Presentation of Patent Owner Celgene Corporation

Coalition for Affordable Drugs VI LLC

v.

Celgene Corporation

Case IPR 2015-01092, -1096, -1102, -1103

Before the Honorable Michael P. Tierney,
Tina E. Hulse, and Grace Karaffa Obermann

Administrative Patent Judges
United States Patent and Trademark Office

"Computer Readable Storage Medium": The Parties' Constructions

Celgene	CFAD
a centralized database that includes all registration information regarding the claimed prescribers, pharmacies, and patients IPR2015-01092, Paper 40 ("'501 Resp.") at 22-25; Ex. 2059 ("'501 Frau Decl.") ¶¶72-73; Ex. 2060 ("'501 DiPiro Decl.") ¶¶21-24	No specific construction offered Only a critique of Celgene's construction Argues that there can be more than one computer readable storage medium IPR2015-01092, Paper 49 ("'501 Reply") at 7-9

"Computer Readable Storage Medium" Claim Construction: The Claims Support Celgene's Construction

United States Patent [19]
Elsayed et al.

[11] Patent Number: 6,045,501
[45] Date of Patent: Apr. 4, 2000

[54] METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE PREVENTING THE EXPOSURE OF A FOETUS OR OTHER CONTRAINDICATED INDIVIDUAL TO THE DRUG

[75] Inventors: Marc Elsayed, Bridgewater; Bruce Williams, Flemington, both of N.J.

[73] Assignee: Celgene Corporation, Warren, N.J.

[21] Appl. No.: 09/143,569

[22] Filed: Aug. 28, 1998

[51] Int. Cl. A61N 5/00

[52] U.S. Cl. 600/300; 600/301; 600/551

[58] Field of Search 434/262, 272, 434/273; 600/300-301, 304, 313, 336, 370, 511, 551; 128/920-925, 897-898

[56] References Cited

U.S. PATENT DOCUMENTS

5,295,121 3/1994 Bell et al. 600/301

5,594,637 1/1997 Eisenberg et al. 600/300
5,619,991 4/1997 Sloane 600/300
5,660,176 8/1997 Iliff 600/300

Primary Examiner—Cary O'Connor
Assistant Examiner—Michael Astorino
Attorney, Agent, or Firm—Woodcock Washburn Kurtz Mackiewicz & Norris LLP

[57] ABSTRACT

Novel methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug. Embodiments are provided in which the involved prescribers, pharmacies and patients are registered in one or more computer databases. Embodiments are also provided in which registered patients receive counseling information concerning the risks attendant to foetal exposure to the drug. Male patients and female patients who are not pregnant may, in certain circumstances, receive the drug.

10 Claims, No Drawings

CFAD VI 1001-0001

What is claimed:

1. A method for delivering a teratogenic drug to patients in need of the drug while avoiding the delivery of said drug to a foetus comprising:

a. registering in a computer readable storage medium prescribers who are qualified to prescribe said drug;

b. registering in said medium pharmacies to fill prescriptions for said drug;

c. registering said patients in said medium, including information concerning the ability of female patients to become pregnant and the ability of male patients to impregnate females;

d. retrieving from said medium information identifying a subpopulation of said female patients who are capable of becoming pregnant and male patients who are capable of impregnating females;

e. providing to the subpopulation, counseling information concerning the risks attendant to fetal exposure to said drug;

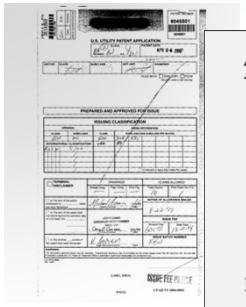
f. determining whether patients comprising said subpopulation are pregnant; and

g. in response to a determination of non-pregnancy for said patients, authorizing said registered pharmacies to fill prescriptions from said registered prescribers for said non-pregnant registered patients.

IPR2015-01092, Ex. 1001 ("'501 patent") at Claim 1; '501 Resp. at 24; '501 Frau Decl. ¶73; '501 DiPiro Decl. ¶23

"Computer Readable Storage Medium" Claim Construction: The File History Supports Celgene's Construction

This Office's Rejection

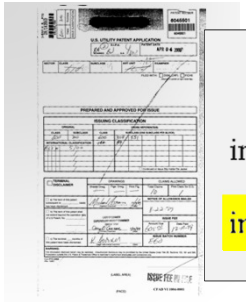


2. Claims 1 and 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane.

In regards to claims 1 and 11, Sloane discloses a method for delivering drugs to patients in need of a drug while avoiding the delivery of said drug to a foetus comprising registering qualified prescriber (12) in a computer readable storage medium (10), registering pharmacies to fill prescriptions (13), registering patients and patient data (11), providing counseling information to a patient (column 3-5, lines 38-8), determining whether the patient is pregnant (65), and authorization of prescriptions to be filled (column 6, lines 47-51).

IPR2015-01092, Ex. 1004 ("'501 File History") at 63; '501 Resp. at 22

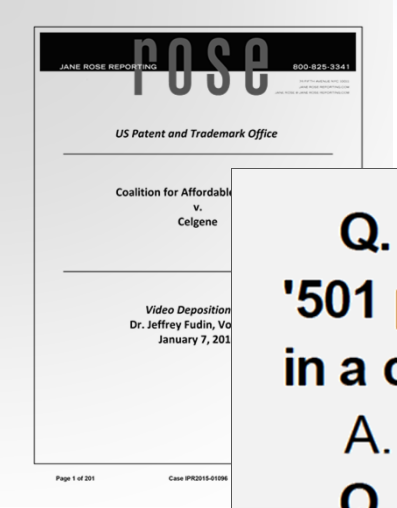
The Inventor's Response



Sloane fails also to teach methods in which the information regarding the parties involved in the disclosed methods, for example, physician, pharmacy and patient, are registered in a central computer readable storage medium.

'501 File History at 78; '501 Resp. at 22-23; '501 Frau Decl. ¶72; '501 DiPiro Decl. ¶22

"Computer Readable Storage Medium" Claim Construction: Dr. Fudin's Testimony Supports Celgene's Construction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Video Deposition
Dr. Jeffrey Fudin, Vo
January 7, 201

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Case IPR2015-01096

Q. In your opinion, do the claims of the '501 patent require centralizing certain information in a computer-readable storage medium?

