

Commissioner=s Decision # 1358
Décision du Commissaire # 1358

TOPICS: B00
SUJETS: B00

Application No. : 2,649,400

Demande n° : 2,649,400

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,649,400, having been rejected under subsection 30(3) of the *Patent Rules*, has been reviewed in accordance with paragraph 30(6)(c) of the *Patent Rules* by the Patent Appeal Board and the Commissioner of Patents. The recommendation of the Board and the decision of the Commissioner are as follows:

Agent for the Applicant:

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INTRODUCTION

- [1] This decision deals with a review of the rejection of patent application number 2,649,400 entitled "AUTOMATIC SMOKE EVACUATOR AND INSUFFLATION SYSTEM FOR SURGICAL PROCEDURES" filed on 30 August 2006 by the Applicant I.C. Medical, Inc.
- [2] A Summary of Reasons [SOR] was sent to the Patent Appeal Board [the Board] on 08 October 2013, which identified a single ground for rejecting this application:

X certain claims are indefinite.

- [3] For the reasons that follow, we recommend that the Applicant be informed that specific amendments are required to make the application compliant with the *Patent Act* and *Rules*.

BACKGROUND

- [4] This application relates to an automatic smoke evacuator and insufflation system for open and/or laparoscopic surgical procedures. The present description teaches a design which features an insufflator that, in addition to initially insufflating the peritoneum with a desired pressure, will automatically replace the volume of gas eliminated by the smoke evacuator at exactly the same time with exactly the same flow rate. In this way the peritoneum will remain at the same pressure that has been chosen by the surgeon. This represents an improvement over previously described automatic smoke evacuators which are not able to efficiently maintain the desired pressure in the peritoneum.
- [5] The role of balancing the pressure is achieved by a series of solenoid valves that are responsible for ensuring that the gas flow from the insufflator is delivered at the exact flow rate at which the smoke evacuator is removing gas, smoke and debris. The solenoid valves also play a role in safety by automatically shutting off gas flow from the insufflator and/or automatically activating the smoke evacuator to remove excess gas when a patient's intra-abdominal pressure exceeds the desired pressure or if the insufflator flow is higher than the smoke evacuator flow.

PROSECUTION HISTORY

- [6] After several Office Actions, this application was rejected in a Final Action [FA] on 08 March 2013. The application was considered defective because all 16 claims were considered obvious. In addition, the FA alleges that the description does not correctly and fully describe the invention and does not comply with subsection 27(3) of the *Patent Act*.
- [7] In response to the FA, the Applicant chose to replace the claims on file with an amended claim set containing 11 claims and continued to argue in favour of the patentability of the claims. The description was also amended to delete language suggesting that the claims are to be viewed as broader than the teachings of the description.
- [8] In an SOR submitted to the Board, the Examiner indicated that the grounds for rejection based on obviousness had been withdrawn. The defect in the description was also no longer an issue in view of the amendment to the description. However, the rejection was maintained based on the identification of a new ground for rejection: indefiniteness.
- [9] A panel of three members of the Board was established and, following an initial review, the Applicant was invited to submit proposed amendments to address the identified claim defects. The panel also pointed out several minor claim ambiguities that had been detected during the review. The Applicant submitted a proposed set of claims on 14 January 2014 to address all outstanding defects.

ISSUES

- [10] In view of the ground for rejection cited by the Examiner and the panel's observations during the initial review we must address the following question:

(1) Are certain claims indefinite for being avoidably ambiguous?

THE CLAIMS

[11] Claims 1-11 on file contain two independent claims, defining an automatic smoke evacuation and insufflation apparatus. The following claims are representative of the claims considered to be defective:

