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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SCOTT B. HURLEY

Appeal 2011-002460
Application 11/906,588
Technology Center 3700

Before LORA M. GREEN, JEFFREY N. FREDMAN, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to contraceptive method. The Examiner rejected the claims as indefinite and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

The Specification teaches “a contraception method having a concomitant use of an immunocontraceptive agent with another method of

contraception to boost the real world efficacy rate of the primary contraceptive method to between 95% and 100% efficacy” (Spec. 5 ¶ 0009).

The Claims

Claims 1-11 and 13-17 are on appeal. Claim 1 is representative and read as follows:

1. A contraceptive method, comprising the steps of:
using a primary contraceptive; and
administering a secondary, immunocontraceptive;
wherein the administering of the secondary,
immunocontraceptive is initiated prior to the using of the
primary contraceptive.

The issues

- A. The Examiner rejected claims 9, 10, and 13 under 35 U.S.C. § 112, second paragraph, as indefinite (Ans. 3-4).
 - B. The Examiner rejected claims 1-9, 11, and 13-17 under 35 U.S.C. § 103(a) as obvious over Oko¹ (Ans. 5-7).
 - C. The Examiner rejected claim 10 under 35 U.S.C. § 103(a) as obvious over Oko and Miller² (Ans. 7).
 - D. The Examiner rejected claims 15 and 16 under 35 U.S.C. § 103(a) as obvious over Oko and Saffir³ (Ans. 7-8).
- A. *35 U.S.C. § 112, second paragraph*

The Examiner finds that “further limiting the method with the step of ‘repeating the administering at predetermined intervals’ is unclear and indefinite since the controlling independent claim requires

¹ Oko et al., US 6,995,252 B2, issued Feb. 7, 2006.

² Miller et al., US 2006/0013821 A1, published Jan. 19, 2006.

³ Saffir et al, US 2,853,071, issued Sep. 23, 1958.

immunocontraceptive administration initiation **prior to the using of the primary contraceptive**” (Ans. 4). The Examiner finds “it is unclear if claims 9 and 10 are attempting to further limit subsequent administration(s) of the immunocontraceptive” (*id.*). The Examiner also finds, regarding claim 13, that “it is unclear how a subsequent method step is to be achieved which limits ‘during use’ or simultaneous administration of immunocontraceptive and primary contraceptive. The claim is indefinite, because it is unclear what applicant is attempting to claim” (*id.*).

Appellant “submit[s] that there is no indefiniteness based on the use of the term ‘initiate’ as is commonly used and as used in the claims” (App. Br. 4). Appellant contends that the claims are “directed to subsequent administrations of the secondary immunocontraceptive after the initial administration” (*id.*). Appellant contends that these “subsequent administrations may be prior to, during, or subsequent to administration of the primary contraceptive” (*id.*). Appellant contends that “[c]laim 13 further limits claim 1 indicating that the immunocontraceptive is also administered during use of the primary contraceptive” (*id.* at 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that claims 9, 10, and 13 are indefinite?

Principles of Law

“The test for definiteness is whether one skilled in the art would understand the bounds of the claims when read in light of the specification.” *Miles Laboratories, Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993).

Analysis

We agree with Appellant that the hypothetical person of ordinary skill in the art would reasonably interpret claims 9 and 10, in light of the Specification, as simply requiring that, after an initial administration of the immunocontraceptive prior to the use of a primary contraceptive consistent with claim 1, additional doses of the immunocontraceptive are administered to the patient, before or after the use of the primary contraceptive. We also agree that claim 13 simply further limits the claim to require that at least one second or later dose of the immunocontraceptive is administered during the use of the primary contraceptive.

Contrary to the Examiner's concern, these claims simply require that additional doses of the immunocontraceptive are administered, after an initial dose prior to primary contraceptive use, without providing a specific time frame for the additional doses. Consistent with claims 9 and 10, the additional doses may, like the first dose, be administered prior to the initiation of the primary contraceptive, or unlike the first dose, be administered later, after initiation of the primary contraceptive.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that claims 9, 10, and 13 are indefinite.

