

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN, INC.,
Petitioner,

v.

AVENTIS PHARMA, S.A.,
Patent Owner.

Case No. IPR2016-00712
Patent No. 8,927,592

REPLY DECLARATION OF DR. RAHUL SETH

TABLE OF CONTENTS

I.	QUALIFICATIONS	1
II.	LEGAL STANDARDS	2
III.	LEVEL OF ORDINARY SKILL AND RELEVANT TIME	3
IV.	STATE OF THE ART.....	4
V.	RESPONSE TO ARGUMENTS FROM AVENTIS AND DR. SARTOR REGARDING THE CLAIMS OF THE '592 PATENT.....	4
VI.	RESPONSE TO ARGUMENTS FROM AVENTIS AND DR. SARTOR REGARDING THE PROPOSED SUBSTITUTE CLAIMS	20
VII.	THE PROPOSED SUBSTITUTE CLAIMS WOULD HAVE BEEN OBVIOUS TO A PERSON OF ORDINARY SKILL	24
VIII.	THE TEACHINGS OF MITA	40
IX.	THE ALLEGED "TEACHING AWAY"	41
X.	CONCLUDING STATEMENTS.....	42
XI.	APPENDIX – LIST OF EXHIBITS.....	44

I, Rahul Seth, declare as follows:

I. QUALIFICATIONS

1. I am the same Dr. Rahul Seth who previously submitted a declaration (EX1002) filed with the petition in this IPR on March 15, 2016 (“Original Declaration”). My Original Declaration and my CV (EX1003) detail my background, education, credentials, experience, and compensation. I also discussed in my Original Declaration some characteristics of a person of ordinary skill in the art. Unless noted otherwise in this declaration, the information and opinions contained in my Original Declaration remain the same.

2. I have been asked by counsel for Mylan Pharmaceuticals Inc. to evaluate and provide my opinions regarding the testimony of Dr. Alton Sartor contained in his First Declaration (EX2001, filed on June 24, 2016) and in his Second Declaration (EX2176, filed on December 13, 2016). In addition to reviewing Dr. Sartor’s First and Second Declarations, I also reviewed and considered the materials cited in his declarations, as well as the materials cited and discussed in this declaration. My opinions are based upon my review of these materials, as well as my knowledge, education, and training.

3. Upon such consideration, it remains my considered opinion that claims 1-5 and 7-30 of the ’592 patent would have been obvious to a person of ordinary skill in the art in view of the prior art as it would be understood by a person of ordinary skill in the art at the time of the claimed invention. Further, it is

also my opinion that the amendments to the claims proposed by the Patent Owner and Dr. Sartor would not alter this analysis, and that the proposed amended claims 31-34 similarly would have been obvious to a person of ordinary skill at the time of the claimed invention.

II. LEGAL STANDARDS

4. My Original Declaration provides my understanding of the legal standards that are applicable in this case. Furthermore, I have been informed that the Board may consider factors referred to as secondary considerations or objective indicia of non-obviousness that are presented by the Patent Owner to rebut a showing of obviousness. I am informed that the Patent Owner bears the burden of providing such evidence, but that the ultimate burden of persuasion on the issue of obviousness falls on the petitioner. I am also informed that for secondary indicia to be probative of non-obviousness, there must be a sufficient connection or “nexus” between the asserted secondary consideration and the novel aspects of the challenged claim.

5. I also understand that evidence of “secondary considerations” may be weighed against evidence of the scope and content of, and the level of skill in, the art to rebut a conclusion of obviousness where appropriate.

6. I understand that such secondary considerations, where in evidence, may include: (i) the commercial success of a product due to the merits of the claimed invention; (ii) the satisfaction by the invention of a long-felt, but

previously unsatisfied need; (iii) the failure of others to find the solution provided by the claimed invention; (iv) deliberate copying of the invention by others; (v) unexpected results achieved by the invention; (vi) praise of the invention by others skilled in the art.

7. I further understand when evaluating unexpected results in relation to the obviousness analysis, the asserted unexpected results should be evaluated based on the expectations of the person of ordinary skill in the art at the time of the invention. I also understand that that an unexpected results analysis should compare the results of the claimed invention to that of the closest prior art. I also understand that unexpected results showing a difference in kind may be more probative than evidence showing simply a difference of degree as compared to the results of the closest prior art.

III. LEVEL OF ORDINARY SKILL AND RELEVANT TIME

8. I explained in my Original Declaration that a person of ordinary skill in the art would be an oncologist, would hold a medical degree (*e.g.*, a D.O. or an M.D.), and would have experience treating patients with prostate cancer by administering chemotherapeutic drugs.

9. Dr. Sartor testified during his deposition that the person of ordinary skill in the art of the '592 patent is a practicing oncologist. Ex. 1041, 140:2-7; *see also* EX2001, ¶24. Dr. Sartor also states that the skilled artisan would have experience evaluating new therapies for prostate cancer and would have access to

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