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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES

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SUPERINDUSTRIA Y COMERCIO

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Dependencia 2020 DIVISION DE NUEVAS CREACIONES

Ref Expediente No 04097769

Solicitud de Patente a nombre de

CODMAN & SHURTLEFF, INC

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la carrera 11 A No 94-76, of 305, obrando como apoderada de la sociedad CODMAN & SHURTLEFF, INC, domiciliada en Raynham, Massachusetts, Estados Unidos de América, solicitante de la patente de la referencia, en respuesta al oficio No 10021 notificado por fijación en lista el día 28 de octubre de 2004, me permito manifestar lo siguiente

- 1 Anexo el documento de cesión suscrito por los inventores a favor de mi mandante

Sobre el particular, es importante resaltar que de conformidad con las normas legales vigentes, artículo 1 de la Resolución 210 de 2001, expedida por el Superintendente de Industria y Comercio y artículo 2 de la Convención de la Haya, el documento en inglés que se pretenda aportar como parte de los trámites de propiedad industrial ante la Superintendencia de Industria y Comercio no requieren traducción. Por otro lado, la legalización consular y/o diplomática de los documentos expedidos en el extranjero no es necesaria. Por lo tanto, el documento de cesión anexo a este memorial es válidamente presentado en idioma inglés y con la correspondiente Apostilla

- 2 Acompaño al presente memorial la copia certificada de la solicitud de Patente Número 10/676,333 presentada en los Estados Unidos de América el día 30 de septiembre de 2003, respectivamente, con la debida traducción de lo pertinente, incluyendo el capítulo reivindicatorio

Espero con esto haber dado cabal cumplimiento a lo solicitado por ese despacho y de conformidad con lo indicado en los artículos 3º, inciso 3, 35 inciso 2 y 59 inciso 2 del CCA, al analizar este memorial, atentamente ruego se traten todas las cuestiones planteadas con motivo del mismo

Señor Superintendente,


JIMENA ESCOBAR URIBE
C C 39 779 452 de Usaquén
T P 68228
Cód 5376

ESTADOS UNIDOS DE AMERICA
A TODOS AQUELLOS A QUIENES EL PRESENTE LLEGUE

DEPARTAMENTO DE COMERCIO DE LOS ESTADOS
UNIDOS

Oficina de Patentes y Marcas de los Estados Unidos

Septiembre 30 de 2004

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada mas adelante, que cumplieron con los requerimientos para concederse una fecha de presentacion de acuerdo con 35 USC 111

Numero de Solicitud 10/676,333

Fecha de Presentacion Septiembre 30 de 2003

Por la autoridad del
Comisionado de Patentes y Marca

(fdo) M Sias
Oficial Certificador
Sello oficial de la Oficina de Patentes y Marcas de los
Estados Unidos de America

REIVINDICACIONES

- 1** Un empaque para un producto de combinación de un medicamento en un dispositivo que comprende

Un empaque exterior que comprende

Una primera hoja impermeable al gas

Una segunda hoja impermeable al gas sellada herméticamente por tres lados con la primera hoja impermeable al gas,

Una cámara de circulación permeable al gas dispuesta en un lado no sellado de la primera hoja impermeable al gas y sellada a la segunda hoja impermeable al gas en dos lados y

en donde la primera y segunda hojas impermeables al gas y la cámara de circulación permeable al gas desde un interior y una apertura que comunica con el interior y

un empaque interior permeable al gas diseñado para alojar dicho producto de combinación de un medicamento en un dispositivo se disponen dentro del empaque exterior
- 2** El empaque de la reivindicación 1 en donde el empaque interior permeable al gas se dispone solamente entre la primera y la segunda hojas impermeables al gas
- 3** El empaque de la reivindicación 1 en donde el empaque interior permeable al gas es una lámina con depresiones (blister)

- 4 El empaque de la reivindicación 1 en donde el empaque interior permeable al gas es una bolsa
- 5 Un empaque para un producto que comprende
 Un producto incorporado con un medicamento
 Un empaque interior permeable al gas calibrado para que contenga el producto y
 Un empaque exterior que comprende
 Una primera hoja que comprende
 Una sección impermeable al gas y
 Una cámara de circulación permeable al gas dispuesta en un primer lado de la sección impermeable al gas
 Una segunda hoja que es impermeable al gas y está herméticamente sellada por tres lados a la primera hoja y
 La primera y segunda hojas formando un interior y una apertura que comunica con el interior en donde el empaque interior se dispone dentro del empaque exterior
- 6 El empaque de la reivindicación 5 en donde el empaque interior permeable al gas se dispone solamente entre la sección impermeable al gas de la primera hoja y la segunda hoja
- 7 El empaque de la reivindicación 5, en donde el empaque interior permeable al gas es una lámina con depresiones (blister)

- 8 El empaque de la reivindicación 5 en donde el empaque interior permeable al gas es una bolsa
- 9 El empaque de la reivindicación 5 en donde el medicamento se selecciona del grupo que comprende agentes antimicrobianos antangiogénicos antiproliferativos y anti-inflamatorios
- 10 El empaque de la reivindicación 9 en donde los agentes antimicrobianos se seleccionan del grupo que comprende antibióticos, antisépticos y desinfectantes
- 11 El empaque de la reivindicación 10 en donde los antibióticos se seleccionan del grupo que comprende tetraciclinas penicilinas macrólidos rifampina gentamicina vancomicina clindamicina azitromicina enoxacina, y combinaciones de ellos
- 12 El empaque de la reivindicación 9, en donde el agente antimicrobiano es por lo menos uno de Rifampicina y Clindamicina
- 13 El empaque de la reivindicación 9 en donde los antangiogénicos se seleccionan del grupo que comprende angiostatina talidomida CC-5013 bevacizumab escualamina endostatina angiostatina angiozima paclitaxel dextrorubicina, epirubicina mitoxantrona y ciclofosfamida
- 14 El empaque de la reivindicación 9 en donde el antiproliferativo es por lo menos uno de Sirolimus y Paclitaxel

15 El empaque de la reivindicación 9 en donde los anti-inflamatorios se seleccionan del grupo que comprende ibuprofeno ketoprofeno motrín o naproxeno

16 El método para empacar un producto de combinación de un medicamento en un dispositivo que comprende

Colocar el producto dentro de un empaque interior permeable al gas,

Sellar el empaque interior

Colocar el empaque interior dentro del empaque exterior en donde el empaque exterior comprende una primera hoja impermeable al gas y una segunda hoja impermeable al gas herméticamente selladas por tres lados y una cámara de circulación permeable al gas dispuesta en un lado no sellado de la primera hoja impermeable al gas y sellada a la segunda hoja impermeable al gas por dos lados

Sellar el extremo superior de la cámara de circulación a la segunda hoja para sellar el empaque interior en el empaque exterior

Esterilizar el producto y

Sellar la primera hoja a la segunda hoja para sellar el empaque interior en un empaque exterior impermeable al gas

17 El método de la reivindicación 16 que además comprende, después de la etapa de esterilización, la remoción de la atmósfera dentro del empaque exterior

- 18 El método de la reivindicación 17 que además comprende después de la etapa de remoción el llenado del empaque exterior con un gas inerte
- 19 El método de la reivindicación 17 que además comprende previo a la etapa de remoción el llenado del empaque exterior con un gas inerte
- 20 El método de la reivindicación 16 que además comprende la remoción de la cámara de circulación permeable al gas
- 21 el método de la reivindicación 16 en donde la etapa de esterilización comprende por lo menos uno de esterilización con vapor esterilización con EtO esterilización con plasma de peróxido gaseoso por radiofrecuencia esterilización por vapor químico y esterilización por enfriamiento
- 22 El método de la reivindicación 16 en donde el producto se incorpora con por lo menos uno de un agente antimicrobiano un antiangiogénico un antiproliferativo y un anti-inflamatorio
- 23 El método de empackado de un producto que comprende
Colocar un producto de combinación de un medicamento en un dispositivo dentro de un interior permeable al gas
Sellar el empaque interior
Colocar el empaque interior dentro de un empaque exterior en donde el empaque exterior comprende una primera hoja que comprende una sección impermeable al gas una cámara de circulación permeable al gas dispuesta en un primer lado de la

sección impermeable al gas una segunda hoja que es impermeable al gas la cual está sellada herméticamente por tres lados a la primera hoja

Sellar la primera hoja a la segunda hoja para sellar el empaque interior en el empaque exterior

Esterilizar el producto y

Sellar la primera hoja a la segunda hoja para sellar el empaque interior en un empaque exterior impermeable al gas

24 El método de la reivindicación 23 que además comprende después de la etapa de esterilización la remoción de la atmósfera dentro del empaque exterior

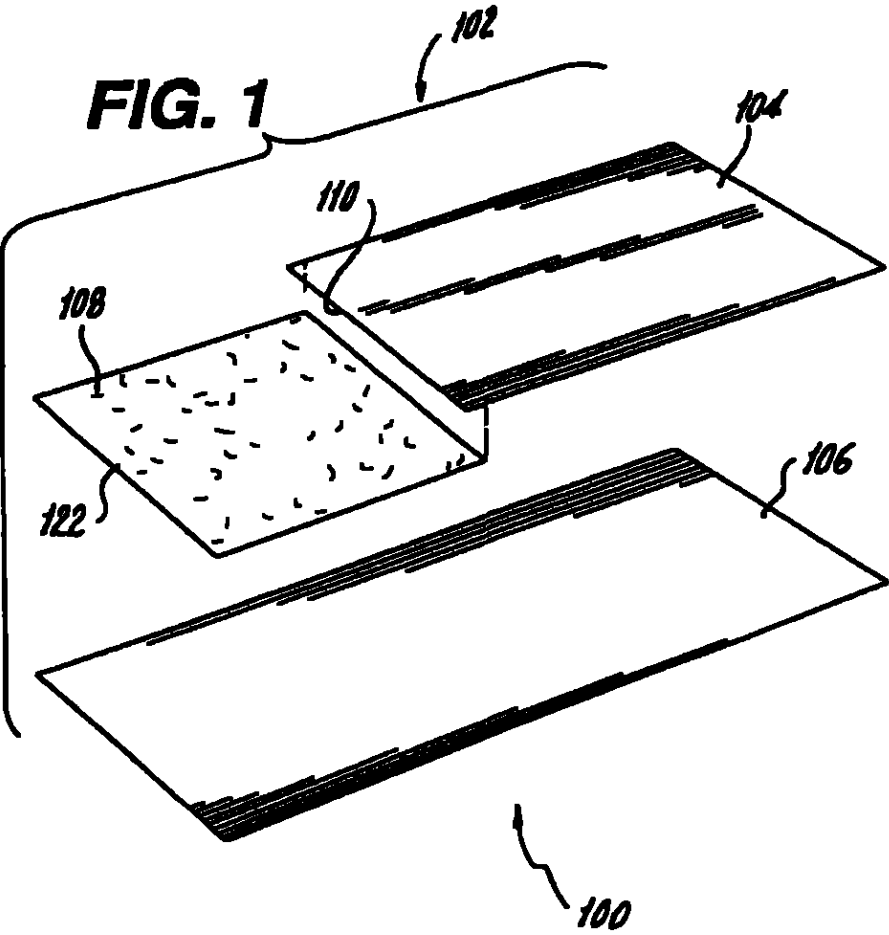
25 El método de la reivindicación 24, que además comprende antes de la etapa de remoción el llenado del empaque exterior con un gas inerte

