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As: 2560/P.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

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Tia. 2 PATENTES

Eve: 1 REGDEPOSITO

Act 583 IMPULSOPROCESAL Folios: 1

Doctor

GIANCARLO MARCENARO JIMÉNEZ

Superintendente Delegado Para la Propiedad Industrial

EXPEDIENTE: 03-040.551

**ASUNTO: Solicitud de patente a nombre de
McNeil-PPC, Inc.**

Estimado Doctor:

En mi calidad de apoderada de la sociedad solicitante de la patente de la referencia manifiesto a usted lo siguiente:

1. Mediante memorial radicado en ese despacho el 08 de noviembre de 2004, el cual no ha sido resuelto aún, solicité que se realizara el examen de patentabilidad.
2. En vista de que han transcurrido 1 año y 10 meses, sin que se haya atendido dicha solicitud, ruego a usted se sirva dar las instrucciones del caso para que se proceda de inmediato a resolver este asunto.

Cordialmente,



JIMENA ESCOBAR URIBE

CC 39.779.452 de Usaquén.

T.P. 68228

DIVISION DE NUEVAS CREACIONES

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RADICACIÓN EXPEDIENTE No. 03-40551

**EL EXTRACTO DE LA PRESENTE SOLICITUD DE PATENTE DE INVENCION
FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 543, DE
FECHA 01 DE SEPTIEMBRE DE 2004, EL TERMINO HABIL SEÑALADO POR
LA LEY EXPIRA EL 29 DE NOVIEMBRE DE 2004.**

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 ☒ _____

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

2020/
Bogotá, D.C.,

Doctora
Jimena Escobar
Apoderada

Oficio N° 12925

REFERENCIA	Radicación	03 40551
	Trámite	002
	Evento	001
	Actuación	430
	Folios	013

Como resultado del examen de patentabilidad de la solicitud de patente de invención N° 03 40551, realizado según el artículo 45 de la decisión 486 de la comisión de la Comunidad Andina, se notifica:

Documentos estudiados:

- . Descripción: folios 5-115
- . Ejemplos:
- . Capítulo reivindicatorio estudiado: folios 116-121
- . Se reivindica prioridad, presentada en Estados Unidos el 15.05.02, bajo el número 10/146471.

Objeto de la Invención

Según las reivindicaciones 1 a 22 de la presente solicitud, se refiere a una forma sólida cubierta que tiene un revestimiento elaborado de una o más películas configuradas cada una teniendo porciones que son visualmente distintas entre sí y que tienen un segmento de línea de transición entre estas porciones.

Clasificación internacional de patentes A 61 K 9/28

Claridad de la solicitud

El artículo 30 de la decisión 486 establece que *"Las reivindicaciones definirán la materia que se desea proteger mediante la patente. Deben ser claras y concisas y estar enteramente sustentadas por la descripción"*

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El término "núcleo cubierto" que aparece a lo largo del capítulo reivindicatorio es tan amplio, que no se encuentra sustentado por la descripción ni los ejemplos, teniendo en cuenta que solamente se está reivindicando formas sólidas recubiertas.

Favor hacer las aclaraciones y correcciones del caso.

Determinación del estado de la técnica:

Consultadas las fuentes de información con que cuenta este despacho, se encontraron los siguientes documentos, anteriores a la fecha de prioridad de la presente solicitud - 15.05.02-, relacionados con la materia de la presente solicitud:

Nº	Documento	Título	Fecha de publicación
1	US 6113945	"Medicamento multicolor"	05.09.00
2	US 5146730	"Núcleo unitario cubierto con película y medicamentos relacionados"	15.09.92
3	US 5672300	"Método para cubrir o rayar cápsulas"	30.09.97
4	US 2624163	"Método de fabricar cápsulas de gelatina coloreadas"	06.01.53

Evaluación de los requisitos de patentabilidad:

El artículo 14 de la decisión 486 de la comisión de la comunidad andina establece que: *"Los países miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*

En cumplimiento del artículo 14 de la decisión 486 de la comisión de la comunidad andina, se procedió a evaluar los requisitos de novedad, nivel inventivo y aplicación industrial con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

Evaluación de la NOVEDAD

El artículo 16 de la decisión 486 establece que *"Una invención se considerará nueva cuando no está comprendida en el estado de la técnica"*

La patente US 6113945, en su figura 3, revela tabletas multicolores cubiertas que tiene una línea de transición de color la cual se encuentra de manera transversal y una capa de sello que se encuentra intersecando la línea de transición.

