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 IPR2015-01102
Patent No. 6,315,720

PATENT OWNER CELGENE CORPORATION'S NOTICE OF APPEAL

Office of the General Counsel
Patent and Trademark Office
Madison East
10B20 600 Dulany Street
Alexandria, VA 22314

Notice is hereby given, pursuant to 37 C.F.R. § 90.2(a), that Patent Owner Celgene Corporation ("Celgene") appeals under 35 U.S.C. §§ 141 and 142 to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered on October 26, 2016 (Paper No. 75) ("Final Written Decision"), modified in part by the Decision Granting Patent Owner's Request for Rehearing entered on September 8, 2017 (Paper No. 78) ("Rehearing Decision"), and all underlying orders, decisions, rulings, and opinions. Copies of the Final Written Decision and the Rehearing Decision are attached. This appeal concerns the same patent claims as those at issue in the appeals of IPR Nos. 2015-01096 and 2015-01103, which are being filed concurrently.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Celgene further indicates that the issues on appeal are: (1) the correctness of the determination that claims 1-9 and 11-32 of U.S. Patent 6,315,720 are unpatentable, and any finding or determination supporting or related to those issues, as well as all other issues decided adversely to Celgene in any orders, decisions, rulings, and opinions; and (2) whether the Patent and Trademark Office may constitutionally void patents

consistent with Article III and the Seventh Amendment of the United States Constitution.

Copies of this Notice of Appeal are being filed simultaneously with the Director, the Board, and the Clerk of the United States Court of Appeals for the Federal Circuit, along with the filing fee to the Federal Circuit.

Dated: November 6, 2017

Respectfully submitted,

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CERTIFICATE OF FILING

I hereby certify that, in addition to being filed electronically through the Patent Trial and Appeal Board's E2E, the foregoing "Patent Owner Celgene Corporation's Notice of Appeal" was filed by on this sixth day of November, 2017, with the Director of the United States Patent and Trademark Office, by hand delivery at the following address:

Office of the General Counsel
Patent and Trademark Office
Madison East
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CERTIFICATE OF FILING

I hereby certify that a true and correct copy of the foregoing "Patent Owner Celgene Corporation's Notice of Appeal," along with the required $500 filing fee, was filed electronically by CM/ECF on this sixth day of November, 2017, with the United States Court of Appeals for the Federal Circuit, and that a paper copy of the foregoing "Patent Owner Celgene Corporation's Notice of Appeal" was hand-delivered to the Federal Circuit's Clerk's Office at the following address:

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EXHIBIT A

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Paper No: 78
Entered: September 8, 2017

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)
Case IPR2015-01102 (Patent 6,315,720 B1)
Case IPR2015-01103 (Patent 6,315,720 B1)[1]

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

OBERMANN, *Administrative Patent Judge*.

DECISION
Granting Patent Owner's Request for Rehearing
37 C.F.R. § 42.71(d)

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[1] Patent Owner filed a substantially identical Request for Rehearing in each proceeding. IPR2015-01096, Paper 74; IPR2015-01102, Paper 76; IPR2015-01103, Paper 77. This Decision addresses issues common to all cases. Accordingly, we issue a single Decision to be entered in each case. For convenience, we refer to papers filed in IPR2015-01096.

I. INTRODUCTION

On November 25, 2016, Celgene Corporation ("Patent Owner") filed a Request for Rehearing of the Final Written Decision. Paper 74 ("Req."). In the Final Written Decision, we held that claims 1–32 of U.S. Patent No. 6,315,720 B1 ("the '720 patent") are unpatentable. Paper 73, ("Dec."). The Request for Rehearing is confined to our holding that claim 10 is unpatentable. Req. 1; *see* Dec. 27–28 (addressing claim 10).

For reasons that follow, we grant the Request for Rehearing. We are persuaded that the Final Written Decision should be modified as to claim 10. Specifically, we hold that Petitioner fails to establish by a preponderance of the evidence that claim 10 of the '720 patent is unpatentable. This Decision does not disturb our holding, stated in the Final Written Decision, that Petitioner establishes by a preponderance of the evidence that claims 1–9 and 11–32 are unpatentable. Dec. 34.

II. ANALYSIS

Patent Owner asserts that the Board overlooked or misapprehended evidence and arguments showing that the subject matter of claim 10 would not have been obvious under 35 U.S.C. § 103(b). Req. 1.

