

AFFIDAVIT OF PROF. JERRY L. ATWOOD

I, the undersigned, Jerry L. Atwood, US Passport No. 028224440 with a business address of Department of Chemistry, 601 S. College Avenue, University of Missouri-Columbia, Columbia, MO 65211, after having been warned that I must state the truth and if I fail to do so I will be liable to penalties prescribed by law, hereby declare in writing as follows:

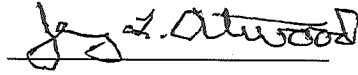
1. I am the same Jerry L. Atwood who submitted an expert opinion in the opposition proceedings against the registration of IL '563. I am making this declaration in response to Dr. Chyall's criticism on the experimental techniques I used for the making of the bis(sitagliptin) phosphoric acid salts and sitagliptin bis(phosphoric acid) salts. This brief declaration is not intended to be a comprehensive response to Teva's arguments. The fact that I do not comment on any particular point does not constitute an agreement.
2. As demonstrated in my first declaration, my robust experiments clearly show that phosphoric acid salts of sitagliptin other than dihydrogenphosphate salts can be made using routine experimental techniques and without any particular difficulty. In my experiments, after the solution solidified, I dried the solid in vacuum, usually over night. Thereafter, the solid was analyzed using a battery of analytical methods. Dr. Chyall argues that before analyzing the solids, I should have washed and filtered them and that "failure" to do so also reflects "poor experimental techniques". This is baseless.
3. I conducted a simple acid-base reaction to make a salt. The reaction resulted in large mass of homogenous solid precipitate in a small volume of solvent. In order to remove remaining solvent, I had the reaction product dried overnight under vacuum. This is a routine work up for such procedure. There was no reason to add filtration or washing steps once it was clear that the reaction went through smoothly and large quantity of material solidified.
4. In any event, in order to completely put to rest Dr. Chyall's baseless assertion, I repeated the procedure for making the 2:1 phosphate salt in isopropanol and water as described in sections 31 and 68 of my declaration, this time with the filtering and washing step suggested by Dr. Chyall. For the purpose of repeating this procedure, I received on July 20, 2012, additional vial of free base from Merck (Lot No. 0000052637. XRPD pattern

attached hereto as Appendix "GG"). The LNB pages describing the making of the 2:1 phosphate salt is attached hereto (Appendix "HH"). Attached hereto are the XRPD pattern, DSC and TGA analysis of the material after this work up (Appendix "II"). Also attached hereto is the elemental analysis of this material as performed by the Robertson external laboratory (Appendix "JJ").

5. In order to demonstrate that Dr. Chyall's work up does not change the product, I attach hereto overlay (Appendix "KK") of the XRPD patterns of the "original" 2:1 salt reported in my previous declaration (Sample 9) v. the "new" 2:1 salt which I prepared with Dr. Chyall's work up. As can be clearly seen, the same 2:1 phosphate salt was obtained in all procedures, with or without Dr. Chyall's suggested work up.
6. In short, Dr. Chyall's criticism of my experiments is artificial and without merit. The same applies to Dr. Chyall's additional arguments. For instance, Dr. Chyall asserts that the concentrations of the starting materials in my experiments were too high and caused the reaction mixture to solidify without adequate mixing. This is baseless.
7. As described in my lab notebooks, the reactants went into solution even before the heating of the reaction mixture. This by itself is a clear indication that the concentrations were absolutely in order. Moreover, in all experiments, I obtained a solid only after the solution with the dissolved reactants was heated, cooled back to room temperature and stirred. Solidification after these process steps is a desired outcome for a reaction to obtain a solid salt. It reflects routine protocol and is a clear indication that there was no premature solidification before the reaction completed.
8. In any event, and just for the sake of completeness, there is nothing "wrong" about using high concentrations. The concentration of the reactants and the temperature affect the kinetics of the reaction. Using low concentrations can significantly slow down the reaction and possibly even prevent the reaction from taking place. Therefore, it is a broadly accepted practice to use the minimal possible volume of solvent to dissolve the reactants.
9. Dr. Chyall further argues that I should have analyzed the solids I obtained by proton or carbon NMR to confirm their identity although solution NMR is not a suitable analytical

