circumstances of the projected  
9 payment to Impax?

10 A. Yes. Based on the -- the market -- the market  
11 degradation at that time, they thought it was probable  
12 that they would move the market enough to the  
13 reformulated Opana that there would be a requirement of  
14 the payment. I think they estimated it to be about 110  
15 million, and that was fully disclosed, and they also  
16 disclosed that it was partially a result of supply  
17 issues with their Opana ER.

18 Q. Do you know what those supply issues were?

19 A. I believe Novartis was unable to supply them  
20 product.

21 Q. Okay. You spoke earlier about the no-AG  
22 provision. Do you recall that?

23 A. Yes.

24 Q. And you talked about it with Complaint Counsel,  
25 about it could have different values depending on the

1 size of the market, correct?

2 A. Correct.

3 Q. Okay. Well, if a branded company takes its  
4 branded drug off the market before the generic can get  
5 on the market, what would be the value of the no-AG  
6 provision to the generic company?

7 A. It would not --

8 MR. TOWEY: Objection. Speculation.

9 THE WITNESS: If there was no --

10 JUDGE CHAPPELL: Hold it. Don't answer when  
11 there's an objection pending.

12 THE WITNESS: Sorry.

13 JUDGE CHAPPELL: Are you going to respond to the  
14 objection?

15 MR. ANTALICS: Could I rephrase it?

16 JUDGE CHAPPELL: Go ahead.

17 BY MR. ANTALICS:

18 Q. When you were reading the settlement agreement  
19 and saw the no-AG provision there, as a businessperson,  
20 were there circumstances in your mind under which the  
21 no-AG provision would have no value?

22 A. Yes. If the -- if the branded market shrunk, it  
23 would have less value. If the -- if the brand company  
24 pulled the AB rated brand drug and moved it to another  
25 brand, it would have no value.

1 Q. And why would it have no value?

2 A. It -- it would not have a -- a substitutable  
3 brand.

4 Q. Okay. You're referring to the automatic  
5 substitution?

6 A. Yes. It wouldn't have an automatic  
7 substitution.

8 Q. Okay. Now, you spoke at length about the  
9 agreement on direct, correct, the settlement agreement?

10 A. Yes.

11 Q. Okay. And you talked about the Endo credit  
12 provision.

13 A. Yes.

14 Q. And you also talked about the no-AG provision  
15 and when that might have value.

16 A. Yes.

17 Q. Okay. Okay. Within that settlement agreement,  
18 there's another provision in there referring to a  
19 co-development and license -- and -- a co-promotion and  
20 development agreement. Do you recall that?

21 A. Yes, yes.

22 Q. Okay. What product did that co-promotion and  
23 development agreement have to do with?

24 A. That's --

25 MR. TOWEY: Objection, Your Honor. Beyond the

1 scope of direct.

2           MR. ANTALICS: Your Honor, Complaint Counsel  
3 talked at length about the agreement, which, as you  
4 know, throughout trial they have linked three payments  
5 they claim from this agreement. They are claiming  
6 there's a payment from the Endo credit, they're claiming  
7 there was a payment from the no authorized generic, and  
8 they're claiming that the co-promotion and development  
9 agreement was inextricably linked and provided yet  
10 another payment --

11          JUDGE CHAPPELL: All right, hold on. The  
12 previous question said --

13          MR. ANTALICS: I was getting into --

14          JUDGE CHAPPELL: -- he was asked about whether  
15 he had talked about the agreement and a co-promotion and  
16 development agreement.

17          MR. ANTALICS: Right.

18          JUDGE CHAPPELL: And is it your position that  
19 you didn't ask about -- anything about what?

20          MR. TOWEY: The co-promotion and development  
21 agreement.

22          JUDGE CHAPPELL: Based on the objection, you  
23 need to lay a foundation.

24          MR. ANTALICS: Well, Your Honor, it's -- it's  
25 within the document that -- that I think they -- I don't

1 recall if they showed it to them, but throughout the  
2 trial, they've said this is part of the agreement --

3 JUDGE CHAPPELL: It doesn't matter what they've  
4 said at trial. It doesn't matter what's in the  
5 agreement. If he didn't ask about it, it's beyond the  
6 scope.

