APOTEX INC., APOTEX CORP.,
APOTEX PHARMACEUTICALS HOLDINGS INC.
and APOTEX HOLDINGS, INC.,
Petitioners,

v.
OSI PHARMACEUTICALS, INC.,
Patent Owner.

IPR2016-01284

APOTEX'S DEMONSTRATIVE FOR ORAL HEARING

United States Patent & Trademark Office Before the Patent Trial & Appeal Board

W. Blake Coblentz, Aaron S. Lukas

Cazan O'Cannar DC

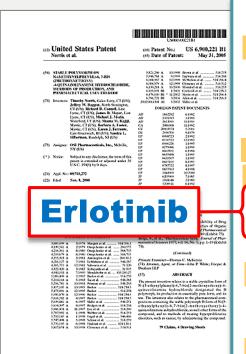


OVERVIEW

- Petitioners' Case that Claims 44-46 and of the '221 Patent are Prima Facie Obv
- Motivation to Combine
- Reasonable Expectation of Success
- Opposition to Patent Owner's Respons
- Secondary Considerations



The Challenged Claims of the '221 Pate



44. A method for the treatment of NSCLC (non smallung cancer), pediatric malignancies, cervical and tumors caused or promoted by human papilloma (HFV), Barrett's esophagus (pre-malignant syndrom neoplastic cutaneous diseases in a mammal com administering to said mammal a therapeutically estamount of a pharmaceutical composition comprised least one of N-(3-ethynylphenyl)-6,7-1 methoxyethoxy)-4-quinazolinamine, or pharmaceutical cacceptable salts thereof in anhydrous or hydrate form a carrier.

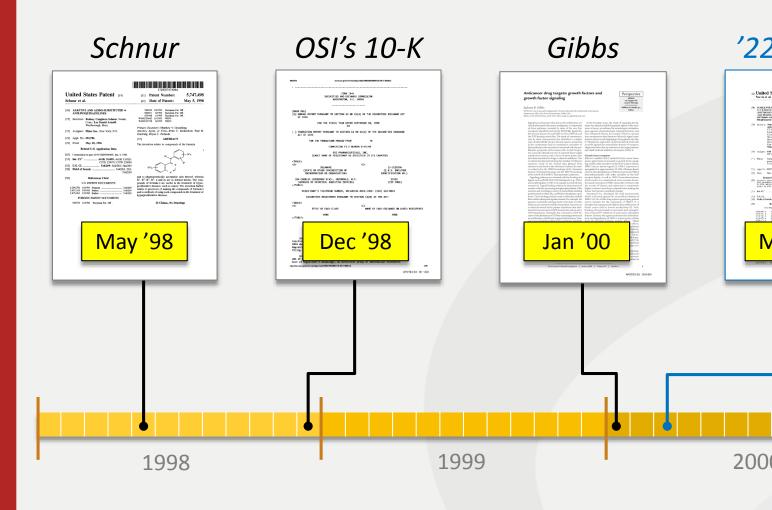
- 45. The method of claim 44, wherein the treatment comprises a palliative or neo-adjuvant/adjuvant therapy.
- 46. The method of claim 44, wherein the treatment comprises blocking epidermal growth factor received (EGFR).

Ex. 1001, '221 Patent at Co

53. The method of claim 44 for the treatment of no cell lung cancer (NSCLC).



The Prior Art References





The Level of Skill in the Art

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

POTEX INC., APOTEX CORP., APOTEX PHAR HOLDINGS INC., and APOTEX HOLDIN Petitioners, v.

v.
OSI PHARMACEUTICALS, INC.
Patent Owner.

U.S. Patent No. 6,900,221 Issue Date: May 31, 2005 Title of Patent: Stable Polymorph on N-(3-ethylphenyl)-6, 4-quinazolinamine hydrochloride, Methods of Productio uses thereof

Case No.: T.B.D.

DECLARATION OF GIUSEPPE GIACCON

DECLARATION OF GIUSEPPE GIACCONE,

52. In my opinion, a person of ordinary skill in the art relevant to patent would have a medical degree and at least some specialized training oncology. More specifically, a person of ordinary skill in the art relevant '221 patent would likely have at least some specialized training in thoraci oncology. Further, in my opinion a person of ordinary skill in the art would several years of clinical experience, and a substantive understanding and experience using the medications and therapies effective for treating various at the relevant time. A person of ordinary skill in the art would be of current advances at the time in the use of various medications and therapter treat cancer.



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