MEDYTOX, INC. V. GALDERMA S.A., Appeal No. 2022-1165 (Fed. Cir. June 27, 2023). Before Reyna, Dyk, and Stark. Appealed from PTAB.

Background:

The patent at issue is directed to a cosmetic treatment by administering botulinum toxin. Galderma filed a petition requesting post grant review of the patent at issue. The petition was granted on all challenged claims. In response, Medytox filed a non-contingent motion to amend seeking to cancel claims and introduce substitute claims. The substitute claims recited, "a responder rate at 16 weeks after the first treatment of 50% or greater" with respect to sustained efficacy. In the final written decision, the PTAB construed this limitation to be a range from 50% to 100%, and found that the full scope of the claimed range was not enabled. Medytox appealed.

Issues/Holdings:

Did the PTAB err in its claim construction and in finding that Medytox's substitute claims were not enabled? No, affirmed.

Discussion:

Medytox argued that the limitation at issue should be construed as a yes-or-no inquiry instead of a range based on expert testimony that any responder rate above 50% is "essentially the same." The Federal Circuit, however, found that Medytox's proposed claim construction is not substantively different from the PTAB's claim construction. During oral arguments, Medytox conceded that a responder rate of 95% would fall within the scope of the claims under either their "yes-or-no" construction or the PTAB's "range" construction. Galderma similarly acknowledged that there was no substantive difference between the proposed claim constructions. In light of these admissions, the Federal Circuit affirmed the PTAB's construction.

As to enablement, the PTAB found that the claims were not fully enabled because the specification fails to enable a skilled artisan to achieve responder rates higher than the maximum disclosed responder rate of 62% in the absence of undue experimentation. For example, the specification only included three working examples of responder rates above 50% at 16 weeks: 52%, 61%, and 62%. Medytox argued that the PTAB erred because the specification does not need to include a working example of "every possible embodiment to enable the full scope of the claims." Medytox further argued that there would not have been undue experimentation because it is "routine to clinically confirm" that the compositions meet the duration limit. In response, Galderma argued that the specification provides no guidance as to which formulations of the treatment would exhibit a responder rate at 16 weeks above 62%. Galderma also pointed to testimony from Medytox's expert who acknowledged that if you changed some of the formulation components, it would be "impossible to speculate" whether the formulation would meet the 50% responder rate limitation.

The Federal Circuit agreed with the Galderma's argument and affirmed the PTAB's finding. The Federal Circuit noted that case law may not require disclosure of every possible working example but, as stated in the Supreme Court's recent decision in *Amgen Inc. v. Sanofi* that "[t]he more one claims, the more one must enable." Accordingly, the Federal Circuit held that a skilled artisan would not have been able to achieve responder rates higher than the limited examples provided in the specification without undue experimentation, and therefore, the substitute claims were not enabled.