A. Yes.

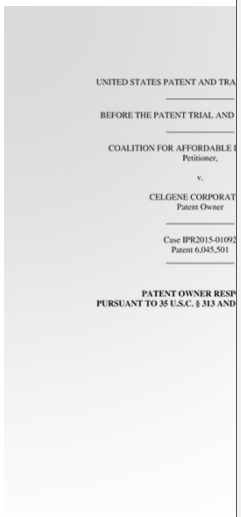
Q. In your opinion, do the claims of the '501 patent require registering information in a central computer-readable storage medium?

A. Yes.

IPR2015-01092, -1096, -1102, -1103, Ex. 2061 ("Fudin Tr.") at 307:9-17; '501 Resp. at 23

The Asserted References Do Not Teach Or Suggest The "Computer Readable Storage Medium": No Centralized Database

Celgene argued:


UNITED STATES PATENT AND TRA

BEFORE THE PATENT TRIAL AND

COALITION FOR AFFORDABLE
Petitioner,

v.

CELGENE CORPORAT
Patent Owner

Case IPR2015-0109
Patent 6,045,501

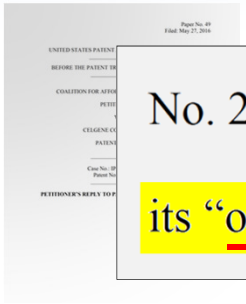
PATENT OWNER RESP
PURSUANT TO 35 U.S.C. § 313 AND

Moreover, CFAD glossed over the fact that Dishman also does not disclose, teach, or suggest the claimed ***centralized*** computer readable storage medium. Instead, Dishman expressly discloses only ***decentralized*** computerized systems. Specifically, as explained in detail above, Dishman discloses that "***each hospital***" has its own computerized clozapine lockout system. *See supra* at § III.B.2.c. Further, even within each hospital, the lockout system is composed of two distinct, pre-existing databases: (1) the hospital's laboratory database; and (2) the outpatient pharmacy dispensing software. *Id.* And Dishman describes the potential for local override of the lockout, further suggesting that the system was not centralized. *Id.* Accordingly, even if Dishman discloses prescriber, pharmacy, and patient registration—it does not—it still fails to disclose that registration occurring in any centralized computer readable storage medium. Ex. 2059 ¶114-115; Ex. 2060 ¶64-71.

'501 Resp. at 42

The Asserted References Do Not Teach Or Suggest The "Computer Readable Storage Medium": No Centralized Database

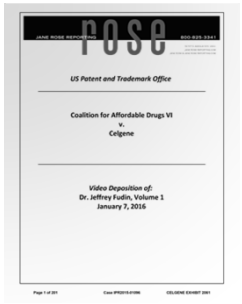
CFAD acknowledges the "fact" that each hospital has its own separate system



No. 20 at 12.) In any case, Celgene's reliance on the fact that each VA hospital had its "own separate system" (POR at 32) is misplaced.

'501 Reply at 19

Dr. Fudin agrees that the NCCC's two databases—the hospital laboratory database and the outpatient pharmacy software—existed separate and apart from the NCCC



Q. (By Mr. Chalson) So like, for example, like we talked about, the hospital laboratory database, the outpatient pharmacy dispensing software. Those things just existed and the NCCC just leveraged information in them for its own purposes, right?

A. Okay. Yes.

Q. Do you agree with that?

A. Yes.

Q. The NCCC did not come in and say we're going to create a brand-new system that has all of these brand-new parts. It just leveraged sources that existed already and, as you said, it took information from different places to provide something to a pharmacist in real time, right?

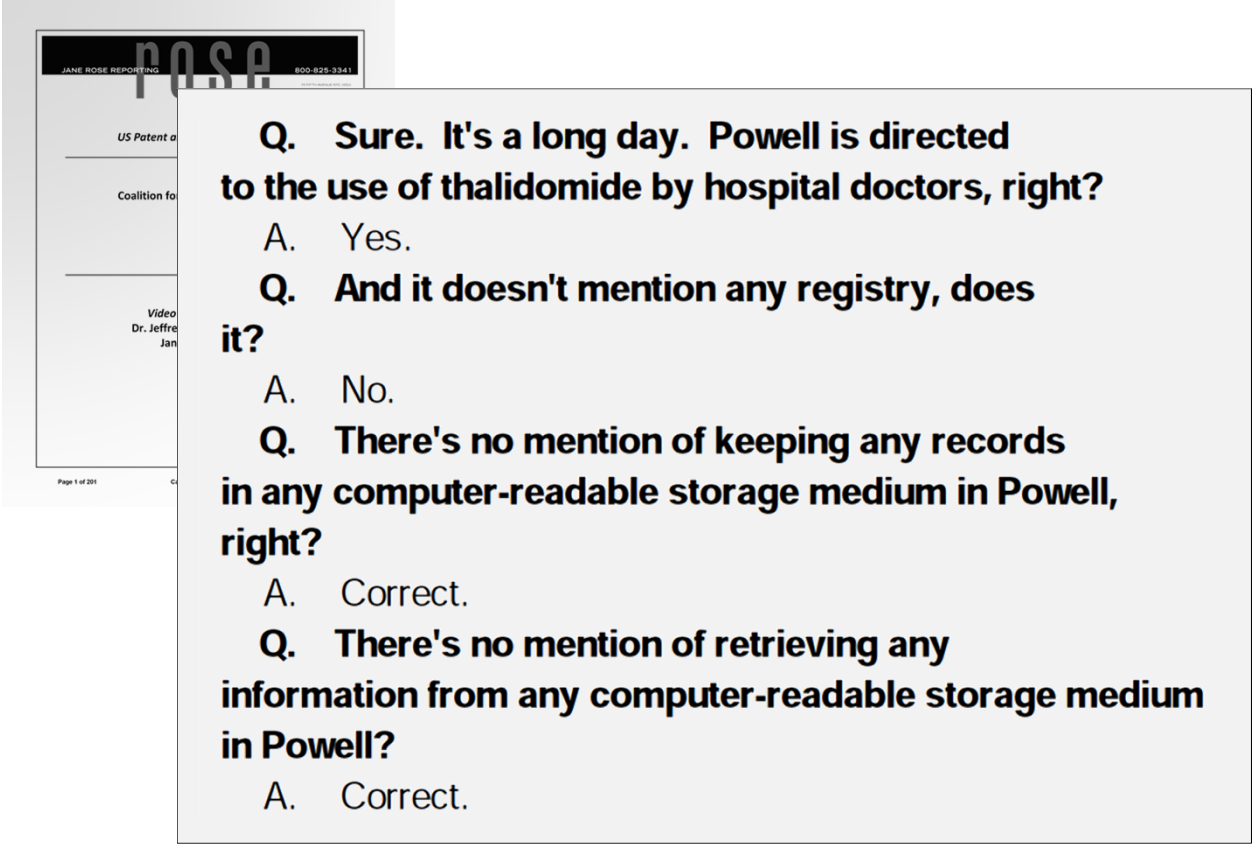
A. I suppose, yes.

