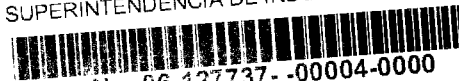


~~135~~
136

Teléfono: (57-1) 347 3611
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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 06-127737- -00004-0000

No. 06-127737- -00004-0000

...anne : 011

Evento : 378**Actuación : 538**

Ernest Bennett

NIT 860.041.367-3

organisms and/or viruses, preferably foodstuffs, particularly preferably milk products or fruit juice products or drinking water, chemical or pharmaceutical products, especially preferably virus vaccines, active substances or proteins produced by genetic engineering, e.g. active substances or proteins from transgenic animals or plants, blood plasma or products produced from blood plasma.

[0044] The following provides a more detailed explanation of specific embodiments of the invention with reference to figures, in which:

[0045] FIG. 1 shows a schematic section through part of an irradiation chamber,

[0046] FIG. 2 shows an annular-gap stirred reactor comprising an anchor agitator, centric UV irradiation and magnetic drive in longitudinal section,

[0047] FIG. 2a shows an enlarged detail from FIG. 2,

[0048] FIG. 3 shows an anchor agitator, carved out in the manner of a cavern, from FIG. 2 with a magnet,

[0049] FIG. 4a shows an impeller drive for the anchor agitator according to FIG. 2 in longitudinal section B-B

[0050] FIG. 4b shows the impeller drive according to FIG. 4a in cross section A-A

[0051] FIG. 5 shows a helical-tube reactor with a half-round tube cross section,

[0052] FIG. 5a shows an enlarged detail from FIG. 5,

[0053] FIG. 6 shows a helical-tube reactor with a rectangular tube cross section,

[0054] FIG. 6a shows an enlarged detail from FIG. 6

[0055] FIG. 7 shows a disassembleable, ducted spiral-tube reactor in longitudinal section,

[0056] FIG. 7a shows an enlarged detail from FIG. 6

[0057] FIG. 8 shows a free-jet reactor driven at the inner diameter of the annular gap and having trapezoidal ducts, in longitudinal section

[0058] FIG. 8a shows an enlarged detail from FIG. 8.

[0059] FIG. 9 shows a redistribution reactor with alternating product feed at the inner and outer diameter of the annular gap,

[0060] FIG. 9a shows an enlarged detail from FIG. 9,

[0061] FIG. 10 shows the top section of an annular-gap reactor with UV sensors.

EXAMPLES

Example 1

[0062] The UV reactor according to FIG. 2 and FIG. 2a consists of a centrally fitted UV lamp 1 (Hg fluorescent tube) having an outer diameter of 25 mm and a length of 850 mm which can be inserted and removed, without coming into contact with product, through a quartz glass jacket 2 (inner quartz glass tube) which is open at the top and has an inner diameter of 26 mm. A seal ensuring the required sterility is provided at the open side of the tube 2 by an O-ring 11 in the top cap 17. Rotating about the glass tube 2, with a small spacing of 0.5 mm, is an anchor agitator 6 fitted

with eight stirrer blades. This is supported in the top cap 17 by a sleeve bearing 18 and in the bottom cap 16 on a centring point 7. It is driven via a magnetic clutch, the power provided by an external magnetic stirrer 10 being transmitted contactlessly and consequently without making use of seals to a counter magnet 8 mounted transversely to the stirrer shaft 5. To ensure the wall spacing between anchor agitator 6 and glass tube 2, the axially symmetric position of the tube 2 is ensured by means of a centring pin 9 which is guided within the shaft 5. The annular gap 26 (irradiation chamber) of 5 mm, in which the inactivation reaction takes place, is bounded on the inside by the outer wall of the tube 2 and on the outside by the inner wall, optionally fitted with four baffles 12 having a width of 3 mm, of the jacket tube 15 which has flanges welded on at both ends to secure the bottom 16 and top cap 17.

[0063] The product is delivered to the spout 13 of the bottom cap at a flow rate of 150-300 l/h and is drawn off at the top cap 17 via a spout 14.