7 Is this witness designated on your witness list?

8 MR. ANTALICS: Your Honor, we reserved the right  
9 to designate witnesses that they called as --

10 JUDGE CHAPPELL: As I've said, you can attempt  
11 to lay a foundation with this witness regarding what he  
12 was asked on direct. If you can't do that, then move  
13 along. I'm sustaining the objection.

14 MR. ANTALICS: Your Honor, my point, though, is  
15 within the agreement that everybody's been talking about  
16 and was talked about on --

17 JUDGE CHAPPELL: It doesn't matter what  
18 everybody's talking about. What matters is what the  
19 witness was asked on direct exam. That's the objection.

20 MR. ANTALICS: Okay, okay.

21 JUDGE CHAPPELL: The objection is not this  
22 hasn't come up in trial before. The objection is what  
23 this witness was asked.

24 BY MR. ANTALICS:

25 Q. Were you asked about the settlement agreement --



1 A. Yes.

2 Q. -- on direct examination?

3 A. Yes.

4 Q. Okay. And were you also asked about the no-AG  
5 provision which is referenced in the settlement  
6 agreement?

7 A. Yes.

8 Q. Okay. Is the co-promotion and development  
9 agreement also referenced in the settlement agreement?

10 A. Yes.

11 MR. ANTALICS: Your Honor, I think it's relevant  
12 if this witness --

13 JUDGE CHAPPELL: Relevance is not the issue.  
14 The objection is beyond the scope.

15 MR. ANTALICS: I think it's within the scope --

16 JUDGE CHAPPELL: If you want to call this  
17 witness on direct and he's on your list, we'll consider  
18 that. If not, I haven't -- I didn't hear any questions  
19 about the co-promotion agreement.

20 MR. ANTALICS: Well, Your Honor --

21 JUDGE CHAPPELL: And you didn't ask him that  
22 question.

23 MR. ANTALICS: Let me try one more, Your Honor.  
24 The Complaint Counsel have offered into evidence and  
25 it's been accepted into evidence this witness'

1 deposition transcript in which, at length, they go into  
2 the co-promotion and development agreement.

3           Now, I suspect we will see at some point some  
4 proposed findings of fact that relate to some of that  
5 testimony. I'd like to give the witness an opportunity  
6 to explain what he knows in a little more detail about  
7 that agreement.

8           MR. TOWEY: And, Your Honor, they did not call  
9 this witness, and they did not list this as a topic that  
10 this witness would be talking about.

11          JUDGE CHAPPELL: You didn't respond to what he  
12 just said. Do you plan on offering any deposition  
13 testimony from the deposition of this witness?

14          MR. TOWEY: Any deposition testimony? At this  
15 point, we don't know what we're going to offer.

16          JUDGE CHAPPELL: The objection's overruled. Go  
17 ahead. That's why he's here. You can question him  
18 about the deposition.

19          MR. ANTALICS: Okay.

20          JUDGE CHAPPELL: If they stood there and told me  
21 they're not offering any excerpts whatsoever, I'm  
22 cutting you off, but he didn't do that, so you go ahead.

23          MR. ANTALICS: Thank you, Your Honor. Okay.

24          JUDGE CHAPPELL: It doesn't make sense to let  
25 his deposition come in and he not be asked about topics

1 in the deposition. Since you didn't exclude that  
2 possibility, you're overruled.