Fudin Tr. 304:4-19; '501 Resp. at 33;
'501 Frau Decl. ¶ ¶ 115; '501 DiPiro Decl. ¶72

The Asserted References Do Not Teach Or Suggest The "Computer Readable Storage Medium": No Pharmacy Registration

Dr. Fudin admitted that Powell does not:

- Mention any registry
- Mention keeping any records in any computer readable storage medium
- Mention retrieving any information from any computer readable storage medium



Q. Sure. It's a long day. Powell is directed to the use of thalidomide by hospital doctors, right?

A. Yes.

Q. And it doesn't mention any registry, does it?

A. No.

Q. There's no mention of keeping any records in any computer-readable storage medium in Powell, right?

A. Correct.

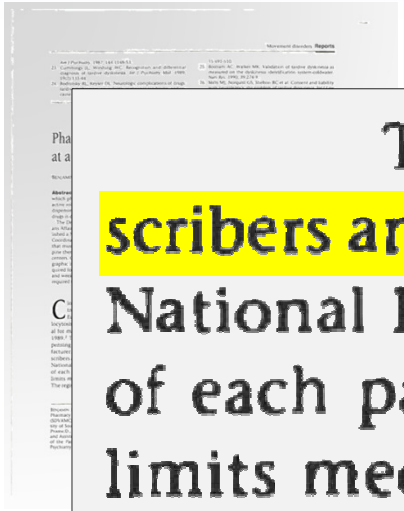
Q. There's no mention of retrieving any information from any computer-readable storage medium in Powell?

A. Correct.

Fudin Tr. 261:12-25; '501 Resp. at 26, 36; '501 Frau Decl. ¶107; '501 DiPiro Decl. ¶56

The Asserted References Do Not Teach Or Suggest The "Computer Readable Storage Medium": No Pharmacy Registration

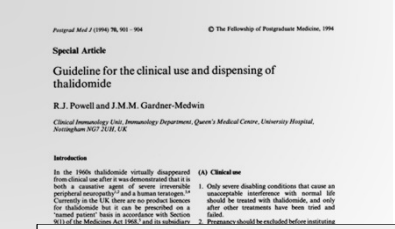
Dishman discloses only prescriber and patient registration:



The manufacturer, Sandoz, requires all prescribers and patients to be registered with the Clozaril National Registry, which requires weekly monitoring of each patient's white blood cell (WBC) count and limits medication dispensing to a one-week supply.[3] The registry permits community and hospital pharmacies to dispense clozapine only upon the pharmacist's verification that the WBC count is within acceptable limits.

IPR2015-01092, Ex. 1007 ("Dishman") at 899; '501 Resp. at 38-39; '501 Frau Decl. ¶112; '501 DiPiro Decl. ¶¶62-63

A POSA Would Not Have Been Motivated To Arrive At The Claimed Male Subpopulation



Postgrad Med J (1994) 70, 901 - 904 © The Fellowship of Postgraduate Medicine, 1994

Special Article

Guideline for the clinical use and dispensing of thalidomide

R.J. Powell and J.M.M. Gardner-Medwin

Clinical Immunology Unit, Immunology Department, Queen's Medical Centre, University Hospital, Nottingham NG7 2UH, UK

Introduction

In the 1960s thalidomide virtually disappeared from clinical use after it was demonstrated that it is both a causative agent of severe irreversible peripheral neuropathy[1] and a human teratogen.[2,3] Currently in the UK there are no product licences for thalidomide but it can be prescribed on a 'named patient' basis in accordance with Section 9(1) of the Medicines Act 1968,[4] and its subsidiary

(A) Clinical use

1. Only severe disabling conditions that cause an unacceptable interference with normal life should be treated with thalidomide, and only after other treatments have been tried and failed.
2. Pregnancy should be excluded before instituting

3. *Damage to babies*: This is very important for all women considering thalidomide. Thalidomide is toxic to the developing baby, especially in the early months of pregnancy. If you wish to consider thalidomide you must be prepared to use adequate contraception throughout the duration of thalidomide therapy and for 3 months after it has finished. Should contraception fail, any resulting pregnancy may incur damage to the baby and consequently, if you miss a period at any time during treatment, **you must stop thalidomide immediately** and contact the doctor who prescribed the thalidomide. A pregnancy test would then be arranged and appropriate counselling given. Should pregnancy be confirmed, further investigations to assess any damage to the baby would be indicated. Your doctor can advise you about adequate contraception. No effects on male sperm are recognized.

IPR2015-01092, Ex. 1005 ("Powell") at 903; '501 Resp. at 43; '501 Frau Decl. ¶124; '501 DiPiro Decl. ¶¶ 74, 75, 80

CFAD Has No Evidence That Thalidomide, Administered To A Father, Can Cause A Malformation Of An Embryo

Q. (By Mr. Chalson) Powell does not report any evidence that sperm could transfer thalidomide to a female patient and thereby potentially impact a developing fetus, right?

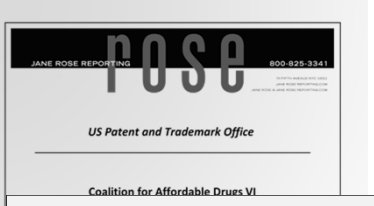
A. He doesn't provide any evidence. That, I agree with. He's not saying that it can't happen.

* * *

Q. Okay. So, again, had Powell had evidence that sperm could transfer thalidomide to a female patient potentially impacting a developing fetus, he didn't report on it, right?

A. He didn't report on it, correct.

Fudin Tr. at 258:20-25, 260:21-25; '501 Resp. at 26-27, 43; '501 Frau Decl. ¶124; '501 DiPiro Decl. ¶75



Q. Sitting here today, you have no actual evidence that thalidomide administered to a father can cause a malformation of an embryo, do you?

A. I do not.

Q. (By Mr. Chalson) And, in fact, there is no evidence to that point directly on this question that, administered to a father, can cause a malformation to an embryo, right?

A. Not that I know of.

Fudin Tr. at 205:8-18; '501 Resp. at 44

No Motivation To Arrive At The '720 Patent's Inventions: S.T.E.P.S. Has Been 100% Successful In Preventing Birth Defects

Dr. Fudin agreed that there have been no birth defects under S.T.E.P.S.® and that there was no problem with S.T.E.P.S.® as of October 2000

Q. (By Mr. Chalson) Despite all of that skepticism, there had been zero birth defects associated with the distribution of thalidomide pursuant to the restricted distribution systems that are claimed in the '501 and '720 patents, right?

