Trials@uspto.gov
571.272.7822

Papel No. 73
Entered: October 26, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI, LLC,
Petitioner,

v.

CELGENE CORPORATION,
Patent Owner.

Case IPR2015-01096
Patent 6,315,720 B1

Before MICHAEL P. TIERNEY, GRACE KARAFFA OBERMANN, and TINA E. HULSE, *Administrative Patent Judges*.

TIERNEY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. §318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Coalition for Affordable Drugs VI, LLC ("Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–32 of U.S. Patent 6,315,720 (Ex. 1001, "the '720 patent"). Paper 1 ("Pet."). Patent Owner, Celgene Corporation, ("Patent Owner") filed a Preliminary Response. Paper 11 ("Prelim. Resp." with redacted version Paper 12). We determined that there was a reasonable likelihood that Petitioner would prevail in challenging those claims as unpatentable. Pursuant to 35 U.S.C. § 314, we authorized an *inter partes* review to be instituted, on October 27, 2015. Paper 21 ("Dec. on Inst.").

After institution, Patent Owner filed a redacted Patent Owner Response. Paper 40 ("PO Resp." with redacted version Paper 41). Petitioner filed a Reply. Paper 52, ("Reply" with readacted version paper 51). Additionally, Petitioner filed a Motion to Submit Supplemental Information (Paper 36), a Motion to Exclude Evidence (Paper 61), and a Motion to Seal (Paper 53). Further, Patent Owner filed a Motion to Exclude Evidence (Paper 60) and Motions to Seal and for Entry of Protective Order (Papers 10 and 39).

An oral hearing was held on July 21, 2016. A transcript of the hearing has been entered into the record of the proceeding as Paper 72 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–32 are unpatentable.

A. Related Proceedings

According to Petitioner, the '720 patent has been the subject of the following judicial matters: *Celgene Corp. v. Lannett Holdings, Inc.*, DNJ-2-15-00697 (filed Jan. 30, 2015); *Celgene Corp. v. Natco Pharma Ltd*., DNJ-2-10-cv-05197 (filed Oct. 8, 2010); *Celgene Corp. v. Barr Laboratories, Inc.*, DNJ-2-08-cv-03357 (filed July 3, 2008); *Celgene Corp. v. Barr Laboratories, Inc.*, DNJ-2-07-cv-05485 (filed Nov. 14, 2007); *Celgene Corp. v. Barr Laboratories, Inc.*, DNJ-2-07-cv-04050 (filed Aug. 23, 2007); *Celgene Corp. v. Barr Laboratories, Inc.*, DNJ-2-07-cv-00286 (filed Jan. 18, 2007). Pet. 2–3. Additionally, the claims of the '720 patent have been challenged in two related *inter partes* review proceedings, IPR2015-01102 and IPR2015-01103.

B. The '720 Patent

The '720 patent specification describes methods for delivering a drug to a patient. Ex. 1001, 1:8–9. For example, the method can be used to deliver a drug known to cause birth defects in pregnant women, while avoiding the occurrence of known or suspected side effects of the drug. *Id*. at 1:9–13, 19–30.

The patent describes prior-art methods that involved filling drug prescriptions, only after a computer readable storage medium was consulted, to assure that the prescriber is registered in the medium and qualified to prescribe the drug, and that the patient is registered in the medium and approved to receive the drug. *Id*. at 2:50–60. The '720 patent specification is said to describe an improvement over the acknowledged prior art, where the improvement involves assigning patients to risk groups based on the risk

that the drug will cause adverse side effects. The improvement further requires entering the risk group assignment in the storage medium. After determining the acceptability of likely adverse effects, a prescription approval code is generated to the pharmacy before the prescription is filled. *Id*. at 2:60–3:4. The specification states that this method may minimize and simplify demands on the pharmacy and reduce the risk that the drug will be dispensed to a contraindicated individual. *Id*. at 2:8–12.

The '720 patent specification states that it is preferable that information probative of the risk of a drug's side effects is collected from the patient. *Id*. at 6:30–33. This information can then be compared with a defined set of risk parameters for the drug, allowing for assignment of the patient to a particular risk group. *Id*. at 6:33–37. If the risk of adverse side effects is deemed acceptable, the patient may receive the drug from a registered pharmacy, subject to conditions such as a negative pregnancy test, but may not receive refills without a renewal prescription from the prescriber. *Id*. at 11:62–12:8.

The '720 patent specification states that its method can be used to deliver teratogenic drugs, and drugs that can cause severe birth defects when administered to a pregnant woman, such as thalidomide. *Id*. at 4:1–14, 8:39–45.

C. Illustrative Claims

The '720 patent contains two independent claims and thirty dependent claims, all of which are challenged by Petitioner. Each of the independent claims, 1 and 28, are directed to a method of delivering a drug to a patient in need of the drug and is written in a Jepson claim format, where the preamble

defines admitted prior art of prescribing drugs only after a computer readable storage medium has been consulted properly. The claimed improvement over the admitted prior art includes defining a plurality of patient risk groups, defining information to be obtained from a patient that is probative of risk of an adverse side effect, assigning the patient to a risk group, determining whether the risk of the side effect is acceptable, and generating an approval code to be retrieved by a pharmacy before filling a prescription for the drug.