B. 35 U.S.C. § 103(a) over Oko

The Examiner finds that “Oko discloses a contraceptive method, comprising the steps of using a primary contraceptive; and administering a secondary, immunocontraceptive such as PT32 and c-Yes proteins (col 21, lines 33-36) to boost overall efficacy of the contraceptives” (Ans. 5). The

Examiner finds that “Oko fails to explicitly disclose in which order the contraceptives are administered, specifically administering the immunocontraceptive prior to using the primary contraceptive” (*id.*).

The Examiner finds it obvious “that in order to achieve an effective contraceptive means utilizing an immunocontraceptive, the peptide product must be administered well in advance of intercourse to ensure that the immunocontraceptive has reached an effective titer level in the user to be efficacious” (*id.*). The Examiner finds “reliance upon a combination of contraceptive means is well known in the art. For instance, it is common for a user to be using a pill based contraceptive, which is ingested or initiated prior to insertion of a sponge or diaphragm before intercourse” (*id.*).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Oko renders claim 1 obvious?

Findings of Fact

1. Oko teaches that the “PT32 and c-Yes proteins also are useful in the field of contraception. Specifically, the PT32 and/or c-Yes protein can be used as targets in conventional immunocontraception methods” (Oko, col. 21, ll. 34-37).

2. Oko teaches that “a chimeric protein containing all or an antigenic portion of PT32 or c-Yes is administered to the mammal in a contraceptively effective dosage” (Oko, col. 21, ll. 45-48).

3. Oko teaches that the proteins “may be administered with a suitable . . . depot (slow release) formulation to allow prolonged exposure of the protein to the host mammal's immune system. A contraceptively effective dosage is a dosage sufficient to elicit the production of an immune

response (e.g., antibody or immune cell production) in the mammal” (Oko, col. 21, ll. 50-56).

4. Oko teaches that “conventional foams, gels, sponges, suppositories, creams, tablets, controlled delivery devices, vaginal-soluble waffles, ointments, lotions, sprays, jellies, patches, and lubricants (e.g., for condoms, diaphragms, cervical caps), and the like can be used in conjunction with the molecules of the invention” (Oko, col. 22, ll. 44-49).

5. Oko teaches that “[s]uch foams, creams, and the like can be administered, e.g., intravaginally, to a mammal to provide a contraceptive (e.g., a contraceptive barrier) in a contraceptive method (e.g., to inhibit fertilization)” (Oko, col. 22, ll. 54-58).

6. Oko teaches that “[p]olypeptides and other molecules of the present invention may be employed alone or in conjunction with other compounds, such as therapeutic or contraceptive compounds” (Oko, col. 22, ll. 61-63).

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417. As noted by the Court in *KSR*, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” 550 U.S. at 421.

“Appellant contends that the references taken singly or together do not teach his characteristic four steps There is no merit in the point here in

the absence of any proof in the record that the order of performing the steps produces any new and unexpected results.” *In re Burhans*, 154 F.2d 690, 692 (CCPA 1946).

Analysis

Okamoto teaches a method of using an immunocontraceptive (FF 1-3). Okamoto further teaches that “conventional foams, gels, sponges, suppositories, creams, tablets, controlled delivery devices, vaginal-soluble waffles, ointments, lotions, sprays, jellies, patches, and lubricants (e.g., for condoms, diaphragms, cervical caps), and the like can be used in conjunction with the molecules of the invention” (Okamoto, col. 22, ll. 44-49; FF 4).

The Examiner acknowledges that Okamoto “fails to explicitly disclose in which order the contraceptives are administered” (Ans. 5).

