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Paper 73
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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 IPR2015-01092
Patent 6,045,501

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

OBERMANN, *Administrative Patent Judge*.

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

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review of claims 1–10 ("the challenged claims") of U.S. Patent No. 6,045,501 (Ex. 1001, "the '501 patent"). We have jurisdiction under 35 U.S.C. § 6. We find that Petitioner shows by a preponderance of the evidence that claims 1–10 are unpatentable under 35 U.S.C. § 103. We deny the parties' Motions to Exclude Evidence. Papers 57, 58. In addition, we deny Petitioner's Motion to Submit Supplemental Information. Paper 36. We grant Patent Owner's combined Motion to Seal and Motion for Entry of Protective Order. Paper 39. We grant Petitioner's Motion to Seal. Paper 50.

A. Procedural History

The Petition for *inter partes* review was filed pursuant to 35 U.S.C. § 311. Paper 1 ("Pet."). Patent Owner filed a Preliminary Response. Paper 10 ("Prelim. Resp."). We instituted trial on the single ground whether claims 1–10 are unpatentable under 35 U.S.C. § 103(a) as obvious over Powell,[1] Mitchell,[2] and Dishman.[3] Paper 20 ("Dec.").

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[1] *Guideline for the clinical use and dispensing of thalidomide*, R.J. Powell and J.M.M Gardner-Medwin, *Postgrad Med. J.* (1994) 79, 901–904 (Ex. 1005, "Powell").

[2] *A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, Allen A. Mitchell *et al.*, *New Eng. J. Med.* (Jul. 13, 1995) 333:2, 101–06 (Ex. 1006, "Mitchell").

[3] *Pharmacists' role in clozapine therapy at a Veterans Affairs medical center*, Benjamin R. Dishman *et al.*, *Am. J. Hosp. Pharm.* (Apr. 1, 1994) 51, 899–901 (Ex. 1007, "Dishman").

Patent Owner filed a Response (Paper 40, "Resp.") and Petitioner filed a Reply (Paper 49, "Reply"). Patent Owner filed a Sur-Reply and Petitioner filed a Response to the Sur-Reply pursuant to authorization provided by the Board during an interlocutory teleconference held June 13, 2016. Paper 59 (order authorizing Sur-Reply, limited to two defined issues, and an Opposition thereto); Paper 60 ("Sur-Reply"); Paper 66 (response to the Sur-Reply). A final oral hearing was held July 21, 2016. The record includes a transcript of the final oral hearing. Paper 72.

B. Related Proceedings

Petitioner identifies six district court actions relating to the '501 patent: *Celgene Corp. v. Lannett Holdings, Inc.*, DNJ-2:15-cv-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.

C. The '501 Patent (Ex. 1001)

The '501 patent relates to a method of delivering a teratogenic drug to a patient while preventing delivery to a fetus. Ex. 1001, Abstract. The patent discusses the history of thalidomide, a drug first synthesized in 1957 and marketed in many countries as a sedative. *Id*. at 1:19-22. Thalidomide was withdrawn from all markets by 1962 after reports of serious birth defects. *Id*. at 1:22–24.

Investigators thereafter discovered that thalidomide might be effective in treating cancer, AIDS-related ulcers, macular degeneration, and other serious conditions. *Id*. at 1:29–36. For example, Patent Owner received approval to market thalidomide for treating a type of leprosy. *Id*. at 1:24–29; 36–39.

According to the specification of the ’501 patent, however, given the severe teratogenic risks associated with thalidomide, at the time of the invention, there was a need for a method to prevent administration of the drug to fetuses and persons for whom the drug was contraindicated. *Id*. at 1:41–46.

The ’501 patent describes an existing pregnancy-prevention program developed for women prescribed Accutane (isotretinoin), a known teratogenic drug effective for treating severe forms of acne. *Id*. at 1:48–60. According to the ’501 patent, enrollment in the Accutane program was voluntary, therefore, “improved methods” were needed to provide a distribution system “more representative of all users of a particular drug, such as thalidomide.” *Id*. at 1:60–67. The ’501 patent also discloses a need for a program “to educate men and women about the risk of teratogenic drugs, such as thalidomide.” *Id*. at 2:1–5.

The specification describes registering patients, prescribers, and pharmacies in a computer readable storage medium; retrieving from the medium information identifying a subpopulation of women capable of becoming pregnant, as well as males capable of impregnating females; providing counseling information about the risks of a teratogenic drug to the subpopulation; determining whether patients in the subpopulation are pregnant; and, in response to a determination of non-pregnancy, authorizing registered pharmacies to fill prescriptions from registered prescribers for non-pregnant registered patients. *Id*. at 2:16–37.

D. Illustrative Claim

Claim 1, the only independent claim, is illustrative and is reproduced below:

> 1. A method for delivering a teratogenic drug to patients in need of the drug while avoiding the delivery of said drug to a foetus comprising:
>
> a. registering in a computer readable storage medium

prescribers who are qualified to prescribe said drug;

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

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

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

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

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

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

II. DISCUSSION

Petitioner alleges that claims 1–10 are unpatentable as obvious over the combined disclosures of Powell, Mitchell, and Dishman.[4] In support of that challenge, Petitioner relies on the Declaration of Jeffrey Fudin, Pharm.D. (Ex. 1002).[5] Patent Owner responds that the claims are not proven invalid, relying

[4] Citations are to original page numbers, not those added by Petitioner.

[5] Dr. Fudin is a registered pharmacist, holding a B.S. in Pharmacy and a Pharm.D. Ex. 1002 ¶¶ 6, 9. Petitioner shows sufficiently that Dr. Fudin has practiced as a

on the Declarations of Dr. Lourdes Frau (Ex. 2059), Dr. Joseph DiPiro (Ex. 2060), and Mr. John Freeman (Ex. 2068).[6] We hold that Petitioner demonstrates by a preponderance of the evidence that the subject matter of claims 1–10 would have been obvious over the combined disclosures of Powell, Mitchell, and Dishman.

A. Principles of Law

Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Obviousness is resolved based on underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of

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Clinical Pharmacy Specialist for more than 20 years, and is the Director of a Pain and Palliative Care Pharmacy Residency. *Id*. at ¶ 4. We determine that Dr. Fudin is qualified to opine on the views of a person of ordinary skill in art at the time of the invention.

