

Señor Jefe
Dirección de Nuevas Creaciones
Superintendencia de Industria y Comercio
E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Referencia: Solicitud de privilegio para Patente de Invención.
Título: SISTEMA INTRAUTERINO PARA SUMINISTRAR UNA SUSTANCIA O PRODUCTO TERAPÉUTICO DIRECTAMENTE DENTRO DEL ÚTERO DE UN PACIENTE Y MÉTODO PARA SU FABRICACIÓN
Solicitante: BAYER OY
Exp. No.: 2010-135.578
Asunto: Respuesta al requerimiento formulado mediante oficio No. 21443 del 27 de noviembre de 2012

JESÚS M. MÉNDEZ BERMÚDEZ, identificado con cédula de ciudadanía No. 13.491.525 de Cúcuta y con Tarjeta Profesional de Abogado No. 99.678 del Consejo Superior de la Judicatura, en mi calidad de apoderado de la sociedad **BAYER OY**, por medio del presente escrito me permito dar respuesta al requerimiento de la referencia.

1. En las reivindicaciones

Con el objeto de atender a la observación hecha por su Despacho con respecto a la reivindicación 1, presento un nuevo capítulo de reivindicaciones en donde se ha modificado dicha reivindicación eliminando la expresión que según su opinión se refiere a un resultado.

2. Análisis de la patentabilidad.

Su despacho, después de efectuar una búsqueda de anterioridades en el estado de la técnica, encuentra el documento, (D1) US 3938515 y el documento (D2) WO 96/29026 y con base en estos documentos concluye que las reivindicaciones 1 a 12 y 16 no cumplen con el requisito de novedad ni con el de nivel inventivo frente a D1 y que las reivindicaciones 13, 14 y 15 no cumplen con el requisito de nivel inventivo frente a D2, según lo establecen los artículos 16 y 18 de la Decisión 486.

Discrepo totalmente de la opinión de su Despacho como se demuestra con los siguientes argumentos. El documento D1 se relaciona con una pared polimérica permeable a fármacos adaptada para liberar un fármaco a una velocidad controlada desde un depósito que contiene el fármaco hasta el ambiente del cuerpo, y con dispositivos para administrar fármacos que incluyen tal pared. También se relaciona con métodos para incrementar la permeabilidad de los polímeros usados para fabricar tales paredes y métodos para modificar la velocidad de liberación del fármaco a través de tal pared.

En el dispositivo de D1 el fármaco está situado dentro del marco, no en un depósito separado conectado con la superficie interior del marco por uno o ambos de sus extremos como en la presente invención. La flexibilidad del dispositivo de D1 es

cuestionable. El documento D1 se concentra en las paredes poliméricas que incluyen aditivos para incrementar la permeabilidad de los polímeros y en modificar la liberación del fármaco a través de tales paredes.

Más aún, como en el dispositivo de D1 el fármaco está situado dentro del marco, la parte que contiene el fármaco está siempre en conexión con las paredes uterinas lo que puede causar irritación. En el dispositivo de la presente invención, un aspecto era dejar solo el marco inerte y flexible en contacto con las paredes uterinas, mientras que el depósito que contiene el fármaco queda separado y así es menos dado a estar en contacto directo con las paredes uterinas.

El documento D2 se relaciona con un sistema intrauterino que comprende una espiral (4) en la forma de una tira de polietileno y su recubrimiento hecho de cobre refinado (8), unidos a un bucle (5). En nuestra opinión la espiral en la forma de una tira y su recubrimiento no constituyen un depósito, ni tampoco es el bucle lo mismo que el marco de forma poligonal como se definió en la presente invención.

En la segunda Opinión escrita emitida por la Autoridad de Examen Preliminar Internacional, ya se había reconocido que la presente invención es novedosa e inventiva frente a D1 y D2. Adjunto a este escrito una copia de dicha Opinión escrita.

El sistema intrauterino de acuerdo con la nueva reivindicación 1 modificada es ahora más claramente diferente de los dispositivos de D1 y de D2. No existe ninguna señal o sugerencia en D1 o en D2 para poder preparar, construir o diseñar un sistema intrauterino tal como lo enseña la presente invención en la reivindicación 1. Con respecto a los avances técnicos de los SIU de acuerdo con la presente invención ya fueron ampliamente explicados en nuestra respuesta a las oposiciones presentada ante su Despacho el 7 de junio de 2012. Le ruego referirse a ella nuevamente para establecer el avance tecnológico de la presente invención frente a estos documentos.

Con base en lo anterior, la solicitante afirma, de manera respetuosa, que la invención definida en el presente capítulo de reivindicaciones es no solo novedosa sino que involucra nivel inventivo en vista de los documentos citados en el Oficio emitido por su Despacho.