3 BY MR. ANTALICS:

4 Q. Mr. Reasons, during your deposition, did you  
5 speak about the drug Rytary?

6 A. I did.

7 Q. And did you also speak in your deposition about  
8 the development drug 203?

9 A. Yes, I did.

10 Q. Okay. Could you explain for the Court first,  
11 what is Rytary?

12 A. Rytary is an extended-release carbidopa-levodopa  
13 for the treatment of symptoms of Parkinson's.

14 Q. Okay. Can you describe generally what 203 is?

15 A. It's our next generation in which it's a  
16 carbidopa-levodopa-based product that hopefully improves  
17 the treatment of those symptoms and also has favorable  
18 dosing over Rytary.

19 Q. Now, during the course of the development of  
20 203, were there delays in that development?

21 A. There were.

22 Q. Okay. And what was the cause of those delays?

23 MR. TOWEY: Your Honor, I would object until  
24 Mr. Antalics can point out where in his deposition this  
25 is discussed, if the deposition is the basis for this

1 line of questioning.

2 JUDGE CHAPPELL: Or lay a foundation that it's  
3 within the deposition.

4 BY MR. ANTALICS:

5 Q. Okay. Do you recall speaking about delays in  
6 the development of 203 which resulted in you not  
7 receiving milestone payments?

8 A. I did.

9 MR. TOWEY: Objection. Is this from the  
10 deposition or earlier testimony?

11 MR. ANTALICS: From the deposition.

12 JUDGE CHAPPELL: Restate the question.

13 BY MR. ANTALICS:

14 Q. Do you recall speaking about not receiving  
15 milestone payments because of delays in the development  
16 of 203 during the course of your deposition?

17 A. I do.

18 Q. Okay. Now, what caused the delay in the  
19 development of 203?

20 A. Well, 203 was the next generation of Rytary. It  
21 was several years behind Rytary in the R&D cycle. When  
22 Rytary was delayed, resources were put to focus on the  
23 approval of Rytary so that we could get that to market,  
24 grow that -- grow that commercially, and it would also  
25 be beneficial to -- when we launched the next generation

1 of 203, to have a robust Rytary market.

2           We felt it would also, to get through the Rytary  
3 and get that approved, it would help from a regulatory  
4 perspective in getting IPX-203 approved as well.

5       Q.   Okay.  Where is 203 today in terms of its  
6 development?

7       A.   203, we've completed -- we've now completed  
8 Phase II-A and II-B, are finishing our final review of  
9 that, and we expect to start Phase III at the beginning  
10 of 2018.  It's our lead compound on the brand side of  
11 our R&D programs.  It's really our strategy to continue  
12 to grow and extend the duration of our Parkinson's  
13 franchise.

14      Q.   Based on your experience, are delays in  
15 development of a new drug unusual?

16      A.   They are very common.

17      Q.   Okay.  And does it, from time to time, happen  
18 that a new product development effort is unsuccessful?

19      A.   It's very common.

20      Q.   Okay.  How many deals have you been involved in?

21      A.   Over my career --

22           MR. TOWEY:  Objection, Your Honor.

23           THE WITNESS:  -- hundreds --

24           JUDGE CHAPPELL:  Hold it.  When someone objects,  
25 you need to hold your answer.

1 THE WITNESS: Sorry.

2 MR. TOWEY: It's beyond the scope. I don't know  
3 of anywhere in the deposition where this was covered,  
4 Your Honor.

5 MR. ANTALICS: Number one, his time frame at  
6 Cephalon was covered. We're talking about and laying a  
7 foundation for why he can speak about the development  
8 progress and how that relates to other drugs. His  
9 experience is certainly a factor in developing that  
10 foundation, I think.

11 MR. TOWEY: Your Honor, I don't know of anywhere  
12 in the deposition that he said anything about his  
13 experience with drug development. He certainly wasn't  
14 noticed for this topic by Respondent.

15 MR. ANTALICS: Your Honor, it's foundational,  
16 his experience.

17 JUDGE CHAPPELL: Regarding what? Regarding  
18 something on direct?

19 MR. ANTALICS: As to why -- yes, as to issues  
20 that he's -- he was -- that he's talked about during his  
21 deposition, such as the delay, such as the \$10 million  
22 payment, such as milestones, things like that.