La patente US 5146730 enseña tabletas recubiertas que muestran un sello alrededor del eje longitudinal.

Las patentes US 5672300 y US 2624163 revelan cápsulas de gelatina blanda hechas a partir de películas de gelatina que muestran patrones de color, tal como líneas de color que tienen líneas de transición que cortan el plano de la película de sellado.

Comparando elemento por elemento, muchos de las formas cubiertas de la presente solicitud, son iguales a las de los documentos citados, y puede afectar la novedad de la presente solicitud.

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Evaluación del NIVEL INVENTIVO

El artículo 18 de la decisión 486 establece que *"Se considerará que una invención tiene nivel inventivo, si para una persona del oficio normalmente versada en la materia técnica correspondiente, esa invención no hubiese resultado obvia ni se hubiese derivado de manera evidente del estado de la técnica"*

La patente US 6113945, en su figura 3, revela tabletas multicolores cubiertas que tiene una línea de transición de color la cual se encuentra de manera transversal y una capa de sello que se encuentra intersecando la línea de transición.

La patente US 5146730 enseña tabletas recubiertas que muestran un sello alrededor del eje longitudinal.

Las patentes US 5672300 y US 2624163 revelan cápsulas de gelatina blanda hechas a partir de películas de gelatina que muestran patrones de color, tal como líneas de color que tienen líneas de transición que cortan el plano de la película de sellado.

Teniendo en cuenta el objeto de la solicitud, el cual es proveer formas de dosificación oral sólidas multicolores que tienen una película de sellado, es una derivación evidente del estado de la técnica ya que las enseñanzas de los documento citados enseñarían a una persona versada en la materia a fabricar las formas multicolores de la presente solicitud.

Finalmente no se demuestran propiedades sorprendentes o inesperadas de las composiciones de la presente solicitud en comparación con los del estado de la técnica.

En conclusión los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

Nº	Documento	Reivindicaciones afectadas	Requisito que afecta
1	US 6113945	1	Novedad
		1-22	Nivel Inventivo
2	US 5146730	1	Novedad
		1-22	Nivel Inventivo
3	US 5672300	1	Novedad
		1-22	Nivel Inventivo
4	US 2624163	1	Novedad
		1-22	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 sesenta días contados a partir de la fecha de la 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 5 del título primero de la Circular Única Nº 10 de 2001


Álix Carmenza Céspedes de Vergel
Jefe de la División de Nuevas Creaciones

09 NOV. 2006

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

CONCEPTO TÉCNICO Número 1731	EXAMINADOR TÉCNICO Código 202024
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US006113945A

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United States Patent [19]
Jacobs et al.

[11] **Patent Number:** **6,113,945**
[45] **Date of Patent:** ***Sep. 5, 2000**

[54] **MULTI-COLORED MEDICAMENT**

[75] **Inventors:** Richard L. Jacobs, Portage; Shirish A. Shah, Kalamazoo, both of Mich.

[73] **Assignee:** L. Perrigo Company, Allegan, Mich.

[*] **Notice:** This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

5,089,270	2/1992	Hampton et al.	
5,146,730	9/1992	Sadek et al.	53/454
5,188,688	2/1993	Boardman et al.	156/69
5,213,738	5/1993	Hampton et al.	
5,228,916	7/1993	Berta	118/30
5,317,949	6/1994	Sauter	
5,405,642	4/1995	Gilis et al.	427/2.23
5,415,868	5/1995	Smith et al.	424/454
5,436,026	7/1995	Berta	427/2.14
5,459,983	10/1995	Sadek et al.	53/560
5,464,631	11/1995	Hoover et al.	424/454
5,824,338	10/1998	Jacobs et al.	424/460

OTHER PUBLICATIONS

Physicians Desk Reference, 36th Edition. Published by Medical Economics Co., Inc. 1982. Product Identification at pp. 403-440.

