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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* MICHAEL M. KAMRAVA

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Appeal 2010-010201  
Application 10/080,177  
Technology Center 3700

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Before LINDA E. HORNER, SCOTT E. KAMHOLZ, and  
MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Michael M. Kamrava (Appellant) seeks our review under 35 U.S.C. § 134 of the Examiner's decision rejecting claims 1-3, 5-8, 10-15, and 27-42. Claims 9 and 16-26 are canceled. Claim 4 is pending but not rejected. We have jurisdiction under 35 U.S.C. § 6(b).

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We AFFIRM-IN-PART and enter NEW GROUNDS of REJECTION pursuant to our authority under 37 C.F.R. § 41.50(b).<sup>1</sup>

### THE INVENTION

Appellant's claimed invention relates to intra-uterine devices for microsurgical use such as those used in the field of embryo implantation. Spec., para. [0002]. Claims 1, 10, and 42 are independent. Claim 1, reproduced below, is representative of the subject matter on appeal.

1. A catheter comprising:

a shaft comprising a body having a length dimension suitable for insertion through an hysteroscope, the body with a proximal portion and a distal portion, the body defining an opening from the proximal portion to the distal portion, the distal portion having an exterior dimension suitable for insertion into a subject as a procedural instrument, the distal portion having an end that is beveled in a first direction across an end opening, a length of the shaft to a first point on the end is a first length and a length of the shaft to a second point on the end is a second length longer than the first length, and at the second point, a portion of the shaft is beveled defining an angled tip, wherein the angled tip has a shape that is suitable for insertion into an endometrial lining of the subject as a microsurgical instrument and comprises a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject.

### THE EVIDENCE

The Examiner relies upon the following evidence:

Gobby US 4,474,576 Oct. 2, 1984

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<sup>1</sup> This appeal is related to Appeal 2011-005321 in related Application 10/725,623 and Appeal 2012-001507 in related Application 11/388,467.

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|         |                 |               |
|---------|-----------------|---------------|
| Lakatos | US 4,997,419    | Mar. 5, 1991  |
| Bacich  | US 5,472,419    | Dec. 5, 1995  |
| Peery   | US 7,063,681 B1 | Jun. 20, 2006 |

## THE REJECTIONS

Appellant seeks review of the following rejections:

1. Claims 34 and 40 are rejected under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter.
2. Claims 2, 3, 14, and 31 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement.<sup>2</sup>
3. Claims 2, 3, 13, and 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.<sup>3</sup>
4. Claims 1-3, 10, 13, 14, 29-33, 36-38, and 42 are rejected under 35 U.S.C. § 102(e) as being anticipated by Peery.
5. Claims 1, 5-8, 10, 11, 15, 27-30, 32, 35-39, 41, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gobby and Bacich.
6. Claims 7 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gobby, Bacich, and Lakatos.

While Appellant includes the indefiniteness rejection in the grounds of rejection to be reviewed on appeal (App. Br. 7), Appellant does not

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<sup>2</sup> The Examiner withdrew claims 35 and 41 from this ground of rejection in the Answer. Ans. 11.

<sup>3</sup> The Examiner withdrew claims 4, 15, and 30 from this ground of rejection in the Answer. Ans. 12. As such, claim 4 is not rejected.

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contest the rejection of claims 2, 3, 13, and 14 on this basis. App. Br. 14-15. As such, we summarily affirm the rejection of claims 2, 3, 13, and 14 under 35 U.S.C. § 112, second paragraph, as being indefinite.

Appellant also seeks the Board's review of the Examiner's objection to claims 1, 3, 4, and 15 and the Examiner's objection to the Specification. App. Br. 7. As correctly noted by the Examiner, these objections are petitionable, not appealable. Ans. 3; *see also Ex parte Frye*, 94 USPQ2d 1072, 1078 (BPAI 2010) (precedential) (for discussion of petitionable matters versus appealable matters).

## ISSUES

The issues presented by this appeal are:

Are claims directed to a catheter/apparatus comprising an embryo in the distal portion directed to patent-ineligible subject matter?

Does the original disclosure contain written description of the subject matter of claims 2, 3, 14, and 31 in a manner to reasonably convey to those skilled in the art that Appellant had possession of the claimed subject matter as of the filing date?

