

MYLAN PHARMACEUTICALS INC. and PFIZER INC., Petitioners,

V.

SANOFI-AVENTIS DEUTSCHLAND GMBH Patent Owner.

Patent No. 8,679,069 Patent No. 8,603,044 Patent No. 8,992,486 Patent No. 9,526,844 Patent No. 9,604,008

REPLY DECLARATION OF KARL R. LEINSING, MSME, PE



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	i.	['069, '044-B, '486-A2, '844-B] Steenfeldt-Jensen teaches a "drive sleeve," "driver," or "driving member" having an internal threading					
	ii.	['486-A2] Claims 30 and 32: Steenfeldt-Jensen teaches a dose dial sleeve having a radial stop near an end of a helical groove					
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	ii.	['069, '044-B, '486-A2] Møller and Steenfeldt-Jensen teach a dose dial sleeve having a helical groove					
	iii.	['486-A2] Møller discloses a dose dial sleeve having a threading that engages a threading provided on a main housing					
	iv.	['044-B] Claim 19: Møller and Steenfeldt-Jensen teach a main housing having a helical rib that is adapted to be seated in the helical groove of the dose dial sleeve; ['486-A2] Claim 4: Møller and Steenfeldt-Jensen teach a helical rib provided on an inner surface of the main housing.					
	v.	['486-A2] Claim 5: Møller teaches a driver having "a cylindrical shape"					
	vi.	['044-B] Claim 15: Møller and Steenfeldt-Jensen teach a clicker having a flexible arm and a spline to provide audible feedback; ['486-A2] Claims 18 and 20: Møller and Steenfeldt-Jensen teach a clicker having at least one flexible extending arm					



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I, Karl Leinsing, declare as follows:

I. BACKGROUND

- 1. I submitted an expert declaration in support of Petitioner Mylan's Petitions for *inter partes* review (IPR) of U.S. Patent Nos. 8,679,069 ("the '069 patent," EX1001), 8,603,044 ("the '044 patent," EX1002), 8,992,486 ("the '486 patent," EX1003), 9,526,844 ("the '844 patent," EX1004), and 9,604,008 ("the '008 patent," EX1005) (collectively, "the challenged patents"). *See generally* EX1011. I understand that IPRs were instituted in the following proceedings¹: IPR2018-01670 ('069), IPR2018-01675 ('044-A), IPR2018-01676 ('044-B), IPR2018-01678 ('486-A2), IPR2018-01679 ('486-B), IPR2018-01680 ('844-A), IPR2018-01682 ('844-B), IPR2018-01684 ('008), and IPR2019-00122 ('486-A1). I also understand that Patent Owner Sanofi submitted Responses to Mylan's Petitions in each of these proceedings. I submit this expert declaration in support of Mylan's and Pfizer Inc.'s Reply to Sanofi's Responses.
- 2. In preparation for this declaration, I have reviewed Sanofi's Responses and the Declaration of Dr. Alexander Slocum in support of those



¹ For ease of reference, I will refer to the proceedings by the labels I used in my prior declaration, which are shown in parenthesis following the proceeding number.

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