

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 17

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte LEONARD L. MAZUR

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Appeal No. 2004-0394  
Application No. 09/915,467

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ON BRIEF

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Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

REQUEST FOR REHEARING

Appellant requests reconsideration (rehearing) of the Board's decision entered February 26, 2004 (Decision), vacating the rejection of record in favor of new grounds of rejection under 37 CFR § 1.196(b). Appellant's "Request for Rehearing" (Request) is premised upon the assertion that the "new grounds for rejection appear based on a misunderstanding of the time sequence of the prior art." Request, page 2.

Claims 1 and 6 are illustrative of the subject matter on appeal and are reproduced below:

1. An educational article of manufacture useful to increase patient awareness of the teratogenicity of a pharmaceutical, said article of manufacture comprising:  
a teratogenic pharmaceutical packaged together with  
a contraceptive; and  
labeling specifying avoidance of pregnancy while using said teratogenic pharmaceutical.

6. A pharmaceutical composition of matter comprising:  
a first pharmaceutical in an amount potentially teratogenic, and  
a second pharmaceutical in an amount effective as a contraceptive,  
said composition of matter in a unit dose form.

The references relied upon by the board are:

Hansen et al. (Hansen)	5,120,546	Jun. 9, 1992
Van Os et al. (Van Os)	5,494,047	Feb. 27, 1996
Elsayed et al. (Elsayed) (102(e) date Aug. 28, 1998)	6,045,501	Apr. 4, 2000
Abrams et al. (Abrams) (102(e) date Aug. 18, 1999)	6,428,809	Aug. 6, 2002

Physicians' Desk Reference (PDR) 1878-1880 (46<sup>th</sup> ed., Medical Economics Company, Montvale, NJ 1992)

#### GROUND OF REJECTION

Claims 1, 2 and 5 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Elsayed, Abrams and PDR.

Claims 3 and 4 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Elsayed, Abrams and PDR in view of Van Os.

Claims 6 and 8-10 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Elsayed, Abrams and PDR.

Claim 7 stands rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Elsayed, Abrams and PDR in view of Hansen.

## DISCUSSION

According to appellant (Request, page 2), “[i]t is undisputed that the prior art acknowledges a long-felt need for the problem of teratogen-related birth defects.” Nevertheless, appellant asserts (Request, page 3), “[d]espite a panoply of proposed solutions, as recently as 2001 the art had failed to solve this problem. This failure to solve the long-felt need is shown both by [pregnancy] data collected by the manufacturer of ACCUTANE® isotretinoin, and by the United States Food & Drug Administration’s interpretation of this data.” According to appellant (Request, page 4), “[t]he reason for these pregnancies, despite ostensibly clear admonitions to avoid pregnancy, is unclear.” However, appellant notes that Woodcock (Appendix to Brief) asserts “exclusive reliance on ‘human memory’ is not an adequate precaution for managing severe risks.” Id. According to appellant (id.),

The Food & Drug Administration thus concluded that “additional systematized measures to manage risk and fully inform patients and families should be instituted, given the devastating impact of potential side effects.” ... Notably, the FDA advanced this position in 2001 – clearly showing that the long-felt need remained unsatisfied at that time.”

Accordingly, appellant asserts (Request, bridging paragraph, pages 4-5, footnotes omitted), since Abrams, Elsayed and PDR “were followed temporally by ... WOODCOCK ... and by Roche Pharmaceuticals, Inc., APPENDIX I ... the long-felt need remained unfulfilled as recently as several months before Appellant filed the immediate application.” In support of this assertion appellant states (Request, page 5, fn. 5):

Notably, ABRAMS, ELSAYED, and THE PHYSICIANS DESK REFERENCE each preceded ROCHE PHARMACEUTICALS, INC., APPENDIX I (2001), and thus by definition lacked knowledge of the data presented there. Thus, an earlier allegation of solving the long-felt need (if such an allegation in fact were shown in the record) would appear baseless, directly contradicted by the subsequent 2001 data, and thus unsustainable as a matter of law.