A. I believe so.

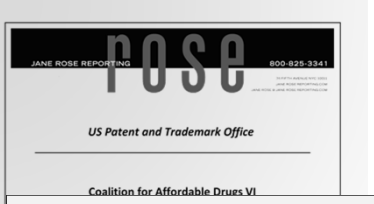
Q. (By Mr. Chalson) I mean, that's reported in the literature as well, right?

A. Yes.

Q. And obviously if such births defects occurred, there would be an outcry and it would be published, right?

A. You can be certain.

Fudin Tr. at 239:23-240:11; IPR2015-01096, Paper 40 ("-1096 Resp.") at 17; IPR2015-01102, Paper 41 ("-1102 Resp.") at 17; IPR2015-01103, Paper 42 ("-1103 Resp.") at 17



Q. (By Mr. Chalson) Sure. Again, my -- I think we're saying the same thing. I'm just trying to make sure we agree that as of October of 2000, it was public and your POSA would have known that the original S.T.E.P.S. system was working. It had avoided the predicted second thalidomide tragedy that many thought was inevitable before Thalomid was approved in 1998, right?

A. Okay. Yes.

Q. (By Mr. Chalson) There's nothing in any of the prior art that you cite to suggest that the original S.T.E.P.S. wasn't working, is there?

A. No.

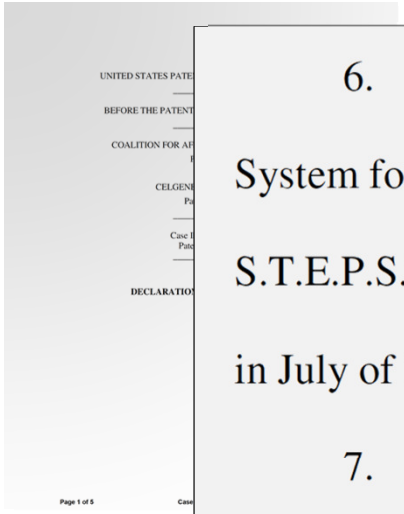
Q. In other words, as of October of 2000, no prior art taught that there was some problem with original S.T.E.P.S. that had to be addressed, right?

A. I don't believe so.

Fudin Tr. at 380:5-22; -1096 Resp. at 4, 5, 17; -1102 Resp. at 4, 5, 17; -1103 Resp.at 4, 5, 17

No Motivation To Arrive At The '720 Patent's Inventions: S.T.E.P.S. Has Been 100% Successful In Preventing Birth Defects

Celgene's Head of Global Drug Safety & Risk Management



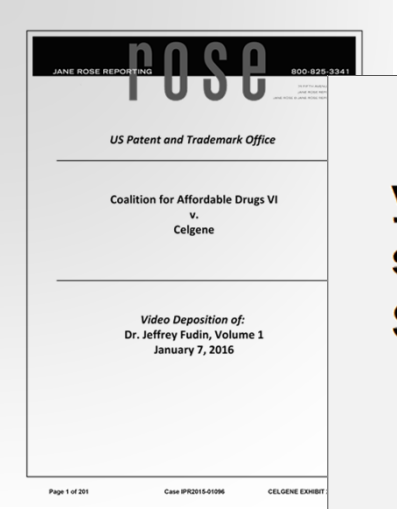
6. I am familiar with the restricted-distribution system known as the System for Thalidomide Education and Prescribing Safety, or S.T.E.P.S.® S.T.E.P.S.® was introduced with Celgene's Thalomid® brand thalidomide capsules in July of 1998.

7. Since July of 1998, there has not been a single birth defect in connection with Thalomid®, in the United States or elsewhere. There have also been zero birth defects associated with two of Celgene's other products, Revlimid® and Pomalyst®, both of which are believed to be teratogenic by the U.S. Food and Drug Administration.

IPR2015-01096, -1102, Ex. 2068; IPR2015-01103, Ex. 2069 ("Freeman Decl.") at ¶¶ 6-7; IPR2015-01096, Ex. 2059 ("-1096 Frau Decl.") ¶21; Ex. 2060 ("-1096 DiPiro Decl.") ¶20; IPR2015-01102, Ex. 2059 ("-1102 Frau Decl.") ¶21; Ex. 2060 ("-1102 DiPiro Decl.") ¶20; IPR2015-01103, Ex. 2059 ("-1103 Frau Decl.") ¶21; Ex. 2060 ("-1103 DiPiro Decl.") ¶20; -1096 Resp. at 4; -1102 Resp. at 4; -1103 Resp.at 4

No Motivation To Arrive At The '720 Patent's Inventions: CFAD's Motivation Is Based On Non-Existent Hypothetical Drugs

Dr. Fudin could only speculate about "future drugs" that "might" require modifying S.T.E.P.S. ®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Coalition for Affordable Drugs VI
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Celgene

Video Deposition of:
Dr. Jeffrey Fudin, Volume 1
January 7, 2016

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Q. Can you answer the question that I asked you, sir? There's nothing in this article that specifies a specific reason to modify the original S.T.E.P.S., is there?

A. Yes, there is.

Q. What is the --

A. It says --

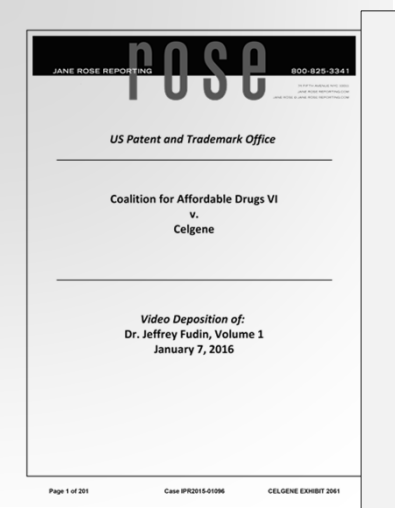
Q. -- specific reason to modify original S.T.E.P.S.?

A. Because future cases, future drugs that are developed might -- might cause a need to change the original S.T.E.P.S. based on those new drugs which we don't even know what they are.

