UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS, INC.,
Petitioner

v.

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners

Inter Partes Review No.: IPR2014-00550

U.S. Patent No. 6,335,031

REPLY DECLARATION OF CHRISTIAN SCHÖNEICH, PH.D.

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I, Christian Schöneich, Ph.D., declare and state as follows:

I. QUALIFICATIONS

1. For a discussion of my qualification and credentials, I refer to my curriculum vitae (Ex. 1023) and my April 2, 2014 declaration (Ex. 1011), which also provides a list of matters in which I have testified over the last four years, and my compensation.

II. INFORMATION CONSIDERED

2. I have reviewed the Declaration of Dr. Klibanov (Ex. 2012) and the documents cited in that report. Dr. Klibanov makes numerous statements in his declaration that are misleading and/or unscientific. I address these statements below.

3. In forming my opinions, I have relied upon my accumulated scientific knowledge and experience. I have reviewed the documents cited in my April 2014 declaration (Ex. 1011), including the documents listed in paragraph 9 of that declaration. I have also reviewed the documents cited in this declaration.

III. REPLY TO DR. KLIBANOV'S DECLARATION

A. Dr. Klibanov's Understanding of a POSA Is Inconsistent with the Clear Teachings in the Art

4. Dr. Klibanov states that a POSA could not make any predictions about the physical or chemical properties of a compound based on its structure:

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> I [Dr. Klibanov] disagree that a POSA would be able to make predictions about the physical or chemical properties of a compound based on its chemical structure.

(Ex. 2012 at ¶ 25.) This statement is incorrect. Ordinarily-skilled artisans in 1998 routinely made predictions about the physical/chemical properties of compounds based on chemical structure. (Ex. 1038 at 3.)

5. As I described in my opening report (*see, e.g.*, Ex. 1011 ¶¶ 14-46 in particular ¶¶ 32-35) and discuss below (*see* ¶¶ 7-15), a POSA could also make reasoned predictions about the strength of particular chemical bonds in a drug molecule and the susceptibility of the molecule to degradation, including oxidative degradation. A POSA was instructed by the prior art to assess a molecule's chemical structure and make such determinations during pharmaceutical formulation development. (Ex. 2020 at 110; Ex. 2014 at 181, in particular see ¶¶ 23-25 below.)

6. Indeed, Dr. Klibanov confirms the predictive value of chemical structure analysis. In his declaration, Dr. Klibanov states that a POSA could predict a molecule's susceptibility to hydrolysis based on whether it contained a monomethyl or a dialkyl carbamate functional group. Dr. Klibanov states that monomethyl carbamates in general were known to degrade by hydrolysis (Ex. 2012 ¶ 82) and "dialkyl carbamates were hydrolytically stable" (Ex. 2012 ¶ 86). These statements are inconsistent with the above statement by Dr. Klibanov that a

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