[0064] The cylinder stirrer 6 carrying eight blades of the shape according to FIG. 3 is fabricated from a precision tube having an outer diameter 31 mm and a wall thickness of 0.8 mm by cutting out 16 cavern-like recesses. For reasons of stability, the recesses do not run continuously across the entire stirrer length, but extend as far as the connecting fins 19. Via a disc 21, the anchor agitator 6 is linked to the stirrer shaft 5. The centring hole 20 which extends right into the shaft 5, is used to centre the tube 2 close to the bottom. The stirrer is centred in turn in the bottom cap 16 via a centring point 7.

Example 2

[0065] The impeller drive which is used as an alternative to the magnetic clutch in the design according to FIG. 2 and likewise does not make use of seals, for the anchor agitator 6 according to FIG. 4a (section B-B) and 4b (section A-A) consists of four convexly curved impellers 23 which are fastened to the stirrer shaft 5 and have a height of 10 mm. The diameter of the impeller is 39 mm. It is driven by the product which is injected tangentially into an upstream annular chamber 24 and is directed onto the side vanes via four slits 22 which are tangentially oriented with respect to the inner chamber and each have a slit width of 0.8 mm.

Example 3

[0066] The UV reactor according to FIG. 5 and FIG. 5a consists of a UV lamp 1 having a diameter of 25 mm, around which a quartz glass tube 27 having a half-round cross section of a diameter of 8 mm and a radius of 4 mm is coiled a small distance away. The UV reactor according to FIG. 6 and FIG. 6a consists of a UV lamp 1 having a diameter of 25 mm, around which a quartz glass tube 27 having a rectangular cross section of a width of 8 mm and a depth of 4 mm is coiled a small distance away. At right angles to the spiral flow 3, secondary vortices 4, so-called Dean vortices are induced which cause the material to be irradiated to be recirculated in the tube 27.

Example 4

[0067] The UV reactor according to FIG. 7 and FIG. 7a consists of a UV radiation source 1 surrounded by a continuous quartz glass tube 2 which at the top 17 and bottom

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES

Abogado
EMILIO FERRERO

ASUNTO	Radicación	06-127737
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	2673
	Folios	10

Patente de Invención ☐ Patente de Modelo de Utilidad ☐

Vía Nacional ☐

Vía PCT (fase nacional) ☐ Cap. I ☐ Cap. II ☐

No. Sol. Internacional PCT/EP2005/006781

Fecha de Presentación Internal. 23/06/2005

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

Descripción: Folios: 53 a 92 como se radicó inicialmente.

Reivindicaciones: Folio: 93 a 96 como se radicó inicialmente

Prioridad: 27/05/2004, US 60/575,310

2. Objeto de la invención

Título de la solicitud: "Inactivación de un patógeno en una muestra mediante un tratamiento con formalina y luz UV".

El objeto de la presente solicitud de patente de invención consiste en proveer un método para inactivar un virus usando formalina y luz UV en un aparato a través de flujo.

El problema planteado en esta solicitud es conseguir un método efectivo de inactivación de virus encapsulados y no encapsulados, logrando su inactivación para la preparación de vacunas a escala industrial

Para solucionar este problema técnico la solicitud en estudio proporciona un método de inactivación de virus contenido en una muestra que permite retener su antigenicidad e inmunogenicidad, que comprende las etapas de: i) tratar la muestra con una concentración efectiva de formalina; y ii) someter la muestra a una dosis efectiva de luz UV en un aparato a través de flujo, en donde estas etapas se pueden realizar en cualquier orden.

IPC: A61L 2/00

3. De la solicitud de Patente

3.1. Reivindicaciones (artículo 30 D 486)

El capítulo reivindicatorio en general carece de claridad por cuánto:

- Existe un alto número de reivindicaciones independientes que se refieren a la misma categoría, esto es a un método para inactivar un virus. Se sugiere ajustar estas reivindicaciones de manera que la reivindicación independiente contenga las características esenciales de la invención y las reivindicaciones independientes definan las alternativas para estas características. Lo anterior se aplica para las reivindicaciones 1 a 4.
- La reivindicación 5 se refiere a un resultado a alcanzar y no a una característica técnica de la invención.
- La reivindicación 7 se refiere a la concentración efectiva de formalina utilizada, sin embargo no se indican las unidades de concentración a la cual se refiere la medida.
- Numerosas reivindicaciones usan términos ambiguos, como "aproximadamente" para referirse a rangos. Esto sucede en las reivindicaciones 5 a 11.
- La reivindicación 12 define el aparato de flujo pasante porque contiene una cámara de capa delgada. Tal definición resulta poco clara para el técnico medio.
- La reivindicación 13 define el flujo de la muestra indicando que es turbio, tal definición resulta altamente subjetiva y falta de claridad.

