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MYLAN PHARMACEUTICALS INC. :
Petitioner, :
v. :
SANOFI-AVENTIS DEUTSCHLAND GmbH, :
Patent Owner. :

Case IPR2018-01675
Case IPR2018-01676
Case IPR2018-01678
Case IPR2018-01680

DEPOSITION OF KARL R. LEINSING

Monday, June 3, 2019

Portsmouth, New Hampshire

Reported by: Deanna J. Dean, RDR, CRR
NH License No. 87
Job No. 86100



3
4 Deposition of KARL R. LEINSING,
5 held at the offices of Hampton Inn and Suites,
6 23 Portwalk Place, Portsmouth, New Hampshire,
7 before Deanna J. Dean, a Registered
8 Professional Reporter, Registered Diplomat
9 Reporter, Certified Realtime Reporter, and
10 Licensed Court Reporter of the State of New
11 Hampshire.
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13 Exhibit 1002 US Patent No. 8,603,044 8
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15 Exhibit 1004 US Patent No. 8,922,486 8
16 Exhibit 1005 US Patent No. 9,526,844 8
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Sanofi Exhibit 2163.002



Number	Description	Page
Exhibit 1015	US Patent Application No. US 2002/0052578 A1 (Moller)	26
Exhibit 1016	US Patent No. 6,932,794 (Giambattista)	26
Exhibit 1017	US Patent No. 6,582,404 (Klitgaard)	26
Exhibit 1020	US Patent No. 4,865,591 (Sams)	84
Exhibit 1032	European Patent Specification No. EP0608343B1	87
Exhibit 2100	Article Titled "Injection Force of SoloSTAR Compared with Other Disposable Insulin Pen Devices at Constant Volume Flow Rates" (van der Burg)	105
Exhibit 2101	Article Titled "An Evaluation of Prefilled Insulin Pens: A Focus on the Next Generation FlexPen" (Davis, et al.)	122
Exhibit 2102	Drawing Created by Attorney Ansley	151
Exhibit 2103	Page of Exhibit 1013 with Witness's Red Marks	189

3 previous answer.

4 In your declaration you discuss the

5 patentability of these five patents. Is that

6 correct?

7 A. Yes.

8 Q. All right. I want to go ahead and produce

9 exhibits premarked 1001 through 1005.

10 (Premarked Exhibits 1001 - 1005 are handed

11 to the witness.)

12 BY MR. ANSLEY:

13 Q. Mr. Leinsing, the court reporter has

14 handed you documents that have been premarked in

15 these IPRs as Exhibits 1001 through 1005.

16 And are these exhibits the Sanofi patents

17 that you analyzed in your declaration?

18 A. Yes.

19 Q. Okay. And for purposes of this

20 deposition, I'm going to refer to the exhibits by

21 the last three digits of the patent number. So

22 I'll refer to Exhibit 1001 as the '069 patent,

23 Exhibit 1002 as the '044 patent, Exhibit 1003 as

24 the '486 patent, Exhibit 1004 as the '844 patent,

25 and Exhibit 1005 as the '008 patent.

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1 PROCEEDINGS

2 KARL R. LEINSING

3 a witness called for examination, having been first

4 duly sworn according to law, was examined and

5 testified as follows:

6 EXAMINATION

7 BY MR. ANSLEY:

8 Q. Good morning.

9 A. Good morning.

10 Q. Could you please state your name for the

11 record.

12 A. Carl R. Leinsing.

13 Q. And how do you spell the last name?

14 A. L-e-i-n-s-i-n-g.

15 Q. Thank you.

16 Do you have an understanding of why you're

17 here to testify today?

18 A. Yes.

19 Q. And what is your understanding?

20 A. That there's been some IPRs that were

21 filed regarding five patents and the declaration I

22 wrote in support of those IPRs.

23 Q. And to clarify, you signed a single

24 declaration that was submitted with each of these

25 IPR petitions. Is that right?

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1 Do you understand that?