Fudin Tr. at 591:15-592:2; -1096 Resp. at 18-20; -1102 Resp. at 18-20; -1103 Resp. at 18-20

No Motivation To Arrive At The '720 Patent's Inventions: No Motivation To Arrive At The Specifically Claimed Elements

Dr. Fudin admitted that a POSA "would not know . . . what kind of development or changes need to be made to the original S.T.E.P.S."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January 7, 2016

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Q. Sure. The article doesn't disclose any modifications that are necessary to the original S.T.E.P.S., does it?

A. It doesn't specifically spell out how it would do that, if that's what you're asking me.

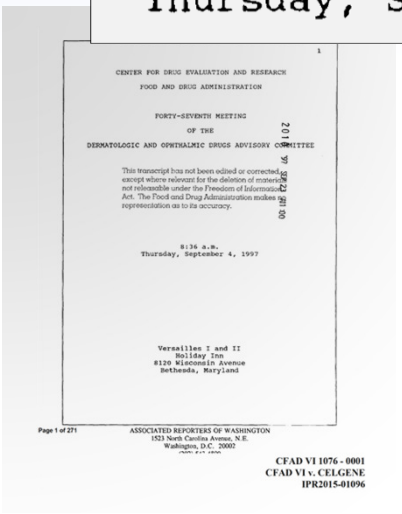
Q. It doesn't say there's a reason to modify original S.T.E.P.S., does it?

A. Give me a second. It did say something in here. Well, I mean the last paragraph says, "Future cases are certain to arise in which a drug offers compelling clinical benefits, but unrestricted distribution poses profound risks to patients or society."

So in my mind a POSA would not know what those potential drugs might be, what's to come in the future and what kind of developments or changes need to be made to the original S.T.E.P.S. in order to make those things successful with future developments.

Fudin Tr. at 590:15-591:8; -1096 Resp. at 18-20; -1102 Resp. at 18-20; -1103 Resp. at 18-20

No Motivation To Arrive At The '720 Patent's Inventions: Confidential Surveys Cannot Provide A Motivation



CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

FORTY-SEVENTH MEETING
OF THE
DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE

This transcript has not been edited or corrected, except where relevant for the deletion of material not releasable under the Freedom of Information Act. The Food and Drug Administration makes no representation as to its accuracy.

8:36 a.m.
Thursday, September 4, 1997

Versailles I and II
Holiday Inn
8120 Wisconsin Avenue
Bethesda, Maryland

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ASSOCIATED REPORTERS OF WASHINGTON
1523 North Carolina Avenue, N.E.
Washington, D.C. 20002

CFAD VI 1076 - 0001
CFAD VI v. CELGENE
IPR2015-01096

Thursday, September 4, 1997

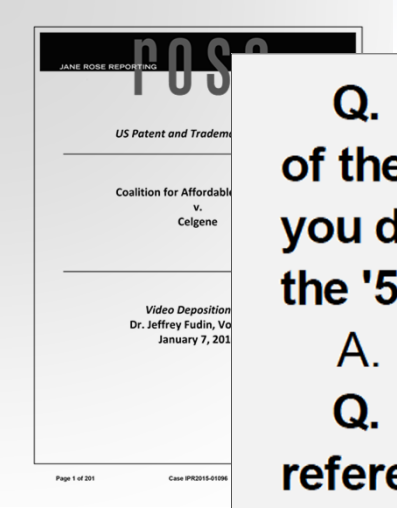
For the registry, we have been working with the Slone Epidemiology Unit at Boston University -- Allen Mitchell's group particularly -- to develop the thalidomide registry. We chose this group because they have had a lot of experience with Accutane, they've understood what works well, and they've got a good perspective on how things could be improved.

All patients will participate. It resolves one of the issues that has been raised in a number of circles about not knowing the end for Accutane. And responses will be confidential to the immediate health care team and the investigators at Boston University.

Female patients will complete the survey monthly, and male patients will complete the survey no less frequently than ever 3 months and at any visit to the physician office. The objectives of the registry are twofold and I think, very importantly, to track compliance with the program because it provides us with a continuous feedback loop in understanding how effective the various elements of the programming are working, what level of compliance we are getting, whether there are pockets or individuals who may be complying less well than all of us would expect, and provides us the opportunity to go back and take corrective action.

IPR2015-01096, Ex. 1076; IPR2015-01102, -1103, Ex. 1012 ("FDA Meeting Part 1") at 118-19; IPR2015-01096, Paper 52 ("-1096 Reply") at 13-14; IPR2015-01102, Paper 54 ("-1102 Reply") at 11; IPR2015-01103, Paper 55 ("-1103 Reply") at 11; IPR2015-01096, Paper 60 at 13-15; IPR2015-01102, Paper 62 at 14-15; IPR2015-01103, Paper 63 at 14-15.

No Motivation To Arrive At The '720 Patent's Inventions: CFAD's Reliance On Cunningham Is Based On Hindsight



Q. So coming back to the section about state of the art, while we're on the subject of Cunningham, you didn't cite Cunningham at all in connection with the '501 patent, right?

A. I don't think so.

Q. And it's certainly not one of the main references you rely on for the '501 patent, is it?

A. No.

Q. That's because the '501 patent doesn't claim a prescription approval code, right?

A. Correct.

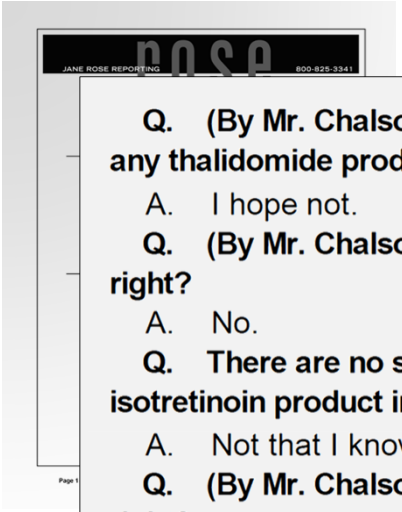
Q. But the '720 patent does claim a prescription approval code, and that's why you cited Cunningham against the '720 patent?

A. Yes.

Fudin Tr. at 415:11-25; -1096 Resp. at 51-52; -1102 Resp. at 51-52; -1103 Resp. at 52-53

No Motivation To Arrive At The '720 Patent's Inventions: CFAD's Reliance On Cunningham Is Based On Hindsight

Dr. Fudin admitted that Cunningham's system would not be applicable to distributing drugs with dangerous side effects like thalidomide, isotretinoin, and clozapine



Q. (By Mr. Chalson) There are no samples of any thalidomide product in the U.S., are there?
A. I hope not.
Q. (By Mr. Chalson) There never have been, right?
A. No.
Q. There are no samples of any Accutane or isotretinoin product in the United States, right?
A. Not that I know of.
Q. (By Mr. Chalson) And there never have been, right?
A. I don't believe so.
Q. That would be, in your opinion you'd agree, gravely irresponsible to be passing out free samples of known human teratogens, right?
A. Yes.
Q. There are no samples of Clozaril or clozapine either, right?
A. I don't believe so.