[6] Patent Owner offers Dr. Frau's opinions to respond to Petitioner's obviousness challenge "through the eyes of" an ordinary artisan as defined by Patent Owner. Patent Owner also advances the testimony of Dr. DiPiro, who "offers no opinion on the appropriate level of ordinary skill in the art, but responds directly to Dr. Fudin's opinions through the eyes of" the ordinary artisan as defined by Petitioner. Resp. 16 n.4. Mr. Freeman provides testimony in support of Patent Owner's contentions regarding secondary considerations of nonobviousness. *Id*. at 59–60.

skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

Petitioner argues that "[t]he level of ordinary skill in the art is apparent from the cited art." Pet. 20. Petitioner also directs us to witness testimony that an ordinary artisan "would typically have either a Pharm. D. or a BS in pharmacy with approximately 5–10 years of related experience and a license to practice as a registered pharmacist in any one or more the United States." *Id*. (citing Ex. 1002 ¶ 15). Patent Owner counters that Petitioner challenge is "fatally flawed" for having failed to define correctly the person of ordinary skill in the art. *Id*. at 13, 15. On that point, Patent Owner argues that an ordinary artisan "would have had at least a bachelor's degree and 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." *Id*. at 16 (citing Ex. 2059 ¶ 60).

We are not persuaded that accepting Patent Owner's view of the qualifications of an ordinary artisan, over the somewhat different qualifications proposed by Petitioner, would materially alter the obviousness inquiry. The prior art references asserted in the Petition are representative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (absence of specific findings on "level of skill in the art does not give rise to reversible error 'where the prior art itself reflects an appropriate level and a need for testimony is not shown'" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985))).

To the extent that a more specific definition of the ordinary artisan is required, we hold that the definition encompasses pharmacists and other persons having experience restricting the distribution of teratogenic drugs. Specifically, we

find that the prior art references, like the '501 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"); Ex. 1005, 901 (Powell, disclosing guidelines for restricting the distribution of thalidomide); Ex. 1006, 101 (Mitchell, describing a method for restricting the distribution of the teratogenic drug Accutane); Ex. 1007, 899 (Dishman, describing a national registry for restricting distribution of the psychoactive drug Clozaril).

Consistent with the prior art, Dr. Fudin testifies that the types of problems encountered by a person of ordinary skill in the art included creating a restricted drug distribution program to prevent adverse side effects, such as teratogenic risks. Ex. 1002 ¶¶ 33–55. The prior art demonstrates that a person of ordinary skill in the art would have experience in controlling the distribution of a drug. We credit Dr. Fudin's testimony that a person of ordinary skill in the art would encompass a pharmacist. Ex. 1002 ¶ 15. We also credit Dr. Frau's testimony that an ordinary artisan would not be limited to pharmacists but also would encompass persons having at least two 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 ¶ 60.

Accordingly, we find that a person of ordinary skill in the art would include pharmacists and persons having at least two years of experience in risk management relating to pharmaceutical products as pharmacists. Additionally, we determine that, even if we were to adopt verbatim Dr. Frau's definition of ordinary skill in the art, 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. 1066, 95:17–96:1. Dr. DiPiro's testimony is consistent with an article he wrote where he stated that pharmacists could 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. 1065, 2. Accordingly, we determine that Petitioner appropriately has conducted its obviousness analysis from the perspective of a person of ordinary skill in the art.

C. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are assigned their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Claim terms generally are given their ordinary and customary meaning as understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). If an inventor acts as his or her own lexicographer, the definition must be set forth with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

No claim term requires express construction for the purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co*., 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). One issue of claim construction, however, requires some discussion. Patent Owner argues that the term "computer readable storage medium" in claim 1 should be read to require a "centralized" computer readable storage medium—namely "a centralized database that includes all registration information regarding the claimed prescribers, pharmacies, and

patients." Resp. 22, 35. We are not persuaded that the wording of the claim, or the disclosure of the '501 patent specification, supports Patent Owner's view.

The word "centralized" does not appear anywhere in claim 1. And Patent Owner's position—that the storage medium of claim 1 must be "centralized" to include, in one database, all registration information—is not supported by the disclosure of the '501 patent specification:

> In accordance with the methods described herein, pharmacies which may fill prescriptions for the particular drug being prescribed including, for example, teratogenic drugs, are also preferably registered in a computer readable storage medium. *The computer readable storage medium in which the pharmacies are registered may be the same as, or different from the computer readable storage medium in which the prescribers are registered.*

Ex. 1001, 4:50–57 (emphasis added); *see id*. at 10:12–16 ("registration into one or more computer readable storage media of the prescriber, pharmacy and patient . . . provide[s] a means to monitor and authorize distribution of" teratogenic drugs).

Patent Owner further argues that the inventors of the '501 patent disavowed the full scope of claim 1 during patent prosecution. Resp. 22–23. That argument is unpersuasive because the prosecution history upon which Patent Owner relies supports the specification disclosure that claim 1 is directed to a method for centralizing access to information, and does not suggest that the information must be located in one single structure, a database, that contains all of the information. *See* Ex. 1004, 78 (prosecution history, distinguishing computer readable storage medium from internet communication); Reply 9 (explaining why prosecution history does not rise to the level of disclaimer of claim scope) (citing Ex. 1003, 1).

Patent Owner also directs us to extrinsic evidence, including Dr. Fudin's deposition testimony, which does not trump the persuasive intrinsic evidence in this case. *See* Resp. 23 and n.5 (arguing that Dr. Fudin

agreed that the challenged claims require a centralized storage medium). In any event, as explained below, even if we were to apply Patent Owner's proposed construction of the term "computer readable storage medium," our ultimate conclusion on the question of obviousness would not change.

D. Patent Owner's Sur-Reply

During an interlocutory teleconference held June 13, 2016, we authorized Patent Owner to file a Sur-Reply limited to two discrete issues. Paper 59 (order relating conduct of proceeding). Patent Owner styles its Sur-Reply as a Motion to Strike and asserts that the Board authorized a Motion to Strike during the teleconference. Sur-Reply 1. On the contrary, we authorized a Sur-Reply limited to addressing: 1) alleged "new" issues raised in Petitioner's Reply; and 2) antedating the references cited in Petitioner's Reply. Order, 3. In this Decision, we consider the Sur-Reply only to the extent that it complies with our Order. *Id*.