Primary Examiner—Robert H. Harrison
Attorney, Agent, or Firm—Price, Hensveld, Cooper, DeWitt & Linton

[21] **Appl. No.:** 08/606,647
[22] **Filed:** Feb. 26, 1996
[51] **Int. Cl.⁷** A61K 9/28; A61K 9/48; A61K 9/64
[52] **U.S. Cl.** 424/474; 424/478; 514/853
[58] **Field of Search** 424/474, 478; 514/853

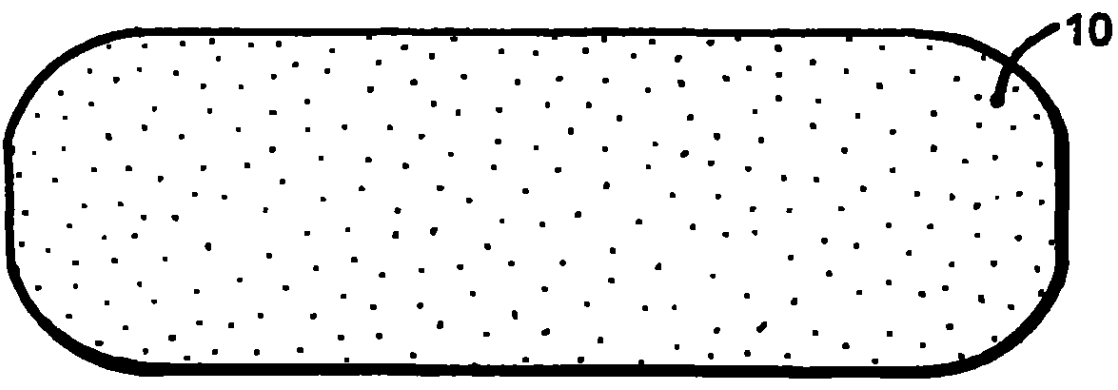
ABSTRACT

The medicament of the present invention and its process of manufacturing employs a caplet or tablet core with a clear or single color uniform covering which can be applied either through an enrobing process, by spraying or by a single dip-coating step. The core itself can have a first color or be colorless, and its clear or single color covering has the outer surface of one end or one side colored by a suitable dye to provide a two-color appearance. The dye can be applied by dipping or spray painting with a suitable jet-spraying apparatus. In a preferred embodiment, the covering is of a clear gelatinous material.

[56] **References Cited**
U.S. PATENT DOCUMENTS

2,373,721	4/1945	Taylor et al.	
3,185,626	5/1965	Baker	
3,981,984	9/1976	Signorino	424/480
4,034,035	7/1977	Schwartz et al.	264/77
4,133,290	1/1979	Melliger	118/668
4,274,830	6/1981	Woznicki et al.	8/495
4,636,261	1/1987	Helmke	105/402
4,725,441	2/1988	Porter et al.	424/479
4,820,524	4/1989	Berta	424/474
4,867,983	9/1989	Berta	
4,966,771	10/1990	Berta	