Por las anteriores razones creemos que las nuevas reivindicaciones que presento definen la invención como nueva y con nivel inventivo.

Pido por lo tanto, de manera respetuosa, a su Despacho continuar con el trámite y otorgar la patente a la presente solicitud.

ANEXOS

1. Nuevo capítulo reivindicatorio.
2. Segunda Opinión de la Autoridad de Examen Preliminar Internacional, por favor si requieren la traducción de este documento infórmenos.

NOTIFICACIONES

Recibiré notificaciones en la Secretaria de este Despacho y en mi oficina, ubicada en la Calle 83ª No. 23-90 de esta ciudad.

Del Señor Jefe,

JESÚS M. MÉNDEZ BERMÚDEZ
C.C. No. 13.491.525 de Cúcuta
T.P.A. No. 99.678 del C. S. de la J.

REIVINDICACIONES

1. Sistema intrauterino, caracterizado porque el sistema intrauterino comprende un depósito y un marco cerrado y flexible, continuo, de forma poligonal, en donde dicho depósito es un elemento alargado similar a una varilla conectado a la superficie interior del marco por uno o ambos de sus extremos y dicho depósito comprende por lo menos una sustancia terapéuticamente activa.

2. Sistema intrauterino de conformidad con la reivindicación 1, caracterizado porque el marco es triangular o pentagonal.

3. Sistema intrauterino de conformidad con la reivindicación 1 o 2, caracterizado porque el marco y el depósito comprenden una composición de polímero flexible.

4. Sistema intrauterino de conformidad con la reivindicación 3, caracterizado porque la composición de polímero comprende elastómero basado en siloxano, poliuretano termoplástico, elastómero de poliuretano termoplástico, EVA, polietileno, elastómero de silicona y poliuretano termoplástico o una mezcla de por lo menos dos de los mismos.

5. Sistema intrauterino de conformidad con la reivindicación 4, caracterizado porque la composición de polímero del marco y el depósito es igual o diferente.

6. Sistema intrauterino de conformidad con una cualquiera de las reivindicaciones 1 a 5, caracterizado porque la sección transversal del marco es circular, semicircular, ovalada, plana, elíptica, rectangular, angular, poligonal o de forma de estrella.

7. Sistema intrauterino de conformidad con cualquiera de las reivindicaciones 1 a 6, caracterizado porque la sección transversal del depósito es circular, ovalada, plana, elíptica, rectangular, angular, poligonal o de forma de estrella.

8. Sistema intrauterino de conformidad con cualquiera de las reivindicaciones 1 a 7, caracterizado porque el depósito comprende por lo menos un núcleo.

9. Sistema intrauterino de conformidad con cualquiera de las reivindicaciones 1 a 8, caracterizado porque por lo menos uno de los núcleos del depósito está envuelto por una capa de polímero.

10. Sistema intrauterino de conformidad con la reivindicación 9, caracterizado porque la composición de polímero de por lo menos un núcleo y la capa de polímero que envuelve al núcleo son iguales o diferentes.

11. Sistema intrauterino de conformidad con cualquiera de las reivindicaciones 1 a 10, caracterizado porque el marco comprende un elemento de soporte que consiste en una composición de polímero o un metal biocompatible.

12. Sistema intrauterino de conformidad con cualquiera de las reivindicaciones 1 a 11, caracterizado porque comprende hilos para la remoción, ubicación o detección del sistema.

13. Sistema intrauterino de conformidad con cualquiera de las reivindicaciones 1 a 12, caracterizado porque el sistema comprende por lo menos un elemento que mejora las imágenes para mejorar la detección y/o la ubicación del sistema.

14. Sistema intrauterino de conformidad con la reivindicación 13, caracterizado porque el elemento que mejora las imágenes es seleccionado entre el grupo que consiste en:

a) un recubrimiento de metal inerte en por lo menos una parte del cuerpo del sistema intrauterino;

b) insertos, broches, anillos o manguitos de metal inerte colocados en forma fija en el cuerpo del sistema intrauterino;

c) partículas o polvo ferromagnético o metálico o sales de metales alcalinos o metales adecuados mezclados durante el paso de mezclado en las materias primas del marco, el núcleo o la membrana del sistema intrauterino, y

d) una copa, conector, adaptador, abrazadera, manguito, eje o soporte metálico fijado en una posición adecuada en el marco, que también se puede usar para anclar o unir el depósito sobre el marco.

15. Sistema intrauterino de conformidad con cualquiera de las reivindicaciones 1 a 14, caracterizado porque el marco o el depósito comprende elementos de retención o bloqueo para retener el depósito y evitar que se desplace.