26 El método de la reivindicación 24 que además comprende después de la etapa de remoción el llenado del empaque exterior con un gas inerte

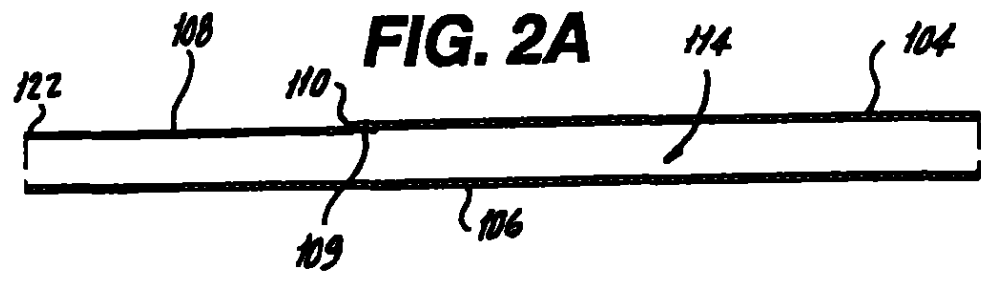
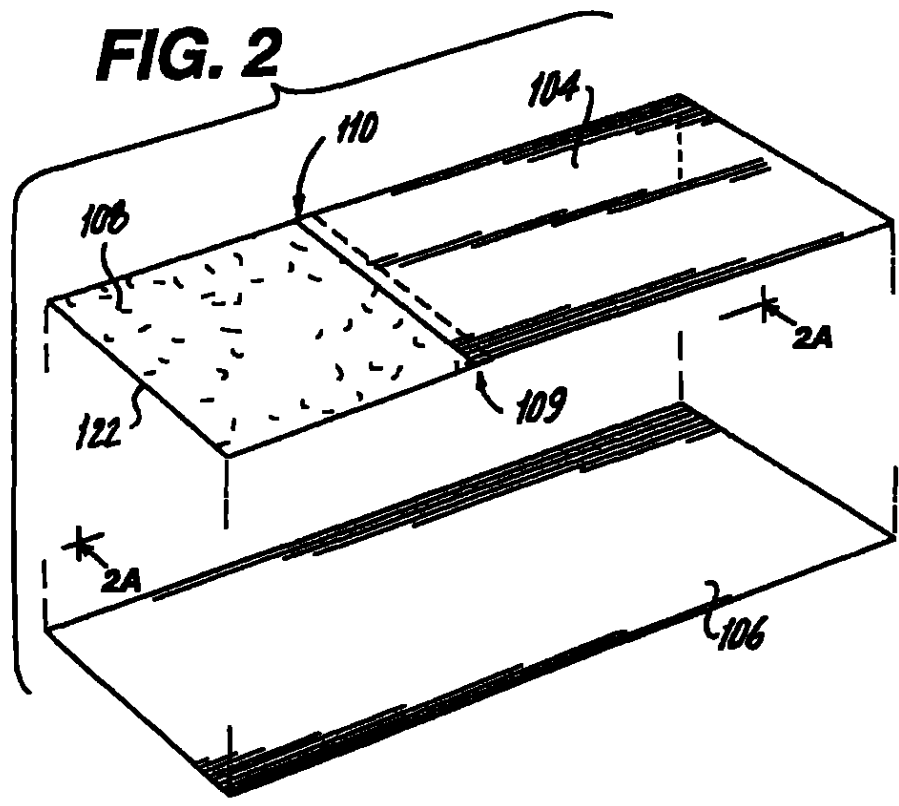
27 El método de la reivindicación 23, que además comprende la remoción de la cámara de circulación permeable al gas

28 El método de la reivindicación 23 en donde la etapa de esterilización comprende por lo menos uno de esterilización con vapor esterilización con EtO esterilización con plasma de peróxido gaseoso por radiofrecuencia esterilización por vapor químico y esterilización por enfriamiento

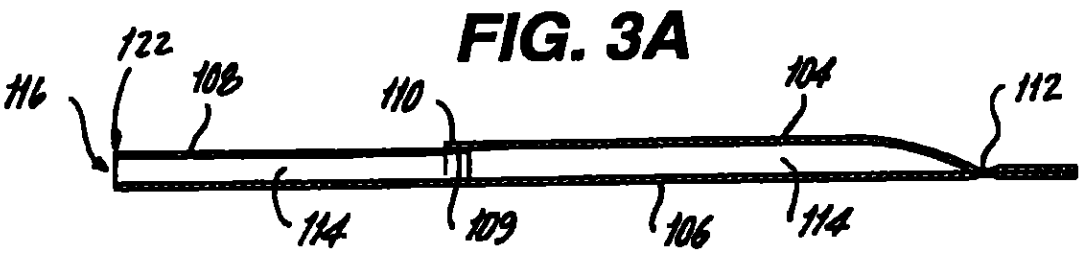
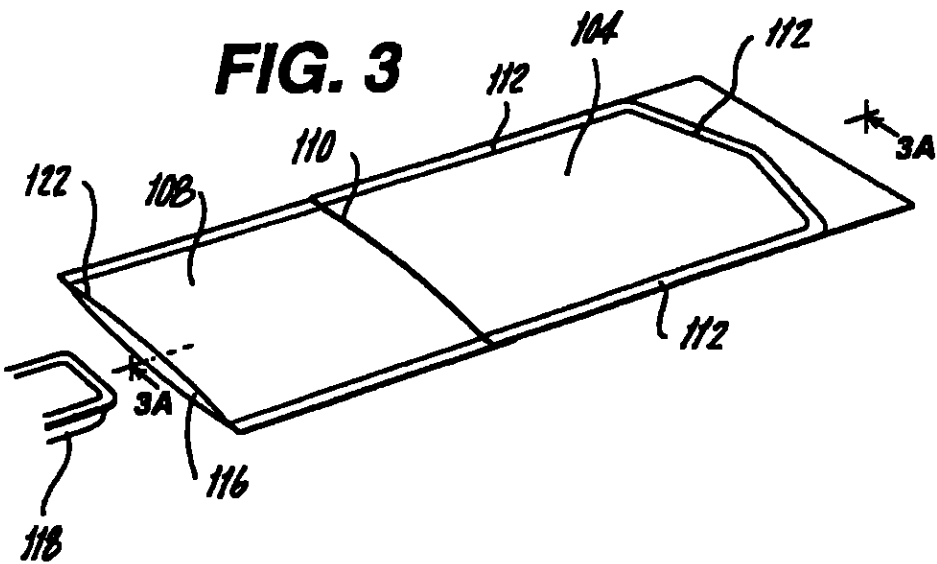
29 El método de la reivindicación 23 en donde el producto se incorpora con por lo menos uno de un agente antimicrobiano un antiangiogénico un antiproliferativo y un anti-inflamatorio



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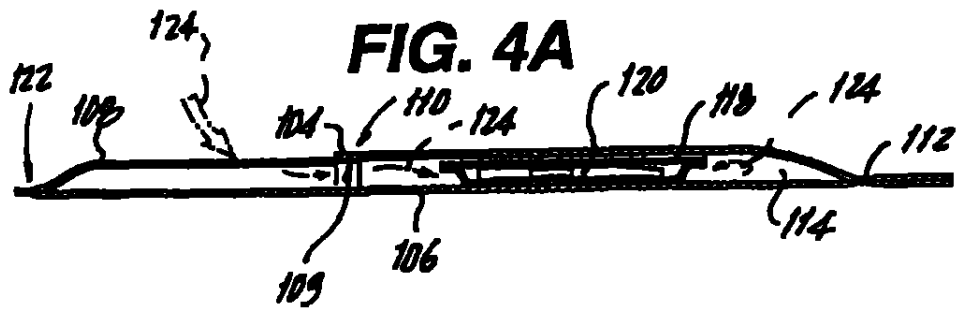
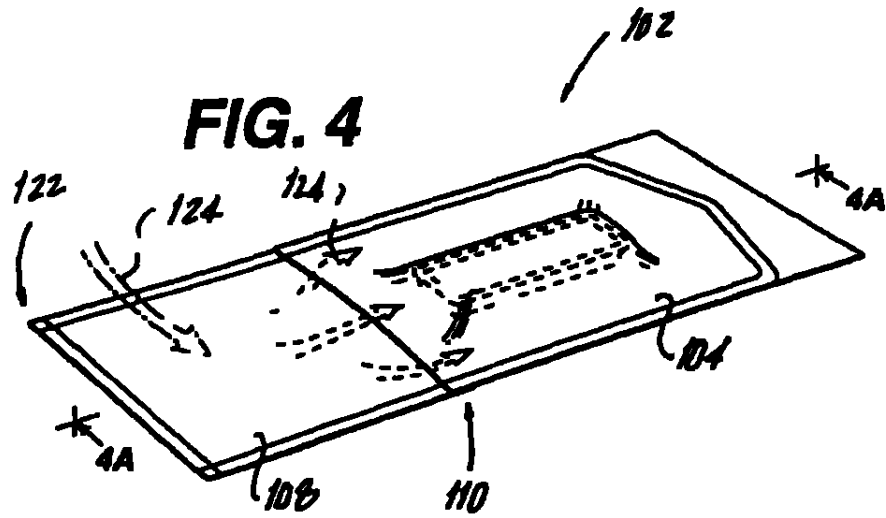


