

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COMPLEX INNOVATIONS, LLC,  
Petitioner,

v.

ASTRAZENECA AB,  
Patent Owner.

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IPR2017-00631

Patent 7,759,328 B2

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**PATENT OWNER'S SUR-REPLY TO PRELIMINARY RESPONSE**

Petitioner inconsistently assumes that (a) the canister is only *partially* filled with liquid when it proposes the 6–10 g fill weight, but that (b) the canister is *completely* filled with liquid when it proposes the 0.9 mg FFD mass. These two assumptions cannot both be correct simultaneously. Thus Petitioner's calculation of FFD weight percentage by dividing the FFD mass by the fill weight is erroneous.

Petitioner made assumption (a) when it argued that a canister having Dr. Beasley's 6–10 g fill weight would be filled with part liquid and part gas HFA227. Reply 2. Petitioner presented no evidence to support the fill weight (Prelim. Resp. 9–10) or to specify what fraction of the canister is filled with liquid. Petitioner's Reply argument highlights this gap in the petition.

Petitioner made assumption (b) when Dr. Beasley stated, again without evidentiary support, that the canister volume is 10–19 mL (*id.*) and used the total canister volume to calculate the FFD mass. *Id.* at 14. The total canister volume is irrelevant to this calculation. Rather, the liquid HFA227 volume is what matters, because it is the liquid phase that carries the drug. *Id.* at 15 n.16; Ex. 1004, 28:14–15 (drug particles not adhered to internal canister surface “remain wetted in the liquid”); Ex. 1005, 4:1–3 (drug suspended in liquid propellant); Ex. 1006, 6:23–25 (same); Ex. 1008, 1:23–24 (drug expelled from inhaler in droplets). Gas HFA227, having a far lower density than liquid (Reply 2), does not count when figuring the volume in which the FFD is suspended.

By multiplying the FFD concentration by the *full* canister weight, Dr. Beasley assumed that no portion of the canister contained gas HFA227 and that it instead was completely filled with liquid. This assumption is inconsistent with Petitioner's other assumption that the canister is only partly filled with liquid HFA227.

If Petitioner's partial liquid fill assumption is correct, then Petitioner's and Dr. Beasley's FFD mass calculation clearly is wrong, because it was calculated from the full volume of the canister. Prelim. Resp. 15–16 & n.16. Moreover, Petitioner presented no evidence or discussion of what fraction of the canister volume is occupied by liquid, even though this parameter is critical to Petitioner's case, leaving a fatal gap in the petition. If instead Petitioner's complete fill assumption is correct, then Petitioner's fill weight of 6–10 g clearly is wrong, because a 10 mL canister filled with liquid HFA227 has a fill weight of about 14 g, not 6–10 g. *Id.* at 12.

In summary, either Petitioner's FFD mass is wrong, or its fill weight is wrong. Petitioner's numbers for these two parameters cannot both be correct at the same time, because the canister cannot be both partially and completely filled with liquid at the same time. Therefore, Petitioner's calculation of FFD weight percentage, which depends on both the FFD mass and the fill weight, cannot be correct.


Petitioner's Reply also does not diminish Patent Owner's other critiques of the petition, such as picking and choosing (*id.* at 2–8, 18–19), lack of evidence supporting the expert (*id.* at 9–10, 19), and failure to show inherency (*id.* at 11–13, 19).

IPR2017-00631  
Patent 7,759,328

Patent Owner's Sur-Reply  
to Preliminary Response

Respectfully submitted,

Dated: June 16, 2017



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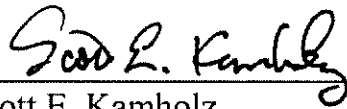
Patent Owner's Sur-Reply  
to Preliminary Response

### CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6, I certify that on the date listed below, a copy of this paper and every exhibit filed with this paper was served by electronic mail, by agreement of the parties, on the following counsel of record.

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