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Paper 20
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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*.

DECISION
Instituting *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner requests an *inter partes* review of claims 1–10 of U.S. Patent No. 6,045,501 (Ex. 1001, "the '501 patent"). Paper 1 ("Pet."). Patent Owner filed a Preliminary Response. Paper 10 ("Prelim. Resp."). Applying the standard set forth in 35 U.S.C. § 314, which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we grant an *inter partes* review of claims 1–10.

A. Related Proceedings

Petitioner identifies six district court actions relating to the '501 patent: *Celgene Corp. v. Lannett Holdings, Inc. et al*., 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. et al*., DNJ-2:08-cv-03357 (filed July 3, 2008); *Celgene Corp. v. Barr Laboratories, Inc. et al*., DNJ-2:07-cv-05485 (filed Nov. 14, 2007); *Celgene Corp. v. Barr Laboratories, Inc. et al*., DNJ-2:07-cv-04050 (filed Aug. 23, 2007); *Celgene Corp. v. Barr Laboratories, Inc. et al*., DNJ-2:07-cv-00286 (filed Jan. 18, 2007). Pet. 2–3.

B. 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 Thalidomide was withdrawn from all markets by 1962 after reports of serious birth defects.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 1:22–25.

Investigators thereafter discovered that thalidomide may 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 1:25–29; 36–39. According to 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 such drug is contraindicated. *Id*. at 1:41–47.

The ’501 patent describes an existing pregnancy-prevention program developed for women who are prescribed Accutane® (isotretinoin), a known teratogenic drug effective for treating severe forms of acne. *Id*. at 1:48–60. According to the patent, enrollment in the Accutane® program is voluntary, therefore, “improved methods are needed which are more representative of all users of a particular drug, such as thalidomide.” *Id*. at 1:60–67. The 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.

One embodiment of the invention involves 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.

C. 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.

D. Evidence Relied Upon

Petitioner asserts the following prior art references in the grounds of unpatentability stated in the Petition:

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");

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");

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");

Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis, Gilbert Honigfeld, *Psychiatric Services* (Jan. 1996) 47:1, 52–56 (Ex. 1009, "Honigfeld"); and

Thalidomide: Potential Benefits and Risks, An Open Public Scientific Workshop, Program and Abstracts, Office of the Director National Institutes of Health (Sept. 9-10, 1997) (Ex. 1015, "NIH").

Petitioner also relies on the Declaration of Jeffrey Fudin, Pharm.D. (Ex. 1002).[1]

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[1] 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 Clinical Pharmacy Specialist for more than 20 years, and is the Director of a Pain and Palliative Care Pharmacy Residency. *Id*. at ¶ 4. For the purposes of this decision, we determine that Dr. Fudin is qualified to opine on the views of a hypothetical person of ordinary skill in art at the time of the invention. Patent Owner's counterviews do not persuade us to deny review. *See* Prelim. Resp. 20–22 (attorney argument that a skilled artisan would have had experience "designing and implementing systems for controlling access to pharmaceutical drug products that have the potential for life threatening adverse events," and that Dr. Fudin is not qualified to opine on the views of such an artisan). Should we reach a final decision, any factual dispute on the issue shall be resolved based on the full trial record.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–10 of the '501 patent on the following grounds:

References	Basis	Claims challenged
Powell, Mitchell, Dishman	§ 103	1–10
NIH, Honigfeld	§ 103	1–10

II. ANALYSIS

A. Claims 1–10 as Obvious over Powell, Mitchell, and Dishman

Petitioner alleges that claims 1–10 of the '501 patent are unpatentable as obvious over the combined disclosures of Powell, Mitchell, and Dishman.[2] For reasons that follow, we determine that Petitioner demonstrates a reasonable likelihood of prevailing on that ground, and we institute an *inter partes* review on that basis.

We consider the asserted prior art references as 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))).

We first turn to claim 1, the only independent claim, and then address dependent claims 2–10.

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

1. Claim 1

The information presented shows sufficiently the following facts about the asserted prior art. 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 clozapine, a potent anti-psychotic drug with potential for serious side effects. Pet. 27–28 (quoting Ex. 1007, 899). Petitioner shows sufficiently that 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).

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 also targets "women of childbearing age (12 to 59 years of age)" for the pregnancy-prevention program. *Id*. (quoting Ex. 1006, 102). On this record, Powell and Mitchell suggest 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)).

Powell further discloses a method of providing "counseling information concerning the risks attendant to fetal exposure to" a teratogenic drug. *Id*. at 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, moreover, "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). On this record, we are persuaded that a skilled 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, moreover, 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). A question arises, however, 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* Prelim. Resp. 33–34.

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 information—the opinion of Dr. Fudin, as supported by Mann[3]—showing that, at the time of the invention, a skilled 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)).