I. Appellant’s implied satisfaction of a long-felt need unsupported by evidence:

Appellant's Request implies that his invention satisfied a long-felt need which was not previously satisfied. However, here, as in In re Cavanagh, 436 F.2d 491, 496, 168 USPQ 466, 471 (CCPA 1971), appellant failed to bring forward evidence of his satisfaction of the need. Accordingly, appellant failed to rebut the prima facie case of obviousness as set forth in the Decision.

II. Appellant's reference to "2001 data" is factually incorrect:

We note that appellant relies on Roche Pharmaceuticals, Inc., (Roche) at Table 1 (see Request, page 4), and the Food and Drug Administration's (FDA) "interpretation of this data" (see Request, pages 3-4). While appellant refers to the data presented in Roche's Table 1 as "2001 data," we find that according to the note following Table 1 there was a "[c]umulative data cut-off date of March 31, 2000." This date is prior to the April 4, 2000 issue date of Elsayed, and the August 6, 2002 issue date of Abrams, which we note is after appellant's filing date. Stated differently, the data presented in Roche's Table 1 is prior to the date that the Elsayed and Abrams patents were public knowledge.<sup>1</sup>

Furthermore, the Roche report does not include data for 1999 and 2000 in most of their reports because the data is unstable for 1999 and 2000. See Roche, section 1.2, fourth paragraph, "[b]ecause the data are unstable for 1999 and 2000, these data are not included in most of the following review tables." Accordingly, most of the Roche

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<sup>1</sup> [A]s a matter of common sense, it is clear that the contents of a patent application which may be available as 'prior art' under § 102(e) to show that another was the first inventor may not have been known to anyone other than the inventor, his attorney, and the Patent Office examiner, and perhaps the assignee, if there was one, until it issued as a patent. As of its filing date it does not show what is known generally to 'any person skilled in the art,' to quote from § 112.

In re Glass, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974). Accordingly, neither Elsayed nor Abrams were available to demonstrate what was generally known to a person of ordinary skill in the art as of the cumulative data cut-off date of March 31, 2000 reported in Roche's report. See also Hazeltine Research v. Brenner, 382 U.S. 252, 254-55, 147 USPQ 429, 431 (1965) (under Section 102(e) a patent is a reference as of its filing date, although its existence is not known until it issues).

report is based on data obtained prior to 1999, and that which is not is only relevant up to the March 31, 2000 cut-off date. Thus, it follows from appellant's assertion (Request, page 3) that the FDA's comments are based on an interpretation of the Roche data, that this interpretation would be accurate only with regard to the data obtained prior to 1999. Any inference drawn from data covering the period from 1999 through the March 31, 2000 cut-off data would be based on data that is characterized by Roche as unstable.

Accordingly, we find appellant's characterization of the Roche data as "2001 data" to be factually unsupported on this record. Therefore, we are not persuaded by appellant's assertion that our earlier finding is "baseless, directly contradicted by the subsequent 2001 data, and thus unsustainable as a matter of law."

III. Appellant's assertion regarding Elsayed is factually incorrect:

Appellant's assertion (Request, page 4, fn. 1, alteration original) that "ELSAYED does not 'provide[ ] patients with a contraceptive device or formulation' Cf. DECISION at 7," is also factually incorrect. See Decision, page 4, emphasis added, "the last two steps (step g and step h) of the Elsayed method require (step g) pharmacies to fill prescriptions for non-pregnant patients, and (step h) provide patients who are capable of becoming pregnant a contraceptive device or formulation. See e.g., Elsayed, claim 1 and claim 10."

IV. An effective program to reduce pregnancy during Accutane treatment:

The Roche data is based, in part, on cases reported by the “Pregnancy Prevention Program for Women on Accutane-conducted by the Slone Epidemiology Unit....” Roche, page 1. In this regard, we note that Elsayed disclose that a survey conducted by the Slone Epidemiology Unit suggests that a pregnancy prevention program can be effective to reduce pregnancy during Accutane treatment. Specifically, as set forth on page 3 of the Decision, footnote omitted:

According to Elsayed (column 1, lines 48-57),

Previous methods for controlling the distribution of drugs have been developed in connection with Accutane (isotretinoin). Accutane, which is a known teratogen, is a uniquely effective drug for the treatment of severe, recalcitrant, nodular acne. A pregnancy prevention program was developed, and the Slone Epidemiology Unit of Boston University designed and implemented a survey to evaluate these efforts. The survey identified relatively low rates of pregnancy during Accutane treatment, which suggests that such a program can be effective.

