AMERIGEN PHARM. LTD., v. UCB PHARMA GMBH, Appeal No. 2017-2596 (Fed. Cir. Jan. 11, 2019). Before Lourie, Chen, and Stoll. Appealed from PTAB.

Background:

UCB owns a patent covering fesoterodine, a drug that treats urinary incontinence. Fesoterodine is a prodrug, meaning that it is inactive until processed within the body into its active form. A prodrug may be used when administering the active form has problems, such as poor bioavailability. A third party petitioned for IPR of UCB's patent, alleging that UCB's patent was invalid for alleged obviousness. Amerigen was later joined as a party to the IPR.

In the IPR, the Board agreed that one of ordinary skill in the art would have selected an active form of the drug as a lead compound for further development. However, the Board found that it would not have been obvious to have modified the lead compound into the claimed prodrug because: (1) one would not have modified the lead compound to solve a problem that did not exist (the active form did not have a bioavailability problem); (2) petitioners did not point to any analogous compounds with the same mechanism of action or in the same field of treatment; and (3) assuming a motivation to modify the lead compound, producing the claimed compound was not a matter of routine optimization (assuming facts most favorable to the petitioner, 86 possible compounds remained, and it was not routine to test each one). Amerigen appealed.

Issue/Holding:

Are the claims obvious? No, affirmed.

Discussion:

The Federal Circuit found that substantial evidence supports the Board's findings. Regarding the issue of bioavailability, the Federal Circuit agreed that a reasonable fact finder could have weighted UCB's unrebutted expert testimony that there was no indication that the lead compound had a bioavailability problem over Amerigen's comparison of the bioavailability of the lead compound to the bioavailability of other compounds. The Federal Circuit found Amerigen's conclusory argument that improving bioavailability is itself sufficient motivation to modify the lead compound did not overcome the substantial evidence supporting the Board's decision.

In addition, when reviewing the evidence relied upon by the Board to support its decision, the Federal Circuit found that there was substantial evidence to support the Boards findings that Amerigen failed to establish a general motivation to modify the lead compound into the claimed prodrug, and that Amerigen failed to point to any discernible error in the Board's analysis.

The Federal Circuit did not address the Board's optimization conclusions, finding that they were not necessary for the Board's judgment.