De esta manera, el capítulo reivindicatorio presentado no cumple con los requisitos establecidos en el art. 30 de la Decisión 486.

4. **Reivindicaciones relativas a un uso o a un segundo uso** (artículos 14 y 21 D 486)

La materia de la reivindicación 18 reclama el uso de del virus purificado inactivado para usarlo en composiciones farmacéuticas como una vacuna; según la norma comunitaria los usos no son materia susceptible de patente.

De esta manera y de acuerdo a lo establecido en los artículos 14 y 21 de la Decisión 486 la materia de la reivindicación 18 no sería patentable.

5. Determinación del Estado de la Técnica

La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es:

Fecha de presentación de la solicitud prioritaria 27/05/2004

Teniendo en cuenta la fecha indicada se realizó la búsqueda en el estado de la técnica de documentos relacionados con la solicitud encontrándose los siguientes documentos más relevantes:

Nº	Documento	Título	Fecha de publicación
D1	GB 802048	"Vaccine products and methods for producing the same"	Sep. 1958
D2	US 2002 096648	"Apparatus for irradiating liquids"	Jul. 2002

6. Análisis de patentabilidad (según requisito) (artículo 14 D486)

6.1. Novedad (artículo 16 D486)

La reivindicación 4 trata sobre un método para inactivar un virus contenido en una muestra, que comprende las etapas de (i) tratar la muestra con una concentración efectiva de formalina, y (ii) someter la muestra con una dosis efectiva de luz UV en un aparato de flujo pasante que comprende una lámpara UV y una cámara de capa delgada en el aparato que es sustancialmente perpendicular al diámetro de la lámpara UV, donde la etapa (i) es realizada antes que la etapa (ii) o viceversa, donde la muestra es pasada a través de la cámara de capa delgada del aparato en la etapa (ii).

El documento GB 802048 (D1) divulga un método para inactivar un virus contenido en una muestra (pág 1, línea 11-18), que comprende los pasos de (i) tratar la muestra con una concentración efectiva de formalina (pág 1, línea 75), (ii) someter la muestra con una dosis efectiva de luz UV (pág 1, línea 71-74) en un aparato de flujo que comprende una lámpara UV y una cámara de capa delgada (pág 2, línea 99-105) que es sustancialmente perpendicular al diámetro de la lámpara UV (pág 3, línea 26-29), donde el paso (i) es realizado antes que el paso (ii) o viceversa (pág 2, línea 10-26), donde la muestra es pasada a través de la cámara de capa delgada del aparato en el paso (ii) (ver ejemplo 1).

De esta manera es evidente que el documento D1, contiene todas las características enumeradas en la reivindicación 4 y por tanto, en vista de D1 la invención detallada en esta reivindicación carece de novedad.

Igualmente, el documento D1 revela la materia caracterizada en las reivindicaciones 5-10, 12 y 16-18, afectando su novedad.

Además de las revelaciones de D1, se encontraron otros documentos que al parecer divulgan este mismo método de inactivación en virus encapsulados, lo cual afectaría las reivindicaciones 2 y 3 de la solicitud.

6.2. Nivel inventivo (artículo 18 D486)

La única diferencia entre D1 y la reivindicación 1, es la indicación de la tasa de flujo de la muestra a través del aparato, que en la solicitud es de 50 litros por hora a aproximadamente 1000 litros por hora, mientras que D1 revela en el ejemplo 1 una tasa de 36 litros por hora.

Sin embargo, tal diferencia resulta evidente de ser cambiada por un técnico versado en la materia, puesto que un flujo de paso de muestra más rápido es una característica siempre deseable cuando se usa un aparato de este tipo.