Claims 2–27 depend, directly or through other dependent claims, upon claim 1. Dependent claims 2–4 require that a prescription is filled only following verified full disclosure and consent of the patient. Dependent claims 5–6 require that the informed consent is verified by the prescriber at the time the patient is registered in a computer, and consent is transmitted via facsimile and interpreted by optical character recognition software. Dependent claims 7–10 require information be obtained from the patient prior to treatment, including the results of diagnostic testing, which can comprise genetic testing. Dependent claims 11–14 and 20–25 further require additional features, such as a teratogenic effect being otherwise likely to arise in the patient, arise in a fetus carried by the patient, and that the drug is thalidomide. Dependent claims 15–19 and 26–27 require defining a second set of information to be collected from the patient on a periodic basis, which can comprise a telephonic survey regarding the results of pregnancy testing, and where the adverse side effect of the drug can be a teratogenic effect.

Dependent claims 29–32 each depend, directly or through other dependent claims, from independent claim 28. Dependent claims 29–32

further require that the information collected be probative of likelihood that the patient may take the drug and other drugs in combination, and that the diagnostic testing test for evidence of the use and adverse effect of the other drug.

Independent claim 1 is illustrative of the challenged claims, and is recited below:

> 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.

Claim 28, the only other independent claim, includes all the elements of claim 1 and adds a wherein clause that "said adverse side effect is likely to

arise in patients who take the drug in combination with at least one other drug." Prelim. Resp. at 15.

D. Prior Art Relied Upon

Petitioner relies upon the following prior art:

"THALOMID™ (thalidomide) Capsules Revised Package Insert" (Jul. 15, 1998) ("Thalomid PI") (Ex. 1006)

U.S. 5,832,449, Nov. 30, 1998 ("Cunningham") (Ex. 1009)

Jerome B. Zeldis et al., *S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide*, CLINICAL THERAPEUTICS® 21:2, 319–30 (1999) ("Zeldis") (Ex. 1012)

Daniel P. Keravich and Charles E. Daniels, *Challenges of Thalidomide Distribution in a Hospital Setting*, AM. J. HEALTH-SYST. PHARM. vol. 56, 1721–75 (Sept. 1, 1999) ("Keravich") (Ex. 1018)

James C. Mundt, *Interactive Voice Response Systems in Clinical Research and Treatment*, PSYCHIATRIC SERVICES (May 1997) 48:5, 611–12, 623 ("Mundt") (Ex. 1024)

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. § 103 based on the following specific grounds (Pet. 14–60):

Reference(s)	**Basis**	**Claims challenged**
Thalomid PI in view of Cunningham and further in view of Keravich, Zeldis, and Mundt[1]	§ 103	1–32

[1] Petitioner's heading merely states that claims 1–32 are obvious over Thalomid PI in view of Cunningham and further in view of the knowledge of one of ordinary skill in the art. Pet. 51. The Petition, however, goes on to rely upon additional art to explain the Thalomid PI reference. Specifically, the Petitioner relies upon Keravich, Zeldis, and Mundt. *Id*. at 17, 24–25, 33,

E. Level of Ordinary Skill in the Art

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational level of active workers in the field. In a given case, one or more factors may predominate. *In re GPAC*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

The challenged claims are directed to the subject matter of 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. The claims are said to be an improvement over prior art distribution systems where the improvement includes using an approval code to help minimize and simplify demands on a pharmacy and reduce the risk that the drug will be dispensed to a contraindicated individual. Ex. 1001 at 2:8–12.

Petitioner contends that a person skilled in the art of pharmaceutical prescriptions, which would involve controlling distribution of a drug, typically would have either a Pharm.D. or a B.S. in pharmacy with approximately 5–10 years of experience and a license to practice as a registered pharmacist in any one or more of the United States. Ex. 1021, Declaration of Dr. Jeffrey Fudin ¶¶ 13, 16. Patent Owner disagrees with Petitioner's definition of a person of ordinary skill in art and contends that

---

42, 46–47, 49–50, and 55–56. In the Decision to Institute we included the additional art relied upon, Keravich, Zeldis, and Mundt, in the stated grounds, so that the record was clear as to the prior art relied upon. Dec. on Inst.

such a person would have at least 2 years of experience in risk management relating to pharmaceutical drug products or a B.S. or M.S. in pharmaceutical drug product risk management or a related field. PO Resp. 12–13.

Based on the record presented, we hold that the cited prior art is representative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). The prior art references, like the '720 patent specification, focus on controlling the distribution of a drug. *See, e.g.*, Ex. 1001, 1:13–16 (describing "the distribution to patients of drugs, particularly teratogenic drugs, in ways wherein such distribution can be carefully monitored and controlled"); *see generally* Exs. 1003, 1006, 1009, 1012, 1018. Consistent with the prior art, Petitioner's Declarant, Dr. Fudin, testifies that the types of problems encountered by one of ordinary skill in the art included creating a restricted drug distribution program to prevent adverse side effects, such as teratogenic risks. Ex. 1021 ¶¶ 44–50. Accordingly, the prior art demonstrates that one of ordinary skill in the art would have experience in controlling the distribution of a drug. To the extent a more specific definition is required, we hold, for the reasons provided below, that a person of ordinary skill in the art would have several years of experience in risk management relating to pharmaceutical drug products, which encompasses experience as a pharmacist.

Patent Owner contends that a pharmacist would not be considered a person of ordinary skill in the art. Patent Owner relies upon the declaration of Dr. Frau, who testifies that "an average pharmacist at the time of the invention would have lacked the ability and the motivation to design an all inclusive system of drug delivery for a hazardous drug that is focused on preprescription patient assessment." Ex. 2059, ¶ 47. The challenged claims,

however, are directed to an improvement of an existing drug distribution method that provides an approval code after a prescriber has prescribed the drug. Specifically, the approval code checks to see if all the requisite information was properly registered in the storage medium and if the approval code is provided the pharmacy provides the drug. Ex. 1001, 14:45–57. Additionally, as to preprescription patient assessment, Dr. Frau fails to explain why pharmacists would lack awareness of preprescription patient assessment for drugs requiring prescriptions, *e.g.*, checking patient history to prevent prescription of contraindicated drugs.

