- VOLUME 1 -

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

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

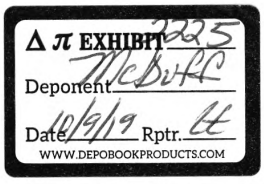
- - -

APPEARANCES:

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

-and-

Leonard A. Dibbs
Valerie J. Gunning
Official Court Reporters



Sanofi, would you like to call a witness?

MR. MARSILLO: Angela Moskow.

... ANGELA MOSKOW, having duly sworn as a witness, was examined and testified as follows ...

DIRECT EXAMINATION

BY MR. MARSILLO:

Q. Good morning, Ms. Moskow.

A. Good morning.

Q. Are you presently employed?

A. Yes, I am.

Q. Where are you presently employed?

A. I'm self-employed.

Q. And what type of business do you have?

A. I have a healthcare marketing consultancy.

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

A. I worked for Sanofi.

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

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

I apologize for my voice.

Q. It's quite all right.

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

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

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

A. Yes.
Q. And where?
A. The first country to launch was Germany, and that was in June of 2000.
Q. And in obtaining approval to market Lantus in the United States, did Sanofi submit data from clinical trials to the FDA?
A. Yes.
Q. So prior to launch of Lantus in the United States, were you aware of any data in those clinical trials or from Sanofi's year-long experience with Lantus in Germany, or from any other source, that indicated to you that there were any issues concerning cloudiness in the Lantus formulation?
A. No.
Q. So what, if any, responsibilities did you have with respect to the launch of Lantus?
A. I had a bunch of responsibilities. Initially market research to understand what were the unmet needs in the marketplace, in the diabetes marketplace. Then understanding the product labeling that we were going to have for Lantus. And then looking at what were the messages or materials that we wanted to build around the launch to communicate the benefits of Lantus moving forward.
Q. So what was the method that Sanofi selected to communicate Lantus in the marketplace?

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

A. I was.
Q. Approximately how many complaints did Sanofi receive within that first year or so?
A. Over the first year I think it was about 150.
Q. And why were the complaints of cloudy vials a concern for Sanofi?
A. Well, the first reason they were a concern is, we didn't know why it was happening. So we first needed to understand why was this happening.
Q. Were there any concerns about how the complaints of cloudiness in the vials would affect the Lantus brand?
A. Yes, absolutely?
Q. Now, in your deposition in this matter, you testified that the complaints about cloudiness were more of a signal than an issue.
What do you mean by that?
A. When the complaints first starting coming in, the number was not very high, especially when you look at the number of complaints per thousands of vials that were in the marketplace.
So I think of it more as a signal. Something that we needed to investigate and to understand. As time went on, though, the complaints continued to increase.
And, so, certainly the company looked at this as an issue that needed to be addressed.

Q. So what did Sanofi do in response to receiving the complaints concerning cloudiness in the Lantus vial?
A. There were multiple things that were done.
The -- of course the first thing we wanted to understand was why, so we had several different parts of the organization investigate why was this happening, why were we getting the complaint of cloudy vials.
One of the areas that I was working on specifically was understanding our distribution channel. And knowing that Lantus is a different insulin, and that it needs to stay under refrigeration from Sanofi to our wholesalers, retailers, and then ultimately to the patient, we wanted to understand was there a breakdown where the product was not refrigerated and not kept within the specifications that are required.
There were others in the company that were looking at the batches that were coming into the U.S. to see whether there was something different about these batches versus what was happening in Europe.
We also had a group that was looking at the needle, and was there some type of contaminant that was being put into the vial when the needle was going into the vial.
So certainly a lot of different things that we needed to understand what exactly was happening.
Q. So when these complaints came in, and Sanofi started

investigating, did any member of the groups that you just describe state that they were immediately aware of what the cause of the cloudiness in the vials was?
A. No, that's why we were trying to understand the situation.
Q. And did you continue to receive complaints concerning cloudiness in the Lantus vials after that first year or so?
A. Yes, we did.
Q. Would you turn with me to Defendant's Exhibit 194.
(Defendant's Exhibit No. 194 was admitted into evidence.)
BY MR. MARSILLO:
Q. It's also on the screen.
A. Yes.
Q. What is that document?
A. This is an internal report that was prepared to give -- it was an executive overview during the time period, May 2003. The number of complaints that were coming in associated with this issue of turbidity. And then also if there were adverse events that were associated with this particular type of complaint.
Q. And if we turn to page 3, there's a chart of the complaints at least during the time period shown?
A. Yes.
Q. Now, did Sanofi communicate with the FDA concerning