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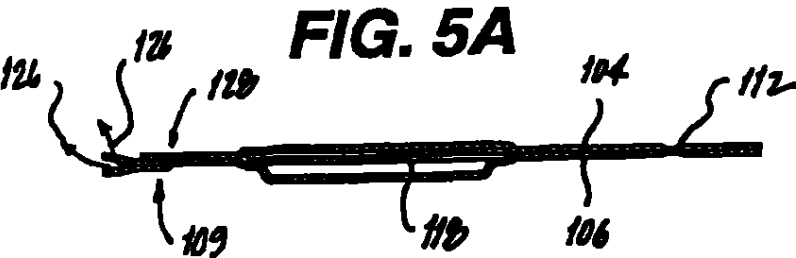
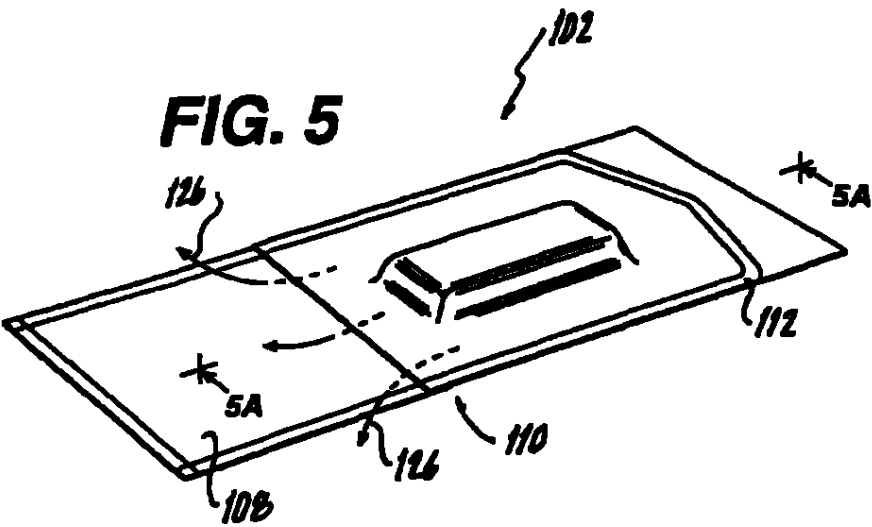


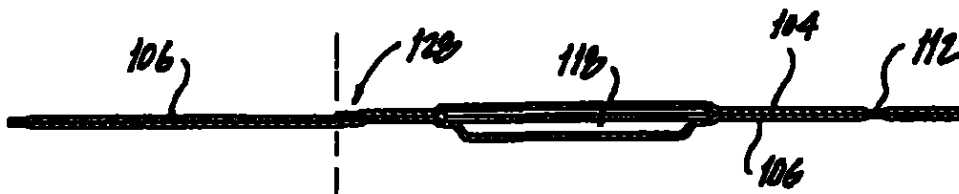
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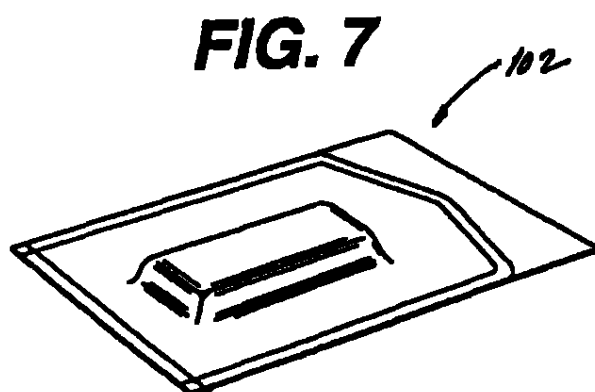
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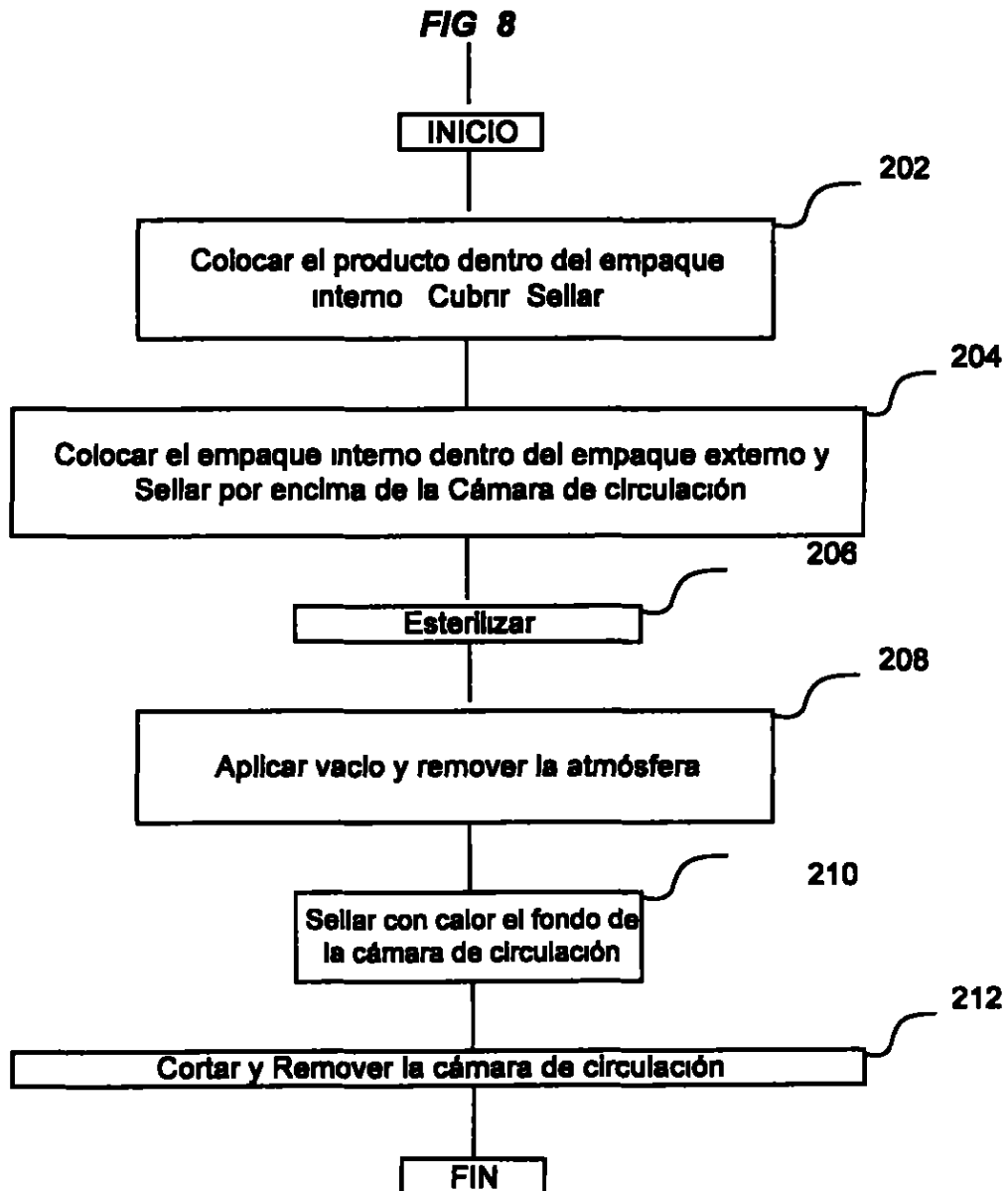
App Aun no asignada Minuta No 02640/00m792 uso
Inventor Ralnika Gupta et al
Título METODO PARA MEJORAR LA ESTABILIDAD Y
EFECTIVIDAD DE UNUN PRODUCTO DE COMBINACION
DE UN MEDICAMENTO EN UN DISPOSITIVO

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PA 2332056

THE UNITED STATES OF AMERICA

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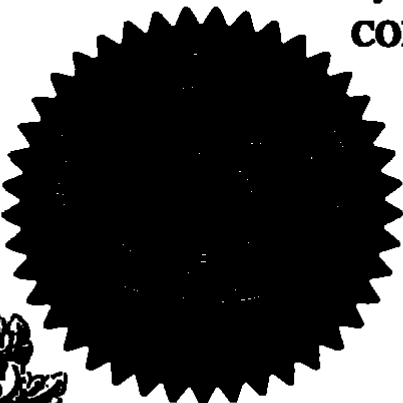
October 01, 2004

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OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE UNDER 35 USC 111

APPLICATION NUMBER 10/676,333

FILING DATE September 30, 2003

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS



M. SIAS
Certifying Officer

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PTO/SB/06 (01-03)

Approved for use through 07/31/2006. OMB 0951-0032
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UTILITY PATENT APPLICATION TRANSMITTAL		Attorney Docket No. 02840/000M792-US0	
(Only for new nonprovisional applications under 37 CFR 1.53(a))		First Inventor Rainuka Gupta	
		Title METHOD FOR IMPROVING STABILITY AND EFFECTIVITY OF A DRUG-DEVICE COMBINATION PRODUCT	
		Express Mail Label No. EV 340063531 US	
APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.		ADDRESS TO: MS Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
1. ☒ Fee Transmittal Form (a.g., PTO/SB/17) (Submit an original, and a duplicate for fee processing)		7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)	
2. ☐ Applicant claims small entity status. See 37 CFR 1.27		8. Nucleotide and/or Amino Acid Sequence Submission (If applicable, all necessary)	
3. ☒ Specification (Total Pages 19) (preferred arrangement set forth below) Description of the Invention Cross Reference to Related Applications Statement Regarding Paid sponsored R & D Reference to sequence listing, a table, or a computer program listing appendix Background of the Invention Brief Summary of the Invention Brief Description of the Drawings (if filed) Detailed Description Claim(s) Abstract of the Disclosure		a. ☐ Computer Readable Form (CRF) b. Specification Sequence Listing enc: L ☐ CD-ROM or CD-R (2 copies); or L ☐ Paper c. ☐ Statements verifying identity of above copies	
4. ☒ Drawing(s) (35 U.S.C. 113) (Total Sheets 8)		9. ☒ Assignment Papers (cover sheet & document(s))	
5. Oath or Declaration (Total Sheets 3) a. ☒ Newly executed (original or copy) b. ☐ Copy from a prior application (37 CFR 1.63(d)) (For continuations/divisionals with Box 16 completed) c. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(a).		10. ☐ 37 CFR 3.73(b) Statement (when there is an assignee) ☐ Power of Attorney	
6. ☒ Application Data Sheet. See 37 CFR 1.76		11. ☐ English Translation Document (if applicable)	
		12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations	
		13. ☐ Preliminary Amendment	
		14. ☒ Return Receipt Postcard (MPEP 803) (Should be specifically itemized)	
		15. ☐ Certified Copy of Priority Document(s) (If foreign priority is claimed)	
		16. ☐ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/05 or its equivalent.	
		17. ☐ Other Certificate of Express Mailing; check in the amount of \$1040.	
18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76: ☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. _____ Prior application information: Examiner _____ Art Unit: _____ For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.			
19. CORRESPONDENCE ADDRESS			
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Signature 		Date September 30 2003	