17 Claims, 3 Drawing Sheets



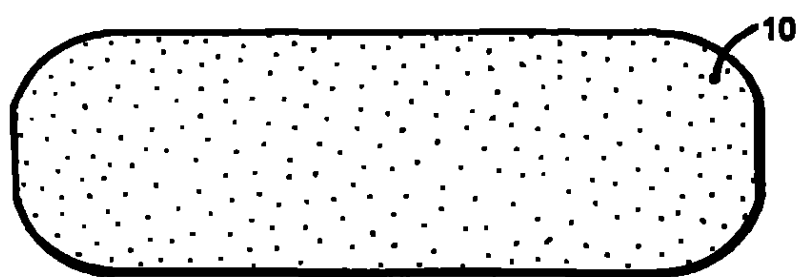


Fig. 1

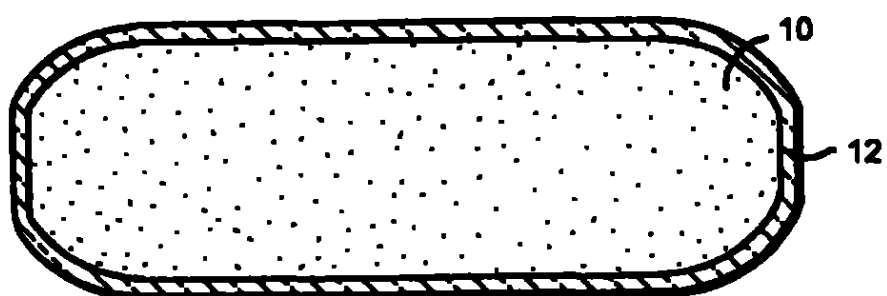


Fig. 2

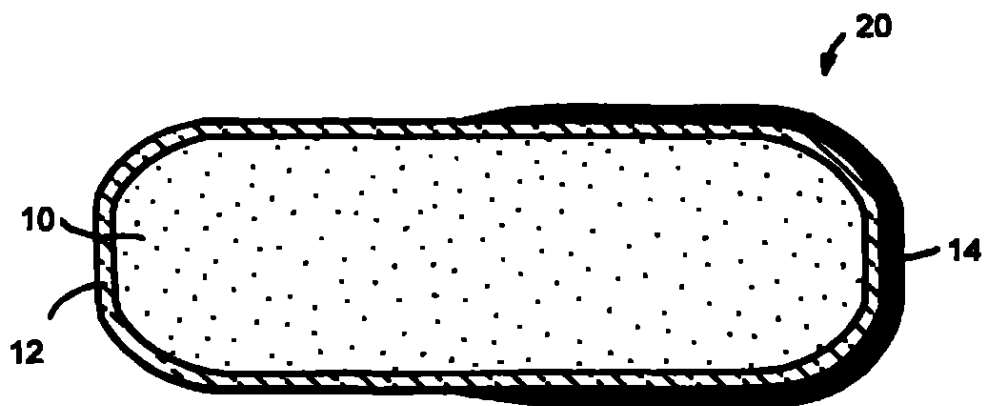


Fig. 3

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caplet-shaped core of any desired color. The active ingredients may be any analgesic such as acetylsalicylic acid, acetaminophen, ibuprofen, or any other NSAID which are commonly known and which can be pressed into the shape of a caplet utilizing conventional existing tableting equipment and processes. The caplet core 10 may include other active ingredients such as antihistamines or a combination of analgesics and antihistamines or other ingredients as is conventional.

The caplet core 10 is subsequently covered with a clear covering 12 which can be any number of medicinally acceptable coverings such as gelatin, "POVIDONE®" (a 1-ethenyl-2-pyrrolidinone polymer or 1-vinyl-2-pyrrolidinone polymer), "OPADRY®" (a dry concentrate polymer and plasticizer), methyl-cellulose or other clear, film-forming material which increases the swallowability of the caplet by providing a slippery covering to ease the physical swallowing process and also masking the taste of the ingredients contained in the caplet core 10. Preferably, the covering 12 is a gelatinous covering which has a thickness of from about 0.002 inches to about 0.010 inches and can be provided either by dipping the caplet 10 in a bath of clear gelatin as taught, for example, in U.S. Pat. No. 2,373,721 and subsequently drying the covered caplet; by spray or pan covering the caplet in a conventional manner, or by an enrobing process as disclosed in U.S. Pat. No. 5,146,730, the disclosure of which is incorporated herein by reference. The covering of the caplet core 10 and the subsequent drying of the combined core 10 and clear covering 12 is conventional and well-known to those skilled in the pharmaceutical art. The color of the core is thus exposed through the clear film or covering 12. The exact equipment and processes will vary depending upon the clear covering material 12 employed. In some embodiments, the covering material such as gelatin can be pigmented in any desired single color by conventional means known to those in the art. In such a case, the end or side of the covered medicament is colored as described below with a contrasting color on the outer surface of this cover.

