Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No. 90/005,757 90/004,138	Patent Under Reexamination 5207675	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ *Prosecution on the merits* is (or remains) closed in this ex parte reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of

(a) ☒ Patent owner's communication(s) filed: *24 August 2001*.

(b) ☐ Patent owner's late response filed: _____.

(c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.

(d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 1.192).

(e) ☒ Other: *Patent owner's response to Interview Summary of Sept 23, 2002*.

Status of *Ex Parte* Reexamination:

(f) Change in the Specification: ☐ Yes, ☒ No

(g) Change in the Drawing: ☐ Yes, ☒ No

(h) Status of the Claim(s):

(1) Patent claim(s) confirmed: *1-16*.

(2) Patent claim(s) amended (including dependent on amended claim(s)): *NONE*.

(3) Patent claim(s) cancelled: *NONE*.

(4) Newly presented claim(s) patentable: NONE.

(5) Newly presented cancelled claims: NONE.

2. ☒ Note the attached statement of *reasons for patentability and/or confirmation*. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."

3. ☒ Note attached NOTICE OF REFERENCES CITED (PTO-892).

4. ☐ Note attached LIST OF REFERENCES CITED (PTO-1449).

5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.

6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of the certified copies have

☐ been received.

☐ not been received.

☐ been filed in Application No. _____.

☐ been filed in reexamination Control No. _____.

☐ been received by the International Bureau in PCT Application No. _____.

* Certified copies not received: _____.

7. ☐ Note attached Examiner's Amendment.

8. ☐ Note attached Interview Summary (PTO-474)

9. ☐ Other: _____

Michael Peffley
Primary Examiner
Art Unit: 3739

cc: Requester (if third party requester)

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding: claims 1-16 are considered patentable/confirmed for the reasons outlined below.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Preliminarily, it is noted that Reexamination Control No. 90/005,757 has been merged with Reexamination Control No. 90/006,115 and Reexamination Control No. 90/006,128. Each Reexamination file includes a slightly different listing of prior art cited against U.S. Patent No. 5,207,675. All of the prior art references will be addressed in this Office action.

Recitation of Argon Gas in the Claims

In the previous Office action of June 11, 2001, the examiner had cited the Manwaring ('138) reference in an anticipation rejection despite no teaching in Manwaring of using an argon gas with the system. It was the position of the examiner that the patented claims recitation of the argon gas was directed to intended use, and not a positive limitation in the claim language. However, the Patent Owner's arguments presented during the personal interview of August 20, 2002 (Paper No. 18) have been

deemed persuasive. In particular, the Patent Owner has argued that during prosecution of the patent application (U.S. Serial No. 07/730,049), applicant had added the recitation "so as to form an ionized gas stream which is capable of coagulating tissue during endoscopic surgery within a patient" into claim 1. Applicant also stated in the response which added this limitation (i.e. the response filed September 4, 1994) that the recitation was added so as to "clearly indicate that an ionized gas stream is formed so as to coagulate tissue during endoscopic surgery within a patient". See page 4 of applicant's September 4, 1992 response in U.S. Serial No. 07/730,049. It is the examiner's position that such arguments in the written record are deemed to reflect applicant's intent to positively claim the inert gas, and allowance of the application was based, at least in part, on this limitation since this was the only amendment made to claim 1. In as much as the claims were originally allowed under the premise that the ionized gas stream was a positive limitation in the claim language, the examiner now of record acknowledges this position and agrees for the record that the claim language of the instant patent positively recites (and requires) an argon gas source.

Failure of the prior art to Anticipate/Obviate the patented claims

Clearly, the most relevant prior art to the patented claims is the Manwaring ('138) reference. The Manwaring device is structurally very similar to the Canady device, but fails to specifically disclose the use of an argon gas for electrocoagulation. In as much as it is now the examiner's position that the Canady patented claims positively recite the argon gas, the Manwaring disclosure cannot anticipate the claim language.

Regarding the use of argon gas in the Manwaring device, the examiner finds no suggestion in the Manwaring patent that an argon gas may be used within the endoscopic device. The Manwaring device is specifically targeted for the treatment of the human brain and neurosurgery, although there is a passing suggestion that the endoscope may have other applications (with none specifically detailed). Manwaring's primary object is to provide a device capable of high temperature tissue vaporization (see col. 2, lines 14+) which is in contradistinction to the Canady coagulation device. While the examiner agrees that a "conductive fluid" may include a conductive gas, it is the examiner's position that there is absolutely no suggestion in the Manwaring patent that a gas could or should be used. Moreover, Dr. Manwaring's Declaration fails to effectively establish that such a suggestion may be gleaned from the Manwaring patent. Specifically, Dr. Manwaring states that the conductive liquid may exit the tube as a gas (element 5 in the Declaration). The examiner cannot support an assertion that this is a suggestion that an argon gas may be substituted for the conductive fluid disclosed in the Manwaring patent. The use of argon gas involves no change in state of the fluid (i.e. from a fluid to a gas). Also, Dr. Manwaring states that it would have been obvious for one of ordinary skill in the art to use argon gas in the Manwaring device due to the widespread knowledge in the 1980's of the use of argon beam coagulation as an effective modality for tissue coagulation. Again, this statement is not persuasive since there is no specific support or teaching of the use of the argon gas in such a flexible endoscopic system. The "widespread knowledge" of the use of argon beam coagulation

in the 1980's is predominantly limited to rigid electrosurgical pencil devices such as taught in the McGreevy et al ('175) and Fleenor ('110) patents. It is the examiner's position that devices such as the McGreevy et al ('175) and Fleenor ('110) coagulation devices fail to specifically suggest the more specialized use of argon gas coagulation in endoscopic devices within a closed environment (i.e. within the body).