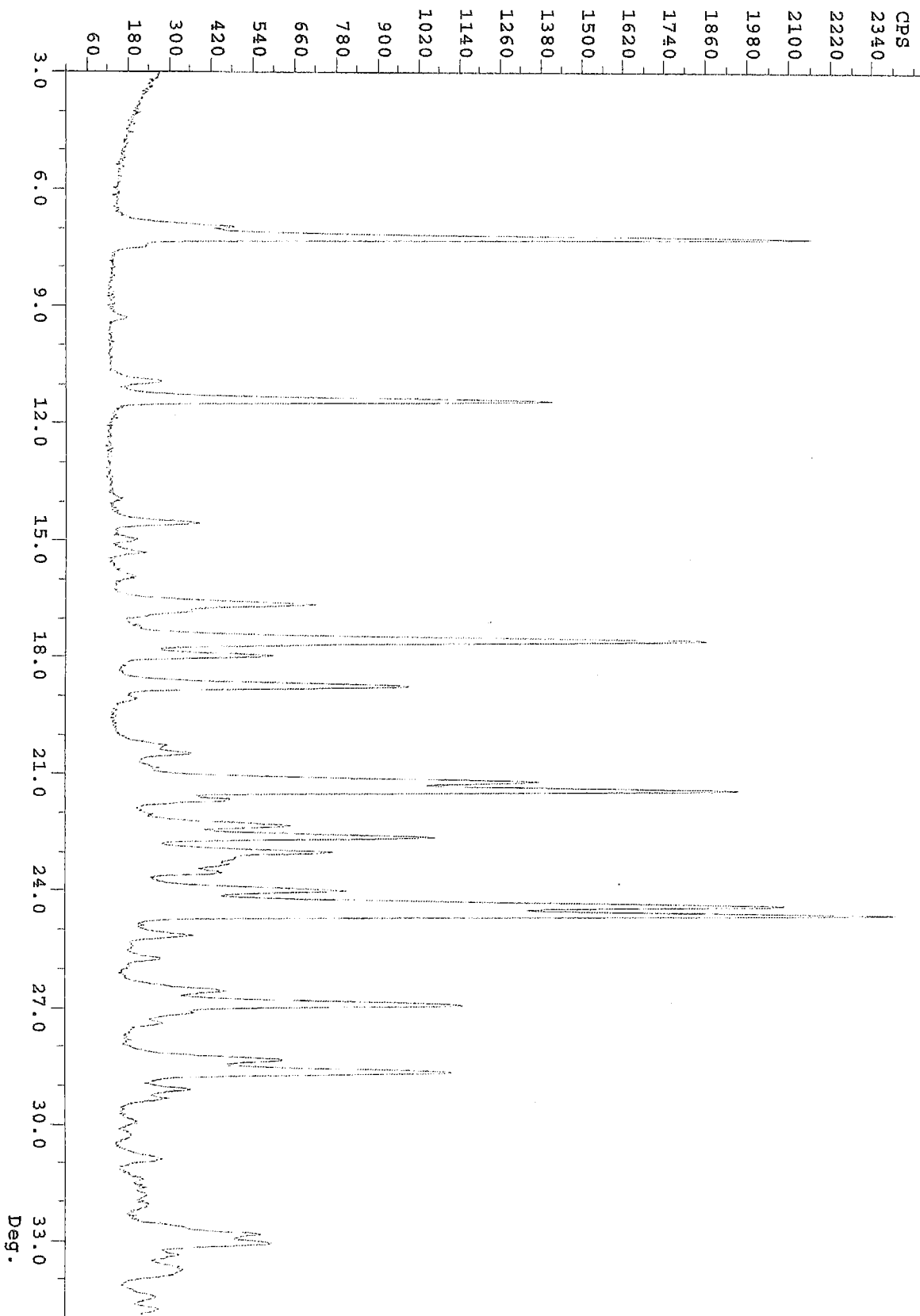
tool in the present matter. In any event, the battery of analytical tools that I used is clearly sufficient to provide unequivocal identification.

10. My name and signature follow and the contents of this affidavit are true.

A handwritten signature in black ink, appearing to read "Jerry L. Atwood", is written over a horizontal line.

Jerry L. Atwood

File: sitagliptin free base, ID: sitagliptin free base 52637
Date: 07/20/12 13:56 Step : 0.020° Cnt Time: 6.000 Sec.
Range: 3.00 - 35.00 (Deg) Cont. Scan Rate : 0.20 Deg/min.



8/14/12 Preparation of (sitagliptin H⁺)₂(HPO₄²⁻). 3430

1.50g sitagliptin base (0.00368 moles, Batch No. 0000052637) was combined with isopropanol (3.2 mL, sigma Aldrich) and distilled water (1.4 mL). The mixture was stirred for 5-10 min to form a clear solution. To this solution was added 0.215 g H₃PO₄ (85% w/w, sigma Aldrich, 0.00186 moles) with stirring. The mixture was heated with stirring at 70°C for 15 min, then cooled to rt and left stirring overnight.

8/15/12 The solution had solidified. The material was placed on a Buchner funnel fitted with a 7 cm diameter piece of Whatman 42 ashless filter paper, with the aid of a stainless steel regulator. Air was drawn through the sample and filter paper for 5 min with an aspirator vacuum. The sample was then washed successively with 3 3mL portions of isopropanol. The sample was dried

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