cloudiness in the Lantus vials?
A. Yes.
Q. Were you kept apprised of those communications?
A. Yes, I was.
Q. Now, did you know what a field alert is?
A. I do.
Q. What is a field alert?
A. A field alert is when a company has information about one of theirs products that is currently marketed to the public. And if there is something that they are seeing, that they feel they need to alert the FDA to get an issue of a field alert.
Q. And when the field alert issued with respect to the cloudiness in the Lantus vial?
A. Yes.
Q. When?
A. I'm sorry?
Q. When?
A. June of 2001.
Q. And did you have concerns about the FDA's response in connection with complaints regarding cloudiness in the Lantus vial?
A. Yes, I did.
Q. What was your understanding as to what the FDA could do in response to concern about cloudiness in the Lantus

vial?
A. The FDA has a lot of different things they can do. We certainly wanted to keep the conversations private in sharing the information that we had. The FDA couldn't decide that they were going to issue a public communication, which we were at the beginning of a launch in trying to establish the brand and that certainly could be detrimental.
The FDA also had the power to potentially do a recall which could be detrimental or even pull the product off the market if they felt strongly about it which, of course, would have been catastrophic for the Lantus brand at that time.
Q. And we talked about some of the complaints that Sanofi received.
As far as you know, were any of those complaints publicly disclosed?
A. No.
Q. Now, what did Sanofi ultimately decide to do after completing its investigation in the cloudiness in the Lantus vial?
A. After we completed the investigation with the project team, we decided that it would be the best solution, and what was presented to the organization was to reformulate Lantus in a vial.
Q. And did Sanofi submit a supplemental NDA concerning

its reformulated Lantus?
A. Yes.
Q. And how much time elapsed between the start of the investigation into the cloudiness in the Lantus vial and submission of the supplemental NDA?
A. It was about three years.
Q. What, if any, effect did the change in the formulation have on the number of complaints that Sanofi received with respect to cloudiness in its vials?
A. They dramatically decreased.
Q. As if?
MR. MARSILLO: If we can take a look at Plaintiff's Exhibit 722?
(Plaintiff's Exhibit No. 722 was admitted into evidence.)
BY MR. MARSILLO:
Q. It's also on the screen.
A. Yes.
Q. What is Plaintiff's Exhibit 722?
A. This is a chart which was compared and looked at over the years after the reformulation was into the U.S. marketplace. The number of complaints and how they decreased over time.
Q. Now, besides marketing Lantus in the vial format, did Sanofi market Lantus in any other format?

A. Yes.
Q. What format?
A. There were two.
One was the reusable pen device which is called Lantus OptiClik and the other was a disposable pen device called Lantus SoloSTAR.
Q. And is OptiClik still distributed by Sanofi in the United States?
A. It is not.
Q. Why did Sanofi discontinue distributing the OptiClik?
A. It was lack of market demands here in the United States.
Q. Now, did Sanofi receive any complaints of cloudiness in either the SoloSTAR pen device or the OptiClik pen device?
A. No.
Q. And the -- if I'm correct, Ms. Moskow, each of those pen devices contain a cartridge that has a formulation in it?
A. That is correct.
Q. And what is the formulation that is used in the Lantus SoloSTAR?
A. It is the original formulation that was approved here in the United States in 2000.
Q. You mentioned SoloSTAR.

Is SoloSTAR still distributed by Sanofi?
A. Yes, it is.
Q. And who designed SoloSTAR?
A. We worked with a firm out of the United Kingdom called DCA.
Q. I'm sorry.
When was SoloSTAR launched?
A. It was launched until July of 2007.
Q. And you may have mentioned this, but when was the Lantus OptiClik launched?
A. In January of 2015 -- sorry -- 2005. January of 2005.
Q. So OptiClik was still on the market at the time that SoloSTAR launched?
A. Yes, it was.
Q. Were there any other injections pens on the market besides Lantus OptiClik and Lantus SoloSTAR, when SoloSTAR launched?
A. Yes, there were multiple pens on the market from a competitive standpoint. Two that we paid close attention to were the Flexpen by Nova Nordis and also Lilly's disposable pen.
Q. And what were your responsibilities with respect to the launch of SoloSTAR?
A. I was leading the marketing team that was responsible for the launch of the Lantus SoloSTAR.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.