EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC., AKORN, INC., MYLAN PHARMACEUTICALS INC., and MYLAN INC.,** **Defendants.**	**Civil Action No. 2:15-cv-1455-WCB** **LEAD** **JURY TRIAL DEMANDED**
ALLERGAN, INC., **Plaintiff,** **v.** **INNOPHARMA, INC.,** **Defendant.**	**Civil Action No. 2:15-cv-1504-WCB**
ALLERGAN, INC., **Plaintiff,** **v.** **FAMY CARE LIMITED,** **Defendant.**	**Civil Action No. 2:16-cv-0401-WCB**
ALLERGAN, INC., **Plaintiff,** **v.** **TWI PHARMACEUTICALS, INC. AND TWI PHARMACEUTICALS USA, INC.** **Defendant**.	**Civil Action No. 2:16-cv-0820-WCB**

SUPPLEMENTAL RESPONSIVE DECLARATION OF ERNING XIA, Ph.D.

I. Introduction

1. I, Erning Xia, Ph.D., submit this supplemental declaration on behalf of Defendants Akorn, Inc. ("Akorn"), Teva Pharmaceuticals USA, Inc. ("Teva"), Mylan Pharmaceuticals Inc., and Mylan Inc. (collectively, "Mylan"), InnoPharma, Inc. ("InnoPharma"), Famy Care Limited ("Famy Care"), and Twi Pharmaceuticals, Inc. and Twi Pharmaceuticals USA, Inc. ("Twi") (collectively, "Defendants") in the above-captioned actions.

2. I am the same Erning Xia, who submitted an opening declaration on August 5, 2016 ("my Opening Declaration"). I incorporate herein by reference my Opening Declaration and supporting exhibits.

3. I have been asked to submit this supplemental responsive declaration to respond to opinions raised in the declaration of Dr. Thorsteinn Loftsson and Allergan's Opening Supplemental Brief submitted on in this case on September 26, 2016. The additional materials that I have considered beyond those already identified in my Opening Declaration, are found below.

II. Response to Dr. Loftsson's Declaration

A. Meaning of the Numerical Values in the Claims

4. Dr. Loftsson opines that it is "difficult or impossible to make a drug product with an 'exact' or 'precise' amount of each ingredient in that formulation." Loftsson Decl. ¶22 I disagree as Dr. Loftsson has ignored that each numerical integer has a certain degree of margin based on rounding and thus it would not be difficult to make a drug product using the ranges inherent in a numerical number.[1]

[1] See Ex. 1,, Catherine W. Johnson et al., *Essential Laboratory Mathematics* (2d ed. 2003) ("Numbers obtained from a measurement are approximate values. There is always some uncertainty due to the

5. For instance, a person of ordinary skill in the art would understand that the ordinary number defined with two decimal points such as "1.25"% means a weight amount between 1.245% to 1.254% based on the reasoning that numbers in this range would be rounded to 1.25%. Similarly, 0.05% may encompass an amount between 0.045% to 0.054% based on conventional scientific rounding.

6. Contrary to Dr. Loftsson's opinions, it would not have been "impossible" to manufacture a drug with ingredients having a given numerical value since that number will inherently have a range based on rounding. For example, even if one of ordinary skill in the art would not have been able to consistently manufacture a drug with 1.250% w/w of a particular ingredient, such individuals would have been able to manufacture a drug at an amount within a range of 1.245 to 1.254 % w/w allowed by the ordinary value of the numbers itself.

7. Although a person of ordinary skill in the art would typically define numbers by rounding off, I understand that an exception to this rule applies in cases where the patentee has itself limited the interpretation ordinarily given to the number. As discussed in my first declaration, during prosecution of the Patents-in-Suit, the patentees argued criticality of the weight percentages and made other statement which created utter confusion as to the scope of the disputed terms.

B. The FDA Tolerances Are Not Relevant to the Meaning of the Claim Terms

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limitations of the measuring devices used and the skill of the individual making the measurement. The figures used to report a result should reflect the precision of the test and the sensitivity of the measuring device that produced the value. To express this precision, the number should contain all the digits that are known plus one digit that is estimated. These are the significant figures (or significant digits). For instance, **a measurement described by the number 2.54 mL has an actual value greater than or equal to 2.535 mL but less than or equal to 2.544 mL**. By simply writing 2.54 mL, we indicate our uncertainty about exactly where in that range the measurement falls.") (emphasis added)

8. Dr. Loftsson opines that a person of ordinary skill in the art would have looked to manufacturing tolerances and shelf-life specification for guidance on the appropriate limits for "about" in the Patents-in-Suit. Loftsson Decl. at ¶22. I disagree.

9. First, one of ordinary skill in the art would not have understood that there is a universal rule to receive a 5 % or 10% "add on" to any claim term having a numerical value *in addition* to the range already given to the ordinary value of the number based on rounding. For instance, a person of ordinary skill in the art would not have understood the claim term 0.05% by weight cyclosporin to encompass the range provided by rounding (0.045 to 0.054) as discussed above and ± 10% of that range (0.0405 to 0.0594) as Dr. Loftsson requires. There is simply nothing in the record which would lead a person of ordinary skill in the art to such a conclusion.

10. Second, I disagree with Dr. Loftsson that a tolerance of ±5% manufacturing and ±10% over the shelf-life of a product is "standard" in the pharmaceutical industry. Loftsson Decl. ¶27. Indeed, nothing in the ICH Guidelines (Ex. C of Loftsson's Declaration) or the Q6A Specification (Ex. D of Loftsson's Declaration) cited by Dr. Loftsson requires a ±5% or ±10% tolerance for all drugs. To the contrary, specifications are quality standards ***proposed*** by the manufacturer which must be ***approved*** by the FDA as conditions of approval. Ex. C to Loftsson's Declaration at AGN_RES1085590. In fact, the ICH Guidelines provide decision trees to determine the acceptable criteria for a given drug substance. Therefore, the release specifications may differ for a given product.

11. Notably, the ICH guidelines and Q6A specification cited by Dr. Loftsson relate to "solid oral products, liquid oral drug products, and parentals (small and large volume)." *See e.g.*, Ex. C at AGN_Res1085599. Ophthalmic emulsions, such as Restasis, are not required to strictly follow the ICH guidelines.

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