We agree with the Examiner that “the peptide product must be administered well in advance of intercourse to ensure that the immunocontraceptive has reached an effective titer level in the user to be efficacious” (*id.*). Therefore, when the “primary contraceptive” in use is one of condoms, sponges, cervical caps, foams, suppositories, diaphragms, or other barrier type methods, it is a necessary and inherent result that the immunocontraceptive will be initiated prior to the use of the primary contraceptive, since unlike the immunocontraceptive which would be administered well in advance of intercourse, primary barrier contraceptives would be administered immediately prior to intercourse.

Appellant “submits that this fails to disclose or suggest the feature of claim 1 that the administering of the secondary, immunocontraceptive is initiated prior to the using of the primary contraceptive” (App. Br. 7).

We are not persuaded. We find that the reasoning in *Burhans* applies. In *Burhans*, the Appellant identified four steps for making an enriched flour, where each of the steps was disclosed in the prior art. *See Burhans*, 154 F.2d 691-2. The court was unpersuaded, finding that in the absence of a secondary consideration, the selection of any order of known process steps would have been obvious. *Id.* We conclude that the same reasoning applies in the instant case, where Oko expressly teaches the combination of immunocontraceptives with other forms of contraception, and either order of administration of immunocontraceptives and hormonal contraceptives or IUDs would have been obvious to the ordinary artisan at the time the invention was made in light of Oko’s teachings (FF 1-6).

Appellant contends that “Oko teaches away from using an immunocontraceptive prior to a primary contraceptive since Oko discloses using ‘polypeptide, antibodies, or test compounds’ *with* a carrier and/or device conventionally used for delivering contraceptive or fertility-enhancing agents” (App. Br. 7).

We do not find the teaching away argument persuasive. A teaching away requires a reference to actually criticize, discredit, or otherwise discourage the claimed solution. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (“The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed”). Appellant does not identify, and we do not find, any teaching in Oko which criticizes, discredits, or otherwise discourages the

initiation of immunocontraception prior to the use of other forms of contraceptives.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that Oko renders claim 1 obvious.

C. 35 U.S.C. § 103(a) over Oko and Miller

The Examiner finds "Miller discloses an immunocontraceptive vaccine in which an immune response can be maintained for a period of months up to years" (Ans. 7). The Examiner finds it obvious to "practice the method steps of Oko according to the administration time frame of between once a month and once every five years as taught by Miller in order to provide an elongated period of contraceptive efficacy that would not require frequent immune boosters" (*id.*).

The Examiner provides sound fact-based reasoning for combining Miller and Oko. We adopt the fact finding and analysis of the Examiner as our own. Appellant's arguments are directed Oko, but not at the combination of Oko and Miller. Therefore, consistent with the rejection which we affirmed above, we affirm this rejection for the reasons stated by the Examiner.

D. 35 U.S.C. § 103(a) over Oko and Saffir

The Examiner finds "Saffir discloses medicament vial or medicament container or bottles for hypodermic solutions including single dose . . . and multiple dose vials" (Ans. 8). The Examiner finds it obvious to package "the contraceptives of Oko with packaging the secondary contraceptive as a single dose, and packaging the secondary contraceptive as a multiple dose

vial in order to provide known packaging techniques that are in line with the needs of different users” (*id.*).

The Examiner provides sound fact-based reasoning for combining Saffir and Oko. We adopt the fact finding and analysis of the Examiner as our own. Appellant’s arguments are directed Oko, but not at the combination of Oko and Saffir. Therefore, consistent with the rejection which we affirmed above, we affirm this rejection for the reasons stated by the Examiner.

SUMMARY

In summary, we reverse the rejection of claims 9, 10, and 13 under 35 U.S.C. § 112, second paragraph.

We affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Oko. Pursuant to 37 C.F.R. § 41.37(c)(1)(2006), we also affirm the rejection of claims 2-9, 11, and 13-17, as these claims were not argued separately.

We affirm the rejection of claim 10 under 35 U.S.C. § 103(a) as obvious over Oko and Miller.

We affirm the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) as obvious over Oko and Saffir.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED

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