2 A. Yes.

3 Q. And I may also refer to the group of these

4 five patents as either the Sanofi patents, the

5 SoloSTAR patents, or the challenged patents.

6 Do you understand that?

7 A. Yes.

8 Q. Okay. You've been deposed before.

9 Correct?

10 A. Yes.

11 Q. And how many times, approximately?

12 A. Approximately 30 times or so.

13 Q. And of those 30 times, how many of those

14 depositions were you serving as an expert?

15 A. Just about all of them.

16 Q. So are there any depositions where you've

17 testified not as an expert?

18 MR. TORCZON: Objection. Scope.

19 A. No, not that I can recall.

20 Q. All right. Well, I'm going to go over

21 some rules and guidelines. Sounds like you're

22 fairly familiar with the process. However, it

23 can't hurt to go over some things.

24 So I'll be asking you a series of

25 questions, and you must provide an answer to each

3 Do you understand?
4 A. Yes.
5 Q. Okay. And if you do not understand a
6 question that I'm asking, please ask for
7 clarification. Okay?
8 A. Okay.
9 Q. We'll take breaks throughout the
10 deposition. If a question is pending, you'll need
11 to answer my question before we go on a break. Is
12 that clear?
13 A. That's clear.
14 Q. All right. And you're represented by
15 counsel today. Is that right?
16 A. Yes.
17 MR. TORCZON: Objection. Form.
18 Q. And who is your counsel today?
19 A. Those that are here present.
20 Q. All right. And so your counsel may object
21 from time to time during the deposition today. You
22 are still obligated to answer any of my questions
23 unless your counsel specifically instructs you not
24 to on the basis of privilege. Do you understand
25 that?

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1 A. Yes.
2 Q. All right. And do you understand that
3 you're under oath to tell the truth today?
4 A. Yes.
5 Q. And throughout the course of this
6 deposition as well. Is that right?
7 A. Yes.
8 Q. And you understand that this is the same
9 oath that you would take before a judge in a court
10 of law. Is that right?
11 A. Yes, that's my understanding.
12 Q. And is there any reason that you cannot
13 provide truthful and accurate testimony during this
14 deposition?
15 A. No.
16 Q. All right. So looking at Exhibits 1001
17 through 1005, have you read each of those documents
18 before?
19 A. Yes.
20 Q. And you've read them in their entirety?
21 A. Yes.
22 Q. And when did you first become aware of any
23 one of these patents?
24 A. I don't know the exact date when I first
25 seen them, but I've seen them in the past in some

3 when you first saw any one of these patents?
4 A. I can't recall.
5 Q. Was it before 2000 or after 2000?
6 MR. TORCZON: Objection. Form.
7 A. I don't know. They look familiar from
8 looking at the embodiment. So whether it was these
9 particular patents or then the preceding patents
10 that they continue from, I don't recall. It's
11 probably all during the 2010 and onward time frame.
12 Q. And when were you first engaged by counsel
13 in this matter?
14 A. I don't remember. I think it was sometime
15 in 2018.
16 Q. And so you believe that you first became
17 aware of at least some of the Sanofi patents before
18 2018. Is that right?
19 A. Yes.
20 Q. Okay. And which patents do you recall
21 seeing or reviewing before 2018?
22 A. I don't recall. They all look the same.
23 Q. Okay. Would you have -- strike that.
24 Do you recall reading any of these patents
25 thoroughly before 2018?