Q. (By Mr. Chalson) As a result, systems that are designed to help track and distribute free samples don't apply to at least thalidomide, isotretinoin and clozapine, right?
A. Correct.

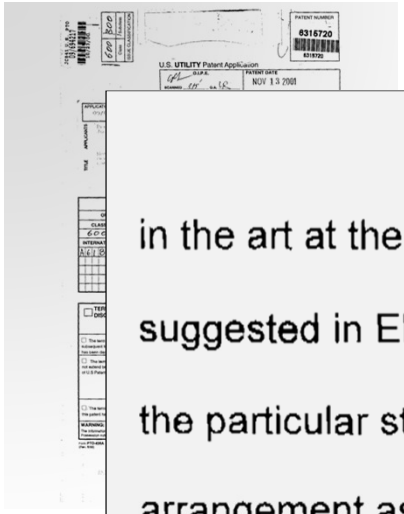
Fudin Tr. at 437:11-438:7, 438:20-25; -1096 Resp. at 56; -1102 Resp. at 56-57; -1103 Resp. at 56-57; '1096 Frau Decl. ¶¶ 61, 75-76; -1096 DiPiro Decl. ¶¶118-19; -1102 Frau Decl. ¶¶70, 84-85; -1102 DiPiro Decl. ¶¶122-23; -1103 Frau Decl. ¶¶68, 82, 84; -1103 DiPiro Decl. ¶¶ 123-24

"Prescription Approval Code": The Parties' Constructions

Celgene	CFAD
a code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable	No specific construction offered Only a critique of Celgene's construction Argues that the only requirement for retrieval of the prescription approval code is registration
-1096 Resp. at 21-24; -1102 Resp. at 21-24; -1103 Resp. at 21-24; '1096 Frau Decl. ¶¶ 50-52; -1096 DiPiro Decl. ¶¶36-40; -1102 Frau Decl. ¶¶50-52; -1102 DiPiro Decl. ¶¶36-40; -1103 Frau Decl. ¶¶50-52; -1103 DiPiro Decl. ¶¶36-40	-1096 Reply at 8-12; -1102 Reply at 6-9; -1103 Reply at 6-9

"Prescription Approval Code" Claim Construction: The File History Supports Celgene's Construction

This Office's Rejection:

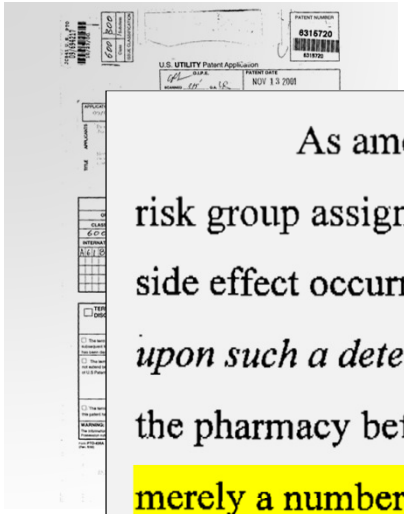


It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the screening for drug contraindications suggested in Elsayed et al. with the method of Schauss et al. since Schauss et al. teach the particular steps for performing the analysis and further to use an automated pharmacy arrangement as taught by Boyer et al. which includes a step for generating a prescription number or code associated with said prescription by a computer workstation since this provides an alternate expedient to the prescription procedure of Elsayed et al.

IPR2015-01096, -1102, -1103, Ex. 1002 ("'720 File History") at 92;
-1096 Resp. at 22; -1102 Resp. at 22; -1103 Resp. at 21-22; '1096 Frau Decl. ¶50; -1096 DiPiro Decl. ¶37;
-1102 Frau Decl. ¶50; -1102 DiPiro Decl. ¶37; -1103 Frau Decl. ¶50; -1103 DiPiro Decl. ¶37

"Prescription Approval Code" Claim Construction: The File History Supports Celgene's Construction

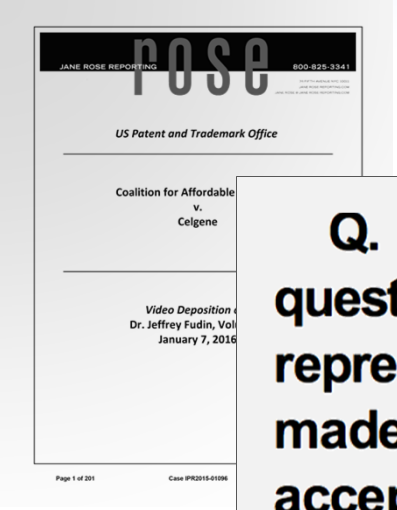
This Inventor's Response:



As amended on March 23, 2001, Claim 1 further requires an assessment, based upon the risk group assignment and the information collected from the patient, as to whether the risk of the side effect occurring is acceptable. Upon a determination that the risk is acceptable, *and only upon such a determination*, a prescription approval code is generated, which must be retrieved by the pharmacy before the prescription may be filled. Thus, the prescription approval code is not merely a number that is associated with the prescription, but instead represents the fact that a determination has been made that the risk of the side effect occurring is acceptable, and that approval--an affirmative decision-- has been made for the prescription to be filled. Boyer does not disclose or suggest such an approval code.

'720 File History at 106-107; -1096 Resp. at 22-23; -1102 Resp. at 22-23; -1103 Resp. at 22-23;
'1096 Frau Decl. ¶51; -1096 DiPiro Decl. ¶¶37-38; -1102 Frau Decl. ¶51;
-1102 DiPiro Decl. ¶¶37-38; -1103 Frau Decl. ¶51; -1103 DiPiro Decl. ¶¶37-38

"Prescription Approval Code" Claim Construction: Dr. Fudin's Testimony Supports Celgene's Construction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Coalition for Affordable
v.
Celgene

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Dr. Jeffrey Fudin, Vol
January 7, 2016

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Q. (By Mr. Chalson) I'll ask you a different question. The claimed prescription approval code represents the fact that a determination has been made that the risk of a side effect occurring is acceptable and that approval and affirmative decision has been made for the prescription to be filled, right?