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METHOD AND APPARATUS FOR PACKAGING

A DRUG-DEVICE COMBINATION PRODUCT

BACKGROUND OF THE INVENTION

1 Field of the Invention

This invention relates to a package for a drug-device combination product having an outer package including a first gas impermeable sheet, a second gas impermeable sheet and a gas permeable header

2 Discussion of the Related Art

Packaging a product in an inner package and then packing the inner package in an outer package is common in the packaging arts Vacuum packaging packaging with an inert gas and multiple methods of sterilizing medical products are known in the medical device packaging art However, drug-device combination products offer a new and unique problem in the packaging and sterilizing of the product while refraining from altering the chemical structure of the drug incorporated in the device

Numerous inventions relate to the use of radiation to sterilize products for medical use, for example, U S Patent No 5,577,368 to Hamilton et al ("Hamilton") and U S Patent No 6,174,934 to Sun et al ("Sun") Both Hamilton and Sun first remove the oxygen/atmosphere from the packaging prior to radiation sterilizing medical implants made of polymeric material Hamilton's and Sun's goal is to reduce the wear resistance of the polymeric implant and radiation typically alters the chemical structures of incorporated drugs

Other inventions known in the art require numerous complex steps to sterilize and seal a medical device in one or more packages. U.S. Patent No. 4,709,819 to Lattuada et al. discloses first sterilizing an outer package, placing an inner package in the outer package and then evacuating both the inner and outer packages. This process is used because Lattuada et al. are packaging biological samples and any sterilization of the inner package would kill the sample.

Further, U.S. Patent No. 4,941,308 to Grabenkort et al. discloses sterilizing the interior of the package before placing the product in the inner package, sterilizing the product in the inner package, and then placing the inner package in the outer package. Additionally, Grabenkort et al. uses ethylene oxide gas (EtO) for the sterilization.

Both Lattuada et al. and Grabenkort et al. require a separate sterilizing step prior to inserting and sealing the inner package in the outer package. This adds steps and cost to the handling of the already sterilized product/inner package prior to inserting it into the outer package.

Thus, there is a need in the art for a packaging product and method to sterilize a drug incorporated device in the minimum number of steps while refraining from altering the chemical structure of the drug incorporated in the device.

SUMMARY OF THE INVENTION

A package for a drug-device combination product includes an outer package, including a first gas impermeable sheet and a second gas impermeable sheet hermetically sealed on three sides. The impermeable sheet material should be flexible and can be selected from among

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many types of high barrier, flexible packaging materials that are commonly used to enclose medical devices. Preferably the impermeable sheet material is a multilayered heat seal peelable packaging material that includes one or more foil layers, various polymer layers and a heat seal coating. Examples of suitable materials are those that include the following layers: polyester film, low density polyethylene-foil, ionomer heat seal coating. Packaging materials having the following layers can also be used: polyester, low density polyethylene-foil, EAA-linear low density polyethylene-heat seal coating, and polyester-Suriyn-nylon-Suriyn-foil-EAA-linear low density polyethylene-heat seal coating. Additionally, polyvinylidene chloride (PVDC) and ethylene vinyl alcohol copolymer (EVOH), are generally key components of a high-barrier film. Nylons, acrylonitrile methacrylate copolymer (AN MA), and other specialty polymers such as certain copolyesters may potentially be used.

A gas permeable header is attached to an unsealed side of the first gas impermeable sheet and sealed to the second gas impermeable sheet on two sides. The first and second gas impermeable sheets and the gas permeable header form an interior and an opening that communicates with the interior to form three sealed sides of the outer package.

A gas permeable inner package is sized to fit the device and disposed within the outer package and preferably disposed only between the first and second gas impermeable sheets. The gas permeable material for both the header and/or the inner package can be Tyvek® or any other durable gas permeable material such as polyethylene, polystyrene or polypropylene. The gas permeable inner package can be a blister tray, a pouch, or any other gas permeable container designed to hold a product to be sterilized. The product can be incorporated with drugs that are antimicrobial agents, antiangiogenesis, antiproliferatives, and anti-

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inflammatorys Incorporating the drug into the product can include, but is not limited to, impregnating, coating and sandwiching the drug between layers of the device

In an embodiment of the product, the antimicrobial agent can be selected from the group comprising antibiotics, antiseptics, and disinfectants Further, the antibiotics can be selected from a group comprising tetracyclines (i e minocycline), penicillins, (i e nafcillin), macrolides (i e erythromycin), rifampin gentamicin vancomycinclindamycin, azithromycin, enoxacin, and combinations thereof A preferred product is incorporated with Rifampicin or Clindamycin

Antiangiogenesis drugs (also called angiogenesis inhibitors) deprive the cancer cells of their blood supply Antiangiogenesis can be selected from the group including angiostatin, thalidomide (Thalomid™) CC-5013 (Revimid™) bevacizumab (Avastin™), squalamine, endostatin, angiostatin, and angiozyme Other antiangiogenesis drugs can include drugs derived from chemotherapy drugs for example, paclitaxel (Taxol™), doxorubicin (Adriamycin™), epirubicin, mitoxantrone, and cyclophosphamide

Antiproliferative drugs can prevent restenosis (a re-narrowing or blockage of an artery at the same site where treatment, such as an angioplasty or stent procedure, has already taken place) of the implanted device Examples of antiproliferatives are Sirolimus™ and Paclitaxel™ Examples of anti inflammatories, including non-steroidal anti inflammatory drugs (NSAID's) are ibuprofen ketoprofen, motrin, and naproxen.

Once the product is sealed within the inner package the inner package is placed within the outer package and a top end of the header is sealed to the second sheet This forms a sealed outer package that has gas permeable and impermeable sections Up to this point, only

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minimal care is required, neither the product, inner package, nor outer package has been sterilized and special handling or handling in a clean environment is not required. However, a preferred embodiment includes handling in a clean room environment to minimize the introduction of contaminants.

The sterilizing compound is then introduced into the interior of the outer package through the header. Since the inner package is also permeable, the sterilizing compound can permeate through the inner package and sterilize the product. As above, the sterilizing compound can be steam, ethylene oxide gas (EtO), gas plasma/radio frequency peroxide (e.g. Sterrad™), chemical vapor (e.g. alcohol, formaldehyde, etc.) and cold sterilization using liquid chemical sterilants/disinfectants that require immersion (e.g. glutaraldehyde and chlorine dioxide). The invention allows for any sterilization process that utilizes a sterilizing agent that can only pass through a permeable layer.

Once the product is sterilized, the atmosphere can be evacuated from the interior to 'vacuum seal' the product, as well as retard further oxidation. The outer package is then sealed by sealing the first gas impermeable sheet to the second gas impermeable sheet at a seal point below the point where the header attaches to the first sheet. The outer package is now a gas impermeable package. The header can either be removed or folded over to complete the packaging.

A key feature of the sterilizing step includes using any sterilizing process that maintains a chemical structure of the drug as well as prevents oxidation of the drug and still sterilizes the product for medical use.

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BRIEF DESCRIPTION OF THE DRAWING FIGURES

The above and still further objects, features and advantages of the present invention will become apparent upon consideration of the following detailed description of a specific embodiment thereof especially when taken in conjunction with the accompanying drawings wherein like reference numerals in the various figures are utilized to designate like components, and wherein

Figure 1 is an exploded perspective view of the outer package of the present invention,

Figure 2 is a perspective view of the outer package of the present invention

Figure 2A is a cross-sectional view along line 2A-2A of Figure 2,

Figure 3 is a perspective view of the assembled outer package prior to the insertion of the inner package,

Figure 3A is a cross-sectional view along line 3A-3A of Figure 3,

Figure 4 is a perspective view of the inner package and outer package during sterilization,

Figure 4A is a cross-sectional view along line 4A-4A of Figure 4,

Figure 5 is a perspective view of the inner package and outer package during evacuation,

Figure 5A is a cross-sectional view along line 5A-5A of Figure 5,

Figure 6 is a perspective view of the inner package and outer package after evacuation

Figure 6A is a cross-sectional view along line 6A-6A of Figure 6,

Figure 7 is a perspective view of the final packaging, and

Figure 8 is a flow chart outlining the method of the present invention

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to Figures 1 through 3A a package 100 for a drug-device combination product is illustrated. Package 100 includes an outer package 102 including a first gas impermeable sheet 104 and a second gas impermeable sheet 106 hermetically sealed on three sides 112 (Figure 3). A gas permeable header 108 is attached at an attachment point 109 located on an unsealed side 110 of first gas impermeable sheet 104 and sealed to second gas impermeable sheet 106 on two sides. First and second gas impermeable sheets 104, 106 and gas permeable header 108 form an interior 114 with an opening 116 communicating with interior 114. The impermeable sheet material should be flexible and can be selected from among many types of high barrier, flexible packaging materials that are commonly used to enclose medical devices. Preferably the impermeable sheet material is a multilayered heat seal peelable packaging material that includes one or more foil layers, various polymer layers and a heat seal coating. Examples of suitable materials are those that include the following layers: polyester film-low density polyethylene-foil-ionomer heat seal coating. Packaging materials having the following layers can also be used: polyester-low density polyethylene-foil-EAA-linear low density polyethylene-heat seal coating, and polyester-Surlyn nylon-Surlyn-foil-EAA-linear low density polyethylene-heat seal coating. Additionally, polyvinylidene chloride (PVDC) and ethylene vinyl alcohol copolymer, (EVOH), are generally key components of a

high barrier film Nylons, acrylonitrile methacrylate copolymer (AN-MA) and other specialty polymers such as certain copolyesters may potentially be used

Referring to Figures 3 through 4A, a gas permeable inner package 118 is disposed within outer package 102. Additionally, gas permeable inner package 118 is preferably disposed only between first and second gas impermeable sheets 104, 106. The gas permeable material for both the header and/or the inner package can be Tyvek® or any other durable gas permeable material such as polyethylene, polystyrene or polypropylene. Gas permeable inner package 118 can be a blister tray, a pouch, or any other gas permeable container designed to hold a product 120 to be sterilized.

