Title: METHOD FOR DRUG DELIVERY TO OCULAR TISSUE USING MICRONEEDLE

Abstract: Methods and devices are provided for administering a drug to a patient’s eye. The methods include (a) inserting a hollow microneedle (130) into the sclera or corneal stroma (34) without penetrating across the sclera or corneal stroma; and (b) fusing a fluid drug formulation (131) through the microneedle and into the sclera or cornea. It further may include partially retracting the microneedle before infusion to enhance delivery. Alternatively, the methods may include (a) inserting a solid microneedle into the sclera or corneal stroma without penetrating across the sclera or corneal stroma, wherein the solid microneedle comprises a first quantity of a drug formulation and inserting causes the solid microneedle to form a pocket in the sclera or corneal stroma; and (b) releasing the drug formulation into the pocket (150) to form a drug depot, whereby a drug is released from the depot. The methods and devices may include an array of multiple microneedles.
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F A61M A61B A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 2002/082543 A1 (PARK JUNG-HWAN [US] ET AL) 27 June 2002 (2002-06-27) cited in the application paragraphs [0018], [0041] - [0043], [0047], [0048], [0056] - [0058], [0064], [0068] - [0070], [0087], [0101], [0109], [0123], [0134]; claims 2,6; figure 10a; example 11</td>
<td>32,35, 39-46, 50-52</td>
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Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents

'A' document defining the general state of the art which is not considered to be of particular relevance

'E' earlier document but published on or after the international filing date

'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

'O' document referring to an oral disclosure, use, exhibition or other means

'S' document published prior to the international filing date but later than the priority date claimed

'1' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

'A' document member of the same patent family

Date of the actual completion of the international search 25 October 2007

Date of mailing of the international search report 07/11/2007

Name and mailing address of the ISA/
European Patent Office, P B 5818 Patentlaan 2 NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx 31 651 epo nl, Fax (+31-70) 340-3016

Authorized officer Merte, Birgit
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<td>page 19, lines 7-14; claims 35,38,40,41,44</td>
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Continuation of Box II.I

Claims Nos.: 1-31

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
The invasive step "inserting a microneedle into the sclera or corneal stroma of an eye", present in the independent claims 1, 15, and 31, makes clear that the methods of claims 1-31 are methods for treatment by surgery.
The purpose of administering a drug to an eye being curative, the said methods are as well methods for treatment of the human or animal body by therapy.
INTERNATIONAL SEARCH REPORT

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1 [Y] Claims Nos 1-31 because they relate to subject matter not required to be searched by this Authority, namely

see FURTHER INFORMATION sheet PCT/ISA/210

2 □ Claims Nos because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically

3 □ Claims Nos because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1 □ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2 □ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3 □ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.

4 □ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)
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