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- VOLUME 1 -

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

SANOFI AVENTIS U.S. LLC, : CIVIL ACTION
SANOFI AVENTIS DEUTSCHLAND :
and SANOFI-AVENTIS WINTHROP :
INDUSTRIES, :

Plaintiffs, :

vs. :

MERCK SHARP & DOHME :
CORPORATION, :

Defendant. : NO. 16-812 (RGA)

- - -

Wilmington, Delaware
Tuesday, May 29, 2018
8:30 o'clock, a.m.

- - -

BEFORE: HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

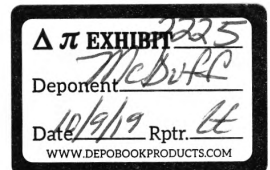
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APPEARANCES:

FISH & RICHARDSON P.C.
BY: MARTINA A. HUFNAL, ESQ.

-and-

Leonard A. Dibbs
Valerie J. Gunning
Official Court Reporters



Moskow - direct

1 **Sanofi, would you like to call a witness?**

2 **MR. MARSILLO: Angela Moskow.**

3 **... ANGELA MOSKOW, having duly**

4 **sworn as a witness, was examined and**

5 **testified as follows ...**

6 **DIRECT EXAMINATION**

7 **BY MR. MARSILLO:**

8 Q. **Good morning, Ms. Moskow.**

9 A. **Good morning.**

10 Q. **Are you presently employed?**

11 A. **Yes, I am.**

12 Q. **Where are you presently employed?**

13 A. **I'm self-employed.**

14 Q. **And what type of business do you have?**

15 A. **I have a healthcare marketing consultancy.**

16 Q. **So prior to starting your own business, what was your
17 most recent employment?**

18 A. **I worked for Sanofi.**

19 Q. **And for how long did you work for Sanofi?**

20 A. **I started working for Sanofi in August of 1990. And I
21 was continuously employed until the end of April 2017.**

22 **I apologize for my voice.**

23 Q. **It's quite all right.**

24 **So understanding that your roles and responsibilities
25 changed during that time, can you briefly describe the roles**

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Moskow - direct

1 and responsibilities that you had at Sanofi during your
 2 tenure?
 3 A. Yes, I started in our sales organization and then
 4 moved over into our marketing area, which is where the
 5 majority of my career was spent. And then finished up in
 6 the corporate affairs area.
 7 Q. And during your time at Sanofi, did you work with any
 8 particular product or products?
 9 A. Yes, predominantly I worked with our Glargine
 10 portfolio, which included both Lantus and Apidra.
 11 Q. So what is Lantus?
 12 A. Lantus is a 24-hour basal insulin also known as
 13 insulin glargine, which is used to treat diabetes.
 14 Q. And as far as your roles and responsibilities, did you
 15 develop a general understanding of Lantus, including its
 16 active ingredients and properties?
 17 A. Yes, I did.
 18 Q. So what is an insulin glargine?
 19 A. Insulin glargine is a molecule that was designed to be
 20 an insulin to have some different properties like to last
 21 longer over a 24-hour period and to mimic more what the
 22 pancreas does for a basal or background break.
 23 Q. So you mentioned that Lantus is 24 hours.
 24 What do you mean by 24-hour Lantus?
 25 A. So, if a patient who has diabetes with one injection,

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Moskow - direct

1 the Lantus profile would last for them, and would work to
 2 lower their glucose for a full 24 hours.
 3 Q. And you also used the term "basal."
 4 What do you mean, the "Lantus with basal insulin"?
 5 A. In patients who have do not have diabetes, or people
 6 who do not have diabetes, the pancreas is always making a
 7 certain amount of insulin that the body needs, so that's
 8 your basal or your background rate that is present.
 9 Q. So going back to your work at Sanofi, specifically
 10 with respect to Lantus, what positions did you have related
 11 to Lantus.
 12 A. I started initially as a promotional manager, which is
 13 role that supports the Products Manager that were getting
 14 ready to launch Lantus.
 15 I then moved into a Product Manager role right before
 16 the launch of Lantus, and then held multiple roles on the
 17 Lantus brand up until the last five years that I was the
 18 head of the Marketing Department for Lantus.
 19 Q. When was Lantus launched in the United States?
 20 A. May of 2001.
 21 Q. And in what format was Lantus marketed when it was
 22 launched in the United States?
 23 A. It was launched in the 10 millimeter vials.
 24 Q. Prior to the launch in the United States, had it been
 25 launched elsewhere?

