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Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO DIVISIÓN DE NUEVAS CREACIONES

E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Rad: 04-122903- -00006-0000
Rec: 2006-09-15 16:14:35 Dep. 2020 NUECREACIONES
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Act 329 CTOINFORMACION Folios: 7

REF: Expediente No.:
Patente de Invención:

04-122.903

**"VEHÍCULOS INYECTABLES
SÓLIDOS DE ÁCIDO
HIALURONICO PARA
ADMINISTRACIÓN DE
PROTEÍNAS OSTEOGENICAS"**

Solicitantes:

**WYETH
FIDIA ADVANCED
BIOPOLYMERS, S.R.L.**

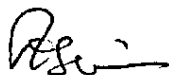
DESTINO: 09

HUMBERTO RUBIO CAMACHO, mayor de edad, domiciliado en Bogotá, D.C., identificado con la cédula de ciudadanía número 17.192.062 de Bogotá, abogado Titulado con Tarjeta Profesional No. 50.007 del Consejo Superior de la Judicatura, actuando en carácter de **APODERADO** de las Sociedades **WYETH**, domiciliada en Five Giralda Farms, New Jersey, Estados Unidos de América, y **FIDIA ADVANCED BIOPOLYMERS, S.R.L.**, domiciliada en Vía Ponte della Fabbrica, 3/B I-35031, Abano Terme, Italia; debidamente reconocido por su Despacho, me permito anexar:

- 1.1. Copia del Reporte de Examen Preliminar Internacional (Art. 36 del tratado de PCT. En el documento en mención, no obran anexos en razón a que no existe modificación sobre la presente invención, conforme fue señalado mediante memorial de 18 de abril de 2005.

Teniendo en cuenta lo anterior solicito respetuosamente continuar con el correspondiente trámite.

Del Señor Superintendente,



HUMBERTO RUBIO CAMACHO
C.C. 17.192.062 de Bogotá
T.P. 50.007 Consejo Superior
de la Judicatura.
COD. 4134

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
ARTHUR S. GARRETT
FINNEGAN, HENDERSON, FARABOW, GARRETT &
DUNNER, L.L.P.
1300 I STREET, N.W.
WASHINGTON, DC 20005-3315

PCT
NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year) **21 APR 2005**

Applicant's or agent's file reference

8702.110-304

IMPORTANT NOTIFICATION

International application No.

PCT/US03/14609

International filing date (day/month/year)

12 May 2003 (12.05.2003)

Priority date (day/month/year)

17 May 2002 (17.05.2002)

Applicant

WYETH

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Form PCT/IPEA/416 (July 1992)

Authorized officer

Jennifer Jane Harle

Telephone No. (571) 272-1600

13/26

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 8702.110-304	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No PCT/US03/14609	International filing date (day/month/year) 12 May 2003 (12.05.2003)	Priority date (day/month/year) 17 May 2002 (17.05.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/18, A61F 2/02 and US Cl.: 424/409, 418, 423; 514/12, 8, 21		
Applicant WYETH		
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet. ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>—</u> sheets. 3. This report contains indications relating to the following items: I ☒ Basis of the report II ☐ Priority III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability IV ☐ Lack of unity of invention V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI ☐ Certain documents cited VII ☐ Certain defects in the international application VIII ☐ Certain observations on the international application		
Date of submission of the demand 08 December 2003 (08.12.2003)	Date of completion of this report 13 April 2005 (13.04.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Jennifer Jane Harle <i>J. Roberts for</i> Telephone No. (571) 272-1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

1. Basis of the report

1 With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-28 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☒ the claims:
pages 29-38 _____ as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☒ the drawings:
pages 1 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/figs NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)) **

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/14609

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-71	YES
	Claims NONE	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-71	NO
Industrial Applicability (IA)	Claims 1-71	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V. 2. Citations and Explanations:

Claims 1-13 lack an inventive step under PCT Article 33(3) as being obvious over Valentini et al. (US 5,929,984).

The instant claims are drawn to a composition having functional intended use. The scaffolding is formed from the mixed solution by drying from the wet state, preferably by lyophilization without freezing (column 7, lines 22-24). Hence, it is clear that prior to drying, Valentini et al. (US 5,939,974) disclose a solution that meets the limitations of the instant claims. The same preferred hyaluronic acid esters - HYAFF[®], the same pore-forming agents, the same tricalcium phosphate and several of the same BMPs, and the same solubilizing organic solvents are explicitly recited as being parts of this composition. There is no indication that the solutions are not injectable, just that it is preferred to dry the solutions to form an implantable porous scaffold.

Claims 1-71 lack an inventive step under PCT Article 33(3) as being obvious over Valentini et al. (US 5,939,974) in view of Wozney et al. (US 6,187,742) and Walter et al. (US 5,716,413) and further in view of Pheulpin (US 3,955,719), Langen et al. (US 4,784,055) and Phillips et al. (US 4,758,233).

The teachings of Valentini et al. (US 5,939,974) have been discussed above. Valentini et al. (US 5,939,974) lack BMP-7 (instantly called OP-1).

Wozney et al. (US 6,187,742) teach the combination of osteogenic proteins (including BMP-7, which is OP-1, and preferably BMP-2, (column 3, lines 26-30) with a number of carriers including porous particulate polymers (including PEG; column 4, line 59- column 5 line 5), sucrose (column 5, lines 40-42), hyaluronic acid and tricalcium phosphate (column 5, lines 53-56). Wozney et al. discuss the use of the preparation by injection through a syringe (column 5 line 63).

Pheulpin (US 3,955,719) discloses a device and methods for injecting pastes of dental products into cavities (abstract), albeit not through the skin.

Walter et al. (US 5,716,413) disclose that it is known in the art of bone repair to prepare a biodegradable, porous prosthesis in cylindrical as well as many other moldable forms.

Langen et al. (US 4,784,055) discloses a device and methods for injecting compositions having paste-like consistency through needles into meat. If the surface of the meat is considered as "skin", this method and device would clearly suffice to make such an injection.

Phillips et al. (US 4,758,233) disclose a device and methods to inject a medicament in the form of a cream or paste into an animal (column 1, lines 4-8). This clearly implies injecting at least through the skin.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

A person of ordinary skill in the art at the time the invention was made would have been motivated to substitute the BMP-7 as taught by Wozney et al. (US 6,187,742) for the BMPs in the composition as taught by Valentini et al. (US 5,939,974) because Wozney et al. (6,187,742) disclose that their BMPs can be formulated into carriers including porous particulate polymers, hyaluronic acid and TCP.

BMPs have been formulated with a range of suitable carriers. The only requirement for formulation appears to be compatibility with the bone matrix to which it is being added. Hence, given that the carriers of Wozney et al. (US 6,187,742) are functionally equivalent and nearly the same as those of Valentini et al. (US 5,939,974) (hyaluronic acid as compared to hyaluronic acid esters) it would involve nothing more than an arbitrary matter of experimental design choice to select one carrier over another. Such a choice is within the skill of the ordinary artisan of bone repairs. Pincus (US 3,955,719), Langen et al. (US 4,784,055) and Phillips et al. (US 4,758,233) are provided to further establish that pastes are injectable even through the skin.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the BMP-7 of Wozney et al. (US 6,187,742) for the BMPs in the composition as taught by Valentini et al. (US 5,939,974) and to inject the paste, even through the skin.

Claims 1-71 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NEW CITATIONS

US 5,716,413 A (WALTER et al.) 10 February 1998 (10.02.1998), see entire document.