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קיבלנו, אני ראיתי את המייל של חברי בערך בשתים עשרה, ענינו לאחר	1
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6

7

<u>ד״ר צ׳ייל, לאחר שהוזהר כחוק, משיב בהמשך חקירה נגדית לעו״ד וטשטיין:</u> 8

כן.

OK, good morning Dr. Chyall, welcome back. 9 : עוייד וטשטיין I appreciate you have some more questions for me. Your : העד 10 honor, before we begin I just wanted to respond to some 11 requests that were made of me to look at some things on 12 the breaks, so I can confirm sir that the calculations with 13 respect to the percentage theoretical values of carbon, 14 those, those are correct. For the samples you asked if I 15 had added the phosphoric acid drop wise for all my 16 experiments and I did. There was one thing that I needed 17 to clear up though - the concentrations of phosphoric 18 acid were different depending on the experiment, and I 19 checked in my declarations so when I write out what I did 20 in my declaration I say what the concentrations of 21 phosphoric acid are. those are correct, I believe that's 22 everything that, 23

OK. : עוייד וטשטיין 24

you have done your homework אוייד בנד : 25

thank you. אעד : העד 26

thank you Dr. Chyall. We will go back to your pH- עו״ד וטשטיין: 27 solubility experiments, and now we'll focus on table 5 of 28 C1 which is page 24 of your first declaration. In this table 29 actually what you attempt to do is to obtain additional 30

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1	: העד	No. they weren't. because even on your summary, even	
2	on your representation to me, as to what I did, you say		
3		4031-27-01 diluted 200. Oh wait a minute, I'm sorry,	
4	: עוייד וטשטיין	0.5 ml of it. 0.5 ml of it.	
5	: העד	you're right, you're right, sorry.	
6	: עוייד וטשטיין	0.5 ml of it.	
7	: העד	sorry.	
8	: עוייד וטשטיין	so it's the same dilution parameters.	
9	: העד	OK.	
10	: עוייד וטשטיין	it's the same scale, right?	
11	: העד	yes.	
12	: עוייד וטשטיין	OK, so our rule of 3, the solubility value of 60 mg per ml	
13		you want to say anything about it? do you agree with it?	
14		simple arithmetic.	
15	: העד	Let me just burrow a calculator. I can be sure, I am sure I	
16		can find the exact value,	
17	: עוייד וטשטיין	rough value is also fine, you know, 1 mg up or down	
18	doesn't matter. I am sure that if we had your standards,		
19		we could have had the exact values.	
20	: העד	I make it to be around 58, just by using another	
21		calibration standard,	
22	: עוייד וטשטיין	OK, fine, that's fine, we won't argue about 2 mg per ml	
23		Dr. Chyall. thank you. So, we have a solubility. We have	
24		a sample at pH 5.9, which is below the pH max, namely it	
25		should be a salt, right?	
26	: העד	yes.	
27	: עוייד וטשטיין	fine. With a solubility which is 58 or 60. And this is the	
28		XRPD of the sample that was,	
29	: כבי סגנית הרשם	רק נסמן ברשותכם <u>מב/117</u> , כן.	

of the sample, of the 117 מב/And this is the XRPD עו״ד וטשטיין:	1
sample of the solids from the measurement in pH 5.9.	2
yes, I remember, this is the co-crystal, this is the sample. העד:	3
כן, רק גברתי איך מסמנים את yes, that's fine. Now, ok, let's, 🛛 אוי״ד וטשטיין:	4
זה!	5
כבי סגנית הרשם : <u>מב/118.</u>	6
אנחנו נתחיל Let's, let's see what we have here. We'll start, אנחנו נעחיל	7
גברתי מהעמוד האחרון.	8
כבי סגנית הרשם : כן.	9
The last page is again the XRPD of the sample which עו״ד וטשטיין :	10
you obtain, of the solids which you obtain at pH 5.9,	11
right? It's the same XRPD which we saw before.	12
yes. אעד:	13
thank you. The second page is Professor Atwood's עו״ד וטשטיין:	14
sample 1.2, the 2:1 salt. I know you don't agree so we	15
will call it the Atwood solids, which he prepared in	16
isopropanol and water.	17
yes. אעד :	18
fine. And the cover page is an overlay of Dr. Atwood's 2:1 עו״ד וטשטיין	19
solids prepared in isopropanol and water, and of the	20
solids which you prepared at pH 5.9. and I see here, Dr.	21
Chyall, a perfect match. So essentially when you ran	22
your pH adjusted solubility tests, you obtained Professor	23
Atwood's salts, or solids, whatever you want to call them,	24
and you concealed this important, this dramatic piece of	25
evidence, from the patent commissioner, for years and	26
years. You have Professor Atwood's solids in your lab,	27
after you ran your first experiments. and you did not tell	28
that not in your second declaration, not after you saw Dr.	29
AtwoodAtwood's declaration not in your third declaration	30

How dare you conceal such	piece of information? You	1
	prepared Atwood's solids.	2

When, I, let me say that first of all I agree that the Atwood 3 : העד solids and this, the crystal material from this pH adjusted 4 experiment, these are the same solid form, these are 5 both, the, the lines of diffraction pattern match up. I did 6 not recognize Professor Atwood's sample while doing 7 this work because I didn't have his declaration at the 8 time. When I first saw this difragotram from the material, I 9 assumed that it was a decomposition product, because 10 of all the difficulties that we had with respect to getting 11 the pH stable, and in the case where we had a stable pH 12 this clearly was not Sitagliptin base or the phosphoric 13 acid salt. so I didn't know what to make of this at the 14 time, and I assumed it was a decomposition product. 15 When Professor Atwood put in his report, I then 16 recognized his crystalline phase as the same phase as 17 this material here. but in my rebuttal reports I was 18 primarily addressing Professor Atwood's criticisms of my 19 work and I didn't, didn't include this in my second report 20 because that was my understanding that I was to rebut 21 his work. 22

Dr Chyall, אוייד וטשטיין 23

with respect to the identity of this sample we did have 24 ample time to characterize it in my third declaration, and I 25 understand this material to be the co-crystal. 26

Dr. Chyall, you submitted your second declaration after27Dr. Atwood submitted his experiments. In Dr. Atwood's28declaration he submits this, these solids, with this29identical X-ray powder diffraction of the 2:1 solids. In your30

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