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Moskow - direct

1 A. Yes.
 2 Q. And where?
 3 A. The first country to launch was Germany, and that was
 4 in June of 2000.
 5 Q. And in obtaining approval to market Lantus in the
 6 United States, did Sanofi submit data from clinical trials
 7 to the FDA?
 8 A. Yes.
 9 Q. So prior to launch of Lantus in the United States,
 10 were you aware of any data in those clinical trials or from
 11 Sanofi's year-long experience with Lantus in Germany, or
 12 from any other source, that indicated to you that there were
 13 any issues concerning cloudiness in the Lantus formulation?
 14 A. No.
 15 Q. So what, if any, responsibilities did you have with
 16 respect to the launch of Lantus?
 17 A. I had a bunch of responsibilities. Initially market
 18 research to understand what were the unmet needs in the
 19 marketplace, in the diabetes marketplace. Then
 20 understanding the product labeling that we were going to
 21 have for Lantus. And then looking at what were the messages
 22 or materials that we wanted to build around the launch to
 23 communicate the benefits of Lantus moving forward.
 24 Q. So what was the method that Sanofi selected to
 25 communicate Lantus in the marketplace?

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Moskow - direct

1 A. The primary method was 24-hour control.
 2 So because Lantus was a new insulin, and there wasn't
 3 one that lasted 24 hours with one injection, that's the area
 4 that we really wanted to focus on.
 5 Q. Was Lantus the first long-acting basal insulin
 6 formulation launched in the U.S. market?
 7 A. Yes.
 8 Q. Now, after the launch of Lantus in the United States,
 9 were you made aware of any information that indicated that
 10 there were issues relating to the cloudiness of the Lantus
 11 formulation in its vials?
 12 A. Yes, we were.
 13 Q. What information were you made aware that that
 14 indicated that there were issues concerning cloudiness in
 15 the Lantus vials?
 16 A. Shortly after the launch of Lantus in the United
 17 States, there were complaints as far as coming into the
 18 company, where patients would identify that they had a vial
 19 of Lantus that they would see white particles or
 20 participants, or it looks cloudy. And this was certainly a
 21 concern.
 22 Q. And did Sanofi track those complaints?
 23 A. Yes.
 24 Q. And as far as your responsibilities, were you made
 25 aware of those complaints?

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Moskow - direct

1 A. I was.

2 Q. Approximately how many complaints did Sanofi receive

3 within that first year or so?

4 A. Over the first year I think it was about 150.

5 Q. And why were the complaints of cloudy vials a concern

6 for Sanofi?

7 A. Well, the first reason they were a concern is, we

8 didn't know why it was happening. So we first needed to

9 understand why was this happening.

10 Q. Were there any concerns about how the complaints of

11 cloudiness in the vials would affect the Lantus brand?

12 A. Yes, absolutely?

13 Q. Now, in your deposition in this matter, you testified

14 that the complaints about cloudiness were more of a signal

15 than an issue.

16 What do you mean by that?

17 A. When the complaints first starting coming in, the

18 number was not very high, especially when you look at the

19 number of complaints per thousands of vials that were in the

20 marketplace.

21 So I think of it more as a signal. Something that we

22 needed to investigate and to understand. As time went on,

23 though, the complaints continued to increase.

24 And, so, certainly the company looked at this as an

25 issue that needed to be addressed.

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Moskow - direct

1 Q. So what did Sanofi do in response to receiving the

2 complaints concerning cloudiness in the Lantus vial?

3 A. There were multiple things that were done.

4 The -- of course the first thing we wanted to

5 understand was why, so we had several different parts of the

6 organization investigate why was this happening, why were we

7 getting the complaint of cloudy vials.

8 One of the areas that I was working on specifically

9 was understanding our distribution channel. And knowing

10 that Lantus is a different insulin, and that it needs to

11 stay under refrigeration from Sanofi to our wholesalers,

12 retailers, and then ultimately to the patient, we wanted to

13 understand was there a breakdown where the product was not

14 refrigerated and not kept within the specifications that are

15 required.

16 There were others in the company that were looking at

17 the batches that were coming into the U.S. to see whether

18 there was something different about these batches versus

19 what was happening in Europe.

20 We also had a group that was looking at the needle,

21 and was there some type of contaminant that was being put

22 into the vial when the needle was going into the vial.

23 So certainly a lot of different things that we needed

24 to understand what exactly was happening.

25 Q. So when these complaints came in, and Sanofi started

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Moskow - direct

1 investigating, did any member of the groups that you just

2 describe state that they were immediately aware of what the

3 cause of the cloudiness in the vials was?

4 A. No, that's why we were trying to understand the

5 situation.

6 Q. And did you continue to receive complaints concerning

7 cloudiness in the Lantus vials after that first year or so?

8 A. Yes, we did.

9 Q. Would you turn with me to Defendant's Exhibit 194.

10 (Defendant's Exhibit No. 194 was admitted into

11 evidence.)

12 BY MR. MARSILLO:

13 Q. It's also on the screen.

14 A. Yes.

15 Q. What is that document?

16 A. This is an internal report that was prepared to give

17 -- it was an executive overview during the time period, May

18 2003. The number of complaints that were coming in

19 associated with this issue of turbidity. And then also if

20 there were adverse events that were associated with this

21 particular type of complaint.

22 Q. And if we turn to page 3, there's a chart of the

23 complaints at least during the time period shown?

24 A. Yes.

25 Q. Now, did Sanofi communicate with the FDA concerning

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Moskow - direct

1 cloudiness in the Lantus vials?