Figure 4A illustrates product 120 which in an embodiment, can be incorporated with a drug (not illustrated) and gas permeable inner package 118 is sized to contain product 120 and be placed only between gas impermeable section of first sheet and second sheet 104 106 The drugs that the product can be incorporated with are antimicrobial agents antiangiogenesis antiproliferatives, and anti inflammatory Incorporating the drug into the product can include, but is not limited to, impregnating, coating and sandwiching the drug between layers of product 120

In an embodiment of product 120, the antimicrobial agent can be selected from the group comprising antibiotics, antiseptics, and disinfectants. Further, the antibiotics can be selected from a group comprising tetracyclines (i.e. Minocycline™), penicillins, (i.e. Nafcillin™), macrolides (i.e. Erythromycin™), rifampin, gentamicin, vancomycin, clindamycin, azithromycin, enoxacin, and combinations thereof. A preferred product 120 is incorporated with Rifampicin™ or Clindamycin™.

Antiangiogenesis drugs (also called angiogenesis inhibitors) deprive the cancer cells of their blood supply. Antiangiogenesis can be selected from the group including angiostatin, thalidomide (Thalomid™), CC-5013 (Revimid™), bevacizumab (Avastin™), squalamine, endostatin, angiostatin, and angiozyme. Other antiangiogenesis drugs can include drugs derived from chemotherapy drugs, for example, paclitaxel (Taxol™), doxorubicin (Adriamycin™), epirubicin, mitoxantrone, and cyclophosphamide.

Antiproliferative drugs can prevent restenosis (a re-narrowing or blockage of an artery at the same site where treatment, such as an angioplasty or a stent procedure, has already taken place) of product 120. Examples of antiproliferatives are Sirolimus™ and Paclitaxel™. Examples of anti-inflammatories, including non-steroidal anti-inflammatory drugs (NSAID's), are ibuprofen, ketoprofen, motrin, and naproxen.

Figures 3 through 4A further illustrate that once product 120 is sealed within inner package 118, inner package 118 is placed within outer package 102. A top end 122 of header 108 is sealed to second sheet 106. A sterilizing compound 124 is then introduced into interior 114 through header 108. Sterilizing compound 124 then permeates through inner package 118 and sterilizes product 120. Sterilizing compound 124 can be steam, ethylene oxide gas (EtO), gas plasma/radio frequency-peroxide (e.g. Sterrad™), chemical vapor (e.g. alcohol, formaldehyde, etc), and cold sterilization using liquid chemical sterilants/disinfectants that require immersion (e.g. glutaraldehyde and chlorine dioxide). The invention allows for any sterilization process that utilizes a sterilizing agent that can only pass through a permeable layer and that process is compatible with the incorporated drug. For example, Rifampicin is not compatible with EtO sterilization but is compatible with steam sterilization.

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Referring to Figures 5 and 5A, optionally, atmosphere 126 can be evacuated from interior 114 to 'vacuum seal' product 120. Outer package 102 is then sealed by sealing first gas impermeable sheet 104 to second gas impermeable sheet 106 at a seal point 128 below attachment point 109 of header 108 to first sheet 104. Outer package 102 is now a gas impermeable package. Optionally, header 108 can either be removed or folded over to complete the packaging (Figure 7).

Figure 8 illustrates a method of packaging a drug-device combination product 120 such as, for example, but not limited to a drug incorporated catheter (e.g. Bactiseal™) and a drug-eluting stent (e.g. Cypher™). The steps include placing product 120 inside gas permeable inner package 118 (step 202), sealing inner package 118, and placing inner package 118 inside outer package 102 (step 204). Outer package 102 is formed as described above. Further steps include sealing the top end 122 of header 108 to second sheet 106 to seal inner package 118 in outer package 102 (step 204). Once inner package 118 is sealed, product 120 is sterilized with sterilizing compound 126 (step 206) and the first sheet 104 is sealed to second sheet 106 to seal inner package 118 in a gas impermeable outer package (step 210). An embodiment includes, after the sterilizing step (206), removing atmosphere 126 from inside outer package 102 (step 208). Once the gas impermeable outer package is sealed, another step includes removing the gas permeable header 108 (step 212), or as an alternative header 108 can be folded under outer package 102.

An embodiment includes, replacing atmosphere 126 with an inert gas (not illustrated) prior to removing the atmosphere 128 (step 208). Another embodiment includes, after

removing the atmosphere (step 208), filling the outer package 102 with an inert gas (not illustrated)

A key feature of the sterilizing step includes using steam EtO, gas plasma/radio frequency-peroxide, chemical vapor, cold sterilization or any sterilizing process that maintains the chemical structure of the incorporated drug, prevents oxidation of the incorporated drug and also maintains the desired mechanical properties (rigidity elasticity, etc) of the device while still sterilizing the product for medical use

While there have been shown, described, and pointed out fundamental novel features of the invention as applied to a preferred embodiment thereof, it will be understood that various omissions substitutions, and changes in the form and details of the devices illustrated, and in their operation, may be made by those skilled in the art without departing from the spirit and scope of the invention For example, it is expressly intended that all combinations of those elements and/or steps which perform substantially the same function in substantially the same way, to achieve the same results are within the scope of the invention Substitutions of elements from one described embodiment to another are also fully intended and contemplated It is also to be understood that the drawings are not necessarily drawn to scale but that they are merely conceptual in nature It is the intention therefore, to be limited only as indicated by the scope of the claims appended hereto

7.5

What we claim is

- 1 A package for a drug-device combination product, comprising
an outer package comprising
a first gas impermeable sheet,
a second gas impermeable sheet hermetically sealed on three sides with the first
gas impermeable sheet
a gas permeable header disposed at an unsealed side of the first gas impermeable
sheet and sealed to the second gas impermeable sheet on two sides, and
wherein the first and the second gas impermeable sheets and the gas permeable header
form an interior and an opening communicating with the interior, and
a gas permeable inner package designed to hold said drug-device combination product
and be disposed within the outer package
- 2 The package of claim 1, wherein the gas permeable inner package is disposed
only between the first and the second gas impermeable sheets
- 3 The package of claim 1, wherein the gas permeable inner package is a blister
tray
- 4 The package of claim 1 wherein the gas permeable inner package is a pouch

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5 A package for a product comprising
a product incorporated with a drug,
a gas permeable inner package sized to contain the product, and
an outer package comprising
a first sheet comprising
a gas impermeable section, and
a gas permeable header disposed to a first side of the gas impermeable
section,
a second sheet being gas impermeable and hermetically sealed on three
sides to the first sheet, and
the first and the second sheets forming an interior and an opening
communicating with the interior, wherein the inner package is disposed within the outer
package

6 The package of claim 5, wherein the gas permeable inner package is disposed
only between the gas impermeable section of the first sheet and the second sheet

7 The package of claim 5 wherein the gas permeable inner package is a blister
tray

8 The package of claim 5, wherein the gas permeable inner package is a pouch

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9 The package of claim 5 wherein the drug is selected from the group comprising antimicrobial agents, antiangiogenesis, antiproliferatives, and anti inflammatory

10 The package of claim 9, wherein the antimicrobial agents are selected from the group comprising antibiotics, antiseptics, and disinfectants

11 The package of claim 10 wherein the antibiotics are selected from the group comprising tetracyclines, penicillins, macrolides, rifampin, gentamicin, vancomycin, clindamycin, azithromycin, enoxacin, and combinations thereof

12 The package of claim 9, wherein the antimicrobial agent is at least one of Rifampicin and Clindamycin

13 The package of claim 9 wherein the antiangiogenesis are selected from the group comprising angiostatin, thalidomide, CC 5013 bevacizumab, squalamine, endostatin, angiostatin, angiozyme paclitaxel, doxorubicin, epirubicin mitoxantrone, and cyclophosphamide

14 The package of claim 9, wherein the antiproliferatives is at least one of Sirohimus and Paclitaxel

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15 The package of claim 9, wherein the anti-inflammatorys are selected from the group comprising ibuprofen, ketoprofen motrin, or naproxen

16 The method of packaging a drug-device combination product, comprising
placing the product inside a gas permeable inner package,
sealing the inner package,
placing the inner package inside an outer package, wherein the outer package comprises a first gas impermeable sheet and a second gas impermeable sheet hermetically sealed on three sides and a gas permeable header disposed at an unsealed side of the first gas impermeable sheet and sealed to the second gas impermeable sheet on two sides,
sealing a top end of the header to the second sheet to seal the inner package in the outer package,
sterilizing the product, and
sealing the first sheet to the second sheet to seal the inner package in a gas impermeable outer package

17 The method of claim 16, further comprising, after the sterilizing step, removing an atmosphere inside the outer package

18 The method of claim 17, further comprising, after the removing step, filling the outer package with an inert gas

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19 The method of claim 17, further comprising, prior to the removing step, filling the outer package with an inert gas

20 The method of claim 16, further comprising removing the gas permeable header

21 The method of claim 16, wherein the sterilizing step comprises at least one of steam sterilization, EtO sterilization gas plasma/radio frequency peroxide sterilization chemical vapor sterilization and cold sterilization.