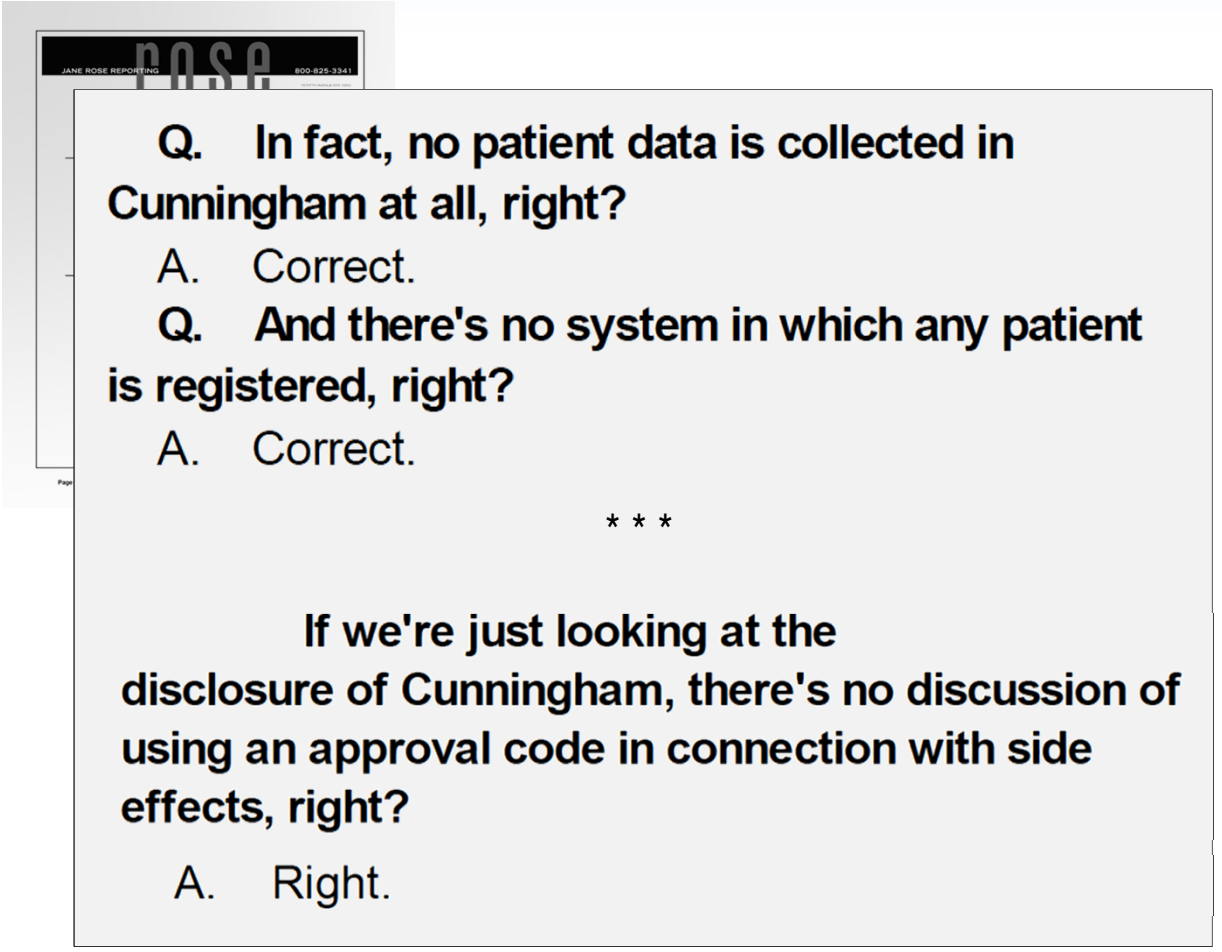
A. Yes.

Fudin Tr. at 434:7-15; -1096 Resp. at 23; -1102 Resp. at 23; -1103 Resp. at 23

The Asserted References Do Not Teach Or Suggest The Claimed "Prescription Approval Code"

Dr. Fudin admitted that Cunningham does not:

- Collect patient data
- Register patients in any system
- Use an approval code in connection with side effects



Q. In fact, no patient data is collected in Cunningham at all, right?

A. Correct.

Q. And there's no system in which any patient is registered, right?

A. Correct.

* * *

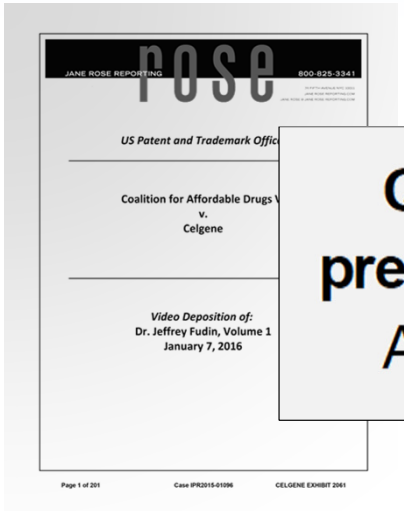
If we're just looking at the disclosure of Cunningham, there's no discussion of using an approval code in connection with side effects, right?

A. Right.

Fudin Tr. at 428:11-16, 432:14-20; -1096 Resp. at 27-28, 37-38; -1102 Resp. at 29-30, 38-39; -1103 Resp. at 30, 39-40; '1096 Frau Decl. ¶64; -1096 DiPiro Decl. ¶53; -1102 Frau Decl. ¶73; -1102 DiPiro Decl. ¶64; -1103 Frau Decl. ¶71; -1103 DiPiro Decl. ¶65

The Asserted References Do Not Teach Or Suggest The Claimed "Prescription Approval Code"

Dr. Fudin admitted that Dishman does not disclose a prescription approval code at all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Dr. Jeffrey Fudin, Volume 1
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Q. And Dishman does not disclose a prescription approval code, does it?

A. No.

Fudin Tr. at 420:18-20; -1102 Resp. at 27, 35; -1103 Resp. at 28, 35

The Asserted References Do Not Teach Or Suggest Prescriber Verification Of Informed Consent At The Time Of Patient Registration

The prior art taught that the pharmacist verifies informed consent when registering the patient

Dear Pharmacist:

Thank you for registering to dispense THALOMID™ (thalidomide). Your registration card has been received and processed, and your pharmacy is now registered in the **System for Thalidomide Education and Prescribing Safety (*S.T.E.P.S.*)** Pharmacy Registry. You will receive patient registration forms that must be completed for every new patient receiving THALOMID™ (thalidomide) with your first THALOMID™ (thalidomide) shipment.