Similarly, the Declaration Mr. Richard P. Fleenor is not deemed persuasive in facilitating an obviousness rejection. Specifically, Mr. Fleenor states that as of 1989, it was obvious to him and others of ordinary skill in the art that argon beam coagulation could be performed endoscopically. While the examiner does not specifically mean to contradict what Mr. Fleenor states he would have considered obvious, his statement cannot effectively be used to support a prior art rejection of the claims. There is no clear showing that it was "known" to use argon beam coagulation in endoscopic devices. As established in MPEP 2132, "known or used" means publicly known or used. That there may have been other persons contemplating the use of argon beam coagulation in endoscopic procedures does not provide an adequate basis for rejecting the claims under prior art. Rather, the prior art teachings must establish that such use of the argon beam coagulator was publicly known.

With the Papp article ("Endoscopic Control of Gastrointestinal Hemorrhage"), the requestor has provided the first clearly public disclosure of the use of argon gas in and endoscopic coagulator. Dr. Papp did not specifically discuss his experience with argon gas, and merely mentions the results which were observed in an article to Dennis et al.

It is noted that the Dennis et al article specifically states that the use of pure argon gas yielded unacceptable results (page 847 of the Dennis et al article), and the use a gas mixture of 50% argon gas and 50% carbon dioxide was more effective. It is the examiner's position that the Papp and Dennis et al articles fail to provide a sufficient suggestion that the use of an argon gas for endoscopic coagulation was a known efficacious treatment modality.

Even if the Papp and Dennis et al articles were deemed a suggestion of the use of argon gas in endoscopic procedures, the examiner maintains that it would not specifically address the design considerations of the Canady device. It is noted that there are several different types of endoscopic systems. Rigid endoscopy entails the use of various endoscopic instruments, each being introduced through it's own rigid trocar and each being used for a specific purpose (i.e. viewing, insufflation, treatment, etc.). Flexible endoscopy is a much different procedure whereby the endoscope is flexible, and includes the plurality of functions (i.e. viewing, insufflation, treatment) within the one single device. It is the examiner's position that the Canady device, as claimed, is clearly directed towards flexible endoscopy. The claims recite a "flexible tube" that is "insertable into and maneuverable within a surgical endoscope". Moreover, the specification supports the assertion that the device is a flexible endoscopic device. The examiner asserts that the relevant prior art suggestion of using an argon gas in endoscopy is directed solely to the use of rigid endoscopes, which fails to address the issues and problems associated with providing an argon gas coagulation device through

a flexible endoscope. Indeed, Mr. Fleenor's Declaration states that he and others of ordinary skill in the art knew in 1989 that it would be necessary to re-dimension the argon beam coagulators designed for open surgery to fit in an endoscope by elongating the instrument so it could be passed through an endoscope to the surgical site. It would be impossible to introduce an argon beam coagulator designed for open surgery (i.e. as taught by Fleenor and McGreevy et al) into a flexible endoscope merely by re-dimensioning the device. The prior art references fail to specifically address the issue of providing such an argon beam coagulator into a flexible endoscope device. This rationale applies equally to the Food and Drug Administration documents of Mr. Fleenor. That is, Mr. Fleenor's device as disclosed to the FDA is deemed to be a rigid endoscope device and is not specifically directed at the field of flexible endoscopy as is Mr. Canady's claimed device. Similarly, Dr. Harry Reich's Declaration is not deemed persuasive because his device is directed toward rigid endoscopic devices. Moreover, there is no specific showing that Dr. Reich's use of argon beam coagulation in endoscopic was "publicly known" at the time of his procedures. Rather, Dr. Reich's procedures were known by a select few in the field, and his Declaration is not deemed to provide conclusive evidence that it was publicly known that argon beam coagulation was used in endoscopic procedures.

Finally, the Schaumberg et al reference (DE 3508784) is not deemed to provide any additional basis for rejection of the claims. Schaumberg et al disclose an RF endoscopic device as is generally known in the art. There is nothing in Schaumberg to

suggest that the device should be used with an argon gas for coagulation. The requestor has made several suggestions that the Canady patent makes references to the known use of argon beam coagulation in electrosurgery. However, the examiner does not feel this is an acquiescence of Canady that it was known to use argon beam coagulation in endoscopic, and particularly in flexible endoscopic, devices. On the contrary, Dr. Canady specifically states that there is a need in the art for an argon beam coagulator which can be used in surgical procedures which are not presently available (i.e. flexible endoscopy). Again, it is the examiner's position that the prior art references fail to provide adequate suggestion of using argon beam coagulation in a flexible endoscopic device as is set forth in the Canady patent claims.

