ASTRAZENECA AB v. APOTEX CORP, Appeal No. 2014-1221(Fed. Cir. April 7, 2015). Before O'Malley, Clevenger, and Bryson. Appealed from S.D.N.Y. (Judge Cote).

Background:

After the Federal Circuit affirmed infringement by Apotex of two AstraZeneca Prilosec® (omeprazole) patents, the District Court awarded damages of $76 million based on a reasonable royalty of 50% of the gross margins of Apotex's sales. The infringement decision was issued two months after the patents expired, and at that time the FDA rescinded Apotex's approval to sell its infringing generic because Astrazenca was entitled a six month "pediatric exclusivity" period after patent expiration. The District Court calculated the damage award based on sales that occurred during the terms of the patents and for the two months after expiration up until Apotex stopped selling due to the FDA withdrawing approval. Apotex appealed the damages award.

Issue/Holding:

Whether the District Court properly decided damages. Yes, as to the reasonable royalty of 50% of Apotex's gross sales margins. No, as to the sales that occurred in the two month period after patent expiration. Affirmed in part, reversed in part, and remanded.

Discussion:

The District Court applied the factors relating to determining a reasonable royalty from *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), to arrive at a royalty rate of 50% of gross margins of Apotex's omeprazole sales. There was abundant factual support for the District Court's conclusion. Included in the calculation was Apotex's expectation that it could (and did) obtain a gross margin for omeprazole more than twice that of its other generic products, and that this expectation would be even higher if Apotex had licensed AstraZeneca's patents (which the Court found AstraZeneca would have been "especially reluctant" to do). Other facts favoring a high royalty included: (1) the high cost for Apotex to produce a non-infringing alternative product, including difficulties and delays in obtaining FDA approval of such an alternative; (2) the unavailability of other alternatives due to other patents on those alternatives; (3) similarly high royalties accepted by other infringers who settled. A 20% royalty paid for an over-the-counter version was less relevant because it is "largely distinct from the prescription drug market." Lastly, the Court was not persuaded by Apotex's argument that the royalty should be applied only to the value of the "inventive element" (the water soluble subcoating) and not to other conventional elements of the claim, because "the subcoating is so important to the viability of the commercial … product that it was substantially responsible for the value of the product."

The Federal Circuit reversed the damage award relating to the extra two month base covering the pediatric exclusivity period. The District Court erred because the basis for patent infringement royalties was AstraZeneca's *patent* exclusivity, not its regulatory exclusivity. Congress authorized the extended exclusivity period; but Congress did not authorize use of the provisions of 35 U.S.C. §284 beyond the term of the patent. The Federal Circuit thus reversed this portion of the District Court's damages determination and remanded for recalculation.