

2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

---

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,

Patent Owner.

---

Case IPR2018-01675

Case IPR2018-01676

Case IPR2018-01678

Case IPR2018-01680

VOLUME II

VIDEO DEPOSITION of KARL R. LEINSING, MSME, PE

Portsmouth, New Hampshire

Tuesday, June 4, 2019

Reported by:

Dana Welch, CSR, RPR, CRR, CRC

Job #86101

Alderson Court Reporting

1-800-FOR-DEPO

[www.AldersonReporting.com](http://www.AldersonReporting.com)

**Sanofi Exhibit 2164.001**

3  
4  
5 June 4, 2019  
6 8:57 a.m.  
7  
8  
9 Deposition of KARL R. LEINSING, MSME, PE,  
10 held at Hampton Inn & Suites Portsmouth Downtown,  
11 23 Portwalk Place, Portsmouth, New Hampshire 03801,  
12 before Dana Welch, Licensed Shorthand Reporter  
13 (NH#118), Registered Professional Reporter,  
14 Certified Realtime Reporter and Notary Public of  
15 the State of New Hampshire.  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

3 FISH & RICHARDSON  
4 BY: JOHN S. GOETZ, ESQ.  
5 601 Lexington Avenue, 52nd Floor  
6 New York, NY 10022-4611  
7 goetz@fr.com  
8  
9 For the Petitioner:  
10 WILSON SONSINI GOODRICH & ROSATI  
11 BY: RICHARD TORCZON, ESQ.  
12 WESLEY E. DERRYBERRY, ESQ.  
13 1700 K Street NW, Fifth Floor  
14 Washington, DC 20006  
15 rtorczon@wsgr.com  
16 wderryberry@wsgr.com  
17 -- and --  
18 WILSON SONSINI GOODRICH & ROSATI  
19 BY: NATHANIEL SHARN, ESQ.  
20 12235 El Camino Real  
21 San Diego, CA 92130  
22 nscham@wsgr.com  
23  
24 Also Present: Matthew Greinert (Mylan)  
25 Jovial Wong, Esq., Winston & Strawn

Page 210

1 APPEARANCES:  
2 For the Patent Owner:  
3 WEIL, GOTSHAL & MANGES  
4 BY: SUTTON ANSLEY, ESQ.  
5 MATTHEW D. SIEGER, ESQ.  
6 2001 M Street, NW, Suite 600  
7 Washington, DC 20036  
8 sutton.ansley@weil.com  
9 matthew.sieger@weil.com  
10 -- and --  
11 SUDIP KUNDU, ESQ.  
12 767 Fifth Avenue  
13 New York, New York 10153  
14 sudip.kundu@weil.com  
15  
16 For the Patent Owner:  
17 FISH & RICHARDSON  
18 BY: MATTHEW COLVIN, ESQ.  
19 1717 Main Street, Suite 5000  
20 Dallas, TX 75201  
21 colvin@fr.com  
22  
23  
24 --- appearances continue ---  
25

Page 212

1 I N D E X  
2 WITNESS:  
3 KARL R. LEINSING, MSME, PE  
4  
5 EXAMINATION: PAGE:  
6 BY MR. ANSLEY 214  
7 BY MR. COLVIN 240  
8 BY MR. GOETZ 306  
9 EXHIBITS MARKED:  
10 NO. DESCRIPTION PAGE:  
11 Exhibit 2104, Figure 5, Mylan Exhibit 252  
12 1003, U.S. Patent 8,992,486  
13 Exhibit 2105, Handwritten drawing 254  
14 Exhibit 2106, Sheet 9 of 9, August 23, 351  
15 2005, U.S. 6,932,794, Mylan Exhibit 1016  
16  
17 EXHIBITS PREVIOUSLY MARKED:  
18 Exhibit 1003, U.S. Patent 8,992,486 241  
19 Exhibit 1005, U.S. Patent 9,604,008 338  
20 Exhibit 1012, Curriculum Vitae Karl R. 384  
21 Leinsing, MSME, PE  
22 Exhibit 1013, U.S. Patent 6,221,046 236  
23 Exhibit 1014, U.S. Patent 6,235,004 - 220  
24 Steinfeldt-Jensen  
25 --- index continues ---

