

Paper No. _____
Filed: April 23, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC

PETITIONER

V.

CELGENE

PATENT OWNER

CASE NO.: UNASSIGNED

PATENT NO. 6,315,720

FILED: OCTOBER 23, 2000

ISSUED: NOVEMBER 13, 2001

INVENTORS: BRUCE A. WILLIAMS AND JOSEPH K. KAMINSKI

TITLE: METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE
AVOIDING THE OCCURRENCE OF AN ADVERSE SIDE EFFECT KNOWN
OR SUSPECTED OF BEING CAUSED BY THE DRUG

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 6,315,720**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	GROUNDS FOR STANDING (37 C.F.R. § 42.104(a)).....	1
III.	MANDATORY NOTICES (37 C.F.R. § 42.8).....	1
	A. Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))	1
	B. Related Judicial and Administrative Matters (37 C.F.R. § 42.8(b)(2)).....	2
	C. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4)).....	3
IV.	PAYMENT OF FEES (37 C.F.R. § 42.15(a) and § 42.103).....	3
V.	IDENTIFICATION OF CHALLENGE.....	3
	A. Overview of U.S. Patent No. 6,315,720	3
	1. The '720 Patent Specification	4
	2. The '720 Claims	5
	3. The '720 Prosecution History.....	6
	B. Claim Construction of Challenged Claims	9
	1. “Consulted”.....	10
	2. “Teratogenic effect”	10
	3. “Adverse side effect”	11
	C. Statement of Precise Relief Requested for Each Claim Challenged	11
	1. Claims for Which Review is Requested	11
	2. Statutory Grounds of Challenge.....	11
	D. Overview of the State of the Art.....	12
VI.	DETAILED EXPLANATION OF THE CHALLENGE.....	14
	A. Ground 1: THALOMID™ (thalidomide) Capsules Revised Package Insert anticipates Claims 1–32 of U.S. Patent No. 6,315,720 under 35 U.S.C. § 102(b).....	14
	1. <i>Thalomid PI</i> anticipates Claim 1.....	17

2.	<i>Thalomid PI</i> anticipates Claims 2–6.....	22
3.	<i>Thalomid PI</i> anticipates Claims 7–10.....	25
4.	<i>Thalomid PI</i> anticipates Claims 11–14 and 20–25.....	28
5.	<i>Thalomid PI</i> anticipates Claim 15.....	30
6.	<i>Thalomid PI</i> anticipates Claims 16–17.....	31
7.	<i>Thalomid PI</i> anticipates Claims 18–19 and 26–27.....	33
8.	<i>Thalomid PI</i> anticipates Claims 28–32.....	34
9.	Claim chart for Ground 1 showing exemplary citations in <i>Thalomid PI</i>	36
B.	Ground 2: Claims 1–32 of U.S. Patent No. 6,315,720 are obvious under 35 U.S.C. § 103(a) over <i>Thalomid PI</i> in view of <i>Cunningham</i> , and in further view of the knowledge of one of ordinary skill in the art.	51
1.	Claims 1(e) and 28(e) are obvious over <i>Thalomid PI</i> in view of <i>Cunningham</i>	52
2.	Claims 5 and 6 are obvious over <i>Thalomid PI</i> in view of the knowledge of one of ordinary skill in the art.	54
3.	Claims 9 and 10 are obvious over <i>Thalomid PI</i> in view of the knowledge of one of ordinary skill in the art.	57
4.	Claim 17 is obvious over <i>Thalomid PI</i> in view of the knowledge of one of ordinary skill in the art.	59
5.	Claim Chart for Ground 2 showing exemplary citations in <i>Cunningham</i>	59
VII.	CONCLUSION	60

TABLE OF AUTHORITIES

Cases

<i>Abbott Labs v. Andrx Pharms., Inc.</i> , 452 F.3d 1331 (Fed. Cir. 2006).....	54
<i>Atlas Powder Co. v. IRECO, Inc.</i> , 190 F.3d 1342 (Fed. Cir. 1999).....	16
<i>Bayer Schering Pharma AG v. Barr Labs., Inc.</i> , 575 F.3d 1341 (Fed. Cir. 2009).....	56
<i>Continental Can Co. USA, Inc. v. Monsanto Co.</i> , 948 F.2d 1264 (Fed. Cir. 1991).....	17, 21
<i>Dow Chem. Co. v. Sumitomo Chem. Co.</i> , 257 F.3d 1364 (Fed. Cir. 2001).....	17
<i>Dystar Textilfarben GmbH v. C.H. Patrick Co.</i> , 464 F.3d 1356 (Fed. Cir. 2006).....	54
<i>In re Am. Acad. of Sci. Tech. Ctr.</i> , 367 F.3d 1359 (Fed. Cir. 2004).....	10
<i>In re Baxter Travenol Labs.</i> , 952 F.2d 388 (Fed. Cir. 1991).....	17
<i>In re Cruciferous Sprout Litigation</i> , 301 F.3d 1343 (Fed. Cir. 2002).....	27
<i>In re Cuozzo Speed Techs., LLC</i> , 778 F.3d 1271 (Fed. Cir. 2015).....	9
<i>In re Glatt Air Techniques, Inc.</i> , 630 F.3d 1026 (Fed. Cir. 2011).....	18
<i>In re Graves</i> , 69 F.3d 1147 (Fed. Cir. 1995).....	21, 25, 27
<i>In re LeGrice</i> , 301 F.2d 929 (CCPA 1962).....	21, 27
<i>In re Venner</i> , 262 F.2d 91 (C.C.P.A. 1958).....	59
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	53
<i>Pacing Techs., LLC v. Garmin Int'l, Inc.</i> , 778 F.3d 1021 (Fed. Cir. 2015).....	10

<i>Pentec, Inc. v. Graphic Controls Corp.,</i> 776 F.2d 309 (Fed. Cir. 1985).....	18
<i>Perfect Web Techs., Inc. v. InfoUSA, Inc.,</i> 587 F.3d 1324 (Fed. Cir. 2009).....	56
<i>Schering Corp. v. Geneva Pharms., Inc.,</i> 339 F.3d 1373 (Fed. Cir. 2003).....	21, 24, 31, 27, 33
<i>SmithKline Beecham Corp. v. Apotex Corp.,</i> 403 F.3d 1331 (Fed. Cir. 2005).....	33
<i>Titanium Metals Corp. v. Banner,</i> 778 F.2d 775 (Fed. Cir. 1985).....	16
<i>Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.,</i> 774 F.3d 968 (Fed. Cir. 2014).....	58
<i>Unigene Labs., Inc. v. Apotex, Inc.,</i> 655 F.3d 1352 (Fed. Cir. 2011).....	58
<i>Verdegaal Bros. v. Union Oil Co. of California,</i> 814 F.2d 628 (Fed. Cir. 1987).....	16

Rules

37 C.F.R. § 42.103	3
37 C.F.R. § 42.15(a)	3
37 C.F.R. § 42.8(b)(1)	1

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.