Regarding appellant’s emphasis (Request, page 4), that Woodcock noted “exclusive reliance on ‘human memory’ is not an adequate precaution for managing severe risks,” we note that the methods of the Elsayed invention “may be desirably and advantageously used to educate and reinforce the actions and behaviors of patients who are taking the drug, as well as prescribers who prescribe the drug and pharmacies which dispense the drug.” See Decision, page 3:

Furthermore, Elsayed discloses (column 3, lines 26-31),

Generally speaking, the methods of the present invention may be desirably and advantageously used to educate and reinforce the actions and behaviors of patients who are taking the drug, as well as prescribers who prescribe the drug and pharmacies which dispense the drug. ... A wide variety of educational materials may be employed to ensure proper prescribing, dispensing and patient compliance according to the methods described herein, including, for example, a variety of literature and other materials, such as, for example, product information, educational brochures, continuing

education monographs, videotapes and the like which may describe the risks and benefits associated with taking the particular drug.

Consistent with Elsayed's emphasis on education, Elsayed discloses (column 9, lines 21-29),

The drug is preferably supplied to the pharmacy (as well as the patient) in packaging, such as individual blister packs, which includes warnings regarding the risks associated with the drug, as well as the importance of various aspects of the present methods such as, for example, pregnancy testing and the use of contraception (in the case of teratogenic drugs), and the dangers associated with sharing the drug with others, among other aspects.

V. Long-felt need satisfied by another prior to appellant's date of invention:

Appellant recognizes that the Decision states at page 10 "in our opinion, the long-felt need was recognized and satisfied by another before the date of the appellant's invention<sup>[2]</sup>." Request, page 6. Nevertheless, appellant asserts (id.), "[t]he DECISION fails to provide any support for this subjective factual assertion (the DECISION fails to say exactly who satisfied this, and when)."

Initially, we note that appellant discloses (specification, page 5), "I have found that one can make teratogenic pharmaceuticals more safe, by combining them as a unit with a contraceptive. ... In so doing, it minimizes the risk that a patient will become pregnant while taking the teratogen." As set forth on page 11 of the Decision, "Abrams discloses a combination isotretinoin – contraceptive composition." As set forth on page 8 of the Decision (alteration original),

as discussed above, Abrams, recognized that "[i]sotretinoin and analogs and isomers used for the treatment of postular acne has a severe danger

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<sup>2</sup> We recognize appellant's statement (Request, page 4, fn. 2), "the record has not addressed 'the date of [a]ppellant's invention'; we deal here only with the date of constructive reduction to practice – the application filing date (July 2001)." We note, however, that the date of invention is presumed to be the filing date of the application until an earlier date is proved. See e.g., Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 449, 230 USPQ 416, 420 (Fed. Cir. 1986); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991). Since there is no evidence on this record regarding an earlier date of invention, we fail to see appellant's point.

if taken by a woman who [is] pregnant,” and therefore teaches, “[t]he incorporation of oral contraceptive medication would eliminate the potential for pregnancy while medicated.” Note again, by way of illustration, that claim 11 of Abrams is drawn to “[a] pharmaceutical delivery package comprising a mixture of [i]sotretinoin and an oral contraceptive.”

Accordingly, Abrams recognizes the need – the severe danger of isotretinoin if taken by a woman who is pregnant; and satisfies the need – a pharmaceutical delivery package (a pharmaceutical composition), comprising a mixture of isotretinoin and an oral contraceptive.<sup>3</sup> Appellant’s claim 6 is drawn to a pharmaceutical composition comprising a unit dose form<sup>4</sup> of a teratogen (e.g. isotretinoin, see appellant’s claim 9), and a contraceptive. Contrary to appellant’s assertion (Request, page 6), Abrams supports our finding of fact and conclusion of law.