16. Método para fabricar un sistema intrauterino que tiene un marco cerrado continuo y flexible de forma poligonal y un depósito que comprende por lo menos una sustancia terapéuticamente activa, depósito que está unido a la superficie interior del marco, el método comprende moldeo por inyección, extrusión o compresión del marco y el depósito simultáneamente, o el uso de un procedimiento secuencial que

comprende los pasos de preparar el marco, preparar la primera composición que comprende una sustancia terapéuticamente activa y una composición de polímero para proveer un núcleo, preparar la segunda composición que comprende una composición de polímero para proveer una membrana que envuelve al núcleo, combinar el núcleo y la membrana para producir un depósito, y unir entre sí el depósito y el marco.

SAAPUNUT

21. 04. 2010

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Oy JALO ANT-WUORINEN Ab

PCT

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

2.6.10

(PCT Rule 66)

1W +
Kaal

To:
OY JALO ANT-WUORINEN AB
Iso Roobertinkatu 4-6 A
FI-00120 HELSINKI
FINLAND

Date of mailing (day/month/year)
19 April 2010 (19.04.2010)

Applicant's or agent's file reference 47233	REPLY DUE within 45 months/days from the above date of mailing
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International application No. PCT/FI2009/050244	International filing date (day/month/year) 01 April 2009 (01.04.2009)	Priority date (day/month/year) 02 April 2008 (02.04.2008)
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International Patent Classification (IPC) or both national classification and IPC
See supplemental box

Applicant
BAYER SCHERING PHARMA OY et al.

1. ☒ The written opinion established by the International Searching Authority: ISA/FI
☒ is ☐ is not
considered to be a written opinion of the International Preliminary Examining Authority.

2. This second (first, etc.) opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.
For an additional opportunity to submit amendments, see Rule 66.4.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary report on patentability
(Chapter II of the PCT) must be established according to Rule 69.2 is: 02 August 2010 (02.08.2010)

Name and mailing address of the IPEA/FI National Board of Patents and Registration of Finland P.O. Box 1160, FI-00101 HELSINKI, Finland Facsimile No. +358 9 6939 5328	Authorized officer Taija Tammi Telephone No. +358 9 6939 500
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WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/FI2009/050244

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b)).
- ☐ publication of the international application (Rule 12.4(a)).
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a)).
2. With regard to the **elements** of the international application, this opinion has been established on the basis of *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed.")*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages _____ received by this Authority on _____
- pages _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages _____ as amended (together with any statement) under Article 19
- pages _____ received by this Authority on _____
- pages _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages _____ received by this Authority on _____
- pages _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____
4. ☐ This opinion 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)).
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____
5. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 66.1(d-bis)).
6. ☐ Supplementary international search report(s) from Authority(ies) _____ have been received and taken into account in drawing up this opinion (Rule 45bis.8(b) and (c)).

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WRITTEN OPINION OF THE
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 17

because:

- ☒ the said international application, or the said claims Nos. 17
relate to the following subject matter which does not require an international preliminary examination (*specify*):
Claim 17 relates to a method for treatment of the human or animal body by therapy (Rule 67.1 (iv) PCT).

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed (*specify*):

- ☒ no international search report has been established for said claims Nos. 17
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
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Box No. 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 1-16		YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims 1-16		NO
Industrial applicability (IA)	Claims 1-16		YES
	Claims		NO
2. Citations and explanations:			
2.1 Documents cited in the International Search Report			
D1: US 3834378 A D2: WO 9629026 A2 D3: US 3938515 A D4: EP 0873751 A2 D5: NL 8601570 A			
2.2 Claimed invention			
The claims have not been amended.			
The subject matter of claims 1-15 relates to an intra-uterine system and the subject matter of claim 16 relates to a method for manufacturing an intra-uterine system.			
2.3 Applicant's response			
In his response (9.2.2010), the applicant disagrees with the written opinion of the International Searching Authority (ISA) and finds the present invention novel over D1-D3 and inventive over D4 and D5.			
The applicant argues that the expression "a particulate metal material dispersed throughout the plastic matrix" used in D1 cannot be regarded as a reservoir.			
Furthermore, the applicant states that the intra-uterine system defined in D2 does not fulfil the definitions of the claimed invention. In D2, the strip and its copper coating do not form a reservoir, nor the shape of the frame is polygonal.			
Referring to document D3, the applicant states that the intra-uterine device does not comprise a separate reservoir connected to the inner surface of the frame at least its one end.			
According to the applicant, document D4 does not mention polygonal structures of the intra-uterine devices.			
Regarding D5, the applicant states that the intra-uterine device does not comprise a reservoir, nor a polygonal structure.			
Continued to next page			

Supplemental Box

Continuation of: Box V (1 / 2)

2.4 Examiner's arguments

The applicant's arguments regarding the novelty of the claimed intra-uterine system are convincing. The examiner agrees with the applicant that D1-D3 do not constitute a novelty bar for the claimed subject matter. However, the examiner thinks, that a person skilled in the art would interpret the expression "a particulate metal material dispersed throughout the plastic matrix" in D1 in a different way than presented in the applicant's response. For the reasons presented in the chapter 2.6, the subject matter of claims 1-7, 11-14 and 16 is still considered to lack an inventive step in view of D1.