Alderson Court Reporting

1-800-FOR-DEPO

www.AldersonReporting.com

Sanofi Exhibit 2164.002



3 Exhibit 1015, U.S. Patent Application 234  
 4 2002/0052578  
 5 Exhibit 1016, U.S. Patent 6,932,794 335  
 6 Exhibit 1017, U.S. Patent 6,582,404 306  
 7  
 8 NOTATIONS:  
 9 Time marked by Mr. Goetz: 4:40 p.m. 353  
 10  
 11  
 12  
 13  
 14  
 15  
 16  
 17  
 18  
 19  
 20  
 21  
 22  
 23  
 24  
 25

3 Q. Okay.  
 4 A. I don't recall exactly.  
 5 Q. And did you review them by yourself or  
 6 with others present?  
 7 A. By myself.  
 8 Q. Okay. And when you said you reviewed the  
 9 prior art, you're referring to the -- one of the  
 10 Burroughs, Steinfeldt-Jensen, Möller, Klitgaard, or  
 11 Giambattista references, correct?  
 12 A. Correct.  
 13 Q. Okay. And when you refer to the exhibits  
 14 in your declaration, are there -- what exhibits  
 15 from pages 471 to 473 did you review?  
 16 A. All of them.  
 17 Q. You re-reviewed all of Exhibits 1001  
 18 through 1034; is that correct?  
 19 A. Yes, except the file histories. I at  
 20 least opened up every single file and just reviewed  
 21 it.  
 22 Q. Okay. During the breaks yesterday, did  
 23 you have any discussions with counsel about the  
 24 substance of your testimony?  
 25 A. No.

Page 214

1 PROCEEDINGS  
 2 KARL R. LEINSING, MSME, PE  
 3 having been previously sworn on oath,  
 4 continued to testify as follows:  
 5 EXAMINATION  
 6 BY MR. ANSLEY:  
 7 Q. We can go on.  
 8 Good morning.  
 9 A. Good morning.  
 10 Q. Welcome back, Mr. Leinsing.  
 11 A. Leinsing.  
 12 Q. Leinsing?  
 13 A. Line (phonetic), like stein, Leinsing.  
 14 Q. Oh, I'm sorry. I hope I haven't been  
 15 saying that incorrectly the entire time.  
 16 Leinsing.  
 17 After the deposition ended for the day  
 18 yesterday, did you do anything to prepare for your  
 19 testimony today?  
 20 A. Yes.  
 21 Q. What did you do?  
 22 A. I just reviewed some of the exhibits on my  
 23 declaration and reviewed the prior art references,  
 24 just skimmed through them.  
 25 Q. And how much time did you spend performing

Page 216

1 Q. Okay. And after the testimony concluded  
 2 yesterday evening, did you have any discussions  
 3 with counsel -- and until this morning, did you  
 4 have any discussions with counsel about the  
 5 substance of your testimony?  
 6 A. No.  
 7 Q. All right. I'd like to refer you to a  
 8 portion of your declaration beginning on paragraph  
 9 258.  
 10 A. Did you say page 258?  
 11 Q. Paragraph 258. Let me know when you're  
 12 there.  
 13 A. I'm there.  
 14 Q. Okay. And in this section that begins  
 15 with paragraph 258, and continues, I believe,  
 16 through paragraph 338, you provide your opinion  
 17 that the challenged claims of the '069, '044, and  
 18 '486 patent are obvious over Steinfeldt-Jensen; is  
 19 that correct?  
 20 MR. TORCZON: Objection, form.  
 21 A. We should probably do the table of  
 22 contents, like you were asking me yesterday.  
 23 Q. Okay.  
 24 A. Regarding Steinfeldt-Jensen, all of my  
 25 opinions using that prior art would include the

