OSI PHARMACEUTICALS, LLC v. APOTEX INC., Appeal No. 18-1925 (Fed. Cir. October 4, 2019). Before Newman, Taranto, and Stoll. Appealed from PTAB.

Background:

OSI owns a patent directed to a method for treating non-small cell lung cancer (NSCLC) by administering N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)-4-quinazolinamine (erlotinib). Apotex challenged the validity of the patent in an IPR proceeding, arguing that the patent claims were obvious over a prior patent ("Schnur") in combination with either a scientific publication ("Gibbs") or a Form 10-K, an annual financial form filed by OSI with the SEC ("OSI's 10-K").

Schnur disclosed erlotinib as a preferred compound among 105 different compounds for treating various human tumors, including lung tumors, but did not specifically identify NSCLC. Gibbs, a review article, disclosed that erlotinib and another drug were in clinical trials and appeared to have good anti-cancer activity in preclinical models, particularly in patients with NSCLC. OSI's 10-K included a section titled "Product Development and Research Programs," disclosing that erlotinib targets a variety of cancers, including NSCLC, and had completed Phase I safety trials and was beginning Phase II clinical trials.

The Board found that a person of ordinary skill in the art would have combined Schnur with the disclosures in Gibbs or OSI's 10-K with a reasonable expectation of success of using erlotinib to treat NSCLC.

Issue/Holding:

Was the Board's finding of a reasonable expectation of success supported by substantial evidence? No, reversed.

Discussion:

The Federal Circuit found that the only reasonable expectation at the time of the invention was failure, not success, because, at the time of invention, NSCLC treatment was highly unpredictable with an over 99.5% rate of failure for drugs entering Phase II clinical trials, and the references did not disclose any data or promising information regarding erlotinib's efficacy in treating NSCLC.

The Federal Circuit also held that the Board misinterpreted the references to teach more than substantial evidence supports. For example, the Board found that there was a clear inference in Gibbs that erlotinib has anti-cancer activity against NSCLC. But the references cited by Gibbs to support the statement that erlotinib and another drug appear to have anti-cancer activity against NSCLC only disclosed efficacy data for the other drug against NSCLC. Dr. Gibbs also confirmed in a declaration before the Board that he was not aware of any publication discussing erlotinib's effect on NSCLC at the time Gibbs was published.

As to the combination of Schnur and OSI's 10-K, the Board emphasized the statement in OSI's 10-K that erlotinib was entering Phase II clinical trials, and relied on evidence that, before entering Phase I safety trials, an Investigational New Drug application containing preclinical efficacy and animal safety information is submitted to the FDA. But the Federal Circuit found that there was nothing in OSI's 10-K suggesting the existence of erlotinib preclinical efficacy data specific to NSCLC, as opposed to other cancers.

The Federal Circuit noted that efficacy data is not always required for a reasonable expectation of success. But, in this case, given the high failure rate, the absence of any efficacy data or other reliable indicator of success is significant.