Filed on behalf of: Abraxis Biosciences, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LTD.,
Petitioner,

v.

ABRAXIS BIOSCIENCE, LLC
Patent Owner

IPR2018-00162; IPR2018-00163; IPR2018-00164
U.S. Patent Nos. 8,138,229; 7,820,788; and 7,923,536

DECLARATION OF CHRISTOPHER VELLTURO, Ph.D.

Filed on behalf of: Abraxis Biosciences, LLC

I, Christopher Vellturo, Ph.D., hereby declare and state as follows:

I. INTRODUCTION

1. I submit this declaration on behalf of Abraxis Bioscience, LLC ("Abraxis" or "Patent Owner"), Patent Owner of U.S. Pat. Nos. 7,820,788 ("the '788 patent"), 7,923,536 ("the '536 patent"), and 8,138,229 ("the '229 patent") (collectively, "the Abraxis Patents") to provide my opinions on certain matters in connection with the petitions for *inter partes* reviews filed by Cipla Ltd., ("Cipla" or "Petitioner") in case nos. IPR2018-00162, IPR2018-00163, and IPR2018-00164 (collectively, the "Cipla IPR Petitions").

II. BACKGROUND & QUALIFICATIONS

2. I am the founder and president of Quantitative Economic Solutions, LLC ("QES"), a microeconomic consulting firm. I received a Doctor of Philosophy degree (Ph.D.) in Economics from the Massachusetts Institute of Technology in Cambridge, Massachusetts in 1989. My fields of specialization include industrial organization and econometrics.

3. I have evaluated pharmaceutical patent issues in the context of commercial success and injunctive relief considerations on numerous occasions. I also have extensive experience in the valuation of intellectual property and in the assessment of economic injury/damages sustained as a result of copyright, trademark, and/or

patent infringement. Industries that I have studied in this context include: pharmaceutical products, over-the-counter medications and instruments, medical devices, consumer products, computer hardware and software, and semiconductors. I have been qualified and have testified as an expert in many Federal Courts throughout the United States as an economist generally, as an expert in statistics/surveys, and as an expert in the economics of the pharmaceutical industry specifically.

4. QES is being compensated for my time spent on this matter at an hourly rate of $850, which is my customary rate. Payment is not contingent on the outcome of this matter. QES is also compensated for the time spent on this matter by persons working at my direction. Those rates are lower than my hourly rate.

5. A copy of my curriculum vitae, including a list of publications I have authored, is attached to this declaration as Appendix A.

III. BASIS OF OPINIONS

6. In forming my opinions, I have reviewed the Cipla IPR Petitions, portions of the Patent Owner's Preliminary Responses in IPR2017-01101; 01103; and 01104 ("Actavis IPRs"), the Institution Decisions in the Actavis IPRs, portions of the Abraxis Patents, portions of the references cited in the Petitions in the Actavis IPRs, as well as the other documents identified below.

7. The opinions expressed herein are also based on my knowledge, skill,

experience, training, and education.

IV. STATEMENTS

8. I have been asked to consider whether the Kadima reference (EX1004) would have provided economic motivation to a skilled artisan "to reduce Capxol™'s albumin-paclitaxel ratio in order to obtain a more cost-effective and commercially viable formulation." ('229 Pet. 50; '788 Pet. 48; '536 Pet. 49)[1] Based on my review of Kadima, Desai (EX1006), and my knowledge in the field of economics with respect to the pharmaceutical industry as of 1998, it is my opinion that Kadima did not provide any such motivation to reduce the weight ratio based on the cost of albumin.

9. Petitioner argues that "[a]s Kadima explains, '[a]lbumin is a cost-limiting component for use in drug stabilization,' because '[a]lbumin is an expensive ingredient.'" ('229 Pet. 50; '788 Pet. 48; '536 Pet. 49.) Petitioner relies on Kadima's table, reproduced as Table 1 below, to provide "examples of cost differences for various ratios of albumin to paclitaxel—ranging from to $10.70 for

[1] '229 Pet. refers to Cipla's Petition for Inter Partes Review in IPR2018-00164. '788 Pet. refers to Cipla's Petition for Inter Partes Review in IPR2018-00162. '536 Pet. refers to Cipla's Petition for Inter Partes Review in IPR2018-00163.

a 0.5:1 ratio to $81:90 for a 10:1 ratio" and that "[b]ased on these significant differences, a skilled artisan would have been motivated to reduce Capxol™'s albumin-paclitaxel ratio in order to reduce the cost of producing the formulation." ('229 Pet. 50; '788 Pet. 49; '536 Pet. 50.)

Table 1

Molar ratio	Paclitaxel (mg)	HSA (g)	Paclitaxel Cost	HSA Cost(1)	Ingredients Total Cost
1:10	30	23.4	$7	$74.90	$81.90
1:5	30	11.7	$7	$37.40	$44.40
1:2	30	4.7	$7	$15.00	$22.00
1:1	30	2.34	$7	$7.49	$14.50
1:0.5	30	1.17	$7	3.74	$10.70

(1) The fair 1999 market value of HSA is approximately $3.20 per gram.

10. I understand that, as Patent Owner pointed out in its Preliminary Response in the Actavis IPRs, and the Board agreed, Kadima does not report weight ratios, only molar ratios. (IPR2017-01101, paper 7 at 32; IPR2017-01103, paper 7 at 31; IPR2017-01104, paper 7 at 32.) I further understand that a paclitaxel-to-albumin molar ratio of 1:10 converts to an albumin-to-paclitaxel weight ratio of 790:1, and the lowest reported molar ratio of 1:0.5 corresponds to a weight ratio of 39:1. (IPR2017-01101, paper 7 at 26; IPR2017-01103, paper 7 at 26; IPR2017-01104, paper 7 at 26.)

11. Based on the fair market value of human serum albumin and the cost of

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