22 The method of claim 16 wherein the product is incorporated with at least one of an antimicrobial agent, an antiangiogenes, and antiproliferative, and an anti-inflammatory

23 The method of packaging a product comprising
placing a combination drug device product inside a gas permeable inner package,
sealing the inner package,
placing the inner package inside an outer package, wherein the outer package comprises a first sheet comprising a gas impermeable section a gas permeable header disposed at a first side of the gas impermeable section, a second sheet being gas impermeable which is hermetically sealed on three sides to the first sheet,

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sealing the first sheet to the second sheet to seal the inner package in the outer package,

sterilizing the product, and

sealing the first sheet to the second sheet to seal the inner package in a gas impermeable outer package

24 The method of claim 23, further comprising, after the sterilizing step removing the atmosphere inside the outer package

25 The method of claim 24, further comprising, prior to the removing step, filling the outer package with an inert gas

26 The method of claim 24, further comprising, after the removing step, filling the outer package with an inert gas

27 The method of claim 23, further comprising removing the gas permeable header

28 The method of claim 23, wherein the sterilizing step comprises at least one of steam sterilization, EtO sterilization gas plasma/radio frequency-peroxide sterilization chemical vapor sterilization and cold sterilization

29 The method of claim 23, wherein the product is incorporated with at least one of an antimicrobial agent, an antiangiogenes, and antiproliferative, and an anti inflammatory

ABSTRACT

A package for a drug-device combination product includes an outer package including a first gas impermeable sheet and a second gas impermeable sheet hermetically sealed there to on three sides. A gas permeable header is attached to an unsealed side of the first sheet and sealed to the second sheet on two sides. The first and second gas impermeable sheets and the header form an interior and an opening communicating with the interior. A gas permeable inner package is disposed within the outer package. A product is sealed within the inner package. The inner package is placed within the outer package and a top end of the header is sealed to the second sheet. The outer package is then sealed by sealing the first gas impermeable sheet to the second gas impermeable sheet at a seal point below the point where the header attaches to the first sheet.

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Customer No: 07278

Docket No. 02640/000M792-US0

**DECLARATION
AND POWER OF ATTORNEY
Original Application**

As a below named inventor, I declare that the information given herein is true, that I believe that I am the original, first and sole inventor if only one name is listed at I below or a joint inventor if plural inventors are named below, of the invention entitled.

**METHOD FOR IMPROVING STABILITY AND EFFECTIVITY OF
A DRUG-DEVICE COMBINATION PRODUCT**

which is described and claimed in.

☒ the attached specification or ☐ the specification in application Serial No. Not yet assigned, filed Concurrently herewith (for declaration not accompanying appl.)

that I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof or patented or described in any printed publication in any country before my or our invention thereof, or more than one year prior to this application, or in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application, that I acknowledge my duty to disclose information of which I am aware which is material to patentability in accordance with 37 CFR §1.56. I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I hereby claim the priority benefits under 35 U.S.C. §119 of any application(s) for patent or inventor's certificate listed below. All foreign applications for patent or inventor's certificate on this invention filed by me or my legal representatives or assigns prior to the application(s) of which priority is claimed are also identified below.

PRIOR APPLICATION(S), IF ANY, OF WHICH PRIORITY IS CLAIMED

COUNTRY	APPLICATION NO	DATE OF FILING
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ALL FOREIGN APPLICATIONS, IF ANY, FILED PRIOR

{M:26400m792m00062038.DOC *26400M792080* }

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TO THE APPLICATION(S) OF WHICH PRIORITY IS CLAIMED

COUNTRY	APPLICATION NO.	DATE OF FILING
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POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agents(s) to prosecute this application and transact all business in the Patent and Trademark office connected therewith:

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07278

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

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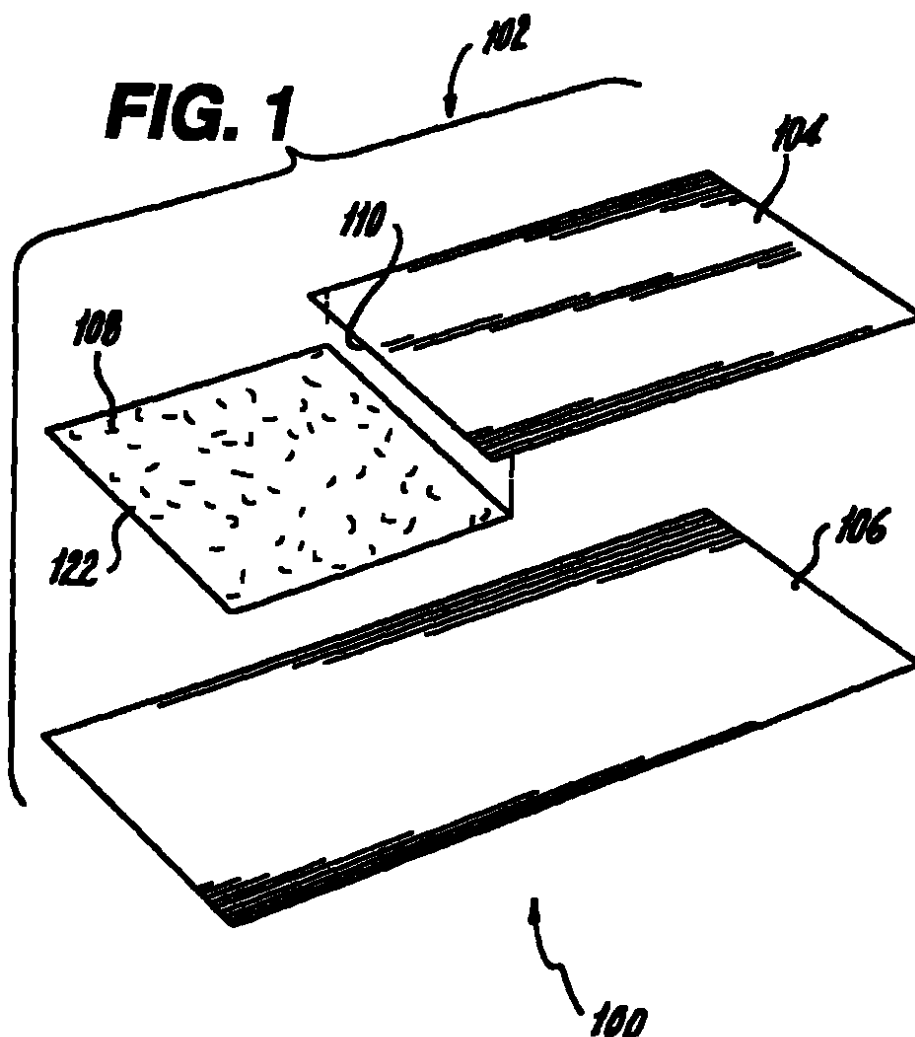
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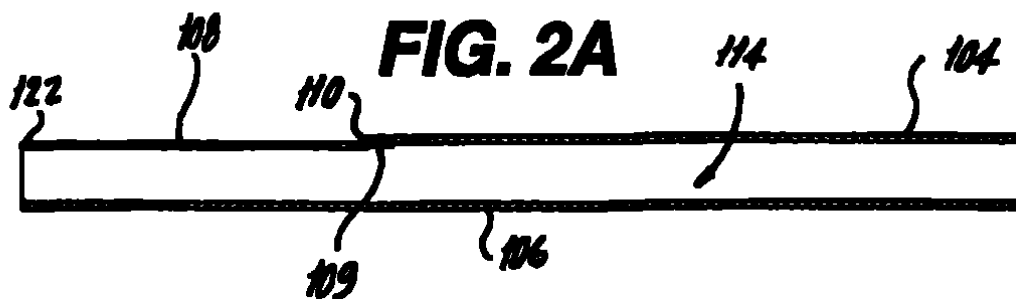
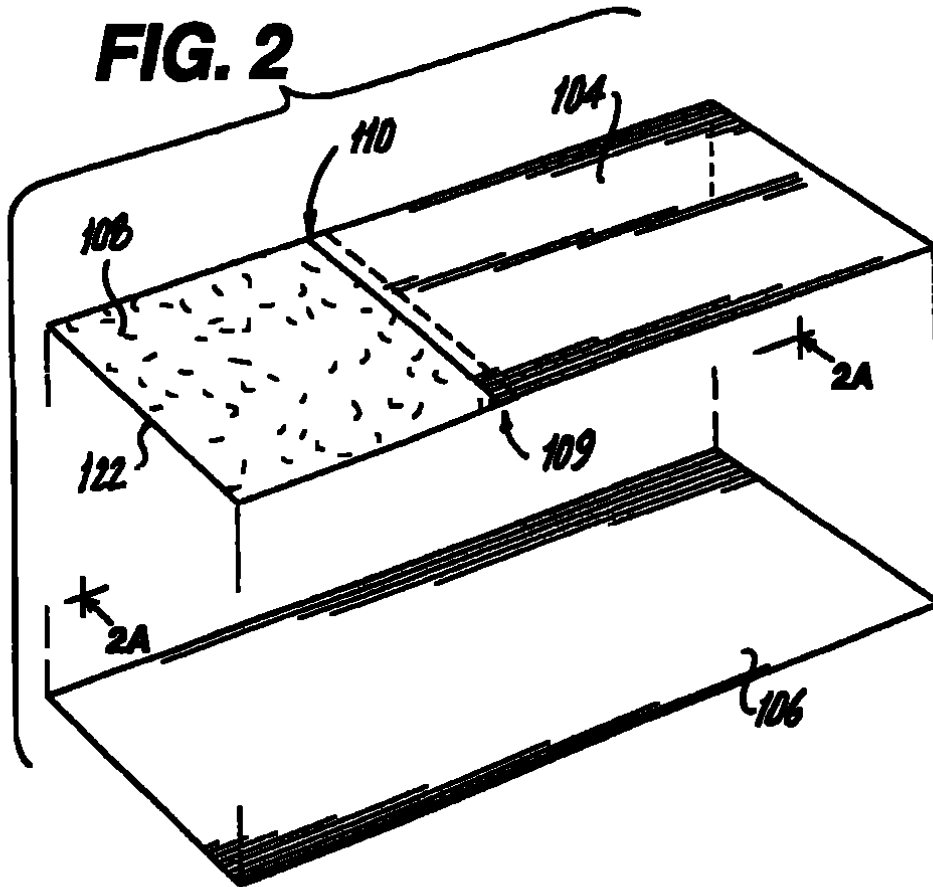
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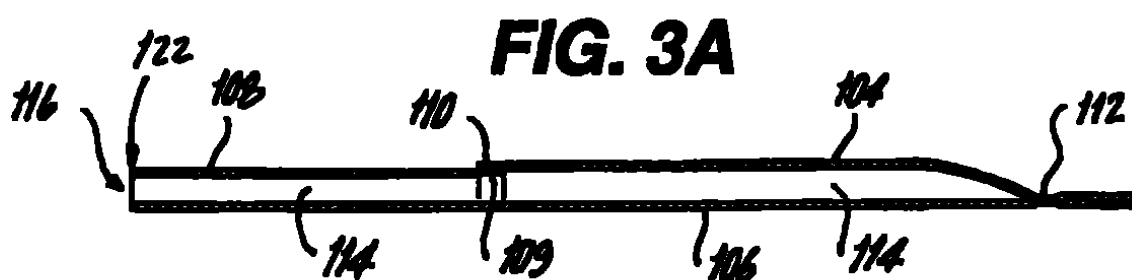
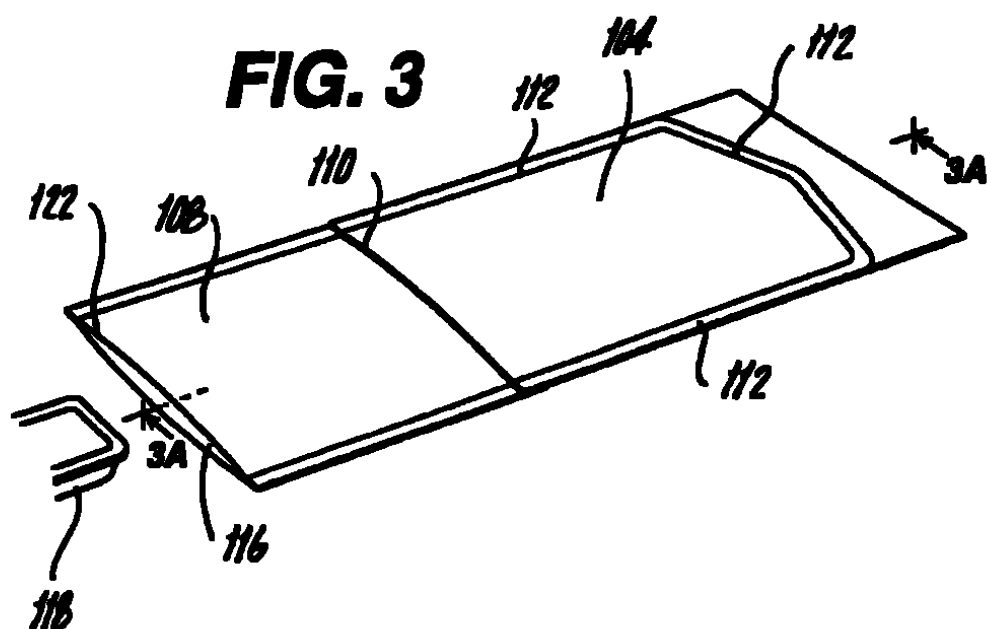