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1 A. I probably read at least one of them.
2 Q. And when was the first time you read any
3 one of these patents in its entirety?
4 MR. TORCZON: Objection. Form.
5 A. I don't recall prior to this case how much
6 I've looked at it, but I know at least in this case
7 I've read it in its entirety.
8 Q. Okay. And you've read in this case each
9 of these patents in its entirety, or no?
10 A. Yes.
11 Q. Okay. So yes, you have?
12 A. Yes, I have.
13 Q. All right. And how many times have you
14 read through the '069 patent in its entirety?
15 A. At least two or three times.
16 Q. And when was the last time you reviewed
17 it?
18 A. Yesterday.
19 Q. How about for the '044? How many times
20 have you read through the '044 patent in this case?
21 A. At least once or twice.
22 Q. And when was the last time you reviewed
23 the '044 patent?
24 A. Saturday.
25 Q. Okay. The '486 patent, how many times

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Sanofi Exhibit 2163.004

3 A. At least once or twice.
4 Q. And when did you last review it?
5 A. I'm not sure. It was probably Saturday of
6 last week.
7 Q. Okay. And would your answer for the '844
8 patent be the same?
9 A. Yes.
10 Q. And for the '008 patent would your answer
11 be the same or different?
12 A. That one's a little bit different. I
13 reviewed that one yesterday and then also last
14 week.
15 Q. And how many times do you think you
16 reviewed the '008 patent in its entirety?
17 A. At least twice.
18 Q. So you testified earlier that you were
19 engaged in this matter sometime in 2018. Is that
20 right?
21 MR. TORCZON: Objection. Asked and
22 answered.
23 A. Yes, sometime in 2018.
24 Q. Okay. When did you begin drafting your
25 declaration?

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1 A. I don't recall.
2 Q. Was it soon after you were engaged?
3 A. No. I was talking to the law firm,
4 actually, for quite a while, because I was actually
5 working on a case against Mylan at the time.
6 Q. Okay. What case was that?
7 A. That was on an EpiPen that failed.
8 Liability case.
9 Q. Did you write the first draft of your
10 declaration?
11 A. I wrote many different sections. It was a
12 huge declaration, and then we pieced it together as
13 time went on.
14 Q. I'm going to introduce Exhibit 1011 that's
15 been premarked in this matter. It is premarked.
16 It will make carrying the box much easier.
17 (Premarked Exhibit 1011 is handed to the
18 witness.)
19 BY MR. ANSLEY:
20 Q. Mr. Leinsing, you've been handed premarked
21 Exhibit 1011.
22 This document is a declaration you
23 prepared for each of the IPR petitions. Correct?
24 A. Correct, minus the exhibits.
25 Q. Minus the exhibits. Okay.

3 the table of contents, and it continues over the
4 next four pages.
5 Do you see that?
6 A. Yes.
7 Q. So which of these sections did you write
8 the first draft for?
9 MR. TORCZON: Objection. Relevance.
10 A. I know I wrote the level of skill in the
11 art -- a lot of these. I'm not sure which ones I
12 started. I think we started off with tossing
13 around a lot of different prior art back and forth.
14 I found some prior art.
15 And then I drafted a lot of the sections,
16 especially the qualifications, legal standards I've
17 had from the past. The attorneys then filled in a
18 lot of that, since that's the legal part.
19 Q. How about any of the sections beginning on
20 page 91 and continuing through page 469?
21 A. I don't recall, you know, who started
22 what. I think they helped put together the tables
23 in the very beginning, and then every single
24 section after that, I went through step by step of
25 each of the prior arts with the attorneys. They

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1 took notes. They drafted everything together.
2 There wasn't any single statement that was made in
3 here that either I didn't create or I didn't
4 approve.
5 Q. You stated that you found some of the
6 prior art.
7 What prior art specifically did you locate
8 and find?
9 A. Well, Klitgaard, for one. Because I was
10 working on some other injector pen-type projects,
11 and the Klitgaard was part of that project.
12 Q. Any others?
13 A. I think I also had found Moller, but I
14 believe they had found Moller as well. And I found
15 Steenfheldt-Jensen, and I think they found that one
16 as well. Then I found many others. I don't recall
17 right now.
18 Q. You stated just now that you were working
19 on some other pen -- I'm sorry. Strike that.
20 You stated just now that you were working
21 on other pen injector type products -- projects.
22 What were these other projects?
23 MR. TORCZON: Objection. Scope.
24 Relevance.
25 A. One was another patent litigation case.

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