Patent Owner contends that neither of the inventors of the challenged patent are pharmacists and relies upon the Dr. Frau's testimony as support for its position. Ex. 2059, ¶ 46. Although Dr. Frau states that the inventors are not pharmacists, Dr. Frau does not provide the basis for her testimony.

Patent Owner contends that the focus of the '720 patent is avoiding adverse events associated with drug products and not pharmaceutical prescriptions. PO Resp. 13. The challenged claims, however, do not prevent a patient taking a drug from experiencing the side effects associated with the drug. Rather, the challenged claims attempt to prevent a person from obtaining a drug where the person has an unacceptable risk associated with the known side effects of the drug. Specifically, the claims seek to control the distribution of a prescribed drug.

Patent Owner, relying on the testimony of Dr. Frau, contends that a person of ordinary skill in the art would have education or experience focused on safety surveillance, pharmacovigilance or pharmacoepidemiology. *Id*. at 14. On cross-examination, Dr. Frau did not identify any schools in the United States that offered a degree in

pharmaceutical risk management or related fields, such as pharmacoepidemiology, but did identify two schools located outside the United States. Ex. 1075, 166:19–167:19.

Patent Owner contends that Dr. Fudin acknowledged on cross-examination that, under his definition, one of ordinary skill in the art would not know how to design the "full system" claimed in the '720 patent. PO Resp. 15 citing Ex. 2061, 199:8–200:25. The challenged claims of the '720 patent are Jepson claims where the preamble defines admitted prior art. On this record it is unclear whether Dr. Fudin was testifying that a person of ordinary skill under his definition would be unable to develop the admitted prior art. Regardless, Dr. Fudin testified that pharmacists "don't need to know how to design it," which is distinct from would not know how to design it. Ex. 2061, 201:1–6.

We credit Dr. Fudin's testimony that a person of ordinary skill in the art would encompass a pharmacist as his testimony is consistent with the '720 patent specification, which states that the use of the approval code is focused on helping a pharmacy and a pharmacist would understand what would help simplify demands on a pharmacy. Ex. 1001 at 2:8–12. We likewise credit Dr. Frau's testimony that the person of ordinary skill in the art is not limited to pharmacists but would likewise encompass persons having at least 2 years of experience in risk management relating to pharmaceutical products, as pharmacists are not the only persons having restricted drug distribution experience and knowledge. Ex. 2059, ¶ 39.

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b).

Generally, Petitioner states that the claim terms are presumed to take on the ordinary and customary meaning that they would have to one of ordinary skill in the art. Pet. at 10. Petitioner however, proposes constructions for several claim terms including "consulted," "teratogenic effect," and "adverse side effect." *Id*. at 9–11. Patent Owner does not propose distinct constructions of these terms. We determine that the identified claim terms should be given their ordinary and customary meaning, as would be understood by one with ordinary skill in the art, and need not be construed explicitly at this time for purposes of this Decision.

Independent claims 1 and 28 are written in a Jepson claim format. Patent Owner acknowledges that the challenged claims are written to be an improvement over its prior program for controlling patient access to thalidomide known as the System for Thalidomide Education and Prescribing Safety, or S.T.E.P.S., which originally was claimed in U.S. Patent No. 6,045,501. Prelim. Resp. at 1, 10.

Patent Owner contends that the term "prescription approval code" requires construction and that the term has a specific meaning. PO Resp. 21–22. According to Patent Owner, the term "prescription approval code" means:

> [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.

Id. at 21, 23. Petitioner disagrees, stating that there is no requirement for an "affirmative" risk assessment. Reply 9–12.

The specification defines prescription approval code such that the prescription approval code is not provided unless certain conditions are met. Ex. 1001, 13:42–52. The conditions include the prescriber, pharmacy, patient, patient's risk group and the patient's informed consent have been properly registered in the storage medium. *Id*. Specifically, the '720 patent specification describes "approval code" as follows:

> In certain embodiments of the invention, the methods may require that the registered pharmacy consult the computer readable medium to retrieve a prescription approval code before dispensing the drug to the patient. This approval code is preferably not provided unless the prescriber, the pharmacy, the patient, the patient's risk group and the patient's informed consent have been properly registered in the storage medium. Additionally, depending upon the risk group assignment, generation of the prescription approval code may further require the registration in the storage medium of the additional set of information, including periodic surveys and the results of diagnostic tests, as have been defined as being relevant to the risk group assignment.

Id. The specification also states that if a patient's risk group assignment so indicates, a prescription approval code "generally" will not be generated until specific periodic diagnostic tests have been performed and satisfactory results entered into the storage medium. *Id*. at 14:37–15:6. As apparent from the specification, the prescription approval code is "preferably" or "generally" not provided unless certain information is properly registered in a storage medium. An affirmative risk assessment, however, is not

mentioned in the specification as a mandatory requirement for generation of the prescription approval code.

Patent Owner contends that during prosecution they overcame a prior-art rejection by defining the term prescription approval code. PO Resp. 22. Specifically, Patent Owner overcame the rejection by noting that the prior art cited by the Examiner merely described an "identifier for the prescription, and . . . not an *approval code* as recited in Applicant's claims." Ex. 1002, 107. Patent Owner also stated that the prior art was merely a prescription identifier and not reflective of a determination that the risk of the side effect occurring has been found to be acceptable. *Id*.