Subsequent to the covering of the caplet 10 as shown in FIG. 2, one end of the now covered caplet core is colored with a coloring agent 14 as seen in FIG. 3 to complete the medicament 20. The coloring 14 may be a suitable ink (or dye) of a color different than that of the caplet core 10 when a clear covering is employed or different than the single color of the cover when pigmented. In the preferred embodiment, a commercially available ink from the Colorcon Division of Berwind Pharmaceutical Services, Inc. was employed. The ink employed conventionally includes excipients to improve adhesion of ink to the gelatin covering and a pharmaceutical glaze or shellac to decrease rub-off of the ink employed. One such ink included a mixture of water, hydroxypropyl cellulose, isopropyl alcohol, FD&C red #40, simethicone, propylparaben and methylparaben for a red ink. For other colors, different coloring agents are employed to color the outer surface of the medicament. For purposes of coloring one end of the caplet, collets are employed to hold the caplets with one end exposed. The caplets are then dipped in the ink which has a viscosity of approximately 20 centipoise. If desired, the now colored end 14 and opposite end of the medicament 20 could be further covered by dipping into a tray of Opagloss®, a pharmaceutical shellac, if desired or could be sprayed using a conventional spray gun from Spraymation, Inc., although such additional covering is not necessary.

The process of manufacturing the medicament 20 is illustrated in FIG. 4. The first step 30 of which is the pressing

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of the caplet or tablet core depending upon the desired shape of the medicament. The core is subsequently covered by the desired pharmaceutically acceptable covering, such as gelatin, as indicated by step 32 utilizing dipping, enrobing or spraying and subsequently one end or side of the core is colored as indicated by step 34. The coloring step for caplets involves inserting one end of the caplet-shaped cores into collets and immersing the exposed end into the colored ink utilizing a dipping collet such as illustrated in U.S. Pat. No. 4,867,983. The now covered and colored core is subsequently dried as indicated by step 36 which, in the preferred embodiment, was in an oven controlled to a temperature up from about 26 to 30 degrees centigrade for a period of approximately 15 minutes. If desired and as indicated in block 38 in phantom form, the medicament 20 can subsequently be over-coated with a pharmaceutical shellac such as Opagloss®, which can be sprayed or dipped over the medicament as desired, followed by a second drying step. This additional covering step may or may not be necessary or desirable depending upon the selection of dyes or inks employed.

Referring now to FIGS. 5-7 in place of the capsule-shaped medicament 20 of the first embodiment of the invention, the invention may also be employed to provide a tablet-shaped medicament 50 as shown in FIGS. 5-7. Beginning with a conventional tablet-shaped core 40 as shown in FIG. 5, which again is pressed utilizing a conventional tableting press, and a blend of excipients and active ingredients to provide an analgesic, antihistamines or combinations of analgesics, antihistamines and other medication in a conventional manner. The tablet-shaped core 40 may be the natural color of the ingredients or can be colored in a conventional manner to any desired color, such as yellow, blue, green, red or different shades thereof, as is conventional. The core 40 is then covered as indicated by layer 42 by a clear or single color film covering such as gelatin, Opadry® or other conventional flavor masking, swallowability enhancing material commonly employed in the pharmaceutical industry for covering the tablets. The coating 42 preferably is a coating of gelatin which is provided by either an enrobing process as disclosed in the above identified U.S. Pat. No. 5,146,730 or can be conventionally applied by dipping the core 40 in a bath of gelatin and subsequently drying the same or by a conventional pan spraying process. Subsequently, the covered tablet shape has the outer surface of one side 44 colored with a coloring agent such as an ink or other suitable non-gelatinous paint as identified above. For such purpose, the tablet can be held utilizing a vacuum holding structure such as disclosed in U.S. Pat. No. 2,373,721 or by spraying the coloring agent 44 onto the side of the tablet to provide a dual-color appearance. Popular color combinations have included blue and white, green and white, red and yellow, white and red and other color combinations signifying the active ingredients of the tablet. Tablet 50, as shown in FIG. 7, is manufactured by the same sequence of processing steps shown in FIG. 4 and may include a subsequent outer covering of a pharmaceutically acceptable shellac as indicated by step 38.

