NOVARTIS AG v. TORRENT PHARMACEUTICALS, Appeal No. 2016-1352 (Fed. Cir. April 12, 2017). Before Taranto, Chen, and Stoll. Appealed from PTAB.

Background:

Novartis owned a patent directed to a solid composition for a drug used to treat multiple sclerosis (MS), suitable for oral administration in pill form. Novartis marketed this drug under the name Gilenya. Torrent petitioned for an *inter partes* review of Novartis' patent based on three grounds: (i) the claims were obvious over Reference 1 in view of Reference 2; (ii) the claims were anticipated by Reference 3; and (iii) the claims were obvious over Reference 1 in view of Reference 3. Later, Apotex and Mylan Pharmaceuticals separately petitioned and asked for joinder. The Board consolidated the two *inter partes* reviews and instituted trial based on only ground (i) of Torrent's petition, declining to institute based on grounds (ii) and (iii).

The Board found all claims of the patent to be invalid as obvious based on ground (i). The Board also found additional evidence in Reference 3, the reference cited in grounds (ii) and (iii). Novartis appealed, arguing that the Board violated the Administrative Procedure Act (APA) by relying on Reference 3 after declining to institute on grounds (ii) and (iii). Novartis asserted it was not given sufficient notice or opportunity to be heard on Reference 3. Also, Novartis argued that the Board erred in its analysis of the motivation to combine and in its treatment of the evidence of nonobviousness.

Issues/Holdings:

Did the Board err in relying on Reference 3 after declining to institute trial based on grounds (ii) and (iii)? No. Did the Board err in finding the claims to have been obvious? No, affirmed.

Discussion:

Regarding the alleged violation of APA due process, Novartis argued that it assumed Reference 3 was entirely removed from the case when the Board declined to institute trial based on grounds (ii) and (iii), and consequently Novartis presented a "vastly different" position than it would have if Reference 3 were at issue. The Federal Circuit disagreed, finding the Board had only declined to consider Reference 3 as an anticipatory reference (ground (ii)) and as a secondary obviousness reference (ground (iii)). In its final decision, the Board had relied on Reference 3 merely as background art reinforcing its finding of obviousness based on ground (i). Moreover, the Federal Circuit found Novartis had had sufficient opportunity to be heard on Reference 3 because the parties debated Reference 3 at length throughout the proceeding.

Regarding the finding of obviousness, Novartis asserted it was clear the Board had overlooked critical evidence of nonobviousness presented by Novartis because the Board's written decision lacked a discussion of that evidence. The Federal Circuit found this argument to lack merit as the Board had in fact considered this evidence, and there was no requirement for the Board to address each and every piece of evidence in its written decision. The Federal Circuit additionally found no error in the Board's finding of a motivation to combine, or in the Board's finding that Novartis' arguments of unexpected results and commercial success were insufficient.