Patent Owner also states both Petitioner's expert (Dr. Fudin) and Patent Owner's expert (Dr. Frau) agree with Patent Owner's claim construction. PO Resp. 23, citing Ex. 2059 ¶¶ 50–52, Ex. 2060 ¶¶ 36–38, Ex. 2061, 434:8–15. Patent Owner notes that Dr. Fudin also insisted that the claimed prescription code is just a number and could even be a credit card. *Id*. citing Ex. 2061 at 432:21–24.

During cross examination, Dr. Fudin was asked questions regarding the meaning of the terms "approval code" and "prescription approval code." Ex. 2061 at 412:17–25, 429:18–430:10, 433:14–434:15. When Dr. Fudin was asked what an "approval code" means as used in the '720 patent claims, Dr. Fudin testified that it meant a code generated to allow a prescription to be filled and noted that it could be like a consumer credit card approval code. *Id*. at 412:17–25. When questioned as to how Cunningham taught an approval code used to represent a determination made concerning risk of side effects, Dr. Fudin testified that the code is used to track things and the technology should allow you to combine it with other materials that you

could track. *Id*. at 429:18–430:10. When Dr. Fudin was asked whether the claimed *prescription* approval code was merely a number, Dr. Fudin stated that it was a number associated with the prescription and agreed that the claimed *prescription* approval code represented a determination that the risk of a side effect occurring was acceptable and that approval and affirmative decision had been made for the prescription to be filled. *Id*. at 433:14–434:15.

Based on the record presented, we adopt Patent Owner's construction of the term prescription approval code. Specifically, we credit Dr. Fudin's testimony that an approval code may be an identifier, such as an approval code identifier used in consumer credit card transactions (approved/declined). We further credit Dr. Fudin's testimony, as well as Dr. Frau and Dr. DiPiro's, that a *prescription* approval code represents the fact that a prescription has been provided and that the prescription approval code thereby represents 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.

B. Claims 1–32 Obviousness over Thalomid PI in view of Cunningham and Further in view of Keravich, Zeldis, and Mundt

Petitioner contends that the challenged claims, which utilize approval codes to implement known drug restriction requirements, represent no more than an arrangement of old elements with each performing the same functions it had been known to perform and yields no more than one would

expect from such an arrangement. Pet. 53–54. Patent Owner disagrees. PO Resp. 16–58.

1. Background on Obviousness

A claimed invention is not patentable under 35 U.S.C. § 103 if it is obvious. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426–27 (2007). In *Graham v. John Deere Co.*, the Supreme Court established the facts underlying an obviousness inquiry.

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Graham v. John Deere Co., 383 U.S. 1, 17 (1966). In addressing the findings of fact, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416. As explained in *KSR*:

> If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

Id. at 417. Accordingly, a central question in analyzing obviousness is "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.*

2. Scope and Content of the Prior Art

a. Thalomid PI

Thalomid PI is a thalidomide capsules revised package insert. Ex. 1006, 1. Thalomid PI states that, in an effort to make the chance of fetal exposure to thalidomide as negligible as possible, thalidomide is approved by the FDA only under a special restricted distribution program. *Id*. The restricted program is called "System for Thalidomide Education and Prescribing Safety," (i.e., "S.T.E.P.S."). *Id*. According to Thalomid PI, only prescribers and pharmacists registered with the program may prescribe and dispense the product. *Id*. Further, under the program, patients must be advised of, and agree to, comply with the S.T.E.P.S. program in order to receive the product. *Id*. For example, Thalomid PI states that prescriptions for thalidomide for women of childbearing potential must not be issued until a written report of a negative pregnancy test has been obtained by the prescriber. *Id*. at 2. For sexually mature males, patients must acknowledge the need for using barrier contraception. *Id*. at 4. Sexually mature males and women of childbearing potential also are required to be capable of complying with a S.T.E.P.S. patient survey. *Id*. at 3–4. Thalidomide is to be supplied only to pharmacists registered with the S.T.E.P.S. program, and patient compliance with the specific informed consent and patient registry and survey are required prior to dispensing thalidomide. *Id*. at 19.

Thalomid PI describes counseling patients by giving patients both oral and written warnings of the hazards of taking thalidomide. *Id*. at 3–4. In addition to counseling, before starting treatment, women of childbearing potential should have a pregnancy test within 24 hours prior to beginning therapy, so as to avoid risks of severe birth defects or death to an unborn

baby. *Id*. at 1–2. Further, women of childbearing potential are to be referred to a qualified provider of contraceptive methods, if needed. *Id*. at 2. Authorization for thalidomide is provided by a physician only after the patient and physician acknowledge that the patient has been given a warning as to the nature, purpose, and risks of the treatment. *Id*. at 21.

When taking thalidomide, Thalomid PI teaches that pregnancy testing should occur weekly during the first month of use, then monthly thereafter. *Id*. at 2. Thalomid PI also teaches that drug prescribing should be contingent upon initial and confirmed negative results of pregnancy testing. *Id*. at 18. In addition to pregnancy testing, white blood cell count and differential should be monitored on an ongoing basis. *Id*. at 10. Patients taking thalidomide must participate in a survey and patient registry. *Id*. at 20–21.