The medicaments manufactured according to the present invention, therefore, provide the desired shape, swallowability and appearance for a solid dosage form which substantially eliminates the tamperability of the medicament. The products manufactured according to the process of this invention can be relatively inexpensively made by the use of conventional equipment and utilizing existing materials. As a result, a high quality medicament which is essentially tamper-proof and which is aesthetically and functionally acceptable to consumers is provided at a relatively reduced cost.

[34] FILM-ENROBED UNITARY-CORE
MEDICAMENT AND THE LIKE

[75] Inventors: Hani Sadek, Calabasas; Gregory L.
Dieta, Moorpark, both of Calif.

[73] Assignee: Banner Gelatin Products Corp.,
Chatsworth, Calif.

[21] Appl. No.: 418,134

[22] Filed: Sep. 20, 1989

[51] Int. Cl. B65B 47/00

[52] U.S. Cl. 53/454; 53/546;
53/553; 53/900

[58] Field of Search 53/900, 454, 453, 560,
53/559, 553, 554, 546

[36] References Cited

U.S. PATENT DOCUMENTS

2,219,578	10/1940	Pittenger	53/560
2,296,294	9/1942	Scherer	18/21
2,323,581	7/1943	Wochner	53/560
2,367,802	1/1945	Scherer	53/560
2,387,747	10/1945	Cowley	53/560
2,503,518	4/1950	Slaughter	53/560
2,513,852	7/1950	Demofrio	53/560
2,608,405	8/1952	Salisbury	53/560
2,663,128	12/1953	Seim et al.	53/5
2,697,317	12/1954	Seim et al.	53/59.5
2,775,080	12/1956	Seim et al.	53/26
2,836,291	5/1958	Stroop	206/36
3,228,789	1/1966	Glanzman	117/118
4,281,763	8/1981	Pace	206/530
4,567,714	4/1986	Chenman	53/454
4,820,534	4/1989	Berta	434/474

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535783	1/1957	Canada	53/454
2141094	10/1981	United Kingdom	53/454

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"Packaging Technology", vol. 17, No. 2, Mar./Apr.
1987, pp. 3,4,7 and 16.

Primary Examiner—Thurman K. Page

Assistant Examiner—Raj Bawa

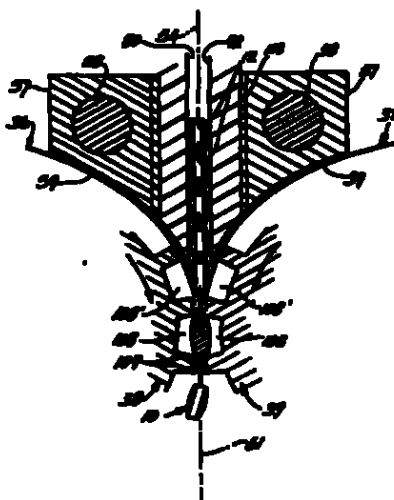
Attorney, Agent, or Firm—Christie, Parker & Hale

[57] ABSTRACT

A medicine tablet is described as a new article of manu-
facture. The table is enrobed in a gelatin coating formed
by application of respective layers of elastic gelatin film
to opposite sides of the tablet. The applied gelatin layers
conform tightly to the tablet surface, bond securely to
the tablet, and are sealed together in essentially edge-to-
edge manner at a seal line which extends around the
tablet at a desired place on the tablet. The gelatin layers
can be colored differently from the tablet and differ-
ently from each other. A range of formulations are
described for film which can be peelable from a tablet
or other product core, and for films which bond to the
core. A presently preferred formulation for producing
tablets having a bonded tamper-evident coating com-
prises a water-based gelatin preparation having about
45% gelatin and about 9% plasticizer (glycerin and/or
sorbitol) by weight.