The examiner disagrees with the applicant on document D4. Considering prior art, it is obvious to a person skilled in the art to modify the frame of D4 to a polygonal shape. For the reasons presented in the chapter 2.6, the subject matter of claims 1, 3-12 and 15 is still considered to lack an inventive step in view of D4.

The examiner agrees with the applicant that the claimed subject matter is novel and inventive in view of D2, D3 and D5.

2.5 Novelty under PCT Article 33(2)

None of the documents discloses all the features of independent claim 1. The intra-uterine system according to claim 1 is, therefore, novel.

None of the documents discloses all the features of independent claim 16, either. The method for manufacturing an intrauterine system according to claim 16 is novel, too.

Because the subject matter of independent claim 1 is novel, the subject matter of dependent claims 2-15 is also novel.

2.6 Inventive step under PCT Article 33(3)

2.6.1 Independent claims

Documents D1 and D4 represent the most relevant prior art.

Document D1 (column 3, lines 62-58; claim 1, Fig) discloses an intra-uterine system that comprises a plastic matrix (16) and a continuous, closed and flexible frame (Fig) of polygonal shape. At least one end of the plastic matrix is connected to the inner surface of the frame and the matrix comprises at least one therapeutically active substance.

Because the term "reservoir" is ambiguous, a plastic matrix material can be considered as a reservoir (storage) for therapeutically active substances to keep them inside the structure. Consequently, the subject matter of independent claim 1 does not involve an inventive step in view of D1.

Document D4 (column 8, lines 28-42; Fig 3) discloses an intra-uterine system for a long-term insertion into the uterine cavity. The system comprises a reservoir (2, 5) and a continuous, closed and flexible frame (6). At least one end of the reservoir is connected to the inner surface of the frame and the reservoir comprises at least one therapeutically active substance.

Document D4 shows in Figure 3 that a drug (2) is enclosed in a diffusion controlled film (5). This structure equals to the claimed reservoir which comprises a therapeutically active substance.

Continued to next page

Supplemental Box

Continuation of: Box V (2 / 2)

Furthermore, document D4 (column 8, lines 35, 40-41) suggests that "the intra-uterine device may take other shapes as far as they don't cause any abnormality to the living body when fitted". This expression is considered to refer to any suitable shape of the device that fits well in the endometrial cavity. Because prior art discloses plurality of intrauterine devices having a shape of the uterus, it is obvious to a person skilled in the art that the intrauterine device of D4 is formed in the shape of the uterus i.e. the polygonal shape.

Consequently, the subject matter of independent claim 1 does not involve an inventive step in view of D4.

Documents D1 (column 3, lines 4-15) and D4 (column 7, lines 19-21) disclose a method for manufacturing an intra-uterine system by compressing.

Consequently, the subject matter of independent claim 16 does not involve an inventive step in view of either D1 or D4.

Documents D2, D3 and D5 represent the general state of the art.

2.6.2 Dependent claims

D1 (column 2, lines 16-21; line 65 – column 3, line 3; Fig) discloses a flat reservoir and a triangular frame that comprise a polymer composition, such as EVA. The system comprises an image enhancing means, such as metal particles or barium sulphate, mixed in the polymer composition.

Thus, the subject matter of dependent claims 2-7 and 11-14 does not involve an inventive step in view of D1.

D4 (column 8, lines 8-12; Fig 3) discloses a reservoir comprising a core, which is encased by a polymer layer, and a frame that comprises a polymer composition, such as EVA or silicon.

Thus, the subject matter of dependent claims 3-12 and 15 does not involve an inventive step in view of D4

2.7 Industrial applicability under PCT Article 33(4)

Claims 1-16 meet the requirement of industrial applicability because the claimed subject matter can be made or used in industry.

WRITTEN OPINION OF THE
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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The technical features mentioned in the claims are not provided with the reference signs placed in parentheses (Rule 6.2(b) PCT).

WRITTEN OPINION OF THE
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Independent claim 1 is not supported by Figure 5 as required by PCT Article 6 because in Figure 5, the frame is not continuous and closed as claimed.

Dependent claim 9 refers to any of claims 1-8, though the word "the core" is mentioned for the first time only in claim 8.

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/FI2009/050244

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: International Patent Classification (IPC)

Int.Cl.
A61F 6/14 (2006.01)