23 JUDGE CHAPPELL: Are these questions in his  
24 deposition?

25 MR. ANTALICS: Yes.

1 JUDGE CHAPPELL: Well, you can offer those  
2 excerpts.

3 MR. ANTALICS: Well, I'd like to hear -- to have  
4 the -- I have maybe five or ten minutes on this, Your  
5 Honor. I'd like the Court to hear -- you know, with the  
6 benefit of the witness on the stand, if you have  
7 questions or --

8 JUDGE CHAPPELL: So you're asking a foundational  
9 question regarding a topic that was covered in the  
10 deposition?

11 MR. ANTALICS: Right.

12 JUDGE CHAPPELL: I'll allow it for now.  
13 Overruled.

14 THE WITNESS: Could you repeat the question?

15 BY MR. ANTALICS:

16 Q. Approximately how many deals were you involved  
17 in in your experience?

18 A. In my career, a hundred.

19 Q. Okay. What kinds of deals were you involved in?

20 A. I mean, they would -- they would vary from major  
21 M&A to in-licensing to co-developments to options to  
22 license, options to co-develop, you know, a full gamut  
23 of structures.

24 Q. Is a \$10 million up-front payment unusual in a  
25 co-development agreement?

1       A.  It's quite --

2           MR. TOWEY:  Objection, Your Honor.  This is  
3 nowhere in the deposition.  He seems to be responding to  
4 the prior witness and not to anything that I asked or  
5 anything in the deposition.

6           JUDGE CHAPPELL:  I haven't heard anything about  
7 the up-front payment.

8           MR. ANTALICS:  The up-front payment -- the \$10  
9 million up-front payment certainly was discussed in the  
10 deposition.

11          MR. TOWEY:  Where was it discussed?

12          MR. ANTALICS:  On page 83.

13          "QUESTION:  Were you aware that Impax got an  
14 up-front payment as part of the co-promotion agreement?

15          "ANSWER:  Yes.

16          "QUESTION:  Do you know how much that up-front  
17 payment was?

18          "ANSWER:  I believe it was 10 million."

19          And it goes on.

20          MR. TOWEY:  And, Your Honor, I see nothing here  
21 that talks about comparisons to other deals or  
22 Mr. Reasons' experience dealing with co-promotion and  
23 development agreements.

24          JUDGE CHAPPELL:  I think this one's getting a  
25 little too far afield.  I'm sustaining that.  You can



1 move on.

2 MR. ANTALICS: I'm sorry, Your Honor?

3 JUDGE CHAPPELL: You're getting a little too far  
4 afield. I'm sustaining the objection. Move on.

5 BY MR. ANTALICS:

6 Q. With respect now to --

7 Your Honor, may I ask a separate question  
8 relating to that \$10 million payment and -- that was --  
9 should I just put forward the question and --

10 JUDGE CHAPPELL: Anything you ask, you need to  
11 connect it to the deposition or the direct with the  
12 witness, which you haven't been doing, because we have  
13 got a foundation objection --

14 MR. ANTALICS: Okay, all right.

15 JUDGE CHAPPELL: -- and a scope objection, both.

16 MR. ANTALICS: May I ask, Your Honor -- the  
17 witness how the company accounted for the \$10 million  
18 payment?

19 MR. TOWEY: It was not addressed on direct  
20 examination, but I believe there is something in the  
21 deposition on it.

22 JUDGE CHAPPELL: Go ahead.

23 BY MR. ANTALICS:

24 Q. How did Impax account for that \$10 million  
25 payment?

1       A. When we received it, we deferred it, and we  
2 recognized it based on R&D work that was then  
3 accomplished going forward.

4       Q. So can you explain a little more what you mean  
5 by that? Did you recognize just a portion of it?

6       A. So we -- we -- when we received it, we  
7 recognized zero, and as we did R&D work, we began to  
8 recognize a portion of it over time, as it was earned,  
9 because we -- it was related to R&D -- future R&D work.