Does Peery disclose a catheter/apparatus comprising a material that has "sufficient flexibility to resist penetration of a uterine muscle of the subject" as called for in claims 1 and 10?

Would the combined teachings of Gobby and Bacich have rendered obvious to one of ordinary skill in the art a catheter having an angled tip that

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has a shape that is suitable for insertion into an endometrial lining of the subject as a microsurgical instrument, as claimed?<sup>4</sup>

## ANALYSIS

### *Rejection under 35 U.S.C. § 101*

The Examiner rejected claims 34 and 40 “because they recite ‘embryo’ and the ‘embryo’ is a part of the human body.” Ans. 3. Appellant argues that claims 34 and 40 do not claim an embryo, but rather claim a catheter having an embryo in the distal portion. App. Br. 11. Appellant further argues that the claimed embryo is not a part of the human body because as claimed “the embryo in the distal portion of the catheter is a non-naturally occurring combination, which does not occur in nature, but rather which is the product of human ingenuity.” Reply Br. 4-5.

We disagree with Appellant’s contention that claims 34 and 40 do not positively recite an embryo. Claims 34 and 40 are directed to the combination of a catheter and an embryo, and thus positively recite an embryo. As noted by the Examiner, if Appellant had intended not to encompass an embryo, the claims could have recited that “the distal portion of the catheter is adapted to receive/hold an embryo.” Ans. 11. Appellant chose, however, to positively claim an embryo within the distal portion.

Appellant does not challenge the Examiner’s determination that an embryo is non-statutory subject matter. Rather, Appellant argues that

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<sup>4</sup> Independent claim 1 recites the claim language as presented in the statement of the issue. Independent claims 10 and 42 similarly recite an apparatus/uterine device having an angled tip that is shaped for insertion into an endometrial lining.

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because the non-statutory subject matter is claimed in combination with statutory subject matter, the claims are directed to statutory subject matter. The fact that the claims cover patent-eligible subject matter, i.e., a catheter or device, in combination with patent-ineligible subject matter, a human embryo, does not render the claims patent-eligible. To allow one to sidestep 35 U.S.C. § 101 by simply pairing in combination patent-ineligible subject matter with patent-eligible subject matter would impermissibly exalt claim strategy (form) over claimed subject matter (substance). As such, we affirm the rejection of claims 34 and 40 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter.

#### NEW GROUNDS OF REJECTION

Claims 35 and 41 depend from claims 34 and 40, respectively, and further recite that the embryo is included in a culture medium that is sandwiched between measures of air in the distal portion. The rejection under 35 U.S.C. § 101 applies equally to claims 35 and 41 by virtue of their dependency from claims 34 and 40. As such, we enter a new ground of rejection of claims 35 and 41 for the same reasons as discussed *supra* and provided by the Examiner in the rejection of claims 34 and 40.

We also enter a new ground of rejection of claims 34, 35, 40, and 41 under section 33(a) of the Leahy-Smith America Invents Act (AIA), which provides, “Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.” AIA, Public Law 112-29, sec. 33(a), 125 Stat. 284 (Sept. 16, 2012). Section 33(a) applies to any application for patent that is pending on, or filed on or after,

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September 16, 2012. *Id.* at sec. 33(b). Section 33(a) creates a statutory expression of the Office’s longstanding position that human organisms are not patent-eligible subject matter. *See* Manual of Patent Examining Procedure § 2105, Eighth Ed., Rev. 9 (August 2012) (“If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human organism, then a rejection under 35 U.S.C. 101 and AIA sec. 33(a) must be made indicating that the claimed invention is directed to a human organism and is therefore nonstatutory subject matter.”).

*Rejection under 35 U.S.C. § 112, first paragraph*

The Examiner rejected claims 2, 3, and 14 because there is no support for the beveled point/end defining an angle of 10 to 45 degrees between the end of the distal portion and the open front end. Ans. 4. The Examiner explained that the disclosure does not define the location of the claimed beveled point or end. Ans. 11. Appellant argues that support is found in paragraph [0028] and Figure 3 of the original disclosure. App. Br. 12.