Method and apparatus for producing such new prod-
ucts are also described. Product cores can be dispensed
on a self-timed basis into essentially simultaneous
contact with two enrobing films which are supported
on locally recessed coacting rotary dies. The cores
contact the films adjacent a nip between the dies at
places on the films which overlie die recesses which are
oversize relative to the cores. The films deform around
each core and are sealed by the dies to each other before
the dies coact to cut the enrobed cores from the films. A
core feeding mechanism can include an alignment device
which causes the cores to have a desired orientation as
they are handled by the dies.

84 Claims, 12 Drawing Sheets



made by this invention over the relevant things previously known.

What is claimed is:

1. A method of film enrobing article preforms such as medicine tablets comprising the steps of

(A) providing a pair of films of selected thickness and composition each defined to be elastic, plastic and self-adhering to the other film, the films each having obverse and reverse surfaces,

(B) moving the films along selected paths including through a place of coaction of a pair of coacting dies where the film obverse surfaces contact each other, the dies having cooperating working surfaces contoured for formation between them upon coaction of the dies of at least one cavity sized and shaped for loosely receiving therein a single article preform,

(C) substantially at the place of die coaction individually dispensing for each cavity formed between the dies an article preform into contact with the obverse surface of at least one of the films at each location on the at least one film which corresponds to the location of a cavity for movement of the dispensed preforms through the place of die coaction,

(D) at the place of die coaction, stretching the films into contact with each other peripherally around the preforms to cause each preform to be enrobed by and between the films, and sealing the films to each other at lines peripherally around and contiguous to each preform, and

(E) separating the enrobed preforms from the films essentially at said peripheral lines to provide the articles of manufacture each of which comprises a single preform sealed between applied layers of the film material.

2. The method according to claim 1 including forming the films from a material comprising gelatin in the range of 32 to 50% by weight, a plasticizer in the range of 17 to 35% by weight, and the balance water and colorants.

3. The method according to claim 1 including forming the films from a material comprising gelatin in the range of 40 to 60% by weight, a plasticizer in the range of from 5% to 12% by weight, colorants and pigments not in excess of 3% by weight, and water.

4. The method according to claim 3 including forming the films from a material comprising about 45% gelatin and about 9% plasticizer.

5. The method according to claim 1 including providing the films of gelatin-base material.

6. The method according to claim 5 including providing the films at a thickness in the range of from 0.005 to 0.04 inches.

7. The method according to claim 6 including providing the films at a thickness in the range of from 0.01 to 0.02 inches.

8. The method according to claim 5 including coloring one film differently from the other film.

9. The method according to claim 5 including, at a location proximate the place of die coaction, heating the obverse surface of at least one of the films to a temperature in the range of from 100° F. to 190° F.

10. The method according to claim 5 wherein the article preforms are unitary hard medicine tablets containing at least one active ingredient and which have a plane of symmetry, and including dispensing the tablets in such manner that, upon enrobement of the tablets by

the films between the dies, there is formed about each tablet a film seam line which is substantially coincident with the tablet plane of symmetry.

11. The method according to claim 10 wherein the tablets are round.

12. The method according to claim 10 wherein the tablets are caplets and the plane of symmetry is parallel to the length of the caplets.

13. The method according to claim 12 including dispensing the caplets with their lengths aligned with the path of movement of the film to which the caplets are dispensed.

14. The method according to claim 1 including providing the dies as rotary dies rotatable about horizontal axes, and dispensing the preforms into contact with the films from above the place of die coaction along a substantially vertical line.

15. The method according to claim 14 including defining the cavities substantially equally between the dies so that, for each cavity formed between coacting dies, substantially one half said volume is within one die and substantially one half said volume is within the other die, and forming the dies with a plurality of the half-cavity volumes in each die working surface aligned along a line circumferentially of the die and with each half volume spaced a selected small distance from each adjacent one thereof along the line about the die.