In pertinent part, 37 C.F.R. § 42.71(d) states:

> The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

Claim 10 depends from claim 7, which depends from claim 1. Claim 1 requires, *inter alia*, defining a set of information to be obtained from a patient. Ex. 1001, 18:30–31. Claim 7 further requires that the "information to be obtained" from the patient "includes the results of diagnostic testing." *Id*. at 18:59–60. Claim 10 requires that "said diagnostic testing comprises genetic testing." *Id*. at 18:66–67.

In the Final Written Decision, we found that the subject matter of claim 10 would have been obvious, even though "the references of record do not disclose or suggest genetic testing." Dec. 27–28. On that point, we credited Dr. Fudin's declaration testimony that genetic testing was a known diagnostic procedure as of the effective filing date of the '720 patent. *Id*. at 28. We reasoned that Dr. Fudin's testimony was consistent with FDA Meeting Minutes (Ex. 1013), which contained a statement from a Dr. Holmes, said to represent the American College of Medical Genetics and the Teratology Society. Ex. 1013, 137. Specifically, 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.

Based on that objective support, we held "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." Dec. 28. Having reconsidered the

record on rehearing, however, we find that this finding is not supported by a preponderance of the evidence.

As an initial matter, Patent Owner argues that the Board improperly shifted the burden of proof by holding that Patent Owner "did not dispute that genetic testing was known in the art for obtaining diagnostic information."[2] Req. 3 (quoting Dec. 27). Patent Owner, in fact, timely disputed that genetic testing would have been understood as common in the art, and identified a gap in Petitioner's evidence on that point. Req. 3 (citing PO Resp. 45–56). Specifically, Patent Owner pointed to the absence of disclosure in the asserted prior art, which teaches various other tests but not genetic testing. PO Resp. 46. Patent Owner argued that the lack of disclosure in the record evidence "undermines Dr. Fudin's opinion that such testing was 'common.'" *Id*.

We agree that the proper focus is not whether Patent Owner disputed that fact, but whether Petitioner came forward with evidence sufficient to demonstrate that genetic testing was known and would have been used in the combination required by claim 10. We also agree that the lack of disclosure in the prior art of record—coupled with the record's disclosure of other types of tests—cuts against a finding "that genetic testing would be used, let alone that it would have been common." Req. 3. Dr. Fudin states that "[i]t was common in the art at the time of" the invention "to conduct genetic

[2] Patent Owner asserts that in its Patent Owner Response it did dispute that genetic testing was known in the art or common. Req. 3. Other than citing its entire argument regarding claim 10, which we already address throughout this Decision, Patent Owner does not identify any specific argument or evidence that we overlooked or misapprehended in connection with this assertion. *Id.*

testing at the same time as the pregnancy testing taught in" the prior art, but directs us to no disclosure in the asserted prior art, or any other objective evidence, on point. Pet. 27–31 (citing Ex. 1021 ¶¶ 141–143).

On that point, Dr. Fudin does not cite, or otherwise explain the significance of, the disclosure in the FDA Meeting Minutes that we relied upon in the Final Written Decision. Ex. 1021 ¶¶ 140–143. PO Resp. 45–46; Pet. 58 (citing Ex. 1021 ¶¶ 229–231); Dec. 28. That disclosure, cited for the first time in Petitioner's Reply[3], does not refer to genetic testing, much less suggest using genetic testing in the combination required by claim 10. Reply 25–26 (citing Ex. 1076[4], 137); *see* Req. 3 (arguing on rehearing that the Petitioner "relied solely on a single passage" in the FDA Meeting Minutes "that focuses on the geneticist acting as a clinical teratologist that might counsel patients on the risks of exposure") (citing Reply 25–26; Ex. 1013, 137). Patent Owner correctly points out that "the cited passage says nothing about genetic testing, nor does it suggest such testing." Req. 3 (emphasis omitted); Ex. 1013, 137; Ex. 1076, 137.

We find that the FDA Meeting Minutes fail to support adequately Dr. Fudin's opinion testimony that genetic testing would have been common at the time of the invention. Contrary to "Dr. Fudin's opinion that [genetic] testing was 'common,'" the asserted prior art references do not disclose, teach, or suggest genetic testing, "despite disclosing various other types of

[3] The Petition cites other disclosures in the FDA Meeting Minutes to support arguments unrelated to the genetic testing limitation of claim 10. Pet. 13–14 (citing Ex. 1013).