10      Q. Okay. And are there any accounting rules or  
11 standards that factored into that decision?

12      A. Yeah. There's a lot. It's -- there's lots of  
13 standards around both revenue recognition and R&D  
14 milestone accounting, and that's -- you know, we --  
15 we -- we issue our financial statements in accordance  
16 with GAAP and follow that.

17      Q. Okay. And are they filed with the SEC?

18      A. They are reviewed quarterly by our independent  
19 accountants, audited annually, and signed off by not  
20 only the accountants but the CEO and myself.

21      Q. Thank you.

22             Your Honor, I have nothing further.

23             JUDGE CHAPPELL: Redirect?

24             MR. TOWEY: Yes, Your Honor.

25             May I have one moment?

1 JUDGE CHAPPELL: Go ahead.

2 (Counsel conferring.)

3 MR. TOWEY: I won't have too many questions,  
4 Your Honor.

5 REDIRECT EXAMINATION

6 BY MR. TOWEY:

7 Q. Is the current version of IPX-203 the product  
8 that was covered by the confidentiality and disclosure  
9 agreement that Impax signed with Endo?

10 A. I'm not sure.

11 Q. And is it the product of the co-promotion and  
12 development agreement?

13 A. I'm not sure.

14 Q. And you were just discussing with Mr. Antalics  
15 when the \$10 million payment was recognized. Is that --  
16 do you recall that?

17 A. Correct.

18 Q. And when was the \$10 million finally recognized?

19 A. It was recognized over time as it was earned,  
20 and then the remainder was recognized when Endo exited  
21 the agreement.

22 Q. So when Endo exited the agreement, Impax had not  
23 yet spent \$10 million on IPX-203?

24 A. We had not fully recognized the milestone  
25 payment, which is based on work accomplished, not spent.

1 Q. So by the time that Endo exited the agreement,  
2 Impax had not accomplished \$10 million worth of work  
3 yet?

4 A. We had not fully recognized the \$10 million  
5 milestone.

6 Q. Right. What I'm asking is, I'm trying to  
7 understand what that means. Does that mean that Impax  
8 had not done \$10 million worth of work by the time that  
9 Endo exited the agreement?

10 A. No, it doesn't.

11 Q. How much work had Impax done?

12 A. We had -- I -- I'd have to go back and look at  
13 how much exactly we'd spent, but I -- I don't recall off  
14 the top of my head.

15 Q. But it had not recognized all \$10 million of  
16 that up-front payment by the time you --

17 A. We had not recognized all 10 million of that  
18 up-front payment, correct.

19 Q. Now, I want to ask some questions --  
20 Mr. Antalics asked you some questions about whether Endo  
21 could have timed the Endo credit such that it might have  
22 been zero. Do you recall that?

23 A. Say it again. I'm sorry.

24 Q. Mr. Antalics asked you some questions about  
25 whether Endo could have timed the Endo credit such that

1 there may have been a zero payment under the Endo  
2 credit.

3 A. Yes.

4 Q. And you don't know, at the time of settlement,  
5 how long Endo thought it would take to convert original  
6 Opana ER to a reformulated Opana ER, do you?

7 A. At the time of settlement? I didn't work at  
8 Impax.

9 Q. So you don't know.

10 A. Right.

11 Q. And, in fact, at any point in time, you don't  
12 know how long Endo thought it would take to convert from  
13 original Opana ER to reformulated Opana ER, correct?

14 A. Correct.

15 Q. And you don't know, under any plan, how much  
16 would be remaining in the distribution channels of  
17 original Opana ER when Impax launched its generic?

18 A. Can you repeat that?

19 Q. Sure.

20 You don't know, under any Endo plan, how long --  
21 how much would be remaining of generic Opana ER in the  
22 distribution channels when Impax launched its generic.