La literatura, reporta diferentes aparatos con un mayor flujo, usados para pasar este tipo de muestras pasadas a través de luz UV, tal como reporta por ejemplo el documento D2 (ver pág 1, párrafo 4), donde la tasa de flujo es de 150-300 litros/hora (ver página 4, párrafo 63).

De lo anterior es evidente, que para el técnico versado en la materia hubiera resultado obvio mejorar el método divulgado en D1, incrementando la tasa de flujo usando un aparato tal como el divulgado en D2.

Por tanto, a la luz de las divulgaciones dadas en D1 y D2, el método de la solicitud carece de nivel inventivo e incumple el artículo 18 de la D486.

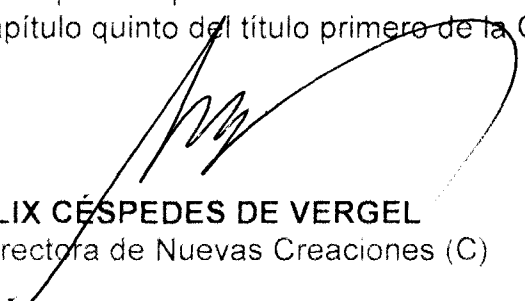
7. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

N°	Documento N°	Reivindicaciones afectadas	Requisito que afecta
D1	GB 802048	4, 5-10, 12, 16-18 1 y dependientes	Novedad Nivel inventivo
D2	US 2002 096648	1 y dependientes	Nivel inventivo

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de 60 días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.


ALIX CÉSPEDES DE VERGEL

Directora de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha

26 FEB. 2010

CONCEPTO TÉCNICO No. 747	EXAMINADOR TÉCNICO Código No.202052
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ALB

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES

Abogado
Emilio Ferrero

ASUNTO	Radicación	06-127737
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	~2677
	Folios	1

Como resultado del examen de búsqueda de anterioridades y con fundamento en el artículo 46 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. SOLICITUD DE SUMINISTRO DE INFORMACIÓN

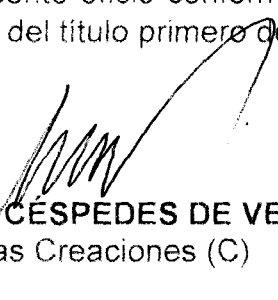
Se determinó que existe en el estado de la técnica el siguiente documento, que eventualmente afectaría los requisitos de patentabilidad de esta solicitud:

DATABASE WPI
Section Ch, Week 199627
Derwent Publications Ltd., London, GB;
Class A96, AN 1996-266694
XPO02337093
& SU 1 367 487 A1 (A MED POLYMYELITIS
VIRAL ENCEPHELITIS)
27 October 1995 (1995-10-27)
abstract

Siendo que la publicación referenciada hace parte del resultado del examen de búsqueda internacional para la solicitud aquí estudiada, y no siendo viable la consecución de dicho artículo por este despacho, se requiere que el solicitante, proporcione las publicaciones completas, con lo que podrá realizarse un análisis absoluto de la patentabilidad de la invención correspondiente a la presente solicitud.

En cumplimiento del artículo 46 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de tres (3) meses contados a partir de la fecha de notificación de la presente comunicación.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto (5), del título primero de la circular única N° 10 de 2001.


ALIX CARMENZA CÉSPEDES DE VERGEL
Directora de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha _____

26 FEB. 2010

CONCEPTO TÉCNICO No. 748	EXAMINADOR TÉCNICO Código No. 202052
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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 08 - 5,097
 FECHA : ENERO 21 DE 2008

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 06-127737-00001-0000

Fecha: 2008-02-13 17:07:34 Dep: 2020 NUECREACIONE
 Tipo: 11 PATENTE Y E: 01378 FASE NACIONAL I
 Act: 538 RECIBO DE FOLIO: 2

***** CONSIGNACION *****

POSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Vr. PAGO
CAVELIER ABOGADOS	CONSIGNACION	BANCO DE BOGOTA	062754387	2908479	21/01/2008	39,545,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	85 EXAMEN DE PATENTABILIDAD DE INVEN	420,000.00
TOTAL :			\$ 420,000.00

SON: CUATROCIENTOS VEINTE MIL PESOS

RESPONSABLE :

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

Cdo 13936-841-009-4

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-127737

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **581** DE

FECHA **31 DE OCTUBRE DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **31 DE ENERO DE 2008**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

NO X

PATENT SPECIFICATION

802.048



Date of Application and filing Complete Specification: March 21, 1956.

