

Confidential

1                   IN THE UNITED STATES DISTRICT COURT  
                  FOR THE DISTRICT OF DELAWARE  
2   - - - - -x  
PFIZER INC. and UCB PHARMA       :  
3   GMBH                               : C. A. No.  
  : 1:15-cv-000079 (GMS)  
4                   Plaintiffs,       : Consolidated  
v.                                       :  
5                                       :  
MYLAN PHARMACEUTICALS INC.,     :  
6                                       :  
                  Defendant.       :  
7   - - - - -x

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11                   Oral deposition of LEONARD J. CHYALL,  
12   Ph.D. taken pursuant to notice, held on Tuesday,  
13   August 23, 2016, at the office of Kilpatrick  
14   Townsend & Stockton, 1114 Avenue of the Americas,  
15   New York, New York, commencing at 9:01 a.m. before  
16   Jamie I. Moskowitz, RPR, CRR, a Registered  
17   Professional Reporter and Notary Public.

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1 going to start with some subset of physiologically  
2 compatible organic or inorganic acids, right?

3 MS. MEDINA: Objection.

4 THE WITNESS: If the salt screen is  
5 for a pharmaceutical application, yes. The  
6 screen should be limited to materials that are  
7 generally regarded as safe.

8 The FDA has what's called a GRAS list,  
9 G-R-A-S, and this is a very large list of all  
10 the chemicals, food additives included, that  
11 are safe for human consumption.

12 BY MR. HOLLOWAY:

13 Q How big is the GRAS list?

14 A It's quite extensive.

15 Q Do you have an idea of what the  
16 numbers is?

17 A Thousands.

18 Q Realistically, the two people working  
19 on this problem of finding an acceptable  
20 pharmaceutical salt of the same active base, they're  
21 not going to start by testing thousands of acids,  
22 correct?

23 A Not thousands, no.

24 Q Instead our two people of ordinary  
25 skill in the art, who are working on the same

1 problem but in different places, are probably going  
2 to choose -- each of them are going to choose an  
3 even smaller subset of acids in an attempt to find  
4 an acceptable pharmaceutical salt, correct?

5 MS. MEDINA: Objection.

6 THE WITNESS: The list of thousands  
7 that are conceivable would be whittled down  
8 initially to a manageable amount. And what one  
9 chemist considers manageable versus another is  
10 going to vary.

11 BY MR. HOLLOWAY:

12 Q And part of what they consider  
13 manageable could in part be dictated by their  
14 available resources that that chemist has at  
15 their -- at their ready, right?

16 A Yes.

17 Q So if I had a team of 15 people  
18 working on the problem, and my other hypothetical  
19 person not at SSCI only has three available people  
20 to work on it, my set might be larger than their set  
21 of acids to try, correct?

22 MS. MEDINA: Objection.

23 THE WITNESS: I don't know.

24 BY MR. HOLLOWAY:

25 Q Would you agree that my set -- even if

1 the amount of active that can be dosed to a patient?

2 MS. MEDINA: Objection.

3 THE WITNESS: I haven't considered  
4 that issue either.

5 BY MR. HOLLOWAY:

6 Q Would you agree with me that a viable  
7 pharmaceutical candidate must be highly crystalline?

8 A No.

9 Q Would you agree with me that when  
10 we're talking about crystalline salts, it's  
11 absolutely necessary to have stable salts which are  
12 chemically and thermally stable on the shelf?

13 MS. MEDINA: Objection to form.

14 THE WITNESS: It depends on what  
15 context we're talking about crystalline salts.

16 BY MR. HOLLOWAY:

17 Q How does it depend on the context when  
18 we're talking about crystalline salts?

19 A Because precisely what surrounds the  
20 issues will determine whether that statement is true  
21 or not.

22 Q Is it safe to say that based on your  
23 experience, and view of salt screening, that the  
24 identification and selection of an acid residue for  
25 a known active base could never be obvious?

1 MS. MEDINA: Objection.

2 THE WITNESS: The outcome of that  
3 acid-based reaction can't be predicted in  
4 advance. The chemistry in solution can be  
5 predictable, but whether or not the solid could  
6 be isolated as a solid even, one doesn't know  
7 that in advance.

8 MR. HOLLOWAY: We have been going over  
9 an hour, so if you want to take a break, let me  
10 know.

11 THE WITNESS: I'm fine.

12 BY MR. HOLLOWAY:

13 Q In your rebuttal report, if you will  
14 go to Paragraph 32, please.

15 A Yes.

16 Q And it references Dr. Janero's report.  
17 And the preceding paragraph is talking about the  
18 Gould reference in a section that's talking about  
19 the Berge reference.

20 THE WITNESS: If you don't mind, could  
21 you withdraw the question? I'd like to take a  
22 quick break, and then you can pick up your  
23 question later or I can answer the question  
24 that you have pending.

25 MR. HOLLOWAY: I haven't asked the

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