We authorized the Sur-Reply specifically to afford Patent Owner an opportunity to address antedating evidence that it claimed to have had in its possession at the time of the teleconference, yet Patent Owner fails to present any antedating evidence in the Sur-Reply. Sur-Reply 3, 9–10. Accordingly, we hold that Patent Owner has waived its opportunity to address any antedating evidence.

Further, Patent Owner in the Sur-Reply does not persuade us that the two prior art references sought to be antedated and excluded (identified by the parties as Marwick (Ex. 2063) and Vanchieri (Ex. 2064) (*id*. at 9; Reply 1)) represent "new" evidence raised improperly in Petitioner's Reply. Patent Owner itself introduced those references into the record by citing them in the Response, and Patent Owner's own experts cited them in support of propositions related to the state of the prior art. Resp. 58; Ex. 2059 ¶¶ 26, 45, 101; Ex. 2060 ¶¶ 99, 103, 104.

On this record, we find unpersuasive Patent Owner's suggestion that those references do not qualify as prior art. Sur-Reply 3, 9–10.

We also find unpersuasive Patent Owner's suggestion that it has been prejudiced by Petitioner's discussion of those references in the Reply. Sur-Reply 3–6. Petitioner's discussion of those background references in the Reply does not unfairly prejudice Patent Owner, where Patent Owner itself introduced them into the record in the context of describing the state of the prior art. Resp. 58; Ex. 2059 ¶¶ 26, 45, 101; Ex. 2060 ¶¶ 99, 103, 104. A third reference (identified as Zeldis (Ex.1068) (Sur-Reply 2)) was fairly raised in the Reply to counter arguments and evidence asserted in the Response addressing whether an ordinary artisan would have formed a reasonable expectation of success in combining the disclosures of the applied prior art, namely, Powell, Mitchell, and Dishman. Resp. 53–54; Reply 10–11.

E. Analysis of the Ground of Unpatentability

The single ground of unpatentability at issue in this case is whether the subject matter of claims 1–10 of the '501 patent would have been obvious to a person of ordinary skill in the art at the time of the invention over the combined disclosures of Powell, Mitchell, and Dishman. We first analyze the prior art against claim 1, the only independent claim, and then address dependent claims 2–10. Before reaching our ultimate conclusion on the question whether the subject matter of any challenged claim would have been obviousness at the time of the invention, we take account of available objective evidence of secondary considerations of nonobviousness.

1. Analysis of Claim 1 over Powell, Mitchell, and Dishman

We first address whether the combined disclosures of the asserted prior art discloses or suggests the invention of claim 1 of the '501 patent. We determine that the following facts are supported by a preponderance of the evidence.

Powell provides guidance regarding "the clinical use and dispensing" of thalidomide. Pet. 21 (quoting Ex. 1005, 901). Mitchell relates to an existing pregnancy-prevention program for women users of Accutane, a Vitamin A analogue of isotretinoin and a known teratogenic drug. Pet. 15; Ex. 1006, 101–102. Dishman describes a registry for pharmacies, prescribers, and users of Clorazil, a potent anti-psychotic drug with potential for serious side effects. Pet. 27–28 (quoting Ex. 1007, 899). A person of ordinary skill in the art would have understood how to implement Powell's teachings "in clinical and pharmacy settings" in view "of the Accutane Pregnancy Prevention Program described in Mitchell and the Clozaril controlled distribution model outlined in Dishman." *Id.* at 21 (quoting Ex. 1002 ¶ 88).

a. Women as a Subpopulation for Controlled Access to Thalidomide

Powell discloses that "women of childbearing potential" should not be treated with thalidomide if they "wish to become pregnant," "have not practiced a reliable form of contraception for 1 year," "are unwilling to take reliable contraceptive precautions," or "are considered not capable of complying with the requirements for reliable contraception." *Id*. at 22 (quoting Ex. 1005, 901). Similarly, Mitchell discloses a program of preventative measures, such as pregnancy-risk warnings on packaging, targeted "specifically at women." *Id*. (quoting Ex. 1006, 101). Mitchell targets "women of childbearing age (12 to 59 years of age)" for the pregnancy-prevention program. *Id*. (quoting Ex. 1006, 102).

The combined disclosures of Powell and Mitchell would have suggested to a person of ordinary skill in the art at the time of the invention the step of identifying "a subpopulation" of female patients who are capable of becoming pregnant, from among a larger group of patients in need of a teratogenic drug. Ex. 1001, claim 1 (step (d)). Both Powell and Mitchell are focused on restricting access of a teratogenic drug to minimize birth defects. Ex. 1002 ¶ 95. Both references address that common problem in the same way—by controlling the distribution of the drug to a subpopulation of patients (pregnant women) likely to realize the potential harm caused by the drug. A person of ordinary skill in the art would have been led to apply known methods for controlling the distribution of drugs that pose the risk of serious side effects—including the known method disclosed in Dishman for controlling distribution of Clorazil, a drug known to present a potential for serious side effects—to further implement a computerized registry for avoiding birth defects from other teratogenic drugs, including the thalidomide disclosed in Powell. Ex. 1002 ¶ 115.

b. Counseling as a Feature for Controlling the Risk of Side Effects

Powell discloses a method of providing "counseling information concerning the risks attendant to fetal exposure to" a teratogenic drug. Ex. 1001, claim 1 (step (e)). Powell states that a prescriber of thalidomide "must inform the patient of any contraindications, warnings, and precautions associated with the use of the drug." Pet. 23–24 (quoting Ex. 1005, 902). Figure 1 of Powell is a sample Patient Information Sheet that reveals potential "[d]amage to babies," and informs that thalidomide is "toxic to the developing baby, especially in the early months of pregnancy." *Id*. at 24 (quoting Ex. 1005, Fig. 1) (emphasis omitted). Powell discusses securing patient agreements to use contraception for 3 months after discontinuing use of thalidomide. *Id*. (citing Ex. 1005, 901–902).

Under Mitchell's program, "physicians were given instructions 'to warn patients of risks' involved in treatment with the teratogenic drug and 'communication between physicians and patients regarding the drug's teratogenic risk and the need to prevent pregnancy' was encouraged." *Id*. at 24 (quoting Ex. 1006, 101, 105). Both Mitchell and Powell suggest the use of pregnancy testing prior to starting drug therapy. *Id*. at 25 (citing Ex. 1005, 901; Ex. 1006, 101). Accordingly, we find that an ordinary artisan would have been led to use pregnancy testing to determine whether patients in the subpopulation "are pregnant." Ex. 1001, claim 1 (step (f)).