1. An automatic smoke evacuation and insufflation apparatus comprising:
 - a vacuum pump for removing at least one of a gas, smoke and debris from a surgical site;
 - a vacuum sensor for sensing a vacuum level generated by the vacuum pump;
 - an insufflator for supplying a gas to a body cavity of a patient to maintain a desired pressure within the body cavity;
 - a flow meter for measuring a flow of the gas from the insufflator; and
 - means for automatically adjusting the insufflator to supply the gas at exactly the same rate as the gas being removed by the vacuum pump which includes at least one sensor for controlling the gas flow from the insufflator whenever the vacuum pump is in an activated mode.
6. The apparatus of claim 1 further comprising a pressure sensor for sensing an actual pressure within the body cavity.
9. The apparatus of claim 1 further comprising at least one of an audio alarm and a visual alarm which are activated if a pressure within the body deviates from the desired pressure.
10. An automatic smoke evacuation and insufflation apparatus comprising:
 - smoke evacuator means for removing at least one of a gas, smoke and debris from a surgical site;
 - a smoke evacuator flow meter for determining a flow rate of gas being removed by the smoke evacuator;
 - an insufflator for supplying a gas to a body cavity of a patient to maintain a desired pressure within the body cavity;
 - an insufflator flow meter for determining a flow rate of gas being supplied by the insufflator; and
 - automatic adjustment means capable of initially filling an intra-abdominal cavity with a desired pressure and then automatically replacing the gas removed by the smoke evacuator means at exactly the same flow rate and at the same time that the gas is removed by the smoke evacuator means.

ARE CERTAIN CLAIMS INDEFINITE FOR BEING AVOIDABLY AMBIGUOUS?

Legal Framework

- [12] The relevant statutory provision for this defect is found in subsection 27(4) of the *Patent Act* which states:

The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

- [13] In *Minerals Separation North American Corp. v. Noranda Mines Ltd.*, (1947) 12 CPR 99 (Ex Ct), aff=d (1950) SCR 36, the Court emphasized the obligation an applicant has to make clear in his claims the ambit of the monopoly sought and the requirement for terms used in the claims to be clear and precise:

By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go. [page 146]

The Examiner=s position and the panel=s initial observations

- [14] In the SOR, the Examiner stated that independent claim 10 was indefinite for containing several ambiguous terms. Specifically, the term Acapable@ was considered to be overly broad. It was also noted that claim 10 made multiple references to the term Aa desired pressure@ which caused a lack of clarity and that a similar situation exists when considering the multiple references to the terms Aa gas@ and Agas.@
- [15] During our initial review the panel noted that, similar to claim 10, claims 5 and 7 also contained the term Acapable@ and claim 1 also made multiple references to Aa gas.@

With respect to claim 1, the panel further requested clarification of the expression "at least one sensor for controlling the gas flow." In particular, if this sensor was meant to refer to a pressure sensor, was this the same pressure sensor referred to in claim 6? We also asked whether claim 9 should depend on claim 6 rather than claim 1, as there is no mention of a pressure sensor in claim 1. Finally, with respect to claim 10, the panel also requested clarification of the reference to an "automatic adjustment means capable of initially filling an intra-abdominal cavity [...] smoke evacuator means" as the adjustment means alone is not a component capable of filling the cavity.

The Applicant's position

[16] In their submissions to the panel, the Applicant proposed a set of claims to address all outstanding defects. Specifically, the following amendments to the claims on file were proposed:

Claim 1: the "at least one sensor for controlling the gas flow" was clarified by reference to "at least one pressure sensor for controlling the gas flow"

Claims 1, 7 and 10: the multiple references to the terms "a gas" and "gas" were clarified by referring to what was being removed by the vacuum pump/smoke evacuator as "gaseous matter"

Claim 5: the expression "capable of" was clarified by replacing this expression with the term "for"

Claims 6 and 7: the "pressure sensor" was clarified by referring to a "further pressure sensor"

Claim 10: the second occurrence of the expression "a desired pressure" was clarified by indicating "the desired pressure"

Claim 10: the expression "an automatic adjustment means capable of" was clarified by referring to "means for automatic adjustment of the insufflator"

Conclusions

[17] In claim 1, we find that the reference to "at least one sensor for controlling the gas flow" causes a lack of clarity when this expression was construed in view of the specification as a whole. Specifically, the description refers to a pressure sensor for monitoring the intra-abdominal pressure for both the smoke evacuator and insufflator. Without this pressure sensor, the insufflator will not function. Based on the description it is apparent that the "at least one sensor" must refer to a pressure sensor. However, dependent claim 6 specifically refers to the apparatus of claim 1 as "further comprising a pressure sensor" which suggests that the "at least one sensor for controlling the gas flow" in claim 1 is referring to another sensor. Consistent with the teachings of the description, the specific amendment to claim 1 to specify "at least one pressure sensor" is necessary. As a result of this amendment, it is also necessary to amend dependent claims 6 and 7 to specify a "further pressure sensor."