16. The method according to claim 15 including disposing a selected plurality of preforms in a column thereof along the vertical line along with the preforms are free to move downwardly by gravity, and allowing the preforms to move freely along the line for movement of the lowermost preform in the column into contact with the films and for movement with the films.

17. The method according to claim 16 including imposing on the films at the place of coaction between the dies a selected amount of tension in each film in the direction of each film path.

18. The method according to claim 14 including performing the dispensing procedure in an internally clocked manner without actively timing movement of the preforms along the vertical with reference to die angular position.

19. A method of film enrobing article preforms such as medicine tablets as articles of manufacture, comprising the steps of

(A) providing a pair of gelatin-base films of selected thickness and formulation which are elastic, plastic and self-adhering to the other film when at a predetermined temperature within a selected range of temperatures, the films each having obverse and reverse surfaces,

(B) moving the films at essentially equal velocities along selected paths around and between a pair of matching coacting cylindrical rotary dies between which the film obverse surfaces are adjacent each other, the dies being essentially identical and each defining along at least one line circumferentially of the die a plurality of closely and uniformly spaced cavities in a surface thereof cooperable with the other die,

(C) stretching the film over the die surfaces at and proximate a place of substantial coaction of the dies with each other,

(D) at a location along the film paths proximate the place of die coaction, heating the obverse surface of the films to the predetermined temperature,

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United States Patent [19]
Schurig et al.

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[45] Date of Patent: Sep. 30, 1997

[54] METHOD FOR STRIPING OR
MARBLEIZING CAPSULES

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[21] Appl. No.: 927,604

[22] Filed: Aug. 18, 1992

(Under 37 CFR 1.47)

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425/5; 425/133.5; 425/375; 425/804

[58] Field of Search 425/5, 804, 130,
425/131.1, 133.5, 375; 264/4, DIG. 37,
73, 74, 75; 53/900

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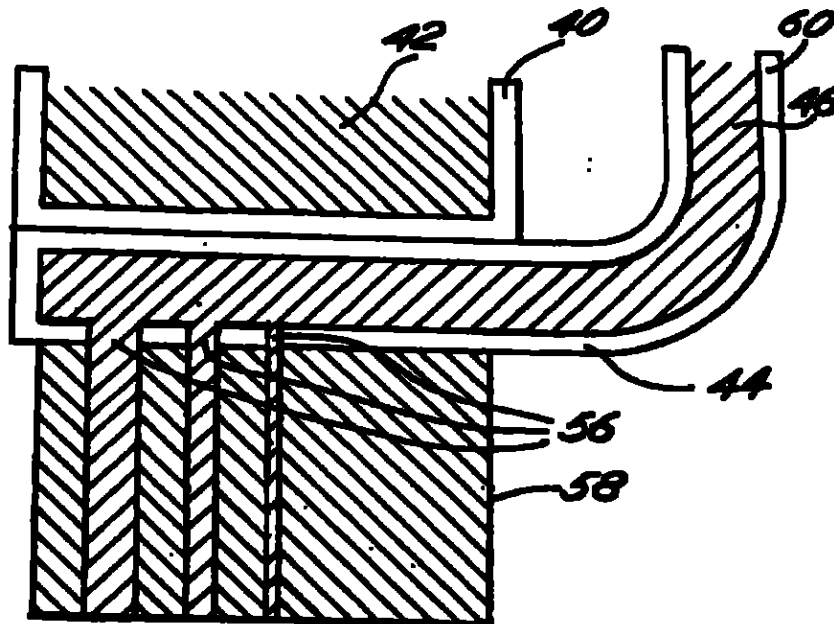
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[57] ABSTRACT

An apparatus and a process useful for producing patterned gelatin ribbons for forming patterned soft gelatin capsules are disclosed. The apparatus and process use multiple spreader boxes to form a wide variety of possible patterns.

17 Claims, 5 Drawing Sheets



28A
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Fig. 9