In Reexamination Control No. 90/006,115, the requestor has cited the Daniell et al articles as a teaching that it was known to perform endoscopic argon beam coagulation prior to the filing of the Canady patent. First, the examiner notes that the Daniell et al articles are not prior art. Both articles were published after the Canady filing date and cannot be used to support a prior art rejection. While Daniell et al articles suggest that endoscopic argon beam coagulation has been tested prior to the Canady filing date, there is no clear showing that these tests/procedures were publicly known prior to the filing of the Canady patent application. As stated in MPEP 2132, "known or used" is understood to mean publicly known or used. There is no evidence that the procedures discussed in the Daniell et al references were publicly known. That others of skill in the argon beam coagulation may have been developing a similar technology is

not in and of itself supportive of a prior art rejection. There must be a clear public disclosure of the teachings if the reference is to qualify as prior art. The Daniell et al articles fail in this capacity.

Even if the Daniell et al articles were deemed a suggestion of the use of argon gas in endoscopic procedures, the examiner maintains that it would not specifically address the design considerations of the Canady device. It is noted that there are several different types of endoscopic systems. Rigid endoscopy entails the use of various endoscopic instruments, each being introduced through it's own rigid trocar and each being used for a specific purpose (i.e. viewing, insufflation, treatment, etc.). Flexible endoscopy is a much different procedure whereby the endoscope is flexible, and includes the plurality of functions (i.e. viewing, insufflation, treatment) within the one single device. It is the examiner's position that the Canady device, as claimed, is clearly directed towards flexible endoscopy. The claims recite a "flexible tube" that is "insertable into and maneuverable within a surgical endoscope". Moreover, the specification supports the assertion that the device is a flexible endoscopic device. There is no teaching or suggestion in the Daniell et al articles that argon beam coagulation was being used in flexible endoscopy.

In Reexamination Control No. 90/006,128, the requestor has cited a number of articles which purportedly teach that endoscopic argon beam coagulation was known prior to the filing of the Canady patent. First, the examiner notes that the Matthew, Daniell et al, Farello et al, Lange et al and Reed articles are not prior art. Each article

was published after the Canady filing date and cannot be used to support a prior art rejection. While these articles suggest that endoscopic argon beam coagulation had been tested prior to the Canady filing date, there is no clear showing that these tests/procedures were publicly known prior to the filing of the Canady patent application. As stated in MPEP 2132, "known or used" is understood to mean publicly known or used. There is no evidence that the procedures discussed in the cited references were publicly known. That others of skill in the argon beam coagulation field may have been developing a similar technology is not in and of itself supportive of a prior art rejection. There must be a clear public disclosure of the teaching if the reference is to qualify as prior art. The cited articles fail in this capacity.

Even if these articles were deemed a suggestion of the use of argon gas in endoscopic procedures, the examiner maintains that it would not specifically address the design considerations of the Canady device. It is noted that there are several different types of endoscopic systems. Rigid endoscopy entails the use of various endoscopic instruments, each being introduced through it's own rigid trocar and each being used for a specific purpose (i.e. viewing, insufflation, treatment, etc.). Flexible endoscopy is a much different procedure whereby the endoscope is flexible, and includes the plurality of functions (i.e. viewing, insufflation, treatment) within the one single device. It is the examiner's position that the Canady device, as claimed, is clearly directed towards flexible endoscopy. The claims recite a "flexible tube" that is "insertable into and maneuverable within a surgical endoscope". Moreover, the

specification supports the assertion that the device is a flexible endoscopic device. There is no teaching or suggestion in the cited articles, including the one available prior art article to Floyd, that argon beam coagulation was being used in flexible endoscopy prior to the filing of the Canady patent application.

The requestor has argued that the patent owner has incorrectly asserted that "The key point of novelty in Dr. Canady's invention, as claimed in the Canady ['675] Patent, is the use of an inert, ionizable gas, and, in particular argon gas, in endoscopic electrosurgery." (Quoted from Reexamination Control No. 90/005,757, and reproduced in Requestor's Request for Reexamination at page 7). It is the examiner's opinion that the key word "flexible" has been omitted from this phrase. That is, it is the examiner's position that the key point of novelty in the claimed Canady invention is the use of argon gas in flexible endoscopic electrosurgery.

While there are several articles which suggest that argon beam coagulation procedures may have been performed prior to the filing of Dr. Canady's patent, there is no specific teaching that it was contemplated to provide such a modality in a flexible endoscope. Again, the declaration of Mr. Richard P. Fleenor suggested that endoscopic use of an argon beam coagulator had been contemplated and it was realized that existing argon beam coagulators would have to be elongated so as to be used in an endoscope. This is not a relevant solution to providing argon beam coagulation in a flexible endoscopic system. It is the examiner's position that the prior art and evidence does not support the use of argon beam coagulation in a flexible

endoscopic system, and there is no clear suggestion in the cited prior art and evidence to provide an ionized argon gas in the Manwaring device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
November 4, 2002

ROBERT L. NASSER
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