

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PATRICK MICHEL CAUBEL and ANDREW JOSEPH FRIEDMAN

Appeal 2007-4127
Application 10/385,867
Technology Center 1600

Decided: October 31, 2007

Before, TONI R. SCHEINER, DEMETRA J. MILLS, and LORA M. GREEN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Claim 1 is the only pending claim.

1. A method of contraception comprising the step of administering to a menstruating female a cycle of contraceptive therapy, said cycle of therapy including the continuous administration for the length of the cycle of a potent sulfatase inhibiting progestogen in a contraceptively effective and breast protecting dose, in the absence of the administration of an estrogen,

wherein the progestogen is selected from the group consisting of norgestimate and norelgestromin.

Grounds of Rejection

Claims 1 stands rejected under 35 U.S.C. § 103, as obvious over de Nijs and Appellants admission in the specification.

Reference Cited

de Nijs	4,957,119	Sept. 18, 1990
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DISCUSSION

Background

"The present invention relates to progestogen-only contraceptive regimens for menstruating females. More particularly, the present invention relates to progestogen only contraceptive regimens containing a potent sulfatase inhibiting progestogen, such as, norgestimate (NGM) or norelgestromin (NGMN)." (Specification 1.)

"A substantial percentage of human breast carcinomas are hormone-dependent. Animal studies and clinical trials have confirmed that estrogens, particularly estradiol, are the most important hormones involved in supporting growth of hormone-dependent breast tumours." (Specification 1.)

Since estradiol is one of the main factors involved in supporting growth of hormone-dependent breast tumours and the sulfatase pathway is the main pathway for the formation of estradiol in the breast, then a decrease of estradiol formation by

suppression of the sulfatase pathway would have potential therapeutic activity in the management of breast cancer... Suppression of the sulfatase pathway will have a breast protective effect.

(Specification 1.)

Obviousness

Claims 1 stands rejected under 35 U.S.C. § 103, as obvious over de Nijs and Appellants' admission in the specification.

According to the Examiner, de Nijs discloses an implant containing a contraceptive agent (abstract). The preferred active agent is a progestogen, for example, levonorgestrel. It can be administered in a daily dosage of 15-30 µg (col. 2, lines 20-27). The implant is used for application in humans, which can bring about a virtually constant release of the active substance. The implant may be applied to the uterus (col. 3, lines 44-58). The constant release of progestogen is over a predetermined term (col. 8, lines 10-12). (Answer 4.)

The Examiner acknowledges that de Nijs fails to disclose the patient population to be menstruating females and fails to specifically mention the claimed progestogens, norgestimate and norelgestromin. (Answer 4.)

The Examiner relies on Appellants' own admission of the prior art, that norgestimate and norelgestromin are known progestogens, and are each well known in the art of contraception therapy (Specification 6: 26-27; Answer 4).

The Examiner concludes that

[i]t would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer this contraceptive implant to menstruating females and to substitute norgestimate or norelgestromin for levonorgestrel.

A person of ordinary skill in the art would have been motivated to administer menstruating females an implant comprising a contraceptive agent because of the reasonable expectancy of successfully preventing contraception.

A person of ordinary skill in the art would have been motivated to substitute norgestimate or norelgestromin for levonorgestrel because: (1) De Nijs teach the general usefulness of progestogen; (2) all three compounds are disclosed to be progestogens; (3) all three are recognized to be art-equivalent. Thus, one of ordinary skill in the art would have had a reasonable expectation of successfully producing a contraceptive regimen with norgestimate or norelgestromin as taught by De Nijs.

(Answer 4-5.)

We agree with the Examiner's analysis and reasoning and find that the Examiner has provided sufficient evidence to support a *prima facie* case of obviousness.

In order to determine whether a *prima facie* case of obviousness has been established, we considered the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present.

The Examiner's evidence establishes that it is known in the art to use a progestogen (progestin) in the absence of estrogen as a contraception agent in a menstruating female. de Nijs indicates that the active progestogen may be selected from known progestogens such as 3-ketodesogestrel, levonorgestrel or gestodene. (de Nijs, col. 2, ll. 20-25.) Appellants also admit that other progestins are known in the art of contraceptive therapy, including norgestimate and norelgestromin. (Specification 6: 26-27.)

