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NOTES/COMMENTS:

International Application No.: PCT/US2006/14790 filed 19 April 2006 for "Use of Biocompatible in-situ Matrices for Delivery of Therapeutic cells to the heart"

1. Response to Written Opinion (1 page);

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IN THE INTERNATIONAL BUREAU OF WIPO

In re Patent Application of
Medtronic, Inc.

Application Serial No.: PCT/US2006/14790

Filed: April 19, 2006

For: USE OF BIOCOMPATIBLE IN-SITU MATRICES
FOR DELIVERY OF THERAPEUTIC CELLS TO
THE HEART

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Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
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Alexandria, VA 22313-1450

RESPONSE TO WRITTEN OPINION

Dear Sir:

This communication is submitted in response to the Notification Of Transmittal of the International Search Report And Written Opinion of the International Searching Authority dated August 2, 2007, issued by Authorized Officer Blaine R. Copenheaver of ISA/US.

LV1 529686v2 10/01/07

REMARKS

Reconsideration of the claims of the instant application is respectfully requested in view of the following remarks. Claims 1-22 have been rejected as lacking novelty over US Patent 5,840,059 ("March") or lacking inventive step over the combination of March and U.S. Patent 6,151,525 ("Soykan). Applicants respectfully disagree with this assertion.

The instant invention is drawn to, *inter alia*, a method for delivering cells to the heart of a subject comprising a) forming channels within a region of a wall of the subject's heart which includes a myocardial layer; and b) delivering to said region a composition comprising living cells and a biocompatible matrix that forms *in situ* upon exposure to a physiological condition, wherein said living cells provide a therapeutic effect.

Claims 1 and 17 are independent claims. Both of these claims require that the composition delivered into the subject's heart should comprise, *inter alia*, a biocompatible matrix which forms *in situ*. In contrast, neither March nor Soykan disclose or suggest such matrices. March discloses viscous carriers or scaffolds, and Soykan discloses polymeric matrices. Clearly, these disclosures come short of the requirement of claims 1 and 17 that the matrices should be formed *in situ*, i.e., upon being administered to the patient. For example, March does not disclose a viscous carrier which congeals into a solid matrix upon being administered to a patient: the scaffolds of March are being administered as solid implants, and the viscous carrier stays liquid upon being administered. Similarly, the disclosure of polymeric matrices in Soykan does not disclose or suggest matrices which are administered as liquid carriers and are transformed into solid matrices. Further, it is known in the art that many conditions can trigger the formation of the matrix, including both physiological and non-physiological conditions. Neither March nor Soykan disclose or suggest that the matrix should be formed in response to a physiological condition. Applicants further submit that the formation of matrices *in situ* is clearly advantageous over March and Soykan. Because the compositions of the instant invention are administered to the subject's heart as liquids, the composition can fill the target area of the heart better than solid carriers and decrease traumatic response which may be caused by implanting the solid matrix into a contractile tissue. In addition, after the compositions solidify, they are not as likely to leak out from the target area as liquid viscous carriers thus diminishing waste of biological factors (e.g., cells or growth factors) and increasing the specificity of treatment.

For at least these reasons, March and Soykan, whether individually or in combination, do not anticipate claims 1 and 17 of the instant invention or negate the inventive step of these claims, and therefore, claims 1 and 17 are patentable. Claims 2-16 depend on claim 1, and

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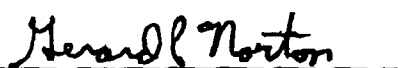
claims 18-23 depend on claim 17. Since claims 1 and 17 are patentable, claims dependent from claims 1 and 17 are also patentable. For these reasons, Applicant respectfully requests the Examiner to withdraw the rejections of claims 1-23 over March and Soykan.

CONCLUSION

In view of these amendments and remarks, Applicant believes that all claims of the instant application are novel and involve an inventive step, and therefore, patentable.

Respectfully submitted,

Date: October 2, 2007


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