

MYLAN PHARMACEUTICALS v. RESEARCH CORPORATION TECHNOLOGIES, Appeal No. 2017-2088 (Fed. Cir. February 1, 2019). Before Lourie, Bryson, and Wallach. Appealed from Patent Trial and Appeal Board.

Background:

Research Corporation Technologies (RCT) owns a patent directed to compounds and compositions for treating central nervous system disorders. Argentum petitioned for an *inter partes* review of this patent, and the PTAB instituted an IPR on grounds of obviousness.

After institution, Mylan, Breckenridge, and Alembic filed petitions for IPR review and motions for joinder. These petitioners had been sued for infringement of the same patent more than a year previously. The PTAB instituted the additional reviews and joined each with the Argentum IPR.

Before the PTAB, Argentum asserted that one skilled in the art would have been motivated to replace an -NH- group in an alkoxyamine group in a compound disclosed in a primary reference with a -CH₂- group. Argentum relied on a drug discovery book chapter for teaching that the -NH- and -CH₂- groups have chemical or physical similarities, and produce broadly similar biological properties.

The PTAB found that a person skilled in the art would not have been motivated to modify the prior art compound as alleged by Argentum. The PTAB found that: (1) the primary reference taught compounds without the -NH- group had reduced activity, and (2) Argentum's proposed modification would have led to a compound with significantly different biological activity. In summary, the PTAB found that the challenged claims were not unpatentable.

Three of the joined petitioners (Mylan, Breckenridge, and Alembic) appealed. RCT challenged whether these petitioners have standing to challenge the PTAB's decision.

Issue/Holding:

(1) Do the appellants, who were joined as petitioners more than one year after being sued, have standing to appeal? Yes.

(2) Did the PTAB err in determining there was no motivation to modify the prior art compound? No, affirmed.

Discussion:

Regarding standing, RCT did not assert that the appellants lack Article III standing but instead argued that appellants' petition was time-barred and thus the appellants lack standing and fail to fall within the zone of interests of 35 U.S.C. § 319. The Federal Circuit examined the use of the term "parties" in both §§ 315(c) and 319. The Federal Circuit found that appellants joined as petitioners, or "parties," to the IPR, as provided in § 315, may appeal pursuant to § 319. The Federal Circuit confirmed that the appellants fall within the zone of interests of § 319 and are not barred from appellate review.

Regarding obviousness, the Federal Circuit found that the appellants had failed to establish a motivation to substitute the -NH- amine group with the -CH₂- group. The Federal Circuit found that one skilled in the art would have expected the modified compound to have: (1) reduced potency, and (2) significant conformational changes that could alter biological activity. Thus, the Federal Circuit found that the PTAB's finding was supported by substantial evidence.