

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

COALITION FOR AFFORDABLE DRUGS VII LLC,  
Petitioner,

v.

POZEN INC.,  
Patent Owner.

---

IPR2015-01241  
Patent 6,926,907

---

**DECLARATION OF LEON SHARGEL, PH.D., R.PH.**

## TABLE OF CONTENTS

<b>I.</b>	<b>Introduction and Bases for Opinions.....</b>	<b>1</b>
A.	Qualifications .....	2
B.	Materials Reviewed.....	4
C.	Legal Principles Used In Analysis .....	10
<b>II.</b>	<b>Background .....</b>	<b>16</b>
A.	State of the Art .....	16
B.	Overview of the '907 Patent.....	28
A.	Applicant's Admitted Prior Art.....	31
B.	Person of Ordinary Skill in the Art (POSA) .....	33
<b>III.</b>	<b>Claim Construction .....</b>	<b>33</b>
A.	"Unit Dosage Form".....	34
B.	"Acid Inhibitor".....	34
C.	"Coordinated Release" .....	35
D.	All Remaining Terms .....	35
E.	The Invalidity Grounds .....	36
1.	Ground 1: Claims 1, 7, 8, 12, 13, 22, and 23 Are Obvious Under 35 U.S.C. § 103(a) .....	36
2.	Ground 2: Claims 1-5 and 7-22 Are Obvious Under 35 U.S.C. § 103(a) .....	36
3.	Ground 3: Claims 1-5, 7-18, 21, and 22 Are Obvious Under 35 U.S.C. § 103(a) .....	37
4.	Ground 4: Claims 1, 5, and 6 Are Obvious Under 35 U.S.C. § 103(a) .....	37

<b>IV. Ground 1: Gimet in View of Chiverton Renders Claims 1, 7, 8, 12, 13, 22, and 23 Obvious Under U.S.C. § 103(a)</b> .....	<b>38</b>
A. A POSA Would Have been Motivated to Combine Chiverton with Gimet.....	38
B. Claim 1: .....	39
1. A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising: .....	39
2. (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms; .....	40
3. (b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms; .....	42
4. and wherein said unit dosage form provides for coordinated release such that: i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher; .....	42
5. ii) at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5. ....	44
C. Claim 7: The pharmaceutical composition of claim 1, wherein said NSAID is a cyclooxygenase-2 (COX-2) inhibitor. ....	45
D. Claim 8: The pharmaceutical composition of claim 7, wherein said COX-2 inhibitor is selected from the group consisting of celecoxib; rofecoxib; meloxicam; piroxicam; valdecoxib, parecoxib, etoricoxib, CS-502, JTE-522; L-745,337; and	

NS398.....	46
E. Claim 12: .....	46
1. The pharmaceutical composition of claim 1 wherein said unit dosage form is a multilayer tablet comprising .....	46
2. a single core and one or more layers outside of said single core, wherein: .....	47
3. i) said NSAID is present in said core;.....	47
4. ii) said coating that does not release said NSAID unless the pH of the surrounding medium is 3.5 or higher surrounds said core; and.....	47
5. iii) said acid inhibitor is in said one more layers outside said core. ....	48
F. Claim 13: The pharmaceutical composition of claim 12, wherein said one or more layers outside of said core do not contain NSAID and are not surrounded by an enteric coating. ....	49
G. Claim 22: .....	50
1. A method of treating a patient for pain or inflammation, comprising.....	50
2. administering to said patient the pharmaceutical composition of any one of claims 1-14.....	50
H. Claim 23: The method of claim 22, wherein said pain or inflammation is due to either osteoarthritis or rheumatoid arthritis.....	50
I. Conclusion.....	51

**V. Ground 2: Gimet in View of Goldman in Further View of Remington Renders Claims 1-5 and 7-23 Obvious Under 35 U.S.C. § 103(a).....51**

A. A POSA Would Have Been Motivated to Combine Goldman and Remington with Gimet .....51

B. Claim 1: .....53

1. A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising: .....53

2. (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms; .....54

3. (b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms; .....55

4. and wherein said unit dosage form provides for coordinated release such that: i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher; .....56

5. ii) at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5. ....57

C. Claim 2: The pharmaceutical composition of claim 1, wherein said acid inhibitor is an H2 blocker.....59

D. Claim 3: The pharmaceutical composition of claim 2, wherein said H2 blocker is selected from the group consisting of: cimetidine; ranitidine; ebrotidine; pabutidine; lafutidine;

# 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.