Like Powell, Mitchell suggests that female patients, who are capable of becoming pregnant, should be isolated for counseling. Pet. 22 (quoting Ex. 1002 ¶ 94). Mitchell describes the use of contraceptive information, a consent form, and warnings about risks of becoming pregnant while taking isotretinoin. *Id*. at 24–25 (quoting Ex. 1006, 101).

c. Men as a Targeted Subpopulation for Receiving Counseling

A question arises whether the combined teachings of Powell and Mitchell would have suggested including males, capable of impregnating females, within the subpopulation isolated to receive counseling. *Compare* Pet. 23, *with* Resp. 44–46. Petitioner alleges that a person of ordinary skill in the art would have understood that "a subgroup of male patients capable of impregnating females" would be among the patients targeted for counseling, because such men "could be affected by the teratogenic nature of the drug," and "the purpose of the programs of Powell and Mitchell is to minimize birth defects." Pet. 23 (quoting Ex. 1002 ¶¶ 95, 97). Petitioner advances credible and persuasive evidence—the opinion of

Dr. Fudin, as supported by Mann[7]—showing that, at the time of the invention, an ordinary artisan would have recognized "that the sperm of male patients could be damaged by teratogenic drugs and consequently result in birth defects, if the male was to impregnate a female." *Id*. (quoting Ex. 1002 ¶ 96 (citing Ex. 1018, 7–8)).

As an initial matter, we determine that Petitioner complies with our rules, and precedent of our reviewing court, by presenting Mann as objective support for Dr. Fudin's opinion testimony. *See* 37 C.F.R. § 42.65(a) (opinion testimony that does not disclose underlying facts "is entitled to little or no weight"); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) (lack of objective support for expert opinion "may render the testimony of little probative value in a validity determination"). We have considered, but find unpersuasive, Patent Owner's counterview that the Board should disregard Mann because, according to Patent Owner, the reference is directed "to teratologists or reproductive toxicologists, not pharmacists or [] those focusing on risk management." Resp. 44. Patent Owner's position on that point is not persuasive in view of Patent Owner's own prior reliance on information supplied by teratologists in connection with the controlled distribution of thalidomide. Reply 16–17 (citing Ex. 2094, 7, 130, 137). Taking account of the full record developed during trial, we credit Dr. Fudin's testimony that a person of ordinary skill in the art would have recognized the desirability of identifying a subpopulation of male patients in view of Mann. Ex. 1002 ¶¶ 95–98.

We are persuaded that Mann reveals the state of the art at the time of the invention, and supports Dr. Fudin's testimony that an ordinary artisan would have

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[7] *Passage of Chemicals into Human and Animal Semen: Mechanisms and Significance*, Thaddeus Mann and Cecelia Lutwak-Mann, CRC Critical Reviews in Toxicology (1982) 11:1, 1–14 (Ex. 1018, "Mann").

understood the necessity of counseling males, capable of impregnating females, about the risks that attend fetal exposure to a teratogenic drug. Pet. 23 (quoting Ex. 1002 ¶¶ 95–98 (citing Ex. 1018, 7–8) (Mann, suggesting that thalidomide was known to become "strongly adsorbed by spermatozoa" and adversely affect the pregnancy in female rabbits mated to males that were administered thalidomide prior to conception)). We have considered, but are not persuaded by, Patent Owner's counterview that one would not have considered Mann's discussion of rabbit sperm to apply to human sperm. Resp. 44–45. As Petitioner points out, Patent Owner previously admitted that studies relating to rabbit sperm were relevant to evaluating the effects of thalidomide on human sperm. Reply 17 (citing Ex. 2064, 951). Dr. Fudin's opinion—that it would have been "apparent that the sperm of male patients could be damaged by teratogenic drugs and consequently result in birth defects, if the male was to impregnate a female"—is supported by objective factual evidence, namely, Mann. Pet. 23 (quoting Ex. 1002 ¶ 96) (citing Ex. 1018, 7–8)).

We recognize that Powell's Patient Information Sheet, under a heading relating to "side effects," contains this statement: "No effects on male sperm are recognized." Ex. 1005, 903; Resp. 45. That isolated statement in Powell, standing alone, does not defeat the sufficiency of Petitioner's evidence that one of ordinary skill in the art would have recognized that the sperm of male patients, treated with teratogenic drugs, could result in birth defects. Pet. 23 (quoting Ex. 1002 ¶ 96) (citing Mann (Ex. 1018, 7–8)). Significantly, the statement in Powell is preceded by a discussion of the necessity of using "adequate contraception throughout the duration of thalidomide therapy." Ex. 1005, 903. When read in the context of the surrounding disclosure, Powell suggests that no *contraceptive* "effects on male sperm are recognized" as a side effect of thalidomide therapy. *Id*.

On this record, Petitioner shows sufficiently that a person of ordinary skill in the art would have recognized the desirability of identifying a subpopulation of male patients having "the ability . . . to impregnate females" and, further, the utility of providing that group with "counseling information concerning the risks attendant to fetal exposure to" a teratogenic drug, as specified in claim 1. Ex. 1001, claim 1 (steps (c) and (e)).

d. Registry as a Known Solution for Controlling Distribution of a Drug

We next turn to the question whether the applied art would have suggested the steps of registering prescribers, pharmacies, and patients in a computer readable storage medium as specified in claim 1. Ex. 1001, claim 1 (steps (a)–(c)). The overarching purpose of Powell and Mitchell is to prevent birth defects by limiting prescriptions for teratogenic drugs to only non-pregnant women. *See*, *e.g.*, Ex. 1005, 901 (Powell, explaining "[p]regnancy should be excluded before instituting therapy with thalidomide"); *see also* Ex. 1006, 101 (Mitchell, disclosing "an aggressive program designed to reduce the risk of pregnancy among women taking" Accutane). Petitioner shows sufficiently that Dishman would have led an ordinary artisan to advance that purpose through an obvious modification; that is, by storing patient, prescriber, and pharmacy records in a computer readable storage medium. *See* Pet. 37–39, 41 (claim chart, steps (a)–(c), (g)).

