TEVA PHARMACEUTICALS USA, INC. v. SANDOZ INC., Appeal No. 2017-1575 (Fed. Cir. October 12, 2018). Before Reyna, Bryson, and Stoll. Appealed from D. Del. (Judge Sleet).

Background:

Teva owns patents directed to methods for treating relapsing-remitting multiple sclerosis, comprising administering glatiramer acetate, marketed under the name COPAXONE®. The claimed methods recite a dosage regimen involving three subcutaneous injections of 40 mg of glatiramer acetate over a period of seven days with at least one day between every injection. Teva sued for infringement based on planned generic versions of COPAXONE® 40 mg administered 3 times per week by Sandoz and others. The district court held that Teva's patent claims were invalid as obvious over disclosures of prior dosing regimens for the drug. The prior dosing regimens included Teva's own FDA approved regimen involving daily injections of 20mg of the drug, as well as studies testing an every other day 40 mg dosage regimen.

Issue/Holding:

Did the district court err in holding the patent claims invalid as obvious? No, affirmed.

Discussion:

The Federal Circuit rejected Teva's argument that the district court impermissibly relied on hindsight and improper "obvious to try" reasoning. The evidence of record supported the district court's finding that there was market pressure to solve a known problem, namely the fact that many patients could not tolerate daily injections due to injection-site reactions and immediate post-injection reactions.

The Federal Circuit further agreed with the district court's finding that there were a finite number of predictable solutions that a person skilled in the art would have had good reasons to pursue. Although the Federal Circuit acknowledged that the universe of potential doses of glatiramer acetate is theoretically unlimited, the universe of doses in the prior art that had clinical support for being effective and safe consisted of only two doses: 20 mg and 40 mg. Additionally, the applied references demonstrated that increasing the dose to 40 mg every other day did not affect adverse reactions, and was at least as effective as the daily administration of 20 mg, but with a more rapid onset.

Moreover, less frequent injections of glatiramer acetate had been demonstrated to be just as effective as daily injections, while improving patient adherence. Therefore, even though there were several injection frequencies not yet tested in the prior art, such as once, twice, or thrice a week, the Federal Circuit found that these still represented a limited number of discrete permutations. Additionally, a thrice-weekly 40 mg injection would result in a total weekly dose (120 mg/week) very close to the total weekly dose (140 mg/week) of the already-approved daily 20 mg injection. Similarly, the thrice-weekly 40 mg dosage regimen would eliminate only one dose every two weeks as compared to the every other day 40 mg injection regimen.

Accordingly, the Federal Circuit concluded that a person skilled in the art would have had a reasonable expectation of success in combining the 40 mg glatiramer acetate dose, which had been demonstrated to be effective, with a frequency of three times per week, which was desirable to increase patient adherence while maintaining efficacy.