No. 8902/56.

Application made in United States of America on August 26, 1955.

Application made in United States of America on Feb. 20, 1956.

Complete Specification Published: Sept. 24, 1958.

Index at acceptance:—Class 81(1), B8.

International Classification:—A61k.

COMPLETE SPECIFICATION

Vaccine Products and method for producing the same

We, PARKE, DAVIS & COMPANY, a corporation organized under the laws of the State of Michigan, United States of America, and having principal offices at Detroit, Michigan, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to vaccines, that is, substances capable of producing antigenic response in man and other mammals, and to methods for preparing the same from viruses capable of producing disease. More particularly, the invention relates to poliomyelitis vaccines and to methods for preparing the same from live poliomyelitis viruses.

Heretofore, poliomyelitis virus vaccine products have been prepared by inactivating poliomyelitis viruses by treatment with either formaldehyde or ultraviolet light. The purpose of such treatment is to render the virus non-infectious by killing it but at the same time not substantially destroying its inherent antigenic property, that is, the property of the virus to cause the production of antibodies when introduced into the blood or tissue of man and other mammals. One of the difficulties with the known formaldehyde method of killing poliomyelitis viruses is that there is a relatively narrow range of safety between the concentration of formaldehyde necessary to kill the virus and the concentration which destroys the antigenic property of the virus. The formaldehyde method has also been reported to produce varying results and in some instances incomplete killing of the virus. Likewise, the method employing ultraviolet irradiation alone produces varying results in that it either fails to satisfactorily kill all of the virus or tends to destroy the antigenic property of the virus. Thus, if irradiation is employed to the extent required for a complete kill of the virus, the antigenicity is essentially totally destroyed.

In view of the foregoing there is a need at the present time for a generally applicable process for producing polio virus products which possess a high degree of antigenicity, are free of living virus and are suitable for use in immunizing against infection by live poliomyelitis virus.

One of the objects of the present invention is to provide a safe and effective method of killing living poliomyelitis viruses with less destruction of the antigenic property of the viruses than is normally encountered in the presently known processes.

Another object of the invention is to provide a method of producing poliomyelitis virus products which are free of toxic agents, possess a high degree of antigenicity and are suitable for immunization against infection by live poliomyelitis virus.

Other objects and advantages of the invention will be apparent by reference to the specification which follows:

In accordance with the invention there is provided a process for producing a poliomyelitis virus vaccine wherein an aqueous medium containing living poliomyelitis virus is subjected to treatment by ultraviolet irradiation and, in addition to incubation for a prolonged period at an elevated temperature, and/or treatment with formaldehyde, such treatments being sequential and in any order, under conditions such that the first killing treatment of the combination is sufficient to kill a high proportion but not all the living poliomyelitis virus present in the original aqueous medium, and that the subsequent killing treatment or treatments of the combination is, or are, sufficient to kill all the residual living poliomyelitis virus present in the medium, and wherein none of the said killing treatments if applied alone to the original aqueous medium is capable of completely killing all of the living poliomyelitis virus present in the medium. The vaccine product obtained by this method is not only free from living poliomyelitis virus but also possesses a higher degree of antigenicity than that obtained by known methods. This result is highly unexpected because the known methods which employ either ultraviolet



US 20020096648A1

142
D2 141(19) **United States**(12) **Patent Application Publication** (10) Pub. No.: US 2002/0096648 A1
Kaiser et al. (43) Pub. Date: Jul. 25, 2002(54) **APPARATUS FOR IRRADIATING LIQUIDS**(30) **Foreign Application Priority Data**

