IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS X LLC,
Petitioner,

v.

ANACOR PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2015-01776
Patent No. 7,582,621

DECLARATION OF JENNIFER AUGSBURGER IN SUPPORT OF PATENT OWNER'S RESPONSE

I, Jennifer Augsburger, hereby declare as follows:

1. I am an IP attorney specialist with the firm of Covington & Burling LLP, which is counsel for Anacor Pharmaceuticals, Inc. ("Patent Owner"). I submit this declaration in support of Patent Owner's Response to Coalition for Affordable Drugs X LLC's Petition for *Inter Partes* Review of Patent No. 7,582,621. I have personal knowledge of the facts stated herein.

2. Attached as Exhibit 2043 to Patent Owner's Response is a true and correct copy of Office of Toxic Substances, Environmental Protection Agency, "Preliminary Investigation of Effects on the Environment of Boron, Indium, Nickel, Selenium, Vanadium and Their Compounds," EPA-65/2-75-005A, (August 1975) that is publically available as a PDF document at http://nepis.epa.gov/Exe/ZyPDF.cgi/9101277V.PDF?Dockey=9101277V.PDF.

3. Attached as Exhibit 2048 to Patent Owner's Response is a true and correct copy of EPA Correspondence, 1992 Labeling Rev., Amended Biobor Label that is publically available as a PDF document linked from https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:102:::NO::P102_REG_NUM:65217-1 and available directly at https://www3.epa.gov/pesticides/chem_search/ppls/065217-00001-19920403.pdf.

4. Attached as Exhibit 2074 to Patent Owner's Response is a true and correct copy of FDA Approved Label for SPORANOX®, (Supplement 034, Action

Date 07/14/2004) that is publically available as PDF documents linked from http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=020083&DrugName=SPORANOX&ActiveIngred=ITRACONAZOLE&SponsorApplicant=JANSSEN%20PHARMS&ProductMktStatus=1&goto=Search.Label_ApprovalHistory and available directly at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/20083s034,035ltr.pdf (letter) and http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/20083s034,035lbl.pdf (label).

5. Attached as Exhibit 2075 to Patent Owner's Response is a true and correct copy of FDA Approved Label for LAMISIL®, (Supplement 012, Action Date 01/21/2004) that is publically available as PDF documents linked from http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=020539&DrugName=LAMISIL&ActiveIngred=TERBINAFINE%20HYDROCHLORIDE&SponsorApplicant=NOVARTIS&ProductMktStatus=1&goto=Search.Label_ApprovalHistory and available directly at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/20539slr012ltr.pdf (letter) and http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/20539slr012_lamisil_lbl.pdf (label).

6. Attached as Exhibit 2076 to Patent Owner's Response is a true and correct copy of FDA Approved Label for Gris-PEG®, (Supplement 046, Action Date 03/26/2003) that is publically available as PDF documents linked from http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=050475&DrugName=GRIS%2DPEG&ActiveIngred=GRISEOFULVIN%2C%20ULTRAMICROSIZE&SponsorApplicant=VALEANT%20PHARMS%20INC&ProductMktStatus=1&goto=Search.Label_ApprovalHistory and available directly at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/50475slr046ltr.pdf (letter) and http://www.accessdata.fda.gov/drugsatfda_docs/label/2003/50475slr046_gris-peg_lbl.pdf (label).

7. Attached as Exhibit 2077 to Patent Owner's Response is a true and correct copy of FDA Approved Label for Penlac®, (Supplement 004, Action Date 12/03/2004) that is publically available as PDF documents linked from http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=021022&DrugName=PENLAC&ActiveIngred=CICLOPIROX&SponsorApplicant=VALEANT%20BERMUDA&ProductMktStatus=1&goto=Search.Label_ApprovalHistory and available directly at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21022s004ltr.pdf

(letter) and

http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21022s004lbl.pdf (label).

8. Attached as Exhibit 2099 to Patent Owner's Response is a true and correct copy of Center for Drug Evaluation and Research, *Guidance for Industry: Clinical Development and Labeling of Anti-Infective Drug Products* (1992) that is publically available as a PDF document linked from http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064980.htm and available directly at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070975.pdf.

9. Attached as Exhibit 2109 to Patent Owner's Response is a true and correct copy of EPA Correspondence, 1997 Labeling Rev., Amended Biobor Label that is publically available as a PDF document linked from https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:102:::NO::P102_REG_NUM:65217-1 and available directly at https://www3.epa.gov/pesticides/chem_search/ppls/065217-00001-19970327.pdf.

10. Attached as Exhibit 2112 to Patent Owner's Response is a true and correct copy of Crane & Sanders, *Evaluation of a Biocidal Turbine-Fuel-Additive*, Aviation Medical Report—AM 67-21, pp. 1-10 (Federal Aviation Administration, Office of Aviation Medicine 1967) that is publically available as a PDF document

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