In making an obviousness determination over a combination of prior art references, it is important to identify a reason why persons of ordinary skill in the art would have attempted to make the claimed subject matter. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007). The Examiner has indicated a reason why one of ordinary skill in the art would have been motivated to substitute other progestins such as norgestimate and norelgestromin known for their contraceptive use, for the levonorgestrel implant described in de Nijs. It is noted that the motivation to combine references does not have to be identical to patent owner's to establish obviousness. *In re Kemps*, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *KSR Int'l Co. v. Teleflex Inc.*, 127 Ct. 1727, 82 USPQ2d 1385 (2007). In the present case, a progestogen is being predictably used in accordance with its established function, as a contraceptive agent.

The Appellants contend that the Examiner admits that de Nijs nowhere teaches or suggests norgestimate or norelgestromin as the active agent. (Br. 9.) Appellants point out that de Nijs nowhere teaches or suggests the continuous administration of a progestin-only contraceptive in which the progestin is a sulfatase inhibiting progestin administered in a dose that is both contraceptive and breast protective. *Id.* Moreover, Appellants argue de Nijs nowhere teaches or suggests such a regimen wherein the sulfatase inhibiting progestin is either norgestimate or norelgestromin. *Id.*

Appellants contend that the de Nijs reference fails to appreciate that certain progestins are both sulfatase inhibiting and contraceptive and, therefore, provide both a breast protective effect and a contraceptive effect. (Id.) Appellants argue that the absence of this appreciation in de Nijs would prevent a person skilled in the art from using this reference as the starting point to the claimed invention. (Br. 9.)

Appellants further argue that the deficiency in de Nijs is not addressed by the prior art statement in the specification cited by the Examiner, since this portion of the specification merely states that norgestimate and norelgestromin are progestogens known in the contraceptive art. *Id.* "The teaching that norgestimate and norelgestromin are both sulfatase inhibiting and contraceptive is provided only by the instant invention, which cannot be used to fill in the deficiencies in the prior art." (*Id.*, at 10.)

While each of Appellants' observations may be true, they are not sufficient to support patentability of the claimed invention. Using the same composition claimed, a progestogen, in the same manner claimed, as a contraceptive agent, naturally results in the same claimed benefit of

contraception. (*Perricone v. Medicis Pharmaceutical Corp.* 432 F. 3d 1368, 1384 77 USPQ2d 1321, 1327 (Fed. Cir. 2005) (“The discovery of a previously unappreciated property of a prior art composition … does not render the old composition patentably new to the discoverer.”); *EMI Group, N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1349, 60 USPQ2d 1423,1428 (Fed. Cir. 2001); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1349 (Fed. Cir. 1999) (“discovery of an inherent property of the prior art [does] not [constitute] the addition of a novel element” and therefore does not serve as patentable subject matter).

This is not a case in which the patentee is claiming a method that consists of a new way of using a previously known product in order to achieve a new result. The Supreme Court explained that “if an old device or process be put to a new use which is not analogous to the old one, and the adaptation of such process to the new use is of such a character as to require the exercise of inventive skill to produce it, such new use will not be denied the merit of patentability.” *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 18 (1892). The Federal Circuit qualified that rule by adding that “the application of an old process or machine to a similar or analogous subject, with no change in the manner of application and no result substantially distinct in its nature, will not sustain a patent even if the new form of result had not before been contemplated.” *Perricone v. Medicis Pharmaceutical Corp.* 432 F. 3d 1368, 77 USPQ2d 1321, 1332 (Fed. Cir. 2005).

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Appellants claim a known method of contraception of administering a known contraceptive agent, a progestin. Progestins are known contraceptive agents as evidenced by the cited prior art. Thus Appellants claim nothing more than use of a known contraceptive agent as a contraceptive.

In view of the above, the obviousness rejection is affirmed.

SUMMARY

The rejection of claims 1 under 35 U.S.C. § 103, as obvious over de Nijs and Appellants admission in the specification is affirmed.

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

AFFIRMED

dm

Philip S. Johnson
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

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