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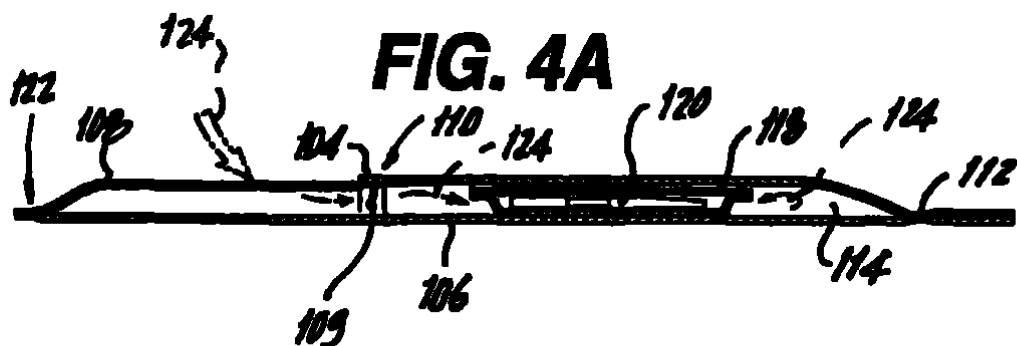
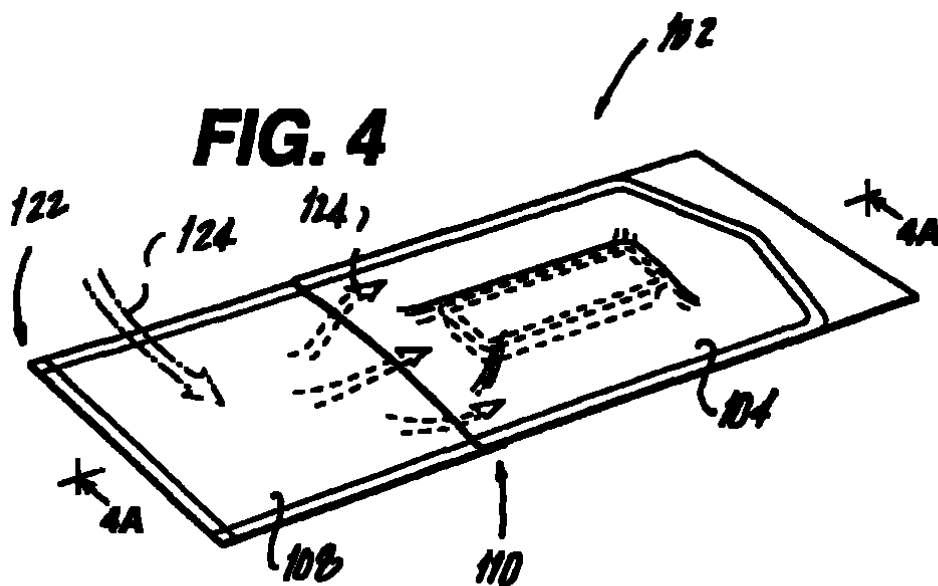
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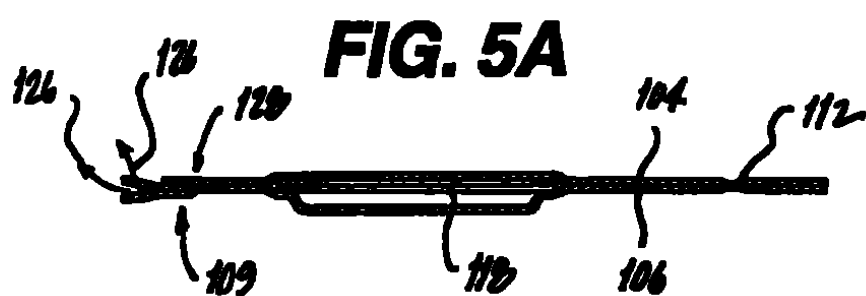
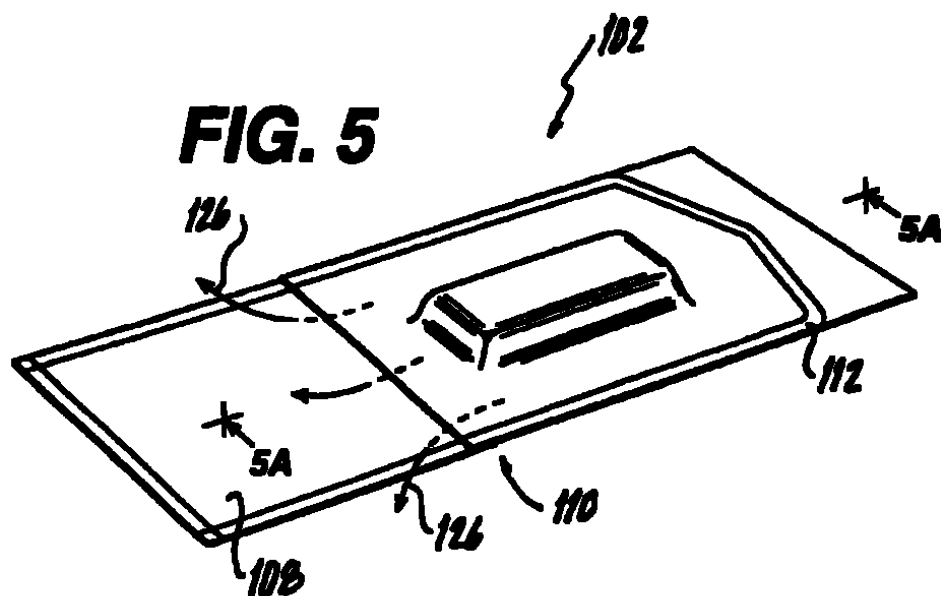
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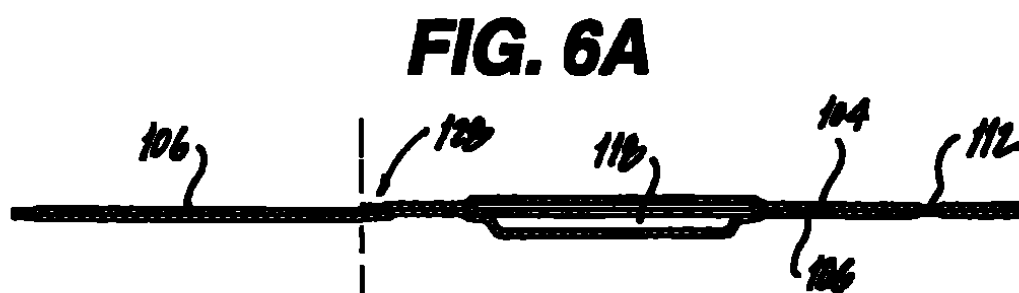
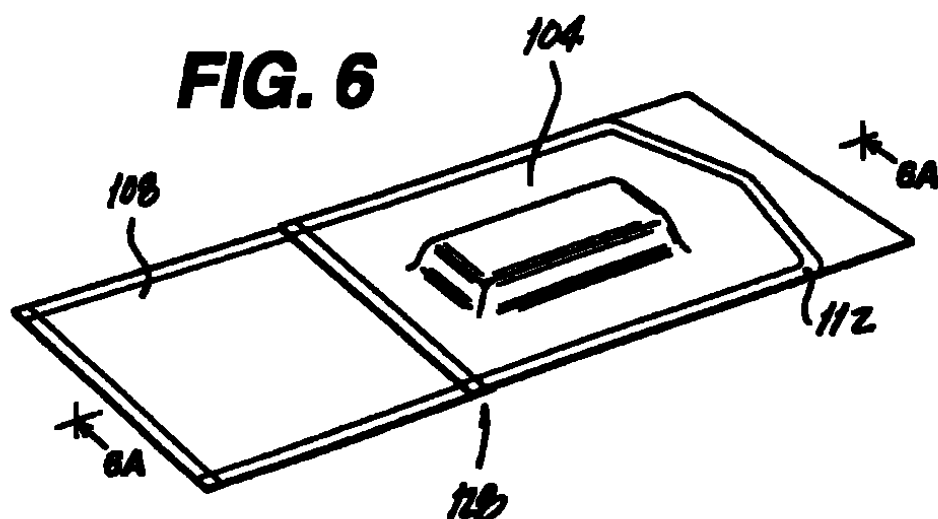
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FIG. 7