Dishman describes a nationwide registry for patients requiring clozapine, a potent anti-psychotic drug with potential for serious side effects. Pet. 27 (quoting Ex. 1002 ¶¶ 116–117). Although Dishman does not expressly relate to side effects that include birth defects, Petitioner shows sufficiently that "a person of ordinary skill in the art would have been motivated to look to the system disclosed in Dishman to further implement a computerized registry for avoiding birth defects from a teratogenic drug." Pet. 26–27 (citing Ex. 1002 ¶ 115). We find that one of

ordinary skill in the art would have turned to Dishman as a source of "ways to restrict access to drugs that could be potentially hazardous." *Id.* at 27 (quoting Ex. 1002 ¶¶ 116–117).

Dishman explains that "all prescribers and patients" of clozapine must "be registered with" the national registry, "which requires weekly monitoring of each patient's white blood cell (WBC) count" and also "limits medication dispensing to a one-week supply." Ex. 1007, 899. The national registry, moreover, is used to store a "pharmacist's verification" relating to the weekly WBC monitoring requirement. Pet. 28 (quoting Ex. 1007, 899); *see* Ex. 1002 ¶ 122 (Dr. Fudin, testifying that Dishman discloses a need for cooperation between patients, physicians, laboratories, and pharmacies). In that context, Dishman refers to "a computerized clozapine prescription lockout system." Ex. 1007, 900; *see* Ex. 1002 ¶ 123 (Dr. Fudin, explaining "that each hospital [must] have a computerized clozapine prescription lockout system" that "ties the hospital's laboratory databases to the outpatient pharmacy dispensing software").

The combined disclosures of Powell, Mitchell, and Dishman would have prompted an ordinary artisan to implement a pregnancy-prevention program for thalidomide patients that makes mandatory the use of a registry for patients, prescribers, and pharmacies; that limitation is suggested by Dishman's disclosure of registering a pharmacist's verification before any patient is authorized to receive a drug. Pet. 21–22 (citing Ex. 1002 ¶ 89).

Patent Owner counters that Dishman does not disclose a registry for pharmacies, asserting that "[t]he pharmacist's verification" in Dishman means that a pharmacist is "obtaining information from, not providing information to" a registry. Resp. 39 n.8, 40 (emphasis omitted). That view runs counter to the disclosure of Dishman. Dishman suggests a registry of pharmacies because it refers to the use of the registry to store a pharmacist's verification. Ex. 1007, 899.

We agree with Petitioner that it defies logic that a pharmacy would be given access to verify information in the registry without being registered itself, because Dishman requires dispensing the restricted drug on a weekly basis, and it would have been impossible to verify that requirement if pharmacists entered no records in the registry. Ex. 1007, 899–900; Reply 18 (citing Ex. 1001 ¶ 121).

Dishman discloses registering physician, patient, and pharmacy information in a computer readable storage medium. For reasons discussed in the claim construction analysis above, we are not persuaded that the claim term "computer readable storage medium" requires a "centralized database" of any sort. Resp. 35. Dishman expressly discloses the use of a "computer readable storage medium" in its description of a "computerized lockout system." Ex. 1007, 900. At the time of the invention, it was well known that prescription records could be and were kept in computerized systems. Pet. 12 (citing Ex. 1012, 175, Fig. 12.1; Ex. 1002 ¶ 48). Pharmacists had been using such systems to track patient data as far back as 1975. *Id*. (citing Ex. 1012, Ch. 12; Ex. 1002 ¶ 48). Petitioner comes forward with credible and persuasive evidence, which is not refuted effectively on this record, that it was well known in the art to isolate groups of patients, including contraindicated individuals, based on computerized sorting of computerized records. *Id*. at 12–13 (citing Ex. 1002 ¶¶ 53–54).

In the alternative, even if Dishman discloses registering patient, prescriber, and pharmacist information in different computers (as expressly disclosed in the '501 patent as a suitable means for carrying out the method of the invention (Ex. 1001, 4:50–57; 10:12–16)), providing that information in a centralized database would have been a predictable variation that provides no patentable distinction over the combined disclosures of the applied prior art references. A person of ordinary skill is also a person of ordinary creativity, not an automaton. *KSR*, 550 U.S. at 421.

e. Retrieving Information from a Registry to Control Distribution of a Drug

We are persuaded that Dishman would have led a person of ordinary skill in the art, seeking to improve the methods of Powell and Mitchell, to maintain the mandatory registry of records in a computer readable storage medium for "ease in sharing and storing." Pet. 26 (quoting Ex. 1002 ¶ 114). The only practical reason for storing information in a computer readable medium is to permit later retrieval of that information. We are directed to no persuasive evidence disputing that fact. Resp. 26, 34, 36 (discussion of the "retrieval" step of claim 1); *see KSR Int'l*, 550 U.S. at 421 (a person of ordinary skill in the art possesses ordinary creativity and is not an automaton). Furthermore, Dishman's disclosure of registering a pharmacist's verification, before any patient is authorized to receive a drug, implies a retrieval of such information. Pet. 21–22 (citing Ex. 1002 ¶ 89). On this record, the applied prior art suggests a method of registering prescriber, pharmacy, and patient information in "a computer readable storage medium," and retrieving information necessary to ensure that prescriptions for a teratogenic drug are authorized for only non-pregnant patients. Ex. 1001, claim 1 (steps (a)–(d)).

Patent Owner's arguments narrowly focus on the express teachings of individual prior art references, to the exclusion of a balanced approach that considers what the combined disclosures of the prior art fairly would have suggested to a person of ordinary skill in the art. We discuss that aspect of the dispute in greater depth in the next section.

f. Further Observations on the Parties' Dispute Surrounding Reasons to Combine

The nub of the dispute in this case is whether a person of ordinary skill in the art would have been led to combine features of known methods for controlling potentially hazardous drugs—such as Mitchell's method for controlling

distribution of Accutane and Dishman's method for controlling distribution of Clozaril—and apply those features to controlling the distribution of another potentially hazardous drug (thalidomide, which Powell discusses as requiring controlled distribution). Patent Owner's contention that a person of ordinary skill in the art would not have recognized or applied the teachings of Mitchell or Dishman to the problem identified in Powell lacks merit. Resp. 49–53. On that point, Patent Owner itself identifies in the Response an article, which explains that Patent Owner's "plan [for thalidomide] is built on experience with restrictions on such other drugs with severe side effects as Accutane . . . and Clorazil." Ex. 2063, 1136; *see* Resp. 6 (quoting Ex. 2063, 1135).