[18] In claims 1 and 10, the multiple references to the terms "a gas" and "gas" also caused a lack of clarity as to whether all occurrences of these terms were meant to refer to the same "gas." It is clear from the description that the gas being removed by the vacuum pump/smoke evacuator is not the same gas that is being supplied by the insufflator.

Therefore, the specific amendment of claims 1 and 10 to indicate that the vacuum pump/smoke evacuator removes "gaseous matter" is necessary to distinguish between the different gases. As a result of this amendment, it is also necessary to replace the term "gas" with "gaseous matter" in dependent claim 7.

[19] Claim 10 also contains the term "capable" which the Examiner considered to be overly broad. Since this term is used to characterize the "automatic adjustment means" the Examiner argued that it is unclear what else the adjustment means is also "capable" of doing, as this adjustment is "for" initially filling the cavity. We find that the term "capable" does cause a lack of clarity in the context of claim 10, however we do not agree with the Examiner's reasoning.

[20] Although this term is used to characterize "automatic adjustment means" it is clear from the description that it is meant to characterize the required functions of the insufflator. As indicated in the description, it is the insufflator which is responsible for initially filling the intra-abdominal cavity with a desired pressure and then automatically replacing the gas removed by the smoke evacuator means at exactly the same flow rate and at the same time at which the smoke evacuator is activated. Further, the insufflator must perform these functions in order for the automatic smoke evacuator and insufflation apparatus to operate as intended. Consistent with the teachings of the description, the specific amendment to replace the expression "automatic adjustment means capable of" with "means for automatic adjustment of the insufflator" places a necessary functional limitation on the insufflator.

- [21] For similar reasons, in claim 5 the specific amendment to replace the expression *Acapable of* with the term *Afor* was considered necessary. In claim 5, the adjective is used to describe that the vacuum sensor *is* capable of shutting off the vacuum pump if the vacuum level is too high thereby indicating that an occlusion is present. The sole function referred to in the description for the vacuum sensor is to ensure that the vacuum pump is shut off when an occlusion is detected. Further, the vacuum sensor must perform this function in order for the automatic smoke evacuator and insufflation apparatus to operate as intended. Consistent with the teachings of the description, the specific amendment to replace the expression *Acapable of* with the term *Afor* places a necessary functional limitation on the vacuum sensor.
- [22] In contrast, in claim 7, the expression *Acapable of* does not cause a lack of clarity. Claim 7 is dependent on claim 6 which already defines that the further pressure sensor is *Afor* sensing an actual pressure within the body cavity. Therefore, indicating that the further pressure sensor is also *Acapable of* fulfilling additional functions in the device to that required by claim 6 i.e. *Adeactivating the automatic adjusting means and activating the vacuum pump if the actual pressure is too high so that [gaseous matter] is removed from the body cavity until the actual pressure returns to a normal level* does not cause a lack of clarity.
- [23] Finally, in claim 10, the recurrent use of an indefinite article to introduce the same term caused a lack of clarity as to whether both occurrences of the term were intended to refer to the same *Adesired pressure*. The specific amendment to claim 10 which replaces the second occurrence of the indefinite article *Aa* with the definite article *Athe* is necessary to indicate that the term *Adesired pressure* does in fact refer to the same *Adesired pressure* in both instances.

RECOMMENDATION

[24] The panel agrees that the amendments proposed by the Applicant are necessary for compliance with the *Patent Act* and *Rules*. Therefore, we recommend that the Applicant be informed in accordance with paragraph 31(b) of the *Patent Rules*, that the amendments as outlined in the correspondence of 14 January 2014, and only those amendments, of the application are necessary for compliance with the *Patent Act* and *Patent Rules*.

Christine Teixeira
Member

Stephen MacNeil
Member

Cara Weir
Member

DECISION OF THE COMMISSIONER

[25] I concur with the findings and recommendation of the Patent Appeal Board. Accordingly, I invite the Applicant to make the above amendments, and only the above amendments, within three months from the date of this decision, failing which I intend to refuse the application.

Sylvain Laporte
Commissioner of Patents

Dated at Gatineau, Quebec,
this 23 day of January, 2014