

Confidential

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

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10 ***RESTRICTED, CONFIDENTIAL***

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13 Videotaped deposition of WILLIAM R. ROUSH,
14 Ph.D, taken pursuant to notice, held on Friday,
15 September 9, 2016, at the office of Kilpatrick
16 Townsend & Stockton, 1114 Avenue of the Americas,
17 New York, New York, commencing at 9:01 a.m. before
18 Jamie I. Moskowitz, RPR, CRR, a Registered
19 Professional Reporter and Notary Public.

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1 BY MR. STOCKWELL:

2 Q Any luck?

3 A I've looked.

4 Q I'll -- I'll move on. It's not that
5 important of a question.

6 A Okay.

7 Q Let me strike that and just move on.
8 We can -- we can try to find another document for
9 you to refresh your recollection.

10 Would you agree that at the time of
11 the invention in 1998 that a skilled artisan would
12 be reasonable in viewing 5-HMT as more hydrophilic
13 than Tolterodine?

14 MS. MORAN: Objection.

15 THE WITNESS: Would -- so at the time
16 of invention would a person of ordinary skill
17 have viewed 5-HMT as being more hydrophilic
18 than Tolterodine, that's your question?

19 BY MR. STOCKWELL:

20 Q Yes.

21 A I think a person of ordinary skill at
22 that time would have had access to the sort of
23 log P, log D determinations that are commonly used
24 to assess lipophilicity, and would have agreed that
25 5-HMT was probably a little more hydrophilic.

1 context here is not clear. I'm sort of asking a
2 relative question here. I think we agreed that the
3 skilled artisan would view 5-HMT as more hydrophilic
4 than Tolterodine, right?

5 MS. MORAN: Objection.

6 THE WITNESS: I said and I used --
7 there's a -- it's a little bit more hydrophilic
8 than Tolterodine.

9 BY MR. STOCKWELL:

10 Q So the question is: Would the skilled
11 artisan then view 5-HMT as potentially less
12 bioavailable than Tolterodine?

13 A And my answer repeatedly to that is,
14 no, a person of skill would not have viewed it that
15 way.

16 Q Do you -- at the time of the invention
17 in 1998, did skilled persons look at the
18 lipophilicity of a drug in assessing the oral
19 activity of a potential compound?

20 A Well, looking at a calculated
21 parameter and assessing are two different things.
22 Yes, a person of skill would -- would consider the
23 lipophilicity values from either measurement or
24 calculation. And if there were a question, if a
25 person of skill were motivated to move forward with

1 Detrol label about the pharmacodynamics of 5-HMT?

2 A I think the conclusions of the --
3 the -- I think the label indicates that the -- well,
4 the label may not use the term "pharmacodynamic
5 effect," but the effect on patients of the extensive
6 metabolizers, a person of skill would appreciate
7 that for the drug generated -- the drug -- the
8 compound strike drug, the compound 5-HMT generated
9 as it was via Detrol had a pharmacodynamic effect
10 seemingly comparable to Tolterodine itself.

11 But the question in the -- that is
12 unanswerable in this is: What would the
13 pharmacodynamic be for -- on patients to whom 5-HMT
14 is directly delivered? And that is not answerable
15 by anything in the Detrol label.

16 Q Would the skilled artisan in 1998 have
17 had a high level of familiarity with Tolterodine?

18 MS. MORAN: Objection.

19 THE WITNESS: A high level of
20 familiarity. Tolterodine was part of the prior
21 art. And -- and the skilled artisan -- the
22 knowledge available about Tolterodine would
23 have been part of the knowledge available to
24 the skilled artisan.

25 But you said a high level. More so

1 than anything else? I think not more so than
2 anything else.

3 BY MR. STOCKWELL:

4 Q Well, I mean, you've kind of focused
5 on the fact that the -- that the label was issued
6 only a couple of months before the priority date
7 here.

8 Wouldn't the skilled artisan as of the
9 priority date have been sort of just recently
10 looking at and investigating the label and becoming
11 familiar with Tolterodine?

12 A Just recently that given in that
13 two-month window, the person of ordinary skill would
14 have been aware of the label and would have read it
15 in comparison and context with everything else
16 that's known for other drugs used to treat OAB.
17 And -- and the person of skill would have made his
18 or her assessments of an appropriate starting place.

19 And, yeah, the Detrol was coming
20 onward, but it wasn't yet in widespread use. And I
21 think all of that -- that's why I said I put
22 Tolterodine at the cusp between my bucket two and
23 bucket one compounds, where bucket one is the area
24 from which a person of skill would select a
25 compound.

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