Furthermore, both of Patent Owner's witnesses acknowledged the relevance of the programs disclosed in Mitchell and Dishman to the problem at hand, namely, controlling distribution of thalidomide. Specifically, Dr. DiPiro testified that, "in some of the literature where isotretinoin [Accutane] and clozapine [Clorazil] systems were discussed," even researchers employed by Patent Owner recognized "that the results from these systems could guide an individual in either direction, as a way to do it or as a way not to do it. So in that sense they are relevant." Ex. 1066, 326:23–327:5. Dr. Frau similarly acknowledged that the clozapine program was a restricted distribution program (Ex. 1067, 112:7–15; 113:3–8) and, thus, addressed the very same problem that would have been focused upon by a person of ordinary skill in the art. We find unpersuasive Patent Owner's assertions that a person of ordinary skill in the art would not have been led to consider the combined disclosures of Mitchell, Dishman and Powell—all of which pertain to controlling the distribution of a drug to a subpopulation of patients likely to suffer serious side effects. Resp. 31–32, 38–41 (arguing that various features of known methods for controlling distribution of Accutane and Clozaril, as

disclosed or suggested by the combined prior art, would not have been applied to controlling distribution of thalidomide in the manner claimed).

Patent Owner, in essence, argues that an ordinary artisan would understand each applied reference only for its express teachings and would not have applied those teachings beyond the specific uses disclosed in the particular prior art reference. However, "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418. In that regard, we are persuaded that the invention of claim 1 represents the "predictable use of prior art elements according to their established functions." *KSR Int'l*, 550 U.S. at 417. Claim 1 is directed to a combination of known steps (registering patients, prescribers, and pharmacies in a computer readable storage medium; identifying and counseling a subpopulation of patients whose access to a teratogenic drug should be restricted; and authorizing drug therapy only for non-pregnant patients) to accomplish a known purpose (prescribing drug only to non-pregnant patients) and achieve a predictable result (preventing fetal exposure to the drug). Pet. 36–41 (claim chart).

We agree with Petitioner that Patent Owner approaches this dispute as if the ground set for trial was based on anticipation. Reply 14 (pointing out that Patent Owner's Response "reads as if [the ground set for trial] was based on an anticipation"). For example, Patent Owner focuses on specific features not present in one applied reference, without meeting head on the question whether all the features would have been suggested by the combined disclosures of the prior art. *See* Resp. 25–29, 31–32, 36–37 (attacking disclosures of each applied reference in isolation). Patent Owner's attack on the individual disclosures of Powell, Mitchell, and Dishman is ineffective to counter Petitioner's evidence that the subject matter of claim 1 would have been obvious over the combined disclosures of those prior

art references. We find that a person of ordinary skill in the art would have been led to combine, in the manner claimed, the disclosures of Powell, Mitchell, and Dishman to address the problem of limiting thalidomide access to patients likely to suffer serious adverse side effects, including birth defects in a developing fetus.

g. Reasonable Expectation of Success

The prior art methods were successful; even the inventors of the '501 patent touted their success in an article entitled *S.T.E.P.S.™ A Comprehensive Program for Controlling and Monitoring Access to Thalidomide*, by inventors Bruce Williams and Mark El Sayed (along with other Celgene authors). Ex. 1068. Patent Owner's arguments in this proceeding are inconsistent with prior assertions that the programs for controlling distribution of Accutane and Clorazil were "successful" and "provided guides" for the controlling and monitoring access to thalidomide. *Id*. at 329. Indeed, the inventors explained that their method was "based partly on 2 existing models—the safety programs developed for isotretinoin and clozapine." *Id*. at 320; *see id*. at 323 (describing programs for controlling distribution of Accutane and Clorazil as "successful" and explaining that elements of both programs were incorporated into the inventors' method for controlling distribution of thalidomide). When it benefitted Patent Owner's interests before the FDA, moreover, Patent Owner freely admitted that its "plan [for thalidomide] is built on experience with restrictions on such other drugs with severe adverse effects as Accutane . . . and Clorazil." Ex. 2063, 1136.

Patent Owner's arguments in this proceeding also are contrary to disclosures of the applied prior art references. For example, Mitchell explicitly points out that the methods of control discussed in connection with Accutane could be used for controlling the distribution of thalidomide. Ex. 1006, 105. Based on the evidence of record, we find unpersuasive Patent Owner's arguments that an ordinary artisan would not have formed a reasonable expectation of success in applying the prior

art programs for controlling the distribution of hazardous drugs to the problem of controlling the distribution of thalidomide. Resp. 53–54.

2. Analysis of Claims 2–10 over Powell, Mitchell, and Dishman

We next turn to Petitioner's contention that the subject matter of claims 2–10, which depend from claim 1, would have been obvious over the combined disclosures of Powell, Mitchell, and Dishman. The following facts are supported by a preponderance of the evidence.

The dependent claims require thalidomide as the teratogenic drug (claim 2); registering information about male patients in the subpopulation (claim 3); determining non-pregnancy by pregnancy testing (claim 4); recording in the computer readable storage medium information about prescription issuance and fulfillment (claim 5); authorizing prescription refills only in response to information contained on the computer readable storage medium (claim 6); that prescriptions are filled for no more than about 28 days (claim 7); that prescriptions are filled together with distribution of literature warning of the effects of the drug on fetuses (claim 8); providing patients with contraception counseling (claim 9); and providing patients capable of becoming pregnant a contraceptive device or formulation (claim 10).

Petitioner's arguments and evidence, including the detailed claim charts, establish adequately that the subject matter of the dependent claims would have been obvious over the combined teachings of Powell, Mitchell, and Dishman. Pet. 30–36 (textual arguments, including citations to Dr. Fudin's testimony); 42–45 (claim charts). Patent Owner makes no additional arguments with respect to claims 3, 4, 7, 8, or 9. Resp. 46–49.[8] Patent Owner's sole argument with respect to

[8] Patent Owner states that Petitioner fails to prove that claim 7 is unpatentable "for the following additional reasons" (Resp. 46) but then declines to

claims 3, 4, and 7–9 is that Petitioner fails to show unpatentability as to claim 1, from which those claims depend. Resp. 46. That argument is unpersuasive, for reasons stated above in our analysis of claim 1.

