

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

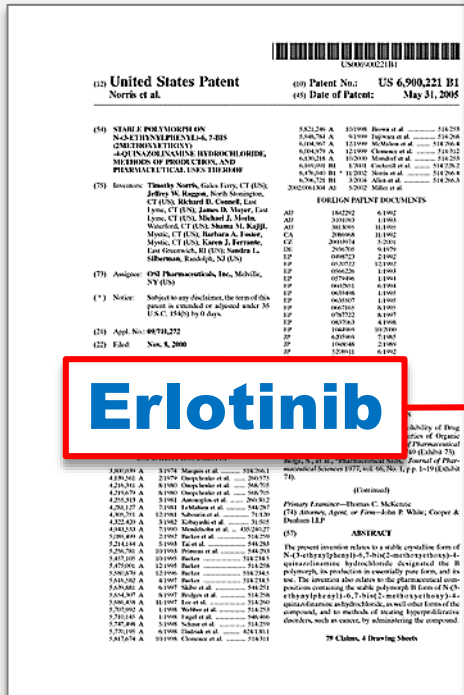
W. Blake Coblenz, Aaron S. Lukas

Casey O'Connor, 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 Patent



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

45. The method of claim 44, wherein the treatment comprises a palliative or neo-adjuvant/adjuvant therapy.

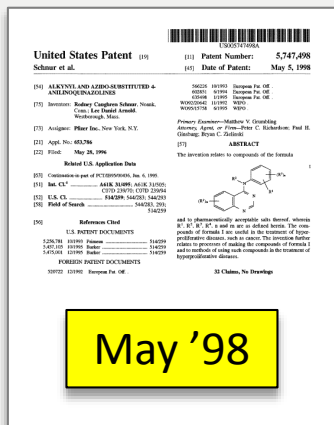
46. The method of claim 44, wherein the treatment comprises blocking epidermal growth factor receptor (EGFR).

Ex. 1001, '221 Patent at Col. 2

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

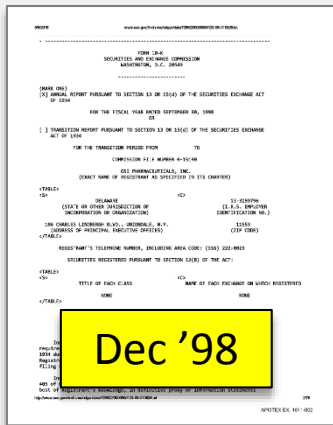
The Prior Art References

Schnur



May '98

OSI's 10-K



Dec '98

Gibbs

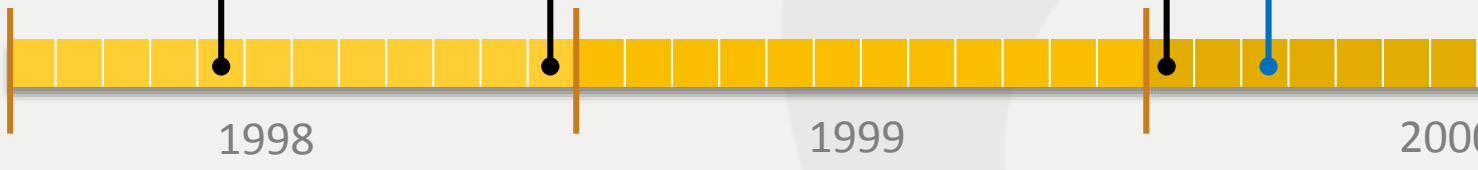


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The Level of Skill in the Art

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., APOTEX PHAR
HOLDINGS INC., and APOTEX HOLDIN
Petitioners,
v.
OSI PHARMACEUTICALS, INC.
Patent Owner.
U.S. Patent No. 6,900,221
Issue Date: May 31, 2005
Title of Patent: Stable Poly morph on N-(2-ethylphenyl)-6-
4-quinazolinamine hydrochloride, Methods of Productio
uses thereof
Case No.: T.B.D.
DECLARATION OF GIUSEPPE GIACCONE

DECLARATION OF GIUSEPPE GIACCONE,

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

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