3 And then page 155 and pretty close to the end of  
4 the declaration, or at least to page 422 -- or,  
5 actually, it goes all the way -- yeah, pretty much  
6 to the end.  
7 Q. So for your opinion that, for example, the  
8 '069 patent is obvious over --  
9 MR. ANSLEY: I'm sorry.  
10 Q. For your opinions that the challenged  
11 claims of the '069 patent are obvious over  
12 Steinfeldt-Jensen, you believe that the section  
13 beginning on page 347 includes opinions in that  
14 regard?  
15 A. No. That would just be the '844. I  
16 thought you meant where I applied Steinfeldt-Jensen  
17 to my analysis.  
18 MR. ANSLEY: Okay. Maybe my question  
19 wasn't so clear. Let me try again.  
20 Q. So on page 155, at the very top there,  
21 under subheading B., you identify for the "[069]  
22 Ground 2: Claim 1 is obvious over  
23 Steinfeldt-Jensen; [044-B] Ground 1: Claims 11,  
24 14-15, and 18-19 are obvious over  
25 Steinfeldt-Jensen."

Page 218

1 And for the [486-A2] Ground 1: Claims  
2 1-6, 12-18, 20, 23, 27-30, 32-33, 36, 38-40 are  
3 obvious over Steinfeldt-Jensen."  
4 And my question is, are the opinions that  
5 you have in support of these grounds, are they  
6 accurately described in this section which includes  
7 paragraphs 258 through 338?  
8 A. The declaration speaks for itself. But  
9 that would be the section for that particular  
10 analysis, which would include the claim  
11 constructions and the overview on page 71.  
12 Q. And are all the opinions you have in  
13 support of these grounds included in this  
14 subsection B., the claim construction section, and  
15 in the overview on page 71?  
16 A. I made references to different sections of  
17 my declaration, so I'm not sure if that has all of  
18 it in that one section. I don't want to narrow it  
19 to one section in the declaration. So the  
20 declaration stands on its own, but that's the basic  
21 area where I make my analysis.  
22 Q. Do you have any opinions outside of this  
23 declaration that Steinfeldt-Jensen alone renders  
24 obvious the challenged claims of the '069 patent,  
25 the '044 patent and the '486 patent, with the

3 A. No. Everything's in my declaration.  
4 Q. Okay. And are all the reasons in support  
5 of these opinions included in your declaration?  
6 A. Yes.  
7 Q. Now, it's your opinion that a person of  
8 ordinary skill in the art would have found it  
9 obvious to modify Steinfeldt-Jensen's fifth  
10 embodiment to swap the threaded circular opening of  
11 a component called member 40 with a slotted or  
12 non-circular opening of a component called driver  
13 tube 85; is that fair?  
14 A. Where are you reading from?  
15 Q. Nowhere in particular, but it's -- I  
16 believe that's your opinion; isn't that correct?  
17 A. Can you repeat that question?  
18 Q. It's your opinion that a person of  
19 ordinary skill in the art would have found it  
20 obvious to modify Steinfeldt-Jensen's fifth  
21 embodiment to swap threaded circular opening of a  
22 component called member 40 with a slotted or  
23 non-circular opening of a component called driver  
24 tube 85; is that correct?  
25 MR. TORCZON: Objection, form.

Page 220

1 A. It's not to swap. I don't know if you  
2 said swap the entire component. It's not to swap  
3 the entire component. It's to swap where the  
4 threads are located within 40 and to locate them in  
5 85, and then the slot in 85 to be put into 40 of  
6 Steinfeldt-Jensen, which is Exhibit 1014.  
7 And I'm looking at Figure 17.  
8 Q. Okay. I see, yeah.  
9 And that is the extent of your proposed  
10 modification; is that correct?  
11 A. That's correct.  
12 Q. Are there any benefits from making this  
13 proposed change?  
14 A. One of the benefits would be the  
15 lengthening of the threads would allow you to do  
16 that in the driver 85 of Figure 17 of Exhibit 1014.  
17 If there were issues with force or additional  
18 stress on the threads in item 40 of Figure 17, then  
19 you could move those to 85, and one skilled in the  
20 art would be motivated to do so.  
21 Q. Are there any other benefits?  
22 A. If the loads were such that it was  
23 creating a frictional issue, and it allowed you to  
24 choose a different material for the driver, that  
25 could be utilized in a longer part than that same