Furthermore, as set forth at page 11 of the Decision, “Elsayed discloses the need to provide educational materials to both the consumer and distributor, as well as, providing isotretinoin together with a contraceptive device or formulation.” See also Decision, pages 3-4. Note as set forth at page 3 of the Decision, “Elsayed discloses (column 3, lines 26-31), ... the methods of the present invention may be desirably and advantageously used to educate and reinforce the actions and behaviors of patients who are taking the drug....” In addition, as set forth on pages 3-4 of the Decision,

Elsayed discloses (column 9, lines 21-29),

The drug is preferably supplied to the pharmacy (as well as the patient) in packaging, such as individual blister packs, which includes warnings regarding the risks associated with the drug, as well as the importance of various aspects of the present methods

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<sup>3</sup> We note that appellant does not maintain his assertion that Abrams does not contain an enabling disclosure. Cf. Brief, pages 3-4.

<sup>4</sup> According to appellant’s specification, page 13, “[t]he term unit dose form means in a form wherein both components are intended to be taken together as one big pill or as two small pills together.” Appellant recognizes (Brief, page 4) that Abrams discloses “combining the two components into a unitary pill,” e.g., “one big pill.” Cf. Decision page 10.

such as, for example, pregnancy testing and the use of contraception (in the case of teratogenic drugs), and the dangers associated with sharing the drug with others, among other aspects.

At page 4 of the Decision, “we note that the last two steps (step g and step h) of the Elsayed method require (step g) pharmacies to fill prescriptions for non-pregnant patients, and (step h) provide patients who are capable of becoming pregnant a contraceptive device or formulation. See e.g., Elsayed, claim 1 and claim 10.”

Accordingly, Elsayed recognizes the need<sup>5</sup>; and satisfies the need<sup>6</sup> – provide educational materials to both the consumer and distributor, as well as, providing the drug with warnings regarding the risks associated with teratogenic drugs<sup>7</sup>, together with a contraceptive device or formulation.

Appellant’s claim 1 is drawn to an educational article of manufacture, wherein a teratogenic pharmaceutical is packaged together with a contraceptive and labeling specifying avoidance of pregnancy while using the teratogenic pharmaceutical. The only difference between claim 1 and Elsayed, is that while Elsayed provides patients who are capable of becoming pregnant a contraceptive device or formulation together with a teratogenic drug; Elsayed does not expressly state that the two components are “packaged together.” However, as set forth on page 5 of the Decision, alteration

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<sup>5</sup> “It is undisputed that the prior art acknowledges a long-felt need for the problem of teratogen-related birth defects.” Request, page 2.

<sup>6</sup> See Decision, page 3 (footnote omitted):  
According to Elsayed (column 1, lines 48-57),  
... A pregnancy prevention program was developed, and the Slone Epidemiology Unit of Boston University designed and implemented a survey to evaluate these efforts. The survey identified relatively low rates of pregnancy during Accutane treatment, which suggests that such a program can be effective.

<sup>7</sup> As set forth on page 2 of the Decision, according to appellant’s specification (page 7), the term ‘teratogenic’ ... include[s] pharmaceuticals associated with an increased risk of birth defects. The term thus includes pharmaceuticals with FDA-approved labeling citing an increased risk of birth defects as a potential side effect. Such teratogenic pharmaceuticals currently listed in the PHYSICIANS’ DESK REFERENCE (Medical Economics Company, publ. 2000) include, for example, isotretinoin (ACCUTANE®)....

original, Abrams, teaches, “[a] pharmaceutical delivery package comprising a mixture of [i]sotretinoin and an oral contraceptive.” Thus, “a person of ordinary skill in the art would have been motivated to package<sup>8</sup> isotretinoin together with a contraceptive.” Id.

As set forth on page 10 of the Decision, “[o]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved.” Newell Companies v. Kenney Mfg. Co., 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988). For the foregoing reasons, as well as the reasons set forth in the Decision, both Elsayed and Abrams individually supply the key element to satisfy the long-felt need. Accordingly, both Elsayed and Abrams, individually or combined, support our finding of fact and conclusion of law that “the long-felt need was recognized and satisfied by another before the date of appellant’s invention.” Decision, page 10.