Thalomid PI describes adverse side effects when taking thalidomide in combination with other drugs. For example, Thalomid PI teaches that thalidomide has been reported to enhance sedative activity of barbiturates, alcohol, chlorpromazine, and reserpine. *Id*. at 12. Further, medications known to be associated with peripheral neuropathy are to be used with caution when taking thalidomide. *Id*. Thalomid PI also teaches testing pharmacokinetic profiles of patients on oral contraceptives. *Id*. at 12.

b. Cunningham

Cunningham describes a method of dispensing, tracking, and managing pharmaceutical product samples. Ex. 1009, 1:6–10. The method involves communicatively linking prescribers and pharmacies to a central computing station. *Id*. at 1:8–11. Specifically, before filling any prescription for a pharmaceutical trial product, a pharmacy must upload

defined information into a central computing station. *Id*. at 11:6–13. Only if the central computing station establishes that the uploaded information is valid, can the central computing station issue a pharmacy approval code for the pharmacy to dispense the pharmaceutical product. *Id*. at 11:13–24.

c. Keravich

Keravich states that pharmacies under the S.T.E.P.S. program are to dispense a maximum 28-day supply and that refills are not authorized. Ex. 1018, 1722. Under the S.T.E.P.S. program, patients are eligible to continue to receive thalidomide, if they participate in a mandatory and confidential patient survey every 30 days for women and 90 days for men. *Id.* Keravich states that Celgene provides telephone and fax services for patient registration, approval, and prescriber verification. *Id*. at 1723–24. Keravich also teaches that the S.T.E.P.S. program patient database provides critical patient related information that is found on a consent form. *Id*. at 1723.

d. Zeldis

Zeldis teaches that the S.T.E.P.S. program provides a method for controlling and monitoring access to thalidomide. Ex. 1012, 319. Zeldis also teaches that thalidomide is efficacious in treating erythema nodosum leprosum (ENL). *Id*. at 320–21.

e. Mundt

Mundt describes the use of interactive voice response systems for clinical research and treatment. Ex. 1024. According to Mundt, the use of interactive voice response systems can strengthen clinical practice, extend

research methods, and enhance administrative support of service quality and value. *Id*. at 612. Mundt also teaches that individuals may disclose sensitive information to a computer that they would be reluctant to discuss with another person and that interactive voice response systems can cost-effectively enhance service. *Id*.

3. Analysis

Petitioner contends that Thalomid PI describes all of the claim limitations recited in independent claims 1 and 28, with the exception of the generation of a prescription approval code to be retrieved by a pharmacy before the prescription is filled. Pet. 52. Petitioner states that one skilled in the art, following the teachings of Thalomid PI and seeking to avoid treating pregnant women with thalidomide, would have implemented the methods disclosed in Cunningham to limit dispensation of a drug associated with adverse effects to certain risk groups. *Id*. at 54. We understand Petitioner as contending that the challenged claims represent a combination of known prior art elements (identifying patient risk groups, collecting patient information relating to the risk, determining whether the risk is acceptable, and controlling dispensation of the drug using both a prescription and an approval code) for their known purpose (control distribution of drug) to achieve a predictable result (avoid giving patients drugs that have an unacceptable risk of side effects). For the reasons provided below, we conclude that Petitioner has demonstrated by a preponderance of the evidence that the challenged claims are obvious over the cited prior art.

a. Person of Ordinary Skill in the Art

Patent Owner contends that Petitioner has failed to demonstrate that the challenged claims would have been obvious to one of ordinary skill in the art. According to Patent Owner, Petitioner conducted its obviousness analysis using the wrong person of ordinary skill in the art. PO Resp. 2. Dr. Fudin, Petitioner's declarant, testified that the art related to pharmaceutical prescriptions and use of computer systems to regulate access to prescription drugs. Ex. 1021, ¶ 13. Dr. Fudin also testified that a person of ordinary skill in the art would typically have either a Pharm.D. or a B.S. in pharmacy with approximately 5–10 years of experience and a license to practice as a registered pharmacist in any one or more of the United States. *Id*. at ¶ 16. Dr. Frau, testifying on behalf of Patent Owner, opined that a person of ordinary skill in the art would have experience in risk management relating to pharmaceutical drug products or B.S. or M.S. in pharmaceutical drug product risk management or related field. Ex. 2059, ¶ 39.

As stated above, we hold on this record that a person of ordinary skill in the art would include a pharmacist and/or persons having at least 2 years of experience in risk management relating to pharmaceutical products as pharmacists. Based on the record presented, we hold that Petitioner has conducted its obviousness analysis from an appropriate person of ordinary skill in the art. Additionally, even we adopted Dr. Frau's definition of ordinary skill in the art verbatim, Patent Owner has failed to present sufficient and credible evidence to persuade us that Patent Owner's defined person of ordinary skill in the art would be led to a different outcome regarding the obviousness of the challenged claims. Specifically, Dr. DiPiro, testifying for Patent Owner, acknowledged that many types of

pharmacists use risk management techniques in their practice on a day-to-day basis. Ex. 1074 at 95:17–96:1. Dr. DiPiro's testimony is consistent with an article he wrote where he stated that pharmacists can be assured of an important role in health care as long as they are focused on needs and problems, such as medication errors and preventable adverse drug effects. Ex. 1073 at 2.

b. Problem to be Solved

Patent Owner states that the challenged claims were conceived as part of Patent Owner's efforts to improve its existing controlled patient access thalidomide program, which is said to be embodied in U.S. Patent No. 6,045,501. PO Resp. 1. Patent Owner states that, as of the effective filing date, the prior art thalidomide program was 100% successful in preventing birth defects associated with thalidomide. *Id*. at 4. Patent Owner contends that Petitioner has not identified any reason to modify or improve upon Patent Owner's prior art thalidomide program. PO Resp. 17. Patent Owner states that Dr. Fudin admitted that there was nothing in the prior thalidomide program that would suggest a problem. *Id*. Additionally, Patent Owner contends that Zeldis, which describes the prior art thalidomide program, fails to supply a person of ordinary skill in the art with any reason to try to improve the restricted distribution program. *Id*. at 18.