Alderson Court Reporting

1-800-FOR-DEPO

www.AldersonReporting.com

Sanofi Exhibit 2164.004

3 I believe the patent talks about it being  
4 pretty much an equal tradeoff in many places, that  
5 it could be in either part.  
6 Q. Any other benefit?  
7 A. It could allow you to make item 40 be an  
8 integral part of the housing and eliminate the use  
9 of an unwinder tool to mold the housing, so it  
10 would make the housing easier to manufacture and  
11 eliminate a component.  
12 Q. Any other benefits?  
13 A. Not that I can think of.  
14 I think the patent clearly says it could  
15 be either way. You could make some of those  
16 arguments going in the other direction. If the  
17 material and the threads work better together in a  
18 shorter distance with a different material in 40  
19 than in 85, a person of skill in the art would  
20 choose either direction as the molding and  
21 manufacturing and function needs were satisfied.  
22 Q. What analysis did you perform to  
23 understand whether there might be issues with force  
24 or stress on the threads in member 40 as depicted  
25 and described in the fifth embodiment of

Page 222

1 Steinfeldt-Jensen?  
2 A. So in doing these analyses, you don't test  
3 extrinsic evidence, you look at the intrinsic  
4 evidence of the prior art from a position of a  
5 person of skill in the art at the time frame of the  
6 asserted patents.  
7 So one skilled in the art knows from  
8 developing these kind of devices that the highest  
9 force you have is between the piston rod and the  
10 cartridge in pushing out the medication, so if  
11 there's a concern with that, then you have an  
12 option to change it.  
13 And then without doing any  
14 experimentation, the patent discusses the option of  
15 moving the threads from the item 40 to item 85 on  
16 Figure 17 of Exhibit 1014 in at least three places.  
17 One, for example, is in column 3, lines 41  
18 to 47. So the inventor is clearly showing that  
19 this is an option to consider in that it would be  
20 simply a design choice to go back and forth,  
21 depending on how manufacturing design requirements  
22 necessitated a change.  
23 Q. So you performed no analysis to understand  
24 whether there would be force or stress on threads  
25 of member 40 that would be unacceptable; is that

3 A. I didn't perform an analysis on -- I don't  
4 have the parts that embody this patent.  
5 One skilled in the art just knows that  
6 that's a high stress area. So if there was a  
7 requirement to move those threads, the patent  
8 clearly says that you can move them if required.  
9 Q. And the patent doesn't say or indicate  
10 that there is high stress on the threads in member  
11 40; is that right?  
12 A. I don't think it says that there's high  
13 stress on the threads, but to a person of skill in  
14 the art, that's the highest force area. Even to a  
15 lay man, I think that would be well understood, that  
16 you're pushing on the medication against the  
17 stopper, that you're going to have significant  
18 forces there, that's where your highest force is.  
19 And then you're trying to reduce that down on the  
20 button end. So that's pretty well understood that  
21 that's the high force area.  
22 Q. How is that force reacted?  
23 A. I don't understand your question.  
24 Q. How is the force reacted from the  
25 cartridge piston to the piston rod reacted

Page 224

1 throughout the rest of the pen injector as  
2 disclosed and described in the fifth embodiment of  
3 Steinfeldt-Jensen?  
4 A. The reaction force would be an axial force  
5 pushing against the piston rod, which would then  
6 exert forces through the threads to item 40 or to  
7 item 85, depending on where you choose to put the  
8 threads.  
9 Q. And if you put the threads on item 85, is  
10 there a further chain in the reactive force path?  
11 A. Can you repeat that question?  
12 Q. Yeah. So if you then put the threads in  
13 item 85 -- you mentioned in your last answer that  
14 the reactive forces would be borne there -- is  
15 there further to that reactive force chain, after  
16 the threads in driver tube 85?  
17 MR. TORCZON: Objection, form.  
18 A. I don't understand your question.  
19 Q. So after forces from the piston rod are  
20 exerted on item 85, if threaded, are there  
21 additional forces in the force chain after that?  
22 A. There would be some reaction-type forces,  
23 rotational forces. So 40 would have to counteract  
24 the torque. It would have the non-circular opening  
25 in 40, so there would be some antitorque forces

Alderson Court Reporting

1-800-FOR-DEPO

www.AldersonReporting.com

Sanofi Exhibit 2164.005

# 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.