Paragraph [0028] describes that “[m]icrocatheter 10 also includes angled or beveled opening 34 angled 10 to 45° (angle  $\gamma$ ), in this case opposite the above-referenced deflection angle  $\alpha$ .<sup>1</sup>” A person of ordinary skill in the art would understand that an angled or beveled opening angled at 10 to 45° refers to the angle formed between the face of the beveled opening and the side of the microcatheter shaft. *See* Spec., fig. 3 (angle marked with an arc). A person of ordinary skill in the art would also understand that the claimed beveled point or end refers to the distalmost point or end on the microcatheter shaft, i.e., tip 35. *See* Spec., para. [0028] (“A point at the

distal end of shaft 25 representing the greatest length of shaft 25 defines tip 35.”). As such, one of ordinary skill in the art would understand from the original disclosure that Appellant was in possession of the subject matter encompassed by claims 2, 3, and 14. Accordingly, we reverse the rejection of claims 2, 3, and 14 under 35 U.S.C. § 112, first paragraph.

The Examiner rejected claim 31 on the basis that there is no support for the second direction being approximately perpendicular to the first direction.<sup>5</sup> Ans. 4. Appellant argues that support is found in paragraph [0028] and Figures 3 and 11 of the original disclosure. App. Br. 13. Paragraph [0028] describes that “[a] portion of the body of shaft 25 including tip 35 may be beveled in a direction opposite bevel angle  $\gamma$  to yield a more refined cutting tool.” We find that one of ordinary skill in the art would understand “direction opposite” in this portion of the Specification to mean merely that the bevel at the tip is in a direction divergent from, and not necessarily perpendicular to, the direction of the bevel of the shaft. We disagree with Appellant’s characterization of Figure 11 as showing the bevels at the tip 35 moving in first and second directions that are approximately perpendicular. App. Br. 13. Rather, one of ordinary skill in the art would not be able to discern that the first and second directions shown in Figure 11 are approximately perpendicular, and no such description of these bevels is provided in the description of Figure 11. As

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<sup>5</sup> Claim 31 depends from claim 30, which depends from claim 1. Claim 30 recites “wherein at the tip the shaft is beveled in a second direction that is different than the first direction.” Claim 31 calls for the second direction to be “approximately perpendicular to the first direction.”

such, one of ordinary skill in the art would not understand from the original disclosure that Appellant was in possession of the subject matter encompassed by claim 31. Accordingly, we affirm the rejection of claim 31 under 35 U.S.C. § 112, first paragraph.

*Rejection under 35 U.S.C. § 102(e)*

Independent claims 1 and 10 call for an angled tip comprising a material that has “sufficient flexibility to resist penetration of a uterine muscle of the subject.” The Examiner found that Peery “teaches cannula (20, 40, 60) may be formed of known cannula material such as plastic or metal (column 6 lines 17-19), of which possesses sufficient rigidity to penetrate the endometrial lining & sufficient flexibility to resist penetration of an uterine muscle of the subject.” Ans. 10.

Peery discloses “a cannula for puncturing the skin of an animal” and having two different angles at the distal end to provide “reduced tissue trauma and tearing during the trocar insertion.” Peery, Abstract; col. 3, ll. 4-9; col. 5, ll. 7-9. Thus, Peery discloses a cannula that is designed to be rigid enough to penetrate through layers of tissue. We agree with Appellant that “since Peery doesn’t disclose that it would be desirable to make the cannulas flexible, there is no reason to assume that they would be flexible. Rather, it is more reasonable to assume that they would be made rigid so that they don’t bend when they aren’t intended to bend. . . .” Reply Br. 19. As such, the Examiner’s determination that Peery’s cannula possesses sufficient flexibility to resist penetration of a uterine muscle of the subject is not supported by a preponderance of the evidence in light of the fact that Peery’s

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cannula is specifically designed and intended to be used to penetrate the skin of an animal. As such, we reverse the rejection of independent claims 1 and 10, and their dependent claims 2, 3, 13, 14, 29-33, and 36-38, under 35 U.S.C. § 102(e) as being anticipated by Peery.

Appellant grouped independent claim 42 with claim 1, and argued that claim 1, and thus claim 42 by its grouping, are not anticipated by Peery because Peery does not disclose “a body having a length dimension suitable for insertion through an hysteroscope” and “a material that has sufficient rigidity to penetrate the endometrial lining of the subject and sufficient flexibility to resist penetration of a uterine muscle of the subject.” App. Br. 24-25. While the argued limitations appear in claim 1, they are not present in independent claim 42. Appellant has not identified any error in the Examiner’s rejection of independent claim 42 as being anticipated by Peery. As such, we affirm the rejection of claim 42 under 35 U.S.C. § 102(e).

