

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., APOTEX PHARMACEUTICALS
HOLDINGS INC., AND APOTEX HOLDINGS, INC.,

Petitioners,

v.

OSI PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2016-01284
U.S. Patent No. 6,900,221

DECLARATION OF JACKSON GIBBS, PH.D.

OSI 2022
APOTEX V. OSI
IPR2016-01284

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I, Jackson Gibbs, Ph.D., declare as follows:

1. My name is Jackson Gibbs.

I. BACKGROUND

2. I am currently an Independent Pharmaceuticals Professional at JBG Pharma Consulting and a Network Partner at Synergy Partners R&D Solutions where I specialize in Oncology and Pharmacology R&D. I am also an Adjunct Professor in the Department of Biochemistry and Molecular Medicine at George Washington University School of Medicine and Health Sciences.

3. Most recently, I worked at AstraZeneca for 6 years as Director, Licensing and Scientific Affairs, Cancer Research. I was a member of the Cancer Management Team in R&D Boston, a member of the Oncology Business Development team, and the Scientific Lead for Oncology Alliance activities with major academic Cancer Centers such as Massachusetts General Hospital and Memorial Sloan Kettering. At AstraZeneca, I helped to plan and implement the scientific strategy and evaluated licensing opportunities.

4. I received my Ph.D. in Pharmacology from the University of Virginia where I trained with faculty that included future Nobel Laureates Alfred Gilman and Ferid Murad. I conducted postdoctoral studies with Edward Scolnick, a member of the National Academy of Sciences. I was at Merck for 23 years working in oncology drug discovery, and rose to the level of Senior Director,

Cancer Research. During my career at Merck, I performed target identification/validation studies, and led multidisciplinary teams on five medicinal chemistry supported projects in the areas of signal transduction, angiogenesis, and cell cycle (three of which led to IND filings – Farnesyl transferase, VEGFR, and c-Met). I also was involved with preclinical/early clinical development (including being the co-Chair of the cross functional VEGFR Project Development team).

5. I am a co-inventor of five issued U.S. patents and an author of 128 research articles, book chapters, and review articles. Some of the invited review articles (published in Cell and Science) focus on the interface between basic research and drug discovery in oncology. I also have been actively involved with the external scientific community. I have made over 100 presentations at universities and meetings.

6. I have been a member of several research advisory boards. For example, I have served on the Medical Affairs Committee of the Children's Tumor Foundation ("CTF"), on the Research Advisory Board for the CTF, and as the Chair of the External Advisory Board for the CTF Preclinical Consortium. Previously, I was Chair of the Integration Panel, U.S. Army Medical Research Program for Neurofibromatosis. I have been invited and participated in setting the Scientific Strategic Vision for the CTF, the Lustgarten Foundation, and the

Multiple Myeloma Research Foundation. I have also served as a member of the External Advisory Board for the Fox Chase Cancer Center.

7. I was an Adjunct Professor of Pharmacology at the University of Pennsylvania School of Medicine for fifteen years. I also was a member of the American Association for Cancer Research (“AACR”) standing committee on Science Policy and Legislative Affairs and a member of the AACR Task Force on Regulatory Science and Policy.

8. My complete curriculum vitae is attached hereto as Appendix 1.

II. BACKGROUND AND CONTEXT OF MY RESEARCH

9. I understand that Apotex has challenged the validity of patent claims from U.S. Patent No. 6,900,221 (“the ’221 Patent”) relating to a method of treating *inter alia* non-small cell lung cancer (“NSCLC”) with a therapeutically effective amount of erlotinib based on a combination of a patent to Schnur and a prior publication drafted by me (i.e., Exhibit 1010).

10. I am the author of Exhibit 1010, Jackson B. Gibbs, *Anticancer drug targets: growth factors and growth factor signaling*, 105 J. Clinical Investigation 9 (2000), which I will refer to as the Gibbs reference. I have been asked to provide factual background and context regarding my work at the time of the article that I drafted.

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