

רשם הפטנטים, המדגמים וסימני המסחר	1
בפני כב' סגנית הרשם: גב' ז'קלין ברכה	2
	3
התנגדות לפטנט מס' 172563	4
<u>דיון מיום 29.01.2015</u>	5
	6
מבקשת הפטנט: Merck Sharp & Dohme CORP	7
מתנגדת: טבע תעשיות פרמצבטיות בע"מ	8
	9
	10
<u>נוכחים מצד המבקשת:</u>	11
עו"ד ליעד וטשטיין	12
עו"ד אמירה מנגלוס	13
עו"ד עדי קרטון	14
עו"ד איתי סלע	15
	16
<u>נוכחים מצד המתנגדת:</u>	17
עו"ד טל בנד	18
עו"ד נועם בליי	19
עו"ד יאיר זיו	20
עו"ד קטיה לאוקומוביץ	21
	22
<u>מעיד בדיון היום:</u>	23
ד"ר לאונרד צ'ייל (עד מטעם המתנגדת)	24
	25

קיבלנו, אני ראיתי את המייל של חברי בערך בשנים עשרה, ענינו לאחר 1
מכן, עמדתנו היא שכל חלק מתצהירו ומחוות דעתו של ד"ר צייל 2
שנסמך על חומרי גלם או ניסויים שלא נמסרו לנו במועד - דינו מחיקה, 3
ואנחנו נטען לעניין הזה בסיכומים. 4
כבי סגנית הרשם: בסדר, נתייחס לזה בהחלטה. כן, בואו נתחיל בחקירה. אפשר להמשיך. 5
כן. 6

ד"ר צייל, לאחר שהוזהר כחוק, משיב בהמשך חקירה נגדית לעו"ד וטשטיין: 8

עו"ד וטשטיין: OK, good morning Dr. Chyall, welcome back. 9
העד: I appreciate you have some more questions for me. Your 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

עו"ד וטשטיין: OK. 24
עו"ד בנד: you have done your homework 25
העד: thank you. 26

עו"ד וטשטיין: thank you Dr. Chyall. We will go back to your pH- 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

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. : עו"ד וטשטיין 4
you're right, you're right, sorry. : העד 5
0.5 ml of it. : עו"ד וטשטיין 6
sorry. : העד 7
so it's the same dilution parameters. : עו"ד 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 : עו"ד 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
כב' סגנית הרשם : רק נסמן ברשותכם מב/117, כן. 29

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

yes, that's fine. Now, ok, let's, : עו"ד וטשטיין 4

רק גברתי איך מסמנים את זה? 5

כב' סגנית הרשם : מב/118. 6

Let's, let's see what we have here. We'll start, : עו"ד וטשטיין 7

גברתי מהעמוד האחרון. 8

כב' 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. : העד 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. : העד 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, עו"ד וטשטיין : 23

with respect to the identity of this sample we did have 24 : העד

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 27 : עו"ד וטשטיין

Dr. Atwood submitted his experiments. In Dr. Atwood's 28

declaration he submits this, these solids, with this 29

identical X-ray powder diffraction of the 2:1 solids. In your 30

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.