Your pharmacy may now dispense prescriptions for THALOMID™ (thalidomide), according to the following procedures:

Dispensing initial prescriptions:

- Note that telephone prescriptions are not permitted with initial prescriptions.
- Do not dispense if prescription was written more than 14 days prior.
- Collect and retain a signed informed consent form.
  - If the patient does not present a completed informed consent form with the prescription, the physician must be notified that the form is mandatory for a prescription to be filled.
  - The physician can order required *S.T.E.P.S.* program materials by calling 1-888-4-CELGENE.
- Enroll the patient in the *S.T.E.P.S.* Patient Registry.
  - Complete the patient registration form and supply the information by calling 1-888-4-CELGENE, or by fax to 1-888-475-2672.
- Dispense no more than a 4-week (28-day) supply of THALOMID™ (thalidomide) therapy. Automatic refill prescriptions are not permitted.

well as prescribing and dispensing guidelines, will be provided to you. This monograph is approved for continuing pharmaceutical education credits upon completion.

To reorder additional patient registration forms, or if you have questions about the procedures required for dispensing THALOMID™ (thalidomide), please call 1-888-4-CELGENE, or fax your inquiry to 1-888-475-2672.

Thank you for helping make certain that THALOMID™ (thalidomide) is made available to your patients in the most responsible fashion. Please see enclosed full Prescribing Information.

Sincerely,

Bruce A. Williams
Vice President, Director of Marketing

Enclosure

System for Thalidomide Education and Prescribing Safety

Patient Registration

Please enter this patient into the S.T.E.P.S. Patient Registry. I have verified that the patient has completed and signed the required informed consent form.

Patient Information

Patient Last Name | Date

Social Security No. (last six digits are required) | M / F Sex (circle) | Date of Birth

Physician Information

Physician Name | DEA No.

Address

City | State | Zip

Pharmacy Information

Pharmacy Name | Phone (include area code)

Address

City | State | Zip

Pharmacy No. (NABP) | Pharmacist Name (Please print)

Submit information by:
FAX 1-888-475-2672
PHONE 1-888-4-CELGENE (1-888-423-5436)

THALOMID® (thalidomide)

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IPR2015-01096, Ex. 2063; IPR2015-01102, -1103, Ex. 2064 ("Pharmacist Letter"); IPR2015-01096, -1102, Ex. 2065; IPR2015-01103, Ex. 2063 ("Patient Registration Form"); -1096 Resp. at 41-45; -1102 Resp. at 43-46; -1103 Resp. at 44-47

The Asserted References Do Not Teach Or Suggest Genetic Testing

"The link between teratology and genetic testing" was not made "explicit" in FDA Meeting Part 1, as CFAD alleges

It may seem strange to you that a genetics society would be standing here, commenting on potential environmental exposures with awful fetal effects, but many clinical geneticists around the country are expected to provide counseling to pregnant women about exposures in pregnancies, so the geneticists, in fact, are often the clinical teratologists. And I am speaking myself as an active clinical teratologist in the Boston area.

FDA Meeting Part 1 at 137; -1096 Reply at 25-26; -1102 Reply at 23; -1103 Reply at 22-23

’720 Patent, Claim 1

(12) **United States Patent**
Williams et al.

(10) **Patent No.: US 6,315,720 B1**
(45) **Date of Patent: Nov. 13, 2001**

(54) **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**

(75) Inventors: **Bruce A. Williams**, Flemington; **Joseph K. Kaminski**, Hampton, both of NJ (US)

(73) Assignee: **Celgene Corporation**, Warren, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/694,217**

(22) Filed: **Oct. 23, 2000**

(51) **Int. Cl.**[7] **A61B 5/00**

(52) **U.S. Cl.** **600/300**; 235/375

(58) **Field of Search** 600/300, 301, 600/551; 395/202-210; 128/630, 700/23, 2, 3; 235/375

(56) **References Cited**

U.S. PATENT DOCUMENTS

(57) **ABSTRACT**

Improved methods for delivering to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug are disclosed. The methods are of the type in which prescriptions for the drug are filled only after a computer readable storage medium has been consulted to assure that the prescriber, pharmacy and patient have been properly registered in the medium before the patient is approved to receive the drug. Embodiments are provided wherein the patients are assigned to risk groups based upon the risk that taking the drug will lead to the side effect, and certain additional information, such as periodic surveys and diagnostic tests probative of the ongoing risk of the side effect developing are obtained before prescriptions for the drug are approved.

32 Claims, No Drawings

1. In a method for delivering a drug to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by said drug, wherein said method is of the type in which prescriptions for said drug are filled only after a computer readable storage medium has been consulted to assure that the prescriber is registered in said medium and qualified to prescribe said drug, that the pharmacy is registered in said medium and qualified to fill the prescription for said drug, and the patient is registered in said medium and approved to receive said drug, the improvement comprising:

a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for said drug;

b. defining a set of information to be obtained from said patient, which information is probative of the risk that said adverse side effect is likely to occur if said drug is taken by said patient;

c. in response to said information set, assigning said patient to at least one of said risk groups and entering said risk group assignment in said medium;

d. based upon said information and said risk group assignment, determining whether the risk that said adverse side effect is likely to occur is acceptable; and

e. upon a determination that said risk is acceptable, generating a prescription approval code to be retrieved by said pharmacy before said prescription is filled.

IPR2015-01096, -1102, -1103, Ex. 1001 (“’720 patent”) at Claim 1; -1096 Resp. at 1; -1102 Resp. at 1; -1103 Resp. at 1

CFAD failed to show that the prior art teaches or suggests the claimed "computer readable storage medium"

CFAD failed to show that the prior art teaches or suggests including a male subpopulation

CFAD failed to show that the prior art teaches or suggests actually providing contraception to a patient, as required by claim 10

CFAD failed to provide a motivation to combine elements from Powell, Mitchell, and Dishman to arrive at the claimed inventions as a whole

CFAD failed to show that the claimed inventions achieve only predictable results

Secondary considerations support the nonobviousness of the claimed inventions

'720 Patent

CFAD failed to provide a motivation to modify the prior art, and ignores that STEPS was 100% successful

CFAD failed to provide a motivation to combine Cunningham with the other asserted references

CFAD failed to show that the prior art teaches or suggests the claimed "prescription approval code"

CFAD does not dispute that actual application of Cunningham's "pharmacy approval code" is above the level of skill in the art

CFAD failed to show that the prior art teaches or suggests prescriber verification of informed consent at the time of patient registration, as recited in claims 5 and 6

CFAD failed to show that the prior art teaches or suggests the genetic testing in claim 10

CFAD failed to show that the prior art teaches or suggests the IVR surveys in claim 17