

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

COMPLEX INNOVATIONS, LLC,
Petitioner,

v.

ASTRAZENECA AB

U.S. Patent 7,759,328

DECLARATION OF MARTIN BEASLEY, Ph.D.

I.	Scope of Analysis	5
A.	Qualifications and Expertise	7
B.	Legal Framework	9
1.	A Person of Ordinary Skill in the Art	9
2.	My Understanding of Claim Construction.....	9
3.	My Understanding of Anticipation	10
4.	My Understanding of Obviousness.....	10
II.	Background.....	11
A.	Inhalable Pharmaceutical Drug Formulations.....	12
1.	The Original, Expired Symbicort Patent.....	14
2.	Transition of Budesonide and Formoterol to HFA.....	15
3.	Mistry Disclosure of an HFA Formulation with PEG and PVP For Stability	16
4.	Rogueda Stability Teachings with Precise References to PEG 1000, and PVP K25.....	18
5.	Development of the 328 Patent in Light of Prior Art Formulations.....	19
B.	Background of the 328 Patent (Ex. 1001).....	20

1.	Stability in the 328 Patent Through PVP.....	22
2.	Valve Lubrication Through PEG in the 328 Patent.....	26
3.	Brief Description of Challenged Claims of the 328 Patent	28
III.	Ground 1: Mistry Anticipates Claims 1, and 4-15 of the 328 Patent.....	30
A.	Background of Mistry	30
B.	Analysis of 328 Patent Claims 1, and 4-15 In View of Mistry.....	31
	Claim 1(a)	31
	Claim elements 1(b) and 1(c) relate to formoterol and budesonide concentrations.	32
	Claim 1(b)	33
	Claim 1(c)	34
	Claim 1(d)	35
	Claim 1(e)	37
	Claims 4-7	40
	Claims 8-11	41
IV.	Ground 2: Rogueda Anticipates Claims 1, and 4-15 of the 328 Patent	42
A.	Background of Rogueda.....	42
B.	Analysis of 328 Patent Claims 1, 4-15 in Light of Rogueda	43

Claim 1(a)	43
Claim Elements 1(b) and (c) Anticipation – Rogueda Examples.....	44
Claim Elements 1(b) and (c) Anticipation – Rogueda Control Samples.....	47
Claim 1(d)	49
Claim 1(e)	50
Claims 4-7	52
Claims 8-11	53
 V. Ground 3: Mistry in View of Rogueda and Carling Renders Obvious Claims	
1, and 4-15.....	54
 A. Motivation to Combine	54
Claim element 1(a).....	56
Claim elements 1(b) and 1(c), and Claims 12-15	56
Claim elements 1(d) and 1(e).....	57
Claims 4-11	60
 VI. Ground 4: Mistry in View of Rogueda, Meade, and Lewis Render Obvious	
Claims 2 and 3.....	61
 VII. Conclusion	64

I, Martin Beasley, declare as follows:

1. I have been retained by Hill, Kertscher & Wharton, LLP, which represents Complex Innovations, LLC, in connection with a petition for *inter partes* review of U.S. Patent No. 7,759,328, titled *Composition for Inhalation* (“328 Patent”). I understand that the 328 Patent is currently assigned to ASTRAZENECA AB.

I. Scope of Analysis

2. I have reviewed and am familiar with the 328 Patent, which issued to Govind, *et al.* on July 20, 2010. I understand that the 328 Patent includes 15 claims. I also understand that the Petition for *inter partes* review that accompanies this Declaration seeks to cancel claims 1-15 of the 328 Patent. My analysis and opinions will focus on all challenged claims 1-15.

3. I am advised that based on the patent law around filing dates and effective filing dates, my analysis should assume that the time of invention is, at the earliest, Feb. 1, 2002, the date of filing of the foreign application in Sweden, and that the Rogueda reference may be used as prior art under 102(a) and 102(b).

4. I have reviewed and am familiar with various references, written materials, and literature, which are itemized below:

- a) Ex. 1001 U.S. Patent No. 7,759,328 to Govind, *et al.* (“328 Patent”)

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.