2 A. Yes.

3 Q. Were you kept apprised of those communications?

4 A. Yes, I was.

5 Q. Now, did you know what a field alert is?

6 A. I do.

7 Q. What is a field alert?

8 A. A field alert is when a company has information about

9 one of their products that is currently marketed to the

10 public. And if there is something that they are seeing,

11 that they feel they need to alert the FDA to get an issue of

12 a field alert.

13 Q. And when the field alert issued with respect to the

14 cloudiness in the Lantus vial?

15 A. Yes.

16 Q. When?

17 A. I'm sorry?

18 Q. When?

19 A. June of 2001.

20 Q. And did you have concerns about the FDA's response in

21 connection with complaints regarding cloudiness in the

22 Lantus vial?

23 A. Yes, I did.

24 Q. What was your understanding as to what the FDA could

25 do in response to concern about cloudiness in the Lantus

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Moskow - direct

1 vial?

2 A. The FDA has a lot of different things they can do. We

3 certainly wanted to keep the conversations private in

4 sharing the information that we had. The FDA couldn't

5 decide that they were going to issue a public communication,

6 which we were at the beginning of a launch in trying to

7 establish the brand and that certainly could be detrimental.

8 The FDA also had the power to potentially do a recall

9 which could be detrimental or even pull the product off the

10 market if they felt strongly about it which, of course,

11 would have been catastrophic for the Lantus brand at that

12 time.

13 Q. And we talked about some of the complaints that Sanofi

14 received.

15 As far as you know, were any of those complaints

16 publicly disclosed?

17 A. No.

18 Q. Now, what did Sanofi ultimately decide to do after

19 completing its investigation in the cloudiness in the Lantus

20 vial?

21 A. After we completed the investigation with the project

22 team, we decided that it would be the best solution, and

23 what was presented to the organization was to reformulate

24 Lantus in a vial.

25 Q. And did Sanofi submit a supplemental NDA concerning

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Moskow - direct

1 its reformulated Lantus?

2 A. Yes.

3 Q. And how much time elapsed between the start of the

4 investigation into the cloudiness in the Lantus vial and

5 submission of the supplemental NDA?

6 A. It was about three years.

7 Q. What, if any, effect did the change in the formulation

8 have on the number of complaints that Sanofi received with

9 respect to cloudiness in its vials?

10 A. They dramatically decreased.

11 Q. As if?

12 MR. MARSILLO: If we can take a look at

13 Plaintiff's Exhibit 722?

14 (Plaintiff's Exhibit No. 722 was admitted into

15 evidence.)

16 BY MR. MARSILLO:

17 Q. It's also on the screen.

18 A. Yes.

19 Q. What is Plaintiff's Exhibit 722?

20 A. This is a chart which was compared and looked at over

21 the years after the reformulation was into the U.S.

22 marketplace. The number of complaints and how they

23 decreased over time.

24 Q. Now, besides marketing Lantus in the vial format, did

25 Sanofi market Lantus in any other format?

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Moskow - direct

1 A. Yes.

2 Q. What format?

3 A. There were two.

4 One was the reusable pen device which is called Lantus

5 OptiClik and the other was a disposable pen device called

6 Lantus SoloSTAR.

7 Q. And is OptiClik still distributed by Sanofi in the

8 United States?

9 A. It is not.

10 Q. Why did Sanofi discontinue distributing the OptiClik?

11 A. It was lack of market demands here in the United

12 States.

13 Q. Now, did Sanofi receive any complaints of cloudiness

14 in either the SoloSTAR pen device or the OptiClik pen

15 device?

16 A. No.

17 Q. And the -- if I'm correct, Ms. Moskow, each of those

18 pen devices contain a cartridge that has a formulation in

19 it?

20 A. That is correct.

21 Q. And what is the formulation that is used in the Lantus

22 SoloSTAR?

23 A. It is the original formulation that was approved here

24 in the United States in 2000.

25 Q. You mentioned SoloSTAR.

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Moskow - direct

1 Is SoloSTAR still distributed by Sanofi?

2 A. Yes, it is.

3 Q. And who designed SoloSTAR?

4 A. We worked with a firm out of the United Kingdom called

5 DCA.

6 Q. I'm sorry.

7 When was SoloSTAR launched?

8 A. It was launched until July of 2007.

9 Q. And you may have mentioned this, but when was the

10 Lantus OptiClik launched?

11 A. In January of 2015 -- sorry -- 2005. January of 2005.

12 Q. So OptiClik was still on the market at the time that

13 SoloSTAR launched?

14 A. Yes, it was.

15 Q. Were there any other injections pens on the market

16 besides Lantus OptiClik and Lantus SoloSTAR, when SoloSTAR

17 launched?

18 A. Yes, there were multiple pens on the market from a

19 competitive standpoint. Two that we paid close attention to

20 were the Flexpen by Nova Nordis and also Lilly's disposable

21 pen.

22 Q. And what were your responsibilities with respect to

23 the launch of SoloSTAR?

24 A. I was leading the marketing team that was responsible

25 for the launch of the Lantus SoloSTAR.

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