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SUBMITTED VIA ECF

Jarrett B. Perlow Clerk of Court United States Court of Appeals for the Federal Circuit 717 Madison Place, NW Washington, DC 20439 (202) 275-8000

Re: Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC, Case No. 2024-1936

Dear Mr. Perlow:

Teva writes to respond to the notice filed by Amneal alerting the Court to the district court's claim construction order, ECF No. 124.

Teva's briefs explain that the Asserted Patents must be listed irrespective of claim construction (Opening Br. 21-34, 49-53; Reply Br. 2-13, 19-21). In the alternative, Teva argues that the district court erred by ordering the Asserted Patents delisted without conducting claim construction (Opening Br. 45-48, 53-54; Reply Br. 23-25).

While the district court has now issued an order on claim construction, and concluded that none of the patents claim a genus of active ingredients as one element, that order is flawed. The claim construction dispute requires first determining the common meaning of the terms to one skilled in the art; however, the district court skipped that step. Rather, the court *assumed* the common meaning does not require the presence of any active ingredient, and then assessed whether Teva has identified any legal basis to "import" an active ingredient requirement "into the claims." Order at 11. The district court never identified the common meaning of terms like "inhaler" or "medicament canister" and failed to even discuss statements in the specification such as the explicit description of the "contents of the canister" as "namely active drug and propellant." Appx135(12:28-29); *see also* Appx130(1:43-45) (describing "a metered quantity of the drug and the propellant to be expelled" from the canister).

If the Court adopts a statutory interpretation that would make the claim construction outcomedeterminative, Teva should be given an opportunity to appeal the district court's claim construction order before any patents are ordered de-listed. However, the claim construction order, which postdated the appealable injunction, is not currently before the Court. Thus, if necessary, the Court should either vacate and remand for the district court to apply its claim construction in light of this Court's statutory interpretation decision (and then enter a decision based upon the claim construction from which Teva could appeal), or order supplemental briefing in this appeal concerning the claim construction.



Respectfully submitted,

/s/ William M. Jay William M. Jay

cc: All counsel of record via ECF