Thalidomide is known to cause severe malformations in children of mothers who took the drug during pregnancy, resulting in over 10,000 birth defects in Europe. PO. Resp. 3. As such, as evidenced by the art of record, there are serious concerns regarding the distribution and use of thalidomide. Zeldis teaches that the prior art thalidomide program provided mechanisms

for close constant monitoring to identify noncompliance or other problems, but concluded by stating that Celgene was committed to making the program succeed and would be willing to make any modifications to the program necessary to ensure its effectiveness. Ex. 1012 at 329. This willingness to make any modifications is consistent with the understanding that the underlying drug remains a safety concern because controlling the distribution of the drug does not negate the actual side effects of the underlying drug. In dealing with such drugs, such as those capable of causing severe birth defects, the highest level of safety is desired. Under such circumstances, consistent with the teachings of Zeldis and the art of record one skilled in the art would understand that where significant safety risks exist with a drug, one would continuously search for safer ways to control the distribution of the drug. Put simply, where significant safety concerns exists, one of ordinary skill in the art would not wait until an accident occurred to seek out improvements.

c. Reason to Combine

As stated above, Petitioner contends that the challenged claims, which utilize approval codes to implement known drug restriction requirements, represent no more than an arrangement of old elements with each performing the same functions it had been known to perform and yields no more than one would expect from such an arrangement. Pet. 53–54. Patent Owner contends however, that the prior art did not teach, disclose, or suggest the claimed prescription approval code. PO Resp. 35–39.

Patent Owner states that Cunningham's pharmacy approval code is part of a method of tracking and managing the dispensing of pharmaceutical

trial products and has no connection to patient information at all. *Id*. at 37. Patent Owner also states that Cunningham's pharmacy approval code is merely a number or identifier associated with samples of pharmaceutical products. *Id*. at 38. Patent Owner contends that a person of ordinary skill in the art would therefore have understood that Cunningham's pharmacy approval code is not the same as the claimed prescription approval code. *Id*. at 38.

Cunningham describes a method of dispensing, tracking, and managing pharmaceutical products whereby prescribers and pharmacies are linked to a central computing station. Ex. 1009, 1:6–11. Certain pharmaceutical drugs, such as thalidomide, were known in the art to require a prescription in order for a patient to be provided the drug whereby a prescriber would authorize a patient to receive a drug from a pharmacy. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. Dr. Fudin testified that the use of an approval code of Cunningham could be like that of a consumer credit card approval code, and is used to track things and the technology should allow you to combine it with other materials that you could track. Ex. 2061 at 412:17–25, 429:18–430:10. Based on the record presented, we hold that a person of ordinary skill in the art would understand that an approval code used by prescribers and pharmacies to track and manage pharmaceutical products could likewise be used by prescribers and pharmacies to track and manage prescription pharmaceutical products. We further hold that the claimed improvement recited in the challenged claims represents a combination of known prior art elements (identifying patient risk groups, collecting patient information relating to the risk, determining whether the

risk is acceptable, and controlling dispensation of the drug using both a prescription and an approval code) for their known purpose (control distribution of drug) to achieve a predictable result (avoid giving patients drugs that have an unacceptable risk of side effects).

Patent Owner raised a new contention at Oral Hearing that, with the prior system, a drunk doctor may have let a patient who wanted to have a baby take thalidomide. Tr. at 41:9–23. According to Patent Owner, in contrast to the prior system, the new improved system embodied by the challenged Jepson claims would have caught such a mistake because of the use of the approval code. *Id*. at 41:23–44:22. Patent Owner did not identify sufficient and credible evidence of record to support such a contention or provide sufficient evidence that the existence of drunk doctor prescriptions was a problem to be overcome. Additionally, parties are not permitted to raise new arguments or evidence at oral hearing. *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012).

As to the dependent claims, claims 2–27 and 29–32, Petitioner provides detailed explanations and claim charts identifying where the additional limitations are taught in the prior art. Pet. 22–60. Additionally, Petitioner relies upon the Declaration of Dr. Fudin to demonstrate that the one of ordinary skill in the art would understand that the prior art teaches each and every requirement of the challenged dependent claims, and that one would have had reason to employ the additional requirements in combination with the subject matter of the independent claims. Ex. 1021 ¶¶ 107–233. For the reasons provided in the Petition, and below with respect to claims 5, 6, 10 and 17, we hold that Petitioner has demonstrated

by a preponderance of the evidence that the dependent claims are unpatentable as obvious over the cited prior art.

d. Dependent Claims 5 and 6

Dependent claim 5 requires that the informed consent be verified by the prescriber at the time the patient is registered in the computer readable storage medium. Claim 6 depends from claim 5 and further requires the use of facsimile and optical character recognition software.

Petitioner states that Thalomid PI teaches that prescribers are to screen risk group assignment and informed consent at the time a patient is registered into the controlled drug distribution program. Pet. 42. Dr. Fudin testifies that one of ordinary skill in the art would have reason to have the prescriber verify both risk group assignment and informed consent at the time of computer entry to eliminate error and delay. Ex. 1021 ¶ 220. Dr. Fudin also testifies that it was well known in the art to use optical character recognition software to interpret paper data. *Id*. at ¶ 128.

Patent Owner states that the prior art discloses that pharmacists, not the prescribers, verified the informed consent at the time of patient registration. PO Resp. 40. Specifically, Patent Owner contends that Thalomid PI discloses that the prescriber only ensures that the patient completes the informed consent form, not that the prescriber verifies the informed consent. *Id*. at 41. Rather, Patent Owner states that the pharmacist registers the patient and verifies the informed consent. *Id*. at 42–44.

Both parties agree that Thalomid PI teaches the use of informed consent forms and that the consent forms were entered into the patient registration database prior to dispensing thalidomide to a patient. As Dr.

