TEVA PHARMACEUTICAL INDUSTRIES LTD. v. ASTRAZENECA PHARMACEUTICALS LP, Appeal No. 2011-1091 (Fed. Cir. December 1, 2011). Before Rader, Linn, and Dyk. Appealed from E.D. Pa. (Judge Yohn).

Background:

Teva sued AstraZeneca for infringement of a reissue patent directed to a stabilized pharmaceutical composition for the treatment of high blood cholesterol levels. AstraZeneca moved for summary judgment of invalidity under §102(g)(2), alleging that it had conceived and reduced its commercial formulation to practice prior to Teva's first conception of the claimed subject matter. AstraZeneca conceded infringement for the limited purpose of advancing its summary judgment motion.

The claims required "a stabilizing effective amount" of a certain component. It was uncontested that AstraZeneca did not understand that one of its components had a stabilizing effect on the composition. At the district court, AstraZeneca successfully asserted that an appreciation of the stabilizing effect of a specific component, as opposed to its appreciation of the stabilization of its overall pharmaceutical composition, was not required under §102(g)(2) to establish the date of conception.

Additionally, AstraZeneca made undisputed showings that before the earliest date Teva asserted that it conceived of or reduced to practice the subject matter of its patent (1) AstraZeneca had manufactured a large batch of a pharmaceutical formulation containing the same ingredients in the same amounts as its commercial formulation, and (2) disclosed the ingredients and quantities for pharmaceutical formulations matching those of all its commercially available dosage strengths. Based on these facts, the district court found that there was no genuine issue of material fact as to whether AstraZeneca arrived at the claimed subject matter before Teva. Thus, the district court granted AstraZeneca's motion and held the asserted claims invalid. Teva appealed.

Issue/Holding:

Did the district court err by failing to require AstraZeneca to prove that it appreciated the stabilizing effect of a component in its drug formulation? No, affirmed.

Discussion:

With reference to *Dow*, *Mycogen Plant Sciences*, and *Invitrogen*, the Federal Circuit indicated that the date of conception is the date the inventor first appreciated the fact of what he made. Thus, to establish prior invention, the party asserting it must prove that it appreciated what it had made. Here, the Federal Circuit determined that there was no question that AstraZeneca had appreciated what it had made because AstraZeneca had appreciated what the components of its formulations were and that its formulations were stable. The Federal Circuit also explained that (1) the prior inventor does not need to know everything about how or why its invention worked and thus Astra-Zeneca did not need to appreciate which component was responsible for the stabilization of its formulations, and (2) there is no requirement that the prior inventor conceive of the invention using the same words as the patentee would later use to claim it. Thus, the Federal Circuit held that the district court correctly entered summary judgment.

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