[4] The same material appears on page 137 of Exhibit 1013, which is cited in the Final Written Decision. Dec. 28.

tests." Req. 2; PO Resp. 46. Given that Dr. Fudin's opinion on that point is unsupported by objective evidence, we assign his testimony little weight in the analysis of claim 10. Req. 2–3; PO Resp. 46 (citing 37 C.F.R. § 42.65(a) and *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985)). The gap in the disclosures of the prior art, occurring at or near the time of the invention, carries more weight than the much later, unsupported opinion of Dr. Fudin.

Petitioner fails to demonstrate that it would have been obvious at the time of the invention to use genetic testing in the method of claim 10. Req. 3. The objective evidence on point consists of a single paragraph from the FDA Meeting Minutes, raised in Petitioner's Reply, which is not relied upon in the relevant witness testimony, and does not disclose genetic testing. Accordingly, we hold that Petitioner fails to establish by a preponderance of the evidence that claim 10 is unpatentable.

II. CONCLUSION

For the foregoing reasons, Patent Owner establishes that the Final Written Decisions in each proceeding should be modified to hold that, based on the record developed in this proceeding, a preponderance of the evidence demonstrates that claim 10 is not proven unpatentable.

III. ORDER

It is

ORDERED that the Request for Rehearing is *granted*;

FURTHER ORDERED that the Final Written Decision is modified to hold that, based on the record developed in this proceeding, a preponderance of the evidence demonstrates that claim 10 is not proven unpatentable;

FURTHER ORDERED that this Decision does not disturb the holding in the Final Written Decision that Petitioner establishes by a preponderance of the evidence that claims 1–9 and 11–32 are unpatentable.

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EXHIBIT B

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Papel No. 75
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 IPR2015-01102
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 41 ("PO Resp." with redacted version Paper 42). Petitioner filed a Reply. Paper 54 ("Reply" with a redacted version Paper 53). Additionally, Petitioner filed Motions to Submit Supplemental Information (Papers 36 and 37), a Motion to Exclude Evidence (Paper 63) and a Motion to Seal (Paper 55). Further, Patent Owner filed a Motion to Exclude Evidence (Paper 62) and Motions to Seal and for Entry of Protective Order (Papers 10 and 40).

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 74 ("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. et al. 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, IPR2015-01096 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, claims 1 and 28, is 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 and 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:

R.J. Powell & J.M.M Gardner-Medwin, *Guideline for the clinical use and dispensing of thalidomide*, 70 POSTGRAD MED. J. 901, 901–04 (1994) ("Powell") (Ex 1006)

Benjamin R. Dishman *et al.*, *Pharmacists' role in clozapine therapy at a Veterans Affairs medical center*, 51 AM. J. HOSP. PHARM. 899, 899–901 (1994) ("Dishman") (Ex 1007)

U.S. 5,832,449; Nov. 3, 1998 ("Cunningham") (Ex. 1008)

James C. Mundt, *Interactive Voice Response Systems in Clinical Research and Treatment*, 48:5 PSYCHIATRIC SERVICES 611, 611–12, 623 (1997) ("Mundt") (Ex. 1017)

Thaddeus Mann & Cecelia Lutwak-Mann, *Passage of Chemicals into Human and Animal Semen: Mechanisms and Significance*, 11:1 CRC CRITICAL REVIEWS IN TOXICOLOGY 1, 1–14 (1982) ("Mann") (Ex. 1018)

Cori Vanchieri, *Preparing for Thalidomide's Comeback*, 127:10 ANNALS OF INTERNAL MED. 951, 951–54 (1997) ("Vanchieri") (Ex. 1019)

Arthur F. Shinn et al., *Development of a Computerized Drug Interaction Database (MedicomSM) for Use in a Patient Specific Environment*, 17 DRUG INFORM. J. 205, 205–10 (1983) ("Shinn") (Ex. 1020)

R. Linnarsson, *Decision support for drug prescription integrated with computer-based patient records in primary care*, 18:2 MED. INFORM. 131, 131–42 (1993) ("Linnarsson") (Ex. 1021)

P.E. Grönroos et al., *A medication database – a tool for detecting drug interactions in hospital*, 53 EUR. J. CLIN. PHARMACOL. 13, 13–17 (1997) ("Grönroos") (Ex. 1022)

M. Soyka et al., *Prevalence of Alcohol and Drug Abuse in Schizophrenic Inpatients*, 242 EUR. ARCH. PSYCHIATRY CLIN. NEUROSCI. 362, 362–72 (1993) ("Soyka") (Ex. 1023)