*Rejections under 35 U.S.C. § 103(a)*

The Examiner acknowledged that Gobby does not disclose a beveled distal end portion as called for in the claims. Ans. 6. Indeed, Gobby discloses that the apparatus, which is used for artificial insemination, has a rounded end so as not to inflict injury during the artificial insemination operation. Gobby, col. 4, ll. 34-42. The Examiner determined that Bacich discloses a transfer catheter body comprising a distal portion having a beveled end, and that it would have been obvious to modify the Gobby apparatus such that the distal portion would be beveled. Ans. 6. The

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Examiner determined that “the Gobby/Bacich angled tip is in a shape that is suitable for insertion into an endometrial lining of a subject.” Ans. 6; *see also* Final Office Action at 7.

Bacich discloses an IVF transfer catheter having a blunt distal end 25 “[t]o reduce the likelihood of trauma.” Bacich, col. 2, ll. 26-27; col. 4, l. 54; figs. 2, 5. As such, Gobby, as modified to add the beveled end of Bacich as proposed by the Examiner, would not result in a device having an angled tip that is in a shape that is suitable for insertion into an endometrial lining of a subject, as called for in independent claims 1, 10, and 42. Accordingly, we reverse the rejection of claims 1, 5-8, 10, 11, 15, 27-30, 32, 35-39, 41, and 42 under 35 U.S.C. § 103(a) as being unpatentable over Gobby and Bacich. The Examiner’s rejection of claims 7 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Gobby, Bacich, and Lakatos suffers from the same deficiency in the base combination of Gobby and Bacich. Ans. 8-9. Accordingly, we also reverse the rejection of claims 7 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Gobby, Bacich, and Lakatos.

#### CONCLUSIONS

The claims directed to a catheter/apparatus comprising an embryo in the distal portion are directed to patent-ineligible subject matter.

The original disclosure contains adequate written description of the subject matter of claims 2, 3, and 14, but does not contain adequate written description of the subject matter of claim 31.

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Peery does not disclose a catheter/apparatus comprising a material that has “sufficient flexibility to resist penetration of a uterine muscle of the subject” as called for in claims 1 and 10.

The combined teachings of Gobby and Bacich would not have rendered obvious to one of ordinary skill in the art a catheter having an angled tip that has a shape that is suitable for insertion into an endometrial lining of the subject as a microsurgical instrument, as claimed.

#### DECISION

We AFFIRM the decision of the Examiner to reject claims 34 and 40 under 35 U.S.C. § 101, and we enter NEW GROUNDS OF REJECTION of claims 35 and 41 under 35 U.S.C. § 101 and of claims 34, 35, 40, and 41 under AIA sec. 33(a).

We summarily AFFIRM the decision of the Examiner to reject claims 2, 3, 13, and 14 under 35 U.S.C. § 112, second paragraph.

We also AFFIRM the decision of the Examiner to reject claim 31 under 35 U.S.C. § 112, first paragraph and the decision of the Examiner to reject claim 42 under 35 U.S.C. § 102(e) as being anticipated by Peery.

We REVERSE the decision of the Examiner to reject claims 2, 3, and 14 under 35 U.S.C. § 112, first paragraph; claims 1-3, 10, 13, 14, 29-33, and 36-38 under 35 U.S.C. § 102(e); and claims 1, 5-8, 10-12, 15, 27-30, 32, 35-39, 41, and 42 under 35 U.S.C. § 103(a).

#### TIME FOR APPEAL/REHEARING OF AFFIRMED REJECTIONS

Regarding the affirmed rejection(s), 37 C.F.R. § 41.52(a)(1) provides “Appellant may file a single request for rehearing within two months from the date of the original decision of the Board.”

In addition to affirming the Examiner’s rejection(s) of one or more claims, this decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.”

37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should Appellant elect to prosecute further before the Examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejections, the effective date of the affirmance is deferred until conclusion of

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the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejections are overcome.

If Appellant elects prosecution before the Examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Patent Trial and Appeal Board for final action on the affirmed rejections, including any timely request for rehearing thereof.

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

AFFIRMED-IN-PART; 37 C.F.R. § 41.50(b)

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