UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COMPLEX INNOVATIONS, LLC,
Petitioner,

v.

AMGEN INCORPORATED

Patent Owner

_____

U.S. Patent 7,829,595

_____

**DECLARATION OF WALTER G. CHAMBLISS, Ph.D.**

I, Walter G. Chambliss, declare as follows:

1. I have been retained by Hill, Kertscher, & Wharton, LLP, which represents Complex Innovations, LLC, in connection with a petition for *inter partes* review of U.S. Patent No. 7,829,595, titled *Rapid Dissolution Formulation of a Calcium Receptor-Active Compound* ("595 Patent"). I understand that the 595 Patent is currently assigned to Amgen, Incorporated.

**SCOPE OF ANALYSIS**

2. I have reviewed and am familiar with the 595 Patent, which issued to Lawrence, *et al.* on November 9, 2010. I understand that the 595 Patent includes 25 claims. I also understand that the Petition for *inter partes* review that accompanies this Declaration seeks to cancel claims 1-25 of the 595 Patent. My analysis and opinions will focus on all challenged claims 1-25.

3. My analysis assumes that the time of invention is September 12, 2003, which is, in this case, the filing date for provisional application 60/502,219.

4. I have reviewed and am familiar with various references, written materials, and literature, which are itemized below:

a) Ex. 1001 U.S. Patent No. 7,829,595 to Lawrence, *et al.* ("595 Patent")

b) Ex. 1002 File History to the 595 Patent ("File History")

c) Ex. 1003 U.S. Patent No. 6,211,244 to Van Wagenen, *et al.* ("Van Wagenen")

d) Ex. 1004 U.S. Patent No. 5,162,117 to Stupak, *et al.* ("Stupak")

e) Ex. 1005 European Patent Application No. 1 321 142 A1 by Vitzling, *et al.* ("Vitzling")

f) Ex. 1006 U.S. Patent No. 5,879,706 to Carter, *et al.* ("Carter")

g) Ex. 1007 Canadian Patent Application No. 2,004,565 by Chang, *et al.* ("Chang")

h) Ex. 1008 U.S. Patent No. 8,703,196 to Babcock, *et al.* ("Babcock")

i) Ex. 1009 U.S. Patent No. 6,733,780 to Tyler, *et al.* ("Tyler")

j) Ex. 1010 U.S. Patent No. 4,931,286 to Johnson, *et al.* ("Johnson")

k) Ex. 1011 Excerpts from The Pharmaceutical Codex: Principles and Practice of Pharmaceutics (12th ed.) (1994) ("Pharmaceutical Codex")

l) Ex. 1012 Excerpts from the Handbook of Pharmaceutical Excipients (3rd ed.) (2000) ("HPE")

m) Ex. 1013 Excerpts from Howard C. Ansel, *et al.*, Pharmaceutical Dosage Forms and Drug Delivery Systems (7th ed.) (1999) ("Ansel")

n) Ex. 1014 Excerpts from Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz (eds.), Pharmaceutical Dosage Forms: Tablets (2nd ed.) (1989) Vol. 1 ("Lieberman I")

o) Ex. 1015 Excerpts from Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz (eds.), Pharmaceutical Dosage Forms: Tablets (2nd ed.) (1989) Vol. 2 ("Lieberman II")

p) Ex. 1016 Particle Size – U.S. Sieve Series and Tyler Mesh Series Equivalents (2002; updated 2013), found at www.azom.com/article.aspx?ArticleID=1417, last accessed August 7, 2015 ("Particle Size")

q) Ex. 1017 *New Agent Reduces PTH Levels in Hemodialysis Patients With Secondary Hyperparathyroidism*, FORMULARY (April 2003) Vol. 38, p. 197 ("Formulary")

r) Ex. 1018 J.C. Chaumeil, *Micronization: A Method of Improving the Bioavailability of Poorly Soluble Drugs*, METH. FIND. EXP. CLIN. PHARMACOL. (1998), pp. 211-215 ("Chaumeil")

s) Ex. 1019 Excerpt from Sir Colin Dollery (ed.), Therapeutic Drugs, (1991) Vol. 2 ("Dollery")

t) Ex. 1020 Gordon T. McInnes, et al., Effect of Micronization on the Bioavailability and Pharmacologic Activity of Spironolactone, J. CLIN. PHARMACOL. 22 (1982), pp. 410-417 ("McInnes")

5. I have been asked to consider how a person of ordinary skill in the art ("POSITA") would have understood the claims subject to *inter partes* review in

light of the disclosure of the 595 Patent. I also have been asked how a POSITA would have understood and applied various references including the Van Wagenen Patent and the HPE, and whether various other references support them, including the Stupak, Carter, Babcock, Tyler, and Johnson Patents, the Vitzling and Chang Patent Applications, and certain material from Ansel, the Pharmaceutical Codex, Lieberman I, and Lieberman II.

6. I am being compensated at my standard hourly rate of $800 dollars per hour for regular consulting and $1000 per hour for live testimony. My compensation is not dependent on the outcome of this *inter partes* review and in no way affects the substance of my testimony in this matter.

**QUALIFICATIONS AND EXPERTISE**

7. My resume/curriculum vitae is attached to this declaration as Exhibit A.

8. For over thirty-eight (38) years, I have been active in the field of pharmacy, with over thirty (30) active years in pharmaceutical drug development.

9. I hold a doctoral degree (Ph.D.) in Pharmaceutics granted by the University of Mississippi in 1982, as well as a Master of Science in Pharmaceutics and Bachelor of Science in Pharmacy, granted by the University of Mississippi in 1980 and 1977, respectively.

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