23 A. I -- I did not know.

24 Q. And you don't know, under any Endo plan, how  
25 much would be remaining in the retail channels.

1 A. I did not know.

2 Q. And you do not know, under any Endo plan, what  
3 percentage of patients would stay with Impax's generic  
4 instead of converting to the reformulated product, if  
5 there was anything left in the distribution and retail  
6 channels, do you?

7 A. Ah, no.

8 Q. So, essentially, your testimony is speculation  
9 based on no knowledge of Endo's plans.

10 A. No.

11 Q. Your testimony is not -- you do know about  
12 Endo's plans?

13 A. Which -- which comments are you talking about?

14 Q. So I just asked you a bunch of questions about  
15 did you know Endo's plans, and you said no to each of  
16 those questions --

17 JUDGE CHAPPELL: Why don't you narrow that  
18 question, because that was -- "your testimony is  
19 speculation," that could include everything he's said.  
20 You need to narrow this.

21 MR. TOWEY: Thank you, Your Honor.

22 BY MR. TOWEY:

23 Q. So your testimony about whether Endo could have  
24 timed the Endo credit to equal zero is speculation about  
25 what Endo thought it could do.

1 A. No. My testimony said that it could be timed.

2 Q. But you don't know if Endo thought that.

3 A. I don't know what Endo thought.

4 Q. And you have not seen any Endo plans that would  
5 allow you to conclude what Endo would do or could do.

6 A. I -- I never said that.

7 Q. So the answer is, no, you don't have any of that  
8 information?

9 A. No, no.

10 Q. You -- also under examination by Mr. Antalics,  
11 you answered that Impax would prefer to sell into a  
12 robust market and have a stream of revenues rather than  
13 a one-time payment, correct?

14 A. Correct.

15 Q. And it's better to sell into that robust market  
16 with only one generic rather than face the possibility  
17 of two generics, correct?

18 A. Correct.

19 Q. But Impax knew that it wouldn't face another  
20 generic because it had the no-AG agreement with Endo  
21 under the settlement agreement, correct?

22 A. Repeat the question, please.

23 Q. So Impax knew that it would not face another  
24 generic in this -- if there was a robust market because  
25 it had the no-AG agreement with Endo from the 2010

1 settlement agreement.

2 A. No. Generic competition would eventually come.

3 Q. But for the exclusivity period --

4 A. Oh, okay, you didn't say that. Repeat the  
5 question, please.

6 Q. Sure.

7 If Impax were launching into a robust market  
8 with first-to-file exclusivity, it would know, because  
9 of the no-AG agreement, that it would not be facing any  
10 generic competition.

11 MR. ANTALICS: Objection, Your Honor. We're  
12 speculating at this point now.

13 JUDGE CHAPPELL: I think I recall him saying he  
14 wasn't up on this exclusivity period, so I'm going to  
15 sustain that without a foundation.

16 BY MR. TOWEY:

17 Q. Mr. Reasons, you said it's better to sell into a  
18 robust market as the only generic, correct?

19 A. Yes.

20 Q. And the no-AG provision precluded Endo during  
21 Impax's first-to-file exclusivity period from selling an  
22 authorized generic, correct?

23 A. Yes.

24 MR. TOWEY: May I confer with counsel, Your  
25 Honor?



1 JUDGE CHAPPELL: Go ahead.

2 (Counsel conferring.)

3 BY MR. TOWEY:

4 Q. You also testified that there was a possibility  
5 that Impax would pay a royalty under the settlement  
6 agreement.

7 A. That's correct.

8 Q. And Impax would only pay that royalty if branded  
9 Opana ER sales increased by certain thresholds prior to  
10 Impax's launch, correct?

11 A. Correct.

12 Q. And in that circumstance, Impax would get value  
13 from the no-AG provision even if it was paying the  
14 royalty, correct?