Edna Hamera et al., *Alcohol, Cannabis, Nicotine, and Caffeine Use and Symptom Distress in Schizophrenia*, 183:9 J. OF NERVOUS AND MENTAL DISEASE 559, 559–65 (1995) ("Hamera") (Ex. 1024)

Thomas R. Kosten & Douglas M. Ziedonis, *Substance Abuse and Schizophrenia: Editors' Introduction*, 23:2 SCHIZOPHRENIA BULLETIN 181, 181–86 (1997) ("Kosten") (Ex. 1025)

Jeffrey C. Menill, *Substance Abuse and Women on Welfare*, NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA UNIVERSITY 1–8 (1994) ("Menill") (Ex. 1026)

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**
Powell and Dishman in view of Cunningham and further in view of Mundt, Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill.[1]	§ 103	1–32

[1] Petitioner's heading merely states that claims 1–32 are obvious over Powell and Dishman in view of Cunningham and further in view of the knowledge of one of ordinary skill in the art. Pet. 17. The Petition, however, goes on to rely upon additional art to explain the knowledge possessed by one skilled in the art at the time of the invention and cites additional references to support its position. Specifically, the Petitioner relies upon Mundt, Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill. In the Decision to Institute we include the additional art relied upon, Mundt, Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill, in the stated grounds, so that the record was clear as to the prior art relied upon. Dec. on Inst.

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. 1027, Declaration of Dr. Jeffrey Fudin, ¶¶ 13, 16. Patent Owner disagrees with Petitioner's definition of a person of ordinary skill in art contends that 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; 1008; 1011; 2062; 2066. 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. 1027 ¶¶ 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, 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. 1086, 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. 10. Petitioner 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 the identified 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. 21–23. 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 22–23. Petitioner disagrees stating that there is no requirement for an "affirmative" risk assessment. Reply 7–9.

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. 22–23. Specifically, Patent Owner overcame the rejection by noting that the

prior art cited by the Examiner merely described an "identifier for the prescription, and is 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 Powell and Dishman in view of Cunningham and further in view of Mundt, Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill

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. 23. Patent Owner disagrees. PO Resp. 24–60.

1. Background on Obviousness

A claimed invention is not patentable under 35 U.S.C. § 103 if it is

obvious. *See KSR Int'l 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. Powell

Powell is an article that describes guidelines designed to promote the safest possible clinical use and dispensing of thalidomide. Ex. 1006, 901. Powell teaches that certain patients should be specifically excluded from treatment with thalidomide. *Id.* Patients to be excluded include women of childbearing potential who have not practiced a reliable form of

contraception for 1 year, are unwilling to take reliable contraceptive precautions, and those who are not considered capable of complying with the requirements for reliable contraception. *Id.* Additionally, Powell excludes pregnant women by requiring that a pregnancy test be taken within the 2 weeks prior to starting therapy. *Id.*

Powell teaches that fully informed consent should be obtained using a written consent form. *Id.* Powell also teaches that appropriate clinical and electrophysiological measurements should be recorded before treatment is commenced, and that follow-up visits should be at monthly intervals. *Id.* at 902. Warnings about possible toxicity and adequate contraception should be reinforced during the follow-up visits. *Id.* Powell provides a sample patient information sheet containing information regarding use and potential side effects of thalidomide including "[*d*]*amage to babies*." *Id.* at 902–903.

b. Dishman

Dishman is an article that describes a Veterans Affairs program for controlling the dispensation of clozapine, an antipsychotic drug. Ex. 1007. A high frequency side effect of clozapine is agranulocytosis, a life-threatening side effect. *Id.* at 899. To avoid such effects, Dishman teaches that prescribers and patients must be registered in a national registry, patients are monitored weekly, and that only a one-week supply is dispensed at a time. *Id.* Further, pharmacists may only dispense clozapine upon the pharmacist's verification that the patient's white blood cell counts are within acceptable limits. *Id.*

To ensure proper patient monitoring, the VA developed its own clozapine monitoring program. *Id.* at 900. The VA established a National

Clozapine Coordinating Center (NCCC) where physicians review each candidate's file before granting approval for use and review weekly patient tracking sheets. *Id.* The NCCC requires each hospital have a computerized clozapine prescription lockout system tied to the hospital's laboratory database and outpatient pharmacy dispensing software. *Id.* The lockout system prevents the filling of a clozapine prescription where the computer notices three consecutive drops in the white blood cell count. *Id.*

