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קיבלנו, אני ראיתי את המייל של חברי בערך בשתים עשרה, ענינו לאחר		1
מכן, עמדתנו היא שכל חלק מתצהירו ומחוות דעתו של דייר ציייל		2
שנסמך על חומרי גלם או ניסויים שלא נמסרו לנו במועד - דינו מחיקה,		3
ואנחנו נטען לעניין הזה בסיכומים.		4
: בסדר, נתייחס לזה בהחלטה. כן, בואו נתחיל בחקירה. אפשר להמשיך.	כבי סגנית הרשם	5
cſ.		6
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שהוזהר כחוק, משיב בהמשך חקירה נגדית לעו"ד וטשטיין:	<u>ד"ר צ'ייל, לאחו</u>	8
OK, good morning Dr. Chyall, welcome back.	:עו"ד וטשטיין	9
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.	: עו"ד וטשטיין	24
you have done your homework	: עוייד בנד	25
thank you.	: 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



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



of the sample, of the מב/And this is the XRPD	:עוייד 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,	: עוייד וטשטיין	4
זה!		5
.118/מב	:כבי סגנית הרשם	6
אנחנו נתחיל Let's, let's see what we have here. We'll start,	: עוייד וטשטיין	7
גברתי מהעמוד האחרון.		8
cţ.	:כבי סגנית הרשם	9
The last page is again the XRPD of the sample which	: עוייד 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.	: העד	13
thank you. The second page is Professor Atwood's	: עוייד 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.	: העד	18
fine. And the cover page is an overlay of Dr. Atwood's 2:1	: עוייד 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	: העד	3
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,	:עו"ד וטשטיין	23
with respect to the identity of this sample we did have	: העד	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 after	: עו"ד וטשטיין	27
Dr. Atwood submitted his experiments. In Dr. Atwood's		28
declaration he submits this, these solids, with this		29
'		



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