Patent Owner raises additional arguments and evidence relating to claims 2, 5, 6, and 10. None is persuasive. For example, as to claim 2, which requires thalidomide as the teratogenic drug, Patent Owner argues that Powell's focus on the use of thalidomide by hospital doctors on a "named patient" basis somehow makes unobvious the application of prior art methods for controlling the distribution of hazardous drugs to the problem of controlling the distribution of thalidomide. Resp. 47–48. On that point, we agree with Petitioner that nothing in Powell suggests "that its methods could not be used on a larger scale." Reply 19. Patent Owner, moreover, ignores that Mitchell explicitly points out that the methods of control discussed in connection with Accutane could be used for controlling the distribution of thalidomide. Ex. 1006, 105 (noting that "[t]halidomide appears to be an effective treatment for various medical conditions" and that "experience gained with [Accutane] can serve as a basis for considering how [thalidomide] should be used and monitored, with a view to ensuring that pregnancies and malformations are reduced to an absolute minimum").

Patent Owner's "additional arguments" as to claims 5 and 6 add nothing beyond the arguments made in connection with claim 1 regarding the construction of the claim term "computer readable storage medium." Resp. 48. Patent Owner's contentions in that regard are unpersuasive for the reasons discussed above in connection with claim 1.

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address claim 7 in the analysis. *Id*. at 46–49. We view Patent Owner to have waived, therefore, arguments pertaining to claim 7 that we rejected as unpersuasive in our Decision to Institute. Dec. 15.

As for claim 10, Patent Owner argues that the step of "providing a contraceptive device or formulation" would not have been obvious because "counseling" about contraception is not the same as "providing" contraception. Resp. 49. On that point, we credit Dr. Fudin's testimony that it would have been obvious from the prior art to "provide contraception," where, for example, Mitchell discloses providing patients with "the necessary forms for a contraception referral program," and an ordinary artisan would understand from this disclosure that the consulting physician would, after ensuring it is medically appropriate, provide contraception. Ex. 1002 ¶¶ 168–169.

3. Secondary Considerations

Before reaching an ultimate conclusion on the question whether the subject matter of claims 1–10 of the '501 patent would have been obvious over the applied prior art, we take account of objective evidence of secondary considerations of nonobviousness. *See Graham*, 383 U.S. at 17–18. We are mindful that "evidence rising out of the so-called 'secondary considerations' must always when presented be considered en route to a determination of obviousness." *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). The totality of the evidence submitted may show that the challenged claims would not have been obvious to one of ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). Secondary considerations may include, for example, long-felt but unsolved need, industry praise, and unexpected results. *Graham*, 383 U.S. at 17; *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349, 1355 (Fed. Cir. 2012). Patent Owner advances objective evidence related to each of those secondary considerations, which we weigh en route to ruling on Petitioner's obviousness challenge. Resp. 54–60.

We consider but find unpersuasive Patent Owner's evidence that the claimed invention satisfied a long-felt but unsolved need for a method of controlling the distribution of thalidomide. On that point, no showing is made that other methods of controlling the distribution of hazardous drugs, which were readily available in the prior art and included the methods disclosed in Mitchell and Dishman, were insufficient to meet any demonstrated need for a controlled distribution system for thalidomide. Patent Owner directs us to studies showing a need for thalidomide, based on findings that thalidomide is useful for various ailments, but does not show persuasively that there existed a long-felt or unmet need for an effective method of distributing a potentially hazardous drug. Resp. 55–57; Reply 21–22.

Patent Owner also directs us to evidence that the claimed method of distributing thalidomide generated some praise within the industry. Resp. 57. Specifically, the National Organization for Rare Disorders praised Patent Owner's "extraordinary courage" in moving ahead toward regulatory approval of thalidomide and for incorporating "numerous safeguards for pregnancy prevention" in connection with its distribution. Resp. 57 (quoting Ex. 2020, 1–2). That evidence is not without some merit, and we give it appropriate weight in reaching our ultimate conclusion on obviousness.

Patent Owner's evidence of unexpected results is less clear. Patent Owner contends that its claimed method "has been 100% successful in preventing birth defects of the type associated with thalidomide." Resp. 58 (citing Ex. 2059 ¶ 143, Ex. 2060 ¶ 100). Petitioner responds with evidence that the method "was not 100 percent successful in achieving" the goal stated in claim 1—namely, preventing fetal exposure—and directs us to evidence of "four confirmed fetal exposures." Reply 24 (emphasis omitted) (quoting Ex. 1064, 5). Claim 1 makes plain that preventing fetal exposure is the goal. Ex. 1001, claim 1. Given that Patent Owner's evidence is predicated on an unsupported assertion that the method of the

invention "has been 100% successful," Patent Owner fails to make out a persuasive showing of unexpected results. In that regard, we are not persuaded that combining the features of the prior art drug distribution programs (according to their known functions) to control distribution of thalidomide in the manner claimed would have produced a result that would have been truly unexpected to a person of ordinary skill in the art. We, therefore, afford Patent Owner's evidence of unexpected results little weight in the ultimate obviousness determination.

When Patent Owner's evidence of secondary considerations is given the appropriate weight to which it is entitled, that evidence is insufficient to overcome the strong showing of obviousness made out by Petitioner on the evidence of the combined disclosures of the prior art. *See Süd-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1009 (Fed. Cir. 2009) ("[E]vidence of unexpected results and other secondary considerations will not necessarily overcome a strong prima facie showing of obviousness."). Accordingly, we hold that Petitioner shows by a preponderance of the evidence that the subject matter of claims 1–10 of the '501 patent would have been obvious to a person of ordinary skill in the art at the time of the invention.

III. MOTIONS TO EXCLUDE EVIDENCE

Both Patent Owner and Petitioner filed a Motion to Exclude Evidence. Papers 57, 58. We address each motion in turn.

A. Patent Owner's Motion to Exclude Evidence

Patent Owner moves to exclude to two prior art references (Vanchieri (Ex. 2064) and Marwick (Ex. 2063)), addressed above in our discussion of the Sur-Reply. Paper 57, 1–3. Patent Owner further moves to exclude Exhibit 2094, which is a document related to an FDA meeting. *Id.* at 3.