15 MR. ANTALICS: Objection. I think we're  
16 speculating again.

17 JUDGE CHAPPELL: He objected to speculation.

18 MR. TOWEY: I'm just asking for the logical  
19 conclusion of what he was talking about with the  
20 royalty.

21 JUDGE CHAPPELL: But a logical conclusion can  
22 still be speculation. Unless you have something else, I  
23 am going to sustain it.

24 MR. TOWEY: I'll ask it a different way, then.

25 JUDGE CHAPPELL: All right.

1 BY MR. TOWEY:

2 Q. If the market for Opana ER grew, the potential  
3 for generic sales would increase as well, correct?

4 MR. ANTALICS: Objection, Your Honor.  
5 Speculation.

6 MR. TOWEY: Your Honor --

7 MR. ANTALICS: It starts with "if." I think  
8 we're automatically into speculation, Your Honor.

9 MR. TOWEY: Your Honor, earlier the witness  
10 testified that Impax would rather sell into a larger  
11 market than not. This is just --

12 JUDGE CHAPPELL: I am going to allow this, but  
13 you need to wrap this up.

14 MR. TOWEY: Okay.

15 JUDGE CHAPPELL: Overruled.

16 BY MR. TOWEY:

17 Q. So let me ask the question again.

18 If the market for Opana ER grew, the potential  
19 for generic sales would increase as well.

20 A. Yes.

21 Q. And in that larger market, there would be no  
22 second generic competitor during Impax's first-to-file  
23 exclusivity period, correct?

24 A. Correct.

25 Q. And that would allow Impax to charge a higher

1 price, correct?

2 MR. ANTALICS: Objection, Your Honor. We're  
3 speculating, if this happens and this happens, then this  
4 would allow something else. It's speculation on  
5 speculation.

6 MR. TOWEY: He's --

7 JUDGE CHAPPELL: I haven't heard him say  
8 anything about pricing.

9 MR. TOWEY: He talked about if there was a  
10 one-generic market versus a two-generic market, it would  
11 have a 30 to 35 percent price difference.

12 JUDGE CHAPPELL: The way you phrased the  
13 question, even if he answers it, it's not going to do  
14 you any good. Sustained.

15 BY MR. TOWEY:

16 Q. In a one-generic marketplace, Impax would have  
17 100 percent of generic Opana ER sales, correct?

18 A. Correct.

19 Q. And if Impax faced competition from an  
20 authorized generic, there would not be any -- Impax  
21 would not have 100 percent --

22 MR. ANTALICS: Objection. We're, again --

23 JUDGE CHAPPELL: I'm allowing this one, but  
24 that's it. Overruled. Answer the question, move on, or  
25 sit down. We have beat this to death.

1 THE WITNESS: Can you say it one more time?

2 Sorry.

3 BY MR. TOWEY:

4 Q. Sure.

5 If Impax faced competition from an authorized  
6 generic, then Impax would not have 100 percent of  
7 generic Opana ER sales, correct?

8 A. Probably.

9 Q. Is there any marketplace which you, in your  
10 experience, have faced where there are two generics and  
11 one of them has 100 percent market share of the generic  
12 product?

13 A. No.

14 MR. TOWEY: I have no more questions, Your  
15 Honor.

16 JUDGE CHAPPELL: Anything else?

17 MR. ANTALICS: Nothing, Your Honor.

18 JUDGE CHAPPELL: Thank you. You may stand down.  
19 We will reconvene Thursday, 9:45 a.m. We're in  
20 recess.

21 (Whereupon, at 5:57 p.m., trial was adjourned.)

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## 1 CERTIFICATE OF REPORTER

2

3 I, Susanne Bergling, do hereby certify that the  
4 foregoing proceedings were recorded by me via stenotype  
5 and reduced to typewriting under my supervision; that I  
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9 or employee of any attorney or counsel employed by the  
10 parties hereto, nor financially or otherwise interested  
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16 s/Susanne Bergling

17 SUSANNE BERGLING, RMR-CRR-CLR

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