

**UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT TRIAL AND APPEAL BOARD**

**Apotex Inc., Apotex Corp., Apotex Pharmaceuticals
Holdings Inc., & Apotex Holdings, Inc.**

v.

OSI Pharmaceuticals, Inc.

IPR2016-01284

U.S. Patent No. 6,900,221

October 3, 2017

OSI 2049
Apotex v. OSI

OVERVIEW

- 1. The Claimed Invention**
 - Background
 - Person of Ordinary Skill in the Art
 - Claim Construction
- 2. Claims 44-46 and 53 of the '221 Patent are Non-Obvious**
 - No Motivation to Combine
 - No Reasonable Expectation of Success
 - Objective Indicia of Non-Obviousness
- 3. Motion to Exclude**

THE CLAIMED INVENTION

A METHOD OF TREATMENT OF NSCLC

- Representative claims:

44. A method for the treatment of NSCLC (non small cell lung cancer), pediatric malignancies, cervical and other tumors caused or promoted by human papilloma virus (HPV), Barrett's esophagus (pre-malignant syndrome), or neoplastic cutaneous diseases in a mammal comprising administering to said mammal a therapeutically effective amount of a pharmaceutical composition comprised of at least one of N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)-4-quinazolinamine, or pharmaceutically acceptable salts thereof in anhydrous or hydrate forms, and a carrier.

53. The method of claim 44 for the treatment of non-small cell lung cancer (NSCLC).

STATE OF THE ART

- **NSCLC was the leading cause of cancer death in the U.S.**
Bunn Decl. ¶¶ 28, 91 (Ex. 2021); Paper 7 at 42; Paper 20 at 8; Paper 33 at 12; Ex. 2010 at Ex. 2010-0027
- **Before targeted therapies, the survival rate was very poor**
Bunn Decl. ¶ 87 (Ex. 2021); Ex. 2019 at 449; Paper 20 at 8; Giaccone Dep., 69:13-70:5, 76:15-77:10 (Ex. 2048); Paper 39 at 3-4
- **Advanced stage at diagnosis and limited treatment options**
Bunn Decl. ¶ 29 (Ex. 2021); Paper 7 at 6-7, 42-43; Paper 20 at 8; Ex. 2001 at 825
- **Before the '221 patent, chemotherapy was the standard of care for advanced NSCLC**
Bunn Decl. ¶ 29 (Ex. 2021); Ex. 2036 at 5813; Paper 20 at 8; Giaccone Dep., 25:3-9, 34:1-11 (Ex. 2048); Paper 39 at 2, 4

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