HOFFMAN-LA ROCHE INC. v. APOTEX INC., App. No. 2013-1128, -1161 to -1164 (April 11, 2014). Before Newman, Lourie and Bryson. Appealed from D.N.J. (Judge Chesler).

Background:

Roche, a brand manufacturer, sued five generic drug manufacturers who had filed Abbreviated New Drug Applications (ANDAs) over Roche's patented method of treating osteoporosis by administering a monthly oral dose of 150 mg of ibandronate. The district court, in two summary judgment rulings, determined that the asserted claims of Roche's two patents would have been obvious. Roche appealed.

Issue/Holding:

Did the district court err in granting summary judgment of obviousness. No, affirmed.

Discussion:

The Federal Circuit's majority opinion pointed out that a monthly oral ibandronate treatment was taught by several prior art references. The dosage of 150 mg was effectively taught by scaling up prior art dosages of 5 mg daily or 35 mg weekly in light of the Riis article, which taught the total dose concept: that the effect of ibandronate on bone formation was due to the cumulative dose for a time interval, and not the size or frequency of individual doses.

The Federal Circuit rejected Roche's contention that those of ordinary skill in the art would have had safety concerns with a 150 mg dose.

The Federal Circuit also held that Roche's claims of unexpected results were insufficient to overcome the *prima facie* showing of obviousness provided by the defendants' prior art. While Roche provided evidence that a 150 mg dose had an unexpectedly high bioavailability in the body, bioavailability was not a direct measure of efficacy and, in any event, did not change the reasonable expectation of success that one of ordinary skill in the art would have had prior to consideration of the bioavailability data.