We have considered, but find unpersuasive, Patent Owner's counter argument that the Board should disregard Mann, because that reference "is not asserted in any ground of unpatentability or even discussed generally in the Petition." Prelim. Resp. 33. Under the particular circumstances presented in this case, 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

[3] *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").

281, 294 (Fed. Cir. 1985) (lack of objective support for expert opinion "may render the testimony of little probative value in a validity determination").

Mann reveals the state of the art at the time of the invention, and supports Dr. Fudin's testimony that a skilled artisan would have 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)). On this record, 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).

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; *see* Prelim. Resp. 34 (arguing that this statement in "Powell teaches away from" including "males in any 'subpopulation'"). That isolated statement in Powell, standing alone, does not defeat the sufficiency of Petitioner's information 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, therefore, 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)).

We next turn to 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 over-arching 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 a skilled 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 nation-wide 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 agree, on this record, that one 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 also* 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").

We are persuaded, on this record, that the combined disclosures of Powell, Mitchell, and Dishman would have prompted a skilled 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). Based on the information presented, moreover, Petitioner shows sufficiently that Dishman would have led a skilled artisan, 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. *Cf*. Prelim. Resp. 32–33 (arguing that a failure to identify a prior art disclosure of a "retrieval" step dooms Petitioner's challenge); *see KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 421 (2007) (hypothetical 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)).

Petitioner shows sufficiently 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. Based on the information presented, claim 1 is directed to a combination of known steps (registering patients, prescribers, and pharmacies in a computer readable 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).

2. Claims 2–10

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 Powell, Mitchell, and Dishman.

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). At this stage of the proceeding, in support of the patentability of claims 2–6 and 8–10, Patent Owner's sole argument is that Petitioner fails to show a reasonable likelihood of prevailing as to claim 1, from which those claims depend. Prelim. Resp. 34–35. That argument is unpersuasive, for reasons stated above in our analysis of claim 1.

Patent Owner raises one argument specific to claim 7, which adds a limitation that "said prescriptions are filled for no more than about 28 days." Ex. 1001, claim 7. In Patent Owner's view, Petitioner fails to explain adequately how the applied art would have led one of ordinary skill in the art "to modify Powell's teaching to use a 3-month supply [of thalidomide] to arrive at the claimed 28-day limitation." Prelim. Resp. 35; *see* Ex. 1005, 904 (Powell's disclosure that "an amount to provide for 3 months prescription for a 'named patient' could be supplied to be held in the pharmacy").

Patent Owner's argument is not persuasive based on the record developed at this stage. In that regard, Petitioner directs us to Powell's disclosure "that, initially, 'follow-up visits' with prescribing physicians 'should be at monthly intervals or less.'" Pet. 33 (quoting Ex. 1005, 902). Petitioner also advances evidence that one of ordinary skill in the art "would understand that the follow up visits would be required before additional drug was dispensed." *Id*. (quoting Ex. 1002 ¶ 150). And Petitioner comes forward with information that a skilled artisan would have arrived at a 28-day restriction based on the "general knowledge in the field" that the "average woman's menstrual cycle is approximately 28 days." *Id*.; Ex. 1002 ¶ 152). Where "avoidance of pregnancy is of paramount importance," and "oral contraceptives are prescribed" in 28-day cycles, Petitioner shows sufficiently that "the claimed time period aligns with other prescribing habits of physicians." *Id*. at 34 (quoting Ex. 1002 ¶¶ 153–154).

On this record, there is a reasonable likelihood that Petitioner would prevail in showing that the subject matter of claims 2–10 would have been obvious over Powell, Mitchell, and Dishman.

B. Claims 1–10 as Obvious over NIH and Honigfeld

Petitioner also challenges claims 1–10 as obvious over NIH and Honigfeld. Pet. 45–60. Given that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1–10 are unpatentable over Powell, Mitchell, and Dishman, we exercise our discretion and deny institution of claims 1–10 on the ground based on NIH and Honigfeld. *See* 35 U.S.C. § 314(a) (institution is discretionary, not mandatory); 37 C.F.R. § 42.108(a) (when instituting an *inter partes* review, the Board is not required to go forward on all asserted grounds of unpatentability).

III. CONCLUSION

Petitioner establishes a reasonable likelihood of prevailing on its assertion that claims 1–10 of the ’501 patent are unpatentable as obvious over the combined disclosures of Powell, Mitchell, and Dishman.

IV. ORDER

It is

ORDERED that an *inter partes* review is instituted on the following ground: Whether claims 1–10 of the ’501 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Powell, Mitchell, and Dishman.

FURTHER ORDERED that no other ground of unpatentability is authorized; and

FURTHER ORDERED that notice is hereby given of the institution of a trial commencing on the entry date of this decision. 35 U.S.C. § 314(c); 37 C.F.R. § 42.4.

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