As an initial matter, we observe that Patent Owner itself introduced into the record each of the exhibits sought to be excluded and, further, Patent Owner itself relies upon each in this proceeding. Resp. 5–6; Ex. 2059 ¶¶ 20, 84; Ex. 2060 ¶ 32 (examples of Patent Owner's own reliance on Exhibit 2064); *see* Resp. 6, 9; Ex. 2059 ¶¶19, 84; Ex. 2060 ¶¶ 32–34 (examples of Patent Owner's reliance on Exhibit 2064); *see also* Resp. 5; Ex. 2059 ¶¶ 18, 86; Ex. 2060 ¶ 31 (examples of Patent Owners reliance on Exhibit 2094). Under the circumstances, we agree with Petitioner that Patent Owner's request to exclude Exhibits 2063, 2064, and 2094 as hearsay, only for Petitioner's purposes, is an "unusual request." Paper 63, 1.

In any event, Patent Owner argues that Exhibits 2063, 2064, and 2094 reflect out-of-court statements offered to prove the truth of a matter asserted and, on that basis, should be excluded as hearsay. *Id*. at 1–3. In actuality, Patent Owner's objections go to the credibility of the statements and not to the admissibility of 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."). We deny Patent Owner's request to exclude Exhibits 2063, 2064, and 2094 as hearsay under Federal Rule of Evidence 801(c).

Patent Owner further alleges that Petitioner relies upon irrelevant evidence and, on that basis, seeks to exclude that evidence. Paper 57, 3–9. Petitioner disagrees and contends that Patent Owner's relevance objections go to the weight given to the evidence. Paper 63, 11–14. 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.

In addition, Patent Owner contends that Petitioner mischaracterized certain portions of Dr. Frau's testimony. Paper 57, 10–14. Patent Owner states that the testimony should be excluded unless the Board considers it in the context of surrounding testimony or relevant redirect testimony. *Id*. at 11. To the extent the Board relies upon the testimony, we review it in that context.

Additionally, Patent Owner seeks to exclude a statement in Petitioner's Reply that is alleged to mischaracterize a fact asserted in the Freeman Declaration advanced by Patent Owner. *Id*. at 15. Here again, we agree with Petitioner that Patent Owner's objection goes to the weight of the evidence, not its admissibility. Paper 63, 14–15.

Patent Owner's Motion to Exclude Evidence 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.

B. Petitioner's Motion to Exclude Evidence

Petitioner also filed a Motion to Exclude Evidence. Paper 58. Specifically, Petitioner seeks exclusion of certain testimony of Dr. Fudin elicited during cross examination on the basis of relevance. *Id*. at 1. Petitioner also seeks to exclude Patent Owner's arguments regarding the cited testimony. *Id*. at 3. Petitioner's Motion to Exclude Evidence is denied as moot because, even taking the evidence into consideration, we hold that Petitioner has established by a preponderance of the evidence that claims 1–10 of the '501 patent are unpatentable as obvious.

IV. PETITIONER'S MOTION TO SUBMIT SUPPLEMENT INFORMATION

Petitioner moves to submit supplemental information to confirm the public accessibility of two documents, described as "*NIH*" (Ex. 1008) and "*CDC minutes*" (Ex. 1015), Paper 36, 1–3. Patent Owner opposes. Paper 41. Because the information sought to be submitted is unnecessary to this Decision, we deny as moot Petitioner's Motion to Submit Supplemental Information.

V. MOTIONS TO SEAL AND FOR ENTRY OF PROTECTIVE ORDER

In a combined Motion to Seal and Motion for Entry of Protective Order, Patent Owner requests that the Board seal Exhibit 2107 in its entirety, along with unredacted versions of the Frau Declaration (Ex. 2059), the DiPiro Declaration (Ex. 2060), and the Freeman Declaration (Ex. 2068), which discuss Exhibit 2107. Paper 39, 1. According to Patent Owner, the documents sought to be sealed disclose Patent Owner's "business confidential information and trade secrets," relating to an agreement between Patent Owner and a non-party. *Id*. Patent Owner states that Exhibit 2107 "has not been previously disclosed to the public and [] remains confidential." *Id*. Patent Owner requests entry of the Board's Default Protective Order to govern the disclosure of confidential information in this proceeding. *Id*. Petitioner filed no opposition.

Petitioner filed a Motion to Seal unredacted versions of Exhibits 1066 and 1067 (deposition transcripts). Paper 50, 1. Petitioner states that those documents discuss Patent Owner's confidential business information. *Id*. at 2. Patent Owner filed no opposition.

We conclude that the documents sought to be sealed reflect confidential business information and, accordingly, grant both motions. The confidential content of documents placed under seal in this proceeding has not been identified in this Decision. We are persuaded that good cause exists to maintain those

documents under seal. The terms of the Board's Default Protective Order shall govern any disclosure of those documents.

The record will be maintained undisturbed pending the outcome of any appeal taken from this decision. At the conclusion of any appeal, 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 or the expiration of the time period for appealing.

IV. CONCLUSION

Taking account of the arguments and evidence presented during trial, including the objective evidence of secondary considerations, we determine that Petitioner establishes by a preponderance of the evidence that claims 1–10 of the '501 patent are *unpatentable* under 35 U.S.C. § 103(a) over the combined disclosures of Powell, Mitchell, and Dishman.

Patent Owner's Motion to Exclude Evidence is *denied*. Petitioner's Motion to Exclude Evidence is *denied*. Petitioner's Motion to Submit Supplemental Information is *denied*. Patent Owner's combined Motion to Seal and Motion for Entry of Protective Order is *granted*. Petitioner's Motion to Seal is *granted*.

V. ORDER

It is

ORDERED that claims 1–10 of the '501 patent are *unpatentable*;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence (Paper 57) is *denied*;

FURTHER ORDERED that Petitioner's Motion to Exclude Evidence (Paper 58) is *denied*;

FURTHER ORDERED that Petitioner's Motion to Submit Supplemental Information (Paper 36) is *denied*;

FURTHER ORDERED that Patent Owner's combined Motion to Seal and Motion for Entry of Protective Order (Paper 39) is *granted*;

FURTHER ORDERED that Petitioner's Motion to Seal (Paper 50) is *granted*;

FURTHER ORDERED that the terms of the Board's Default Protective Order shall govern the disclosure of sealed documents in this proceeding; and

FURTHER ORDERED that, because this is a Final Written Decision, any party 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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