

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

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**

## TABLE OF CONTENTS

I.	BACKGROUND .....	1
II.	LEGAL STANDARDS .....	2
III.	OVERVIEW OF THE LEVEL OF SKILL .....	2
IV.	RELEVANT TIMEFRAME OF THE '844 PATENT .....	3
V.	CLAIM CONSTRUCTION .....	10
A.	“an interior of a flange” .....	10
B.	“main housing” .....	23
C.	“tubular clutch” .....	25
VI.	DETAILED EXPLANATION OF OPINIONS .....	26
A.	[’069] Ground 1: Claim 1 is Obvious over Burroughs; [’044-A] Ground 1: Claims 11, 14, and 18-19 are Obvious over Burroughs; [’486-A1] Ground 1: Claims 1-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 are Obvious over Burroughs.....	27
i.	[’069, ’044-A, ’486-A1] Burroughs renders obvious a dose dial sleeve having a helical groove that engages with a threading on a main housing .....	28
ii.	[’069, ’044-A, ’486-A1] Burroughs teaches a tubular clutch .....	31
iii.	[’044] Burroughs renders obvious a dose dial sleeve having a helical groove with a lead that is different from the lead of an internal threading of a drive sleeve .....	34
B.	[’069] Ground 2: Claim 1 is Obvious over Steinfeldt-Jensen; [’044-B] Ground 1: Claims 11, 14-15, and 18-19 are Obvious over Steinfeldt-Jensen; [’486-A2] Ground 1: Claims 1-6, 12-18, 20, 23, 27-30, 32-33, 36, and 38 are Obvious over Steinfeldt-Jensen; [’844-B] Ground 1: Claims 21-29 are Obvious over Steinfeldt-Jensen .....	41

i.	[’069, ’044-B, ’486-A2, ’844-B] Steinfeldt-Jensen teaches a “drive sleeve,” “driver,” or “driving member” having an internal threading.....	42
ii.	[’486-A2] Claims 30 and 32: Steinfeldt-Jensen teaches a dose dial sleeve having a radial stop near an end of a helical groove.....	55
iii.	[’844-B] Claim 22: Steinfeldt-Jensen teaches a piston rod having a circular cross-section .....	57
C.	[’844-B] Ground 2: Claim 30 is Obvious over Steinfeldt-Jensen and Klitgaard .....	60
D.	[’486-B] Ground 3: Claim 56 is Anticipated by Steinfeldt-Jensen; [’486-B] Ground 4: Claim 56 is Obvious over Steinfeldt-Jensen.....	60
E.	[’069] Ground 3: Claim 1 is Obvious over Møller and Steinfeldt-Jensen; [’044-B] Ground 2: Claims 11, 14-15, and 18-19 are Obvious over Møller and Steinfeldt-Jensen; [’486-A2] Ground 2: Claims 1-6, 12-18, 20, 23, 27-30, 32-33, 36, and 38-40 are Obvious over Møller and Steinfeldt-Jensen.....	63
i.	[’069, ’044-B] Møller and Steinfeldt-Jensen teach a drive sleeve that extends along a portion of the piston rod .....	64
ii.	[’069, ’044-B, ’486-A2] Møller and Steinfeldt-Jensen teach a dose dial sleeve having a helical groove .....	68
iii.	[’486-A2] Møller discloses a dose dial sleeve having a threading that engages a threading provided on a main housing .....	74
iv.	[’044-B] Claim 19: Møller and Steinfeldt-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 Steinfeldt-Jensen teach a helical rib provided on an inner surface of the main housing. ....	76
v.	[’486-A2] Claim 5: Møller teaches a driver having “a cylindrical shape”.....	76
vi.	[’044-B] Claim 15: Møller and Steinfeldt-Jensen teach a clicker having a flexible arm and a spline to provide audible feedback; [’486-A2] Claims 18 and 20: Møller and Steinfeldt-Jensen teach a clicker having at least one flexible extending arm .....	77

vii.	[’486-A2] Claim 26: Møller and Steinfeldt-Jensen teach the dose dial sleeve is radially inward of the main housing .....	78
viii.	[’486-A2] Claims 30 and 32: Møller and Steinfeldt-Jensen teach a radial stop positioned near an end or near a distal end of the helical groove .....	78
F.	[’486-B] Ground 6: Claim 56 is Anticipated by Møller .....	78
G.	[’844-A] Ground 1: Claim 22 is Anticipated by Giambattista.....	83
H.	[’844-A] Ground 3: Claim 30 is Obvious over Giambattista and Klitgaard.....	87
I.	[’008] Ground 1: Claims 1, 3, 7-8, 11, and 17 are Obvious over Møller and Steinfeldt-Jensen .....	92
i.	[’008] A person of ordinary skill would have combined the teachings of Møller and Steinfeldt-Jensen .....	92
ii.	[’008] Møller and Steinfeldt-Jensen teach a threaded housing and a threaded insert.....	99
iii.	[’008] Claim 3: Møller and Steinfeldt-Jensen teaches an insert secured in the housing against rotational and longitudinal movement .....	101
iv.	[’008] Claim 11: Møller and Steinfeldt-Jensen teach an internally threaded housing.....	102
J.	Secondary Considerations .....	104
VII.	CONCLUDING STATEMENTS.....	105
VIII.	APPENDIX - LIST OF EXHIBITS .....	107

...

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 proceedings<sup>1</sup>: 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

---

<sup>1</sup> 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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.