Nov. 13, 2000 (DE)..... 10056096.2

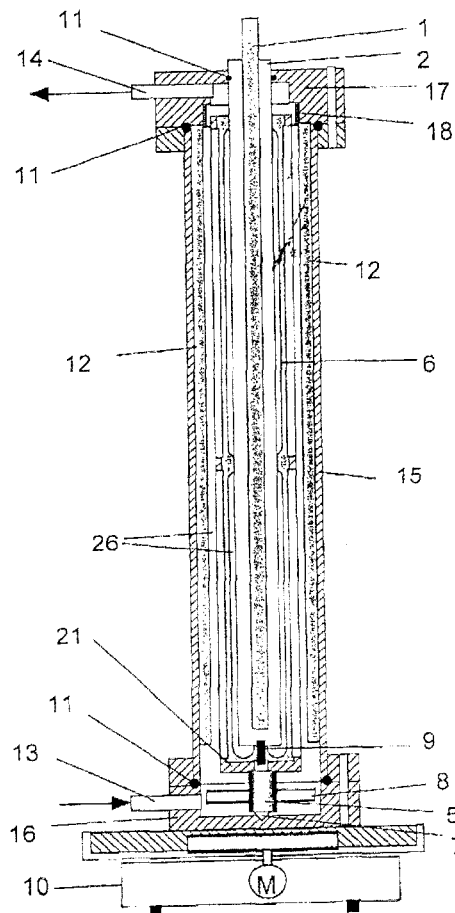
(76) Inventors: **Klaus Kaiser**, Koln (DE); **Jorg Kauling**, Koln (DE); **Hans-Jurgen Henzler**, Solingen (DE); **Isabell Gunther**, Leverkusen (DE); **Franz Schmitt**, Bergisch Gladbach (DE); **Erhard Beckers**, Burscheid (DE); **Stefan Quest**, Leichlingen (DE)**Publication Classification**(51) Int. Cl.⁷ G21G 5/00
(52) U.S. Cl. 250/492.1(57) **ABSTRACT**

Described is a reactor for irradiating ultraviolet light into a fluid reaction medium (3). The reactor consists of at least one housing (15) which encloses a tubular cavity, with a radiation source (1) for generating ultraviolet light and an inner tube (2) which, together with the housing (15), forms an irradiation chamber (26) which, in particular, is of annular shape, the irradiation chamber (26) being connected at least with an inlet (13) and an outlet (14) for the reaction medium (3) and is perfused by reaction medium (3) in the longitudinal direction of the tube (2), the irradiation chamber (26) being equipped with means (6, 25) for generating an additional radial flow routing of the reaction medium (3).

Correspondence Address:
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220 East 42nd Street
New York, NY 10017 (US)

(21) Appl. No.: 10/011,141

(22) Filed: Nov. 12, 2001



APPARATUS FOR IRRADIATING LIQUIDS

[0001] The invention relates to a reactor for irradiating ultraviolet light into a fluid reaction medium. The reactor consists of at least one housing which encloses a tubular cavity, with a radiation source for generating ultraviolet light and an inner tube which, together with the housing, forms an irradiation chamber which, in particular, is of annular shape, the irradiation chamber being connected at least with an inlet and an outlet for the reaction medium and is perfused by reaction medium in the longitudinal direction of the tube, the irradiation chamber being equipped with means for generating an additional radial flow routing of the reaction medium.

[0002] The sterilization of liquid media is an essential precondition when employing production methods in the field of biotechnology and food technology. The objective is reliable and complete depletion of microorganisms and/or viruses hand in hand with virtually complete preservation of valuable substances. Sterilization is applied both to the feed stock (e.g. nutrient media for fermentations) and end products (e.g. milk products or pharmaceutical active proteins). For the food industry, the sterilization techniques are used, inter alia, with a view to longer shelf life, whereas their use in the pharmaceutical industry is regulated by strict quality assurance requirements. For example, the use of pharmaceutical products of human or animal origin requires a number of virus deactivation steps which are based on different principles of action and must each ensure viral depletion by at least four powers of ten. The need to ensure "viral safety" of course also applies to pharmaceuticals produced by genetic engineering methods.