Fudin testifies, one of ordinary skill in the art would have reason to have the prescriber verify the informed consent at the time the informed consent form is completed. Specifically, Dr. Fudin testifies that one of ordinary skill in the art would understand that prescribers verifying patient consent and associated risk group assignment at the time the consent forms are completed could eliminate error and delay. Ex. 1021, ¶ 220. We credit Dr. Fudin's testimony as it is consistent with the understanding that allowing verification at the time the consent forms are completed reduces the potential for delays associated with incorrectly completed forms.

e. Dependent Claim 10

Claim 10 depends from claim 7, which depends from claim 1. Claim 7 requires that the set of information obtained from a patient include diagnostic testing and claim 10 requires the diagnostic testing comprise genetic testing.

Petitioner contends that genetic testing was a well-known diagnostic procedure as of the effective filing date of the '720 patent. Pet. 58. Petitioner states that it would have been obvious to include genetic testing given that genetic testing was well-known and that such testing was to precede last-resort treatments, such as that disclosed in Thalomid PI. *Id*.

Patent Owner states that the references of record do not disclose or suggest genetic testing. PO Resp. 45. Patent Owner further states that Dr. Fudin has failed to provide evidence in support of his opinion that genetic testing was "common" as of the effective filing date. *Id*. at 46. Patent Owner however, did not dispute that genetic testing was known in the art for obtaining diagnostic information.

Based on the evidence of record, we credit Dr. Fudin's testimony that genetic testing was a known diagnostic procedure as of the effective filing date. Dr. Fudin's testimony is consistent with the FDA Meeting Minutes (Ex. 1013), which contain a statement from a Dr. Holmes, said to represent the American College of Medical Genetics and the Teratology Society. Ex. 1013, 137. According to the FDA Meeting Minutes, Mr. Holmes stated that:

> 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.

Id.

We hold that the genetic testing of dependent claim 10 represents a combination of known elements for their known use to achieve a predictable result, genetic testing to obtain information for diagnosis and treatment.

f. Dependent Claim 17

Claim 17 depends from claim 16, which depends from claim 15. Claim 15 depends from claim 1 and requires defining, obtaining, and entering a second set of information for each risk group. Claim 16 further requires the second set of information comprise a survey regarding patient behavior and compliance. Claim 17 further requires that the survey be conducted telephonically using an integrated voice response system.

Petitioner relies upon Thalomid PI for its teaching of collecting patient survey data regarding behavior and compliance. Pet. 46 (citing Ex. 1006 at 3, 4, 10, 20, and 21). Petitioner also relies upon Mundt, which

teaches that use of interactive voice response systems can strengthen clinical practice, extend research methods, and enhance administrative support of service quality and value. Pet. 59 (citing Ex. 1024, 611–612, 623). Petitioner contends that it would have been obvious to a person of ordinary skill in the art to utilize an integrated voice response system in conducting surveys as such surveys were well known in the art as of the effective filing date and that it is not inventive to provide a mechanical or automatic means to replace a manual activity. Pet. 59.

Patent Owner contends that no single reference disclosed, taught, or suggested the limitation recited in claim 17. PO Resp. 47. Patent Owner notes that Keravich and Zeldis disclose that the patient surveys are physical paper forms. *Id*. at 48. As to Mundt, Patent Owner states that Mundt does not mention using integrated voice response systems for risk group assignments. *Id*. at 49. Additionally, Patent Owner contends that one skilled in the art would not have expected the claimed voice response system to accomplish the same result as paper surveys as paper surveys allow for interactive prescriber/patient risk counseling. *Id*.

Based on the record presented we find that one of ordinary skill in the art would have understood that there are benefits and detriments to both paper surveys and integrated voice response systems. For example, Mundt teaches that individuals may disclose sensitive information to a computer that they would be reluctant to discuss with another person and that interactive voice response systems can cost-effectively enhance service. Ex. 1024 at 612. One of ordinary skill in the art would have been familiar with collecting patient information and would have been able to determine which collection method best served their needs, automated process or in-person

process. We hold that the record demonstrates that the use of integrated response systems in combination with a controlled distribution drug program is a combination of known elements being used for their known purpose to achieve a predictable result, obtaining patient information through an automated process to aid in assessing risk group assignment for prescribing drugs.

g. Remaining Arguments

We have considered Patent Owner's remaining arguments, *e.g.*, implementation would be beyond the level of ordinary skill in the art, but do not find them persuasive. For example, at Oral Hearing, Patent Owner acknowledged that a person of ordinary skill in the art need only to design the invention, and does not need to be able to implement the invention. Tr. 69:12–75:11, 87:11–94:11. Additionally, Patent Owner acknowledged at Oral Hearing that they were not arguing unexpected results for the '720 patent. Tr. at 35:15–18.

We hold that Petitioner has demonstrated by a preponderance of the evidence that claims 1–32 of the '720 patent are unpatentable as obvious over the combined teachings of Thalomid PI in view of Cunningham and further in view of Keravich, Zeldis, and Mundt.

III. Motions to Exclude

Patent Owner filed a Motion to Exclude Evidence. Paper 60. Patent Owner alleges that Petitioner relied improperly upon Mundt (Exhibit 1024) and FDA Meeting (Exhibit 1076). *Id*. at 2. Patent Owner states that Petitioner made statements that are not supported by the exhibits and that the

exhibits should therefore be excluded as out-of-court statements to prove the truth of the matter asserted. *Id*. Patent Owner's objection to Petitioner's statements go to the credibility of the statements made by Petitioner and do not go to the exhibits themselves. A prior art document "is offered simply as evidence of what it described, not for proving the truth of the matters addressed in the document." *See, e.g.*, *Joy Techs., Inc. v. Manbeck*, 751 F. Supp. 225, 233 n.2 (D.D.C. 1990), *judgment aff'd*, 959 F.2d 226 (Fed. Cir. 1992); Fed. R. Evid. 801(c) 1997 Adv. Comm. Note ("If the significance of an offered statement lies solely in the fact that it was made, no issue is raised as to the truth of anything asserted, and the statement is not hearsay."). Therefore, Mundt and the FDA Meeting exhibits are not hearsay under Federal Rule of Evidence 801(c).

Patent Owner alleges that Petitioner relied upon irrelevant evidence and seeks to exclude the evidence as they are irrelevant for the purposes for which it is offered. Paper 60, 3. Petitioner disagrees with Patent Owner and contends that Patent Owner's relevance objections go to the weight given to the evidence. Paper 64, 5–8. We agree with Petitioner. It is the Board's discretion to assign the appropriate weight to be accorded the evidence and we hold that, in this instance, it is not necessary to resort to a formal exclusion of the identified evidence in assessing the sufficiency of the evidence.

Patent Owner contends that Petitioner mischaracterized certain portions of Dr. Frau's testimony. Paper 60, 9–13. Patent Owner states that the testimony should be excluded unless the Board considers the testimony surrounding the context and/or relevant redirect testimony. *Id*. at 9. To the

extent the Board has relied upon the testimony, the Board has reviewed the testimony and the surrounding context.

Additionally, Patent Owner seeks to exclude Exhibit 1076 at page 119 as Petitioner allegedly mischaracterized the particular statement made by Mr. Williams and mischaracterized and/or ignored the full testimony on the issue. *Id*. at 13. Patent Owner states that the Board should exclude the exhibit unless the Board also considers the testimony at Exhibit 1076 pages 118–119. *Id*. at 15. To the extent the Board has relied upon the testimony, the Board has reviewed the testimony and the surrounding context.

Patent Owner's Motion to Exclude is denied for the reasons stated above. Patent Owner is reminded that a motion to exclude is limited to explaining why the evidence is not admissible. A motion to exclude is not the place to challenge the sufficiency of the evidence to prove a particular fact.

Petitioner filed a Motion to Exclude Evidence. Paper 61. Specifically, Petitioner requests that the Board exclude certain testimony of Dr. Fudin elicited during cross examination as the testimony is said to be irrelevant. *Id*. at 1. Petitioner also seeks to exclude Patent Owner's arguments regarding the cited testimony. *Id*. at 3. Petitioner's Motion to Exclude is denied as moot as even taking the evidence into consideration, we hold that Petitioner has established by a preponderance of the evidence that claims 1–32 of the '720 patent are unpatentable as obvious.

IV. Motion for Supplemental Information

Petitioner moves to submit supplemental information concerning FDA Meeting Transcripts (Ex. 1013, 1014) and CDC minutes (Ex. 1015).

Paper 36. Specifically, Petitioner seeks to introduce supplemental evidence that is said to confirm the public availability of Exhibits 1013, 1014 and 1015. *Id*. at 2–3. Patent Owner opposes. Paper 42.

As our Decision does not exclude the disputed exhibits, we deny Petitioner's Motion to Supplement as moot.

V. Motions to Seal

Patent Owner requests that the Board seal Exhibit 2007 in its entirety, along with the unredacted version of the Preliminary Response (Paper 11) and for entry of the Board's Default Protective Order. Paper 10, 1. Patent Owner also requests that the Board seal the unredacted versions of the Patent Owner Response (Paper 40), the Frau Declaration (Ex. 2059) and the DiPiro Declaration (Ex. 2060), which discuss confidential Exhibit 2007. Paper 39, 1. According to Patent Owner, the documents discuss a confidential, non-public submission to the U.S. Food and Drug Administration. *Id*.

Petitioner requests that the Board seal its unredacted Petitioner's Reply to Patent Owner Response (Paper 52) and Exhibits 1074 and 1075 (deposition transcripts). Paper 53, 1. Petitioner states that the documents to be sealed discuss Patent Owner's confidential business information.

Neither party opposes the grant of the motions to seal.

We have reviewed documents sought to be sealed. We conclude that they discuss confidential business information. The content of those documents that is asserted as constituting confidential business information has not been identified in this Final Written Decision in reaching a determination in this proceeding with respect to the claims of the '720

patent. We are persuaded that good cause exists to have those documents remain under seal.

The record will be maintained undisturbed pending the outcome of any appeal taken from this decision. At the conclusion of any appeal proceeding, or if no appeal is taken, the documents may be made public. *See* Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). Further, either party may file a motion to expunge the sealed documents from the record pursuant to 37 C.F.R. § 42.56. Any such motion will be decided after the conclusion of any appeal proceeding or the expiration of the time period for appealing.

VI. CONCLUSION

For the foregoing reasons, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–32 of the '720 patent are unpatentable as obvious over Thalomid PI in view of Cunningham and further in view of Keravich, Zeldis, and Mundt.

VII. ORDER

In consideration of the foregoing, it is:

ORDERED that claims 1–32 of the '720 patent are held unpatentable;

FURTHER ORDERED that Patent Owner and Petitioner's Motions to Seal are *granted*;

FURTHER ORDERED that Patent Owner and Petitioner's Motions to Exclude are *denied*;

FURTHER ORDERED that Petitioner's Motion to File Supplemental Information is *denied*;

and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Sarah Spires
Parvathi Kota
Skiermont Puckett LLP
1096CFAD6@skiermontderby.com

PATENT OWNER:

F Dominic Cerrito
Quinn Emanuel Urquhart & Sullivan, LLP
nickcerrito@quinnemanuel.com

Anthony M. Insogna
Jones Day
aminsogna@jonesday.com