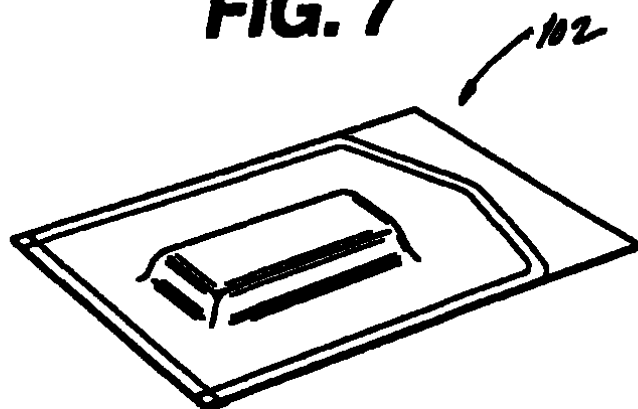
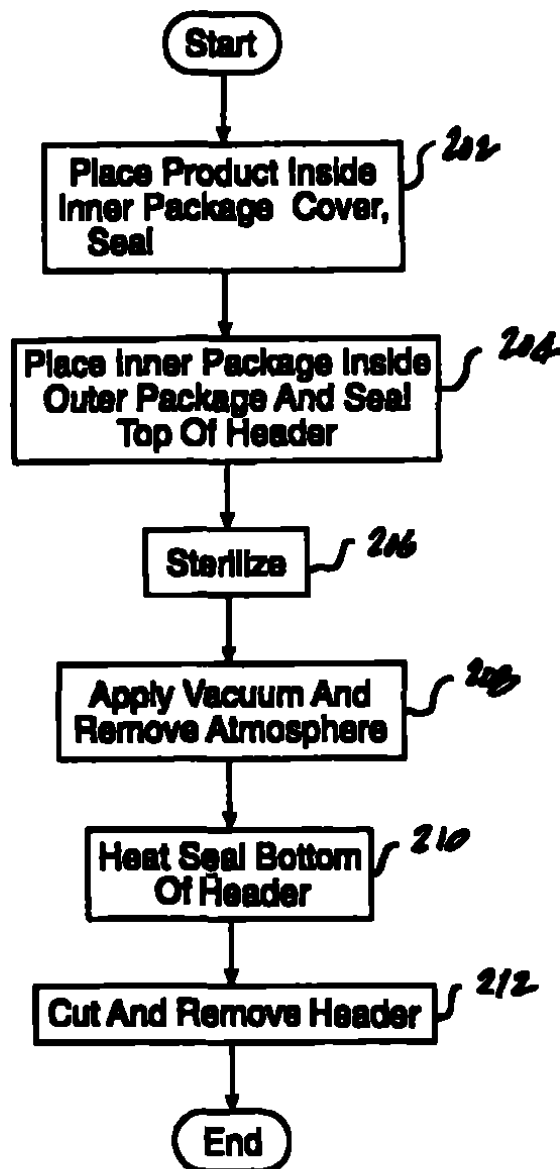


FIG. 8



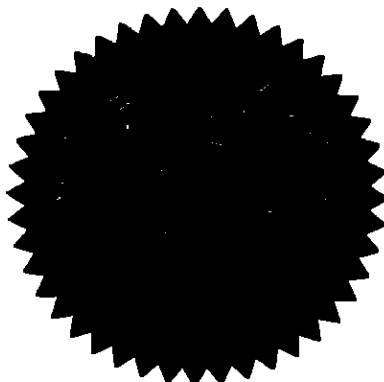
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March 2, 2005**



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REEL/FRAME 014570/0168
NUMBER OF PAGES 3

BRIEF ASSIGNMENT OF ASSIGNOR S INTEREST (SEE DOCUMENT FOR DETAILS)

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GUPTA RAINUKA

DOC DATE 09/30/2003

ASSIGNOR

DEXTRADEUR ALAN J

DOC DATE 09/30/2003

ASSIGNEE

CODMAN & SHURTLEFF INC
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RAYNHAM MASSACHUSETTS 02767

SERIAL NUMBER 10676333

FILING DATE 09/30/2003

PATENT NUMBER

ISSUE DATE

TITLE METHOD FOR IMPROVING STABILITY AND EFFECTIVITY OF A DRUG-DEVICE COMBINATION PRODUCT

10-14-2003

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(Rev. 03/01)
OMB No. 0851-0027 (exp. 6/31/2002)

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Rainuka Gupta (09/30/2003) and Alan J. Desnoeur
(09/30/2003)

Additional name(s) of conveying party(ies)
attached? ☐ Yes ☒ No

3. Nature of Conveyance

☒ Assignment☐ Merger☐ Security Agreement☐ Change of Name☐ Other

Execution Date see Box 1, conveying parties

2. Name and address of receiving party(ies)

Name: Codman & Shurtleff, Inc.

Internal Address: _____

Street Address
325 Paramount Dr

City: Raynham

State: MA

Zip: 02767

Additional name(s) &
address(es) attached ☐ Yes ☒ No

4 Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the new application is: _____

A. Patent Application No.(s):

This application

B. Patent No.(s):

Additional numbers attached? ☐ Yes ☒ No

5 Name and address of party to whom correspondence concerning document should be mailed

Name: Malvin C. Garner
DARBY & DARBY P.C.

Internal Address Atty Dkt. 02840/000M792-US0

Street Address
P O Box 5257

City
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State
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Zip:
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6. Total number of applications and patents involved

1

7 Total fee (37 CFR 3.41)

8 40.00

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Docket No 02640/000M792-US0

ASSIGNMENT

I, Raimuka GUPTA, a citizen of U.S.A., residing at 79 Fifth St., #2 Cambridge, MA 02141 and

I, Alan J DEXTRADEUR, a citizen of U.S.A. residing at 15 Lyons Street, Franklin, MA 02038

(hereinafter called "ASSIGNOR") in consideration of the sum of One Dollar (\$1.00) or the equivalent thereof, and other good and valuable consideration, receipt of which is hereby acknowledged, paid to me by

CODMAN & SHURTLEFF, INC.

a corporation organized under the laws of New Jersey located at 325 Paramount Dr Raynham, MA 02767 (hereinafter called the "ASSIGNEE"), do hereby sell and assign to said ASSIGNEE, its successors and assigns, all my right, title and interest, throughout the world, including priority rights, in and to my invention entitled.

METHOD FOR IMPROVING STABILITY AND EFFECTIVITY OF A DRUG-DEVICE COMBINATION PRODUCT

invented by me, as a co-inventor if other inventors are identified above, and described in Application Serial No. Not Yet Known, filed Concurrently Herewith for United States Letters Patent therefor and all divisions, reissues, continuations and extensions thereof, said interest being my entire ownership interest in said Letters Patent when granted, to be held and enjoyed by said ASSIGNEE, its successors, assigns or other legal representatives, to the full end of the term for which said Letters patent may be granted, as fully and entirely as the same would have been held and enjoyed by me if this assignment and sale had not been made

And I hereby agree to sign and execute any further documents or instruments which may be necessary, lawful, and proper in the prosecution of said above-named application or in the preparation and prosecution of any continuing, continuation-in-part, substitute, divisional, renewal or reissue applications, or in any amendment, extension, or interference proceedings, or otherwise to secure the title thereto in said ASSIGNEE,

And I hereby authorize and request the Commissioner of Patents and Trademarks to issue said Letters Patent to said ASSIGNEE.

I declare under penalty of perjury under the laws of the United States of America that I have signed this document as my own free act and that all of the foregoing is true and correct.

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Ramuka Gupta
Ramuka GUPTA

DATED 9/30/03

Alan J Dextraeur
Alan J DEXTRADEUR

DATED 9/30/03

2° EXAMEN DE FORMA PATENTE DE INVENCION

Radicacion N° **04-97769**

Folio **99**

Concepto Tecnico N° **744**

Clasificacion Internacional de Patentes **A61J 1/00**

Practicado el examen de acuerdo a lo establecido en el Art 38 de la Decisión 486 se determino que esta solicitud de **Patente**

- SI ☒ NO ☐ Contiene un resumen de la invención (Art 26-e)
- SI ☒ NO ☐ Contiene el titulo o nombre de la invención (Art 27-d)
- SI ☒ NO ☐ Contiene la descripción de la invencion (Art 26 b)
- SI ☒ NO ☐ NO ES APLICABLE ☐ Contiene los dibujos necesanos para comprender la invencion (Art 26-d)
- SI ☒ NO ☐ Contiene una o más reivindicaciones (Art 26-c)
- SI ☐ NO ☐ NO ES APLICABLE ☒ Han sido desarrollados los productos a partir de recursos genéticos o de sus productos dervados de los que cualquiera de los Paises Miembros es país de origen (Art 26 h)
- SI ☐ NO ☐ NO ES APLICABLE ☒ Los productos y o procedimientos han sido obtenidos o desarrollados a partir a partir de los conocimientos tradicionales de las comunidades indigenas afro americanas o locales de los Paises Miembros de acuerdo a lo establecido en la Decision 391 y sus modificaciones y reglamentaciones vigentes (Art 26-i)
- SI ☐ NO ☒ La invención se refiere a un producto relativo a un material biológico (Art 26-j)
- SI ☒ NO ☐ NO ES APLICABLE ☐ La pnoridad coincide con la matena reivindicada
- SI ☒ NO ☐ **CUMPLE LOS REQUISITOS TÉCNICOS**

OBSERVACIONES Y OTROS SI ☐ NO ☐ Ver hoja(s) anexa(s)

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EXAMINADOR TÉCNICO 202051

Bogota D C septiembre 30 de 2005

2020
Bogota D C

Doctor(a)
JIMENA ESCOBAR URIBE
Apoderado (a)

REFERENCIA	Radicacion N°	04 97769
	Trámite	002
	Evento	001
	Actuación	416
	Oficio N°	998
	Folios	001

Teniendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en la referencia reúne los requisitos de forma establecidos en los artículos 26 y 27 de la Decisión 486 de la Comisión de la Comunidad Andina y en las demás disposiciones vigentes sobre la materia se envía el extracto de la solicitud a la oficina de comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial conforme lo establece el artículo 40 de la Decisión 486

Cumplase

Dado en Bogotá D C

04 OCT 2020


ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe División de Nuevas Creaciones

202051