[0003] One of the viral depletion methods proposed in the literature as having minimal impact on the product is the irradiation with ultraviolet light. The treatment of plasma and blood products with UV light is known in principle. As early as during the second world war, large quantities of plasma were collected and irradiated with UV light. The UV treatment of blood derivatives is of particular interest, however, with respect to non-enveloped, heat-resistant viruses. Chin et al (Chin, S., Jin, R., Wang, X. L., Hamman, J., Gerard Marx, Xiaode Mou, Inger Andersson, Lars-Olof Lindquist, and Bernhard Horowitz (1997). Virucidal Treatment of Blood Protein Products with UVC Radiation. *Photochemistry and Photobiology* 65(3): 432-435.) were able to show that a treatment of plasma products with UV light results in activation of hepatitis A and parvoviruses.

[0004] UV irradiation is aimed at mutagenic changes in the genetic material of the microorganisms or viruses which, above a minimum radiation dose, lose their ability to reproduce. It is an object of the invention to develop for this purpose a reliable and optimally effective apparatus for irradiation with UV light.

[0005] Problems in the use of reactors for radiating ultraviolet light into liquid reaction media are caused by the fact that the radiation intensity in the medium to be treated decreases exponentially with increasing distance from the radiation source. Microorganisms and viruses at a greater distance from the radiation source are therefore destroyed more slowly or even not at all. Because of this effect, which is magnified considerably as the optical absorbance of the medium increases, very large irradiation surface areas are employed in the prior art, as found e.g. in thin-film reactors.

The thin-film reactors currently in use can be scaled up only with difficulty to industrial scales, as the only way to keep the film thickness constant in the scale-up is to increase the diameter in proportion with the throughput, which on an industrial scale results in infeasibly large reactors. A further negative factor is the unfavourable residence time behaviour of the liquid films, which given the generally low penetration depth of the UV radiation to the reaction medium are necessarily very thin and consequently exhibit laminar flow, in which any transfer transverse to the principal flow direction is absent by definition. The layers close to the wall remain for considerably longer times, because of the velocity profile dropping linearly to zero towards the wall, than the layers further away from the wall. In order to achieve the minimum radiation dose necessary for destruction even in the more rapidly flowing liquid layer far from the wall, the mean residence time of the film has to be increased. This, however, leads to an increased radiation exposure and consequently to greater damage to the products.

[0006] Also known and described are so-called annular-gap reactors. A UV annular-gap reactor of conventional design consists of a tubular metal housing set into which is a quartz tube containing a rod-shaped UV radiation source, thereby forming an annular-gap chamber. In this reactor type, the reaction medium flows through the annular chamber only in an axial direction, which likewise is not advantageous with a view to good mass transfer—a similar situation as with the thin-film reactors.

[0007] The disadvantages described of the reactor types should be capable of being overcome by more favourable flow routing which, in addition to a narrow residence time spectrum, also permit good transfer in the liquid perpendicular to the principal flow direction. Proposals for this purpose include tangential-inflow annular gap reactors. From EP 803 472 A1 e.g. is a reactor for radiating ultraviolet light into a reaction medium, comprising an annular chamber as the irradiation zone, in which the design of the inlet is such that the reaction medium enters the annular chamber tangentially.

[0008] The performance of a reactor with tangential inflow has marginal advantages, compared with a "classic" annular-gap reactor. Process engineering studies show that wall friction causes the tangential flow profile to be transformed into an axial profile very soon after the inlet. The Dean vortices, which are theoretically postulated at least for the region of tangential cross flow and by means of which the cross-transfer of the reaction medium within the annular gap is to be intensified, are not present according to visual studies and CFD studies (flow simulation), which means that tangential-inflow annular-gap reactors of this type do permit some improvement in the mixing behaviour, but still do not allow complete exchange. The secondary flow and the concomitant improved mass transfer is therefore restricted to the zones near the inlet.

[0009] It was possible to demonstrate that this behaviour can be tolerated in the treatment of weakly absorbing reaction media (e.g. water treatment), as mixing is adequate for this purpose and the UV dose can be increased to circumvent this drawback. For applications in connection with the treatment of protein solutions this appeared impossible, as the proteins would suffer irreversible damage in the process.