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<sup>8</sup> We note that appellant defines “packaged together” as “a unitary package for sale as an undivided unit.” See appellant’s Specification, page 9.

VI. The art does not teach away from the claimed invention:

According to appellant (Request, page 3), the art teaches away from the claimed combination. In support of this assertion, appellant relies (id.) on Shangold<sup>9</sup> (column 11, lines 49-54), which according to appellant “teaches to not use contraceptives where there is a ‘concomitant use of isotretinoin (Accutane), tretinoin (Renova or Retin-A) or has taken them within the 30 day period immediately prior to the screening visit.” In our opinion, appellant has mischaracterized the cited section of the reference. Shangold is drawn to a method of contraception and a triphasic oral contraceptive. See claims. The section of Shangold cited by appellant refers to a portion of the criteria used by Shangold to exclude subjects from a “randomized, multi-center study to evaluate three blinded regimens of norgestimate and ethinyl estradiol (NGM/EE) oral contraceptive and an open-label control regimen.” See Shangold, column 10, line 20 through column 11, line 54. Thus, while Shangold excluded subjects using isotretinoin (Accutane) from the study, we find no disclosure in Shangold that “teaches to not use contraceptives where there is a ‘concomitant use of isotretinoin (Accutane)...” as asserted by appellant.

In addition appellant relies on Gaull<sup>10</sup> to teach “combining isotretinoin not with a contraceptive, but with taurine, a compound ‘which reduces the side effects of isotretinoin.’” Request, page 3. Apparently, appellant believes that since the art taught an alternative to the combination of isotretinoin with a contraceptive the art teaches away from appellant’s claimed invention. We note, however, that the mere fact that

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<sup>9</sup> Shangold et al. (Shangold)

6,214,815

Apr. 10, 2001

<sup>10</sup> Gaull

4,545,911

Oct. 8, 1985

alternatives may exist does not preclude the development of a new model that is obvious over the prior art. See In re Beattie, 974 F.2d 1309, 1312-13, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) (holding that an alternative to a well-entrenched theory does not preclude a finding of obviousness because the recommendation of a new system “does not require obliteration of another”). For this same reason, we disagree with appellant’s assertion (Request, page 6), “if an inventor(s) truly believes they have satisfied a long-felt need, they would appear disinclined to spend further effort on an already-completed task.” On this record, the combination of prior art relied upon provides an obvious alternative to Gaull.

VII. The prior art relied upon provides a suggestion to combine:

Appellant is correct (Request, page 5) in that a suggestion to combine must be identified in the prior art of record. In re Lee, 277 F.3d 1338, 1343-44, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002). For the reasons set forth in the Decision, we believe that a suggestion to combine is set forth in the prior art relied upon. For his part, however, appellant fails to state with particularity the reason why he believes the Decision fails to identify a suggestion to combine the prior art relied upon. 37 CFR § 1.197(b). To the contrary, the Decision recognizes (see e.g., bridging paragraph, pages 5-6):

“The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art.” In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Based on the evidence set forth above, we find that it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to package a contraceptive formulation and/or device together with isotretinoin (Accutane), and label said composition according to the official labeling information set forth in the PDR.

For the foregoing reasons, as well as those presented in the Decision, we are not persuaded by appellant's assertion that the "references do not suggest the claimed combination." Request, pages 5-6 and n. 3.

CONCLUSION

We have carefully reviewed the original opinion in light of appellant's Request, but we find no point of law or fact that we overlooked or misapprehended in arriving at our decision. Therefore, appellant's request has been granted to the extent that the decision has been reconsidered, but such request is denied with respect to making any modifications to the Decision.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REHEARING DENIED

	)	
William F. Smith	)	
Administrative Patent Judge	)	
	)	
	)	BOARD OF PATENT
	)	
Donald E. Adams	)	APPEALS AND
Administrative Patent Judge	)	
	)	INTERFERENCES
	)	
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Eric Grimes	)	
Administrative Patent Judge	)	

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