Dishman teaches that the NCCC requires extensive patient evaluation and documentation. *Id.* In particular, a complete physical examination is required and certain clozapine therapy contraindications are noted including seizures and pregnancy. *Id.*

c. Cunningham

Cunningham describes a method of dispensing, tracking, and managing pharmaceutical product samples. Ex. 1008, 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.

d. Mundt

Mundt describes the use of interactive voice response systems for clinical research and treatment. Ex. 1017. 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*.

e. Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill

The references, Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill (Exs. 1018–1026) are cited by Petitioner as indicative of the knowledge of one of ordinary skill in the art. For example, Petitioner cites Mann and Vanchieri as demonstrating that it was well known in the art that certain drugs, such as thalidomide, could be transmitted to a sexual partner of a male undergoing treatment with the drug. Pet. 31–32. Petitioner cites Shinn, Linnarsson, and Grönroos as demonstrating that it was well known in the art that drug-drug interactions could cause serious and even lethal adverse side effects. *Id.* at 41–42. Petitioner states that Dishman's regimen was designed to treat schizophrenics and that Soyka, Hamera and Kosten demonstrate that it was well known in the art that substance abuse was prevalent among schizophrenics. *Id.* at 42–43. Further, Petitioner cites Menill as demonstrating that it was well known in the art that people are generally reluctant to admit to alcohol or drug abuse and addiction. *Id.* at 43–44.

3. Analysis

Petitioner contends that one skilled in the art would understand that Powell describes the desirability of obtaining patient information and defining patient risk groups, based on the information, when treating patients with drugs associated with adverse side effects to certain risk groups. Pet. 19. Petitioner states that Powell teaches a checklist for assigning patients to risk groups, for example, risk groups that can and cannot be administered drugs such as thalidomide. *Id*. Petitioner states further that Powell discloses that risk groups include women who wish to become pregnant, and patients who cannot comply with the prescribing instructions. *Id*. at 19–20. Petitioner acknowledges that Powell does not describe explicitly the use of a specific computerized registry to store the risk group information. *Id*. Petitioner states that one skilled in the art would recognize that storing risk group assignments in a computer registry, such as that described by Dishman, would be useful. *Id*. at 20–21.

Petitioner relies upon Dishman for its disclosure of a program for tightly controlling the dispensation of the antipsychotic drug clozapine. *Id*. at 20. Specifically, Petitioner cites Dishman for its description of a computerized clozapine lockout system that ties a hospital's lab database to outpatient pharmacy dispensing software. *Id*. at 21. The lockout system prevents the filling of clozapine prescriptions where the computer notices three consecutive drops in white blood cell count. *Id*. at 22. Although Dishman does not mention an approval code, Petitioner states that it would have been obvious to one of ordinary skill in the art at the time of the invention to employ an approval code system in the system of Dishman. *Id*. at 22–24. According to Petitioner, it would have been obvious to combine

Dishman's computer lockout system with the computer approval code system taught by Cunningham to limit the dispensation of a drug, where the drug was known to be associated with adverse effects to certain risk groups. *Id*. at 23–24.

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. 1027, ¶ 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 the perspective of an appropriate person of ordinary skill in the art. Additionally, even if 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. 1085 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. 1084 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. 1011 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. 23. Patent Owner contends however, that the prior art did not teach, disclose or suggest the claimed prescription approval code. PO Resp. 34–40.

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 38. Patent Owner also states that Cunningham's pharmacy approval code is merely a number or identifier associated with samples of pharmaceutical products. *Id*. at 39. Patent Owner contends that a person of ordinary skill in the art would have therefore understood that Cunningham's pharmacy approval code is not the same as the claimed prescription approval code. *Id*. at 39–40.

Cunningham describes a method of dispensing, tracking, and managing pharmaceutical products whereby prescribers and pharmacies are linked to a central computing station. Ex. 1008, 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 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).

We conclude that, based on the evidence of record, Petitioner has demonstrated by a preponderance of the evidence that the independent claims would have been obvious to one of ordinary skill in the art over the cited prior art.

As to the dependent claims, claims 2–27 and 29–32, Petitioner provides detailed claim charts identifying where the additional limitations are taught in the prior art. Pet. 48–60. For example, as to claim 4, which requires filling a prescription only after informed consent, Petitioner identifies how Powell teaches that thalidomide should only be prescribed after fully informed consent has been obtained using a written consent formed. Pet. 49; Ex. 1006, 901. 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. 1027 ¶¶ 109–202. 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 Powell teaches that a doctor prescribing thalidomide is responsible for the patient's welfare and that the patient is to be given an information sheet that counsels as to the severe side effects of thalidomide, including toxicity to developing babies. Pet. 25–26. Petitioner further states that Powell teaches that fully informed consent should be obtained using a written consent form and signed agreement. *Id.* at 26. Petitioner also relies upon Dishman for its teaching that pharmacists fax tracking sheets containing weekly follow-up evaluations to a central coordinating center. *Id*. at 26–27. Petitioner states that it was known in the art to transfer paper data into a computer database by fax and use optical character recognition to interpret the data. *Id*. at 27 (citing Ex. 1027, ¶ 121).

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. 41–45. Specifically, Patent Owner contends that Powell merely teaches that the prescriber give the patient an information sheet and provides risk counseling. *Id*. at 41. As to Dishman, Patent Owner contends that Dishman teaches only that the pharmacist forwards patient information to the central coordinating center and the doctors at the coordinating center review the patient file before approving usage of the drug. *Id*. at 42.

Powell specifically states that the physician prescribing thalidomide is entirely responsible for the patient's welfare. Ex. 1006 at 902. The doctor is responsible for informing the patient of any contraindications, warning and precautions associated with thalidomide. *Id*. Suppliers, however, are not required to provide contraindications, warnings and precautions. *Id*. Dishman teaches that, to avoid physician's having to evaluate candidates who are not ineligible for clozapine therapy, candidates are to be screened by pharmacists by reviewing the patient file and interviewing the patients. Ex. 1007 at 900. We credit Dr. Fudin's testimony that it would have been obvious to have the prescribing doctor verify the patient's informed consent and risk group assignment, as Powell teaches that doctors, as opposed to pharmacists, are required to provide patients with contraindications, warnings and precautions.

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. 29–30. 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 Powell and Dishman. *Id*.

Patent Owner states that the references of record do not disclose or suggest genetic testing. PO Resp. 47. 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 47–48. 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. 1012, 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 Powell and Dishman for their teaching of collecting patient survey data regarding behavior and compliance. Pet. 36 (citing Ex. 1006 at 901 and Ex. 1007 at 900). 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. 37 (citing Ex. 1017 at 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. *Id*.

Patent Owner contends that Mundt failed to disclose, teach or suggest the limitation recited in claim 17. PO Resp. 48. Specifically, Patent Owner states that Mundt does not mention using integrated voice response systems for risk group assignments. *Id*. Patent Owner also contends that Powell and Dishman's surveys would have been completed during in-person patient interviews and follow-up appointments and that Keravich and Zeldis disclose that their patient surveys are physical paper forms. *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. 1017 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 Powell and Dishman in view of Cunningham and further in view of Mundt, Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill.

III. Motions to Exclude

Patent Owner filed a Motion to Exclude Evidence. Paper 62. Patent Owner alleges that Petitioner relied improperly upon Mundt (Exhibit 1017) and FDA Meeting (Exhibit 1012). *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 they are offered. Paper 62, 3. Petitioner disagrees with Patent Owner

and contends that Patent Owner's relevance objections go to the weight given to the evidence. Paper 66, 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 62, 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 10. 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 1012 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 14. Patent Owner states that the Board should exclude the exhibit unless the Board also considers the testimony at Exhibit 1012 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 63. 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. 1012, 1013) and CDC minutes (Ex. 1014). Paper 36. Specifically, Petitioner seeks to introduce supplemental evidence that is said to confirm the public availability of Exhibits 1012, 1013 and 1014. *Id*. at 2–3. Patent Owner opposes. Paper 43.

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

Petitioner also moves to submit supplemental information concerning Menill to demonstrate its public accessibility. Paper 36, 2. Patent Owner opposes. Paper 44. As Patent Owner did not challenge the public accessibility of Menill, 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 41), the Frau Declaration (Ex. 2059) and the DiPiro

Declaration (Ex. 2060), which discuss confidential Exhibit 2007. Paper 40, 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 54) and Exhibits 1085 and 1086 (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 Powell and Dishman in view of Cunningham and further in view of Mundt, Mann, Vanchieri, Shinn, Linnarsson, Grönroos, Soyka, Hamera, Kosten, and Menill.

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 Motions to File Supplemental Information are *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.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), this is to certify that I caused to be served a true and correct copy of the foregoing "Patent Owner Celgene Corporation's Notice of Appeal" on November 6, 2017, by a Priority Mail Express® to counsel for Petitioner at the following addresses:

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Date: November 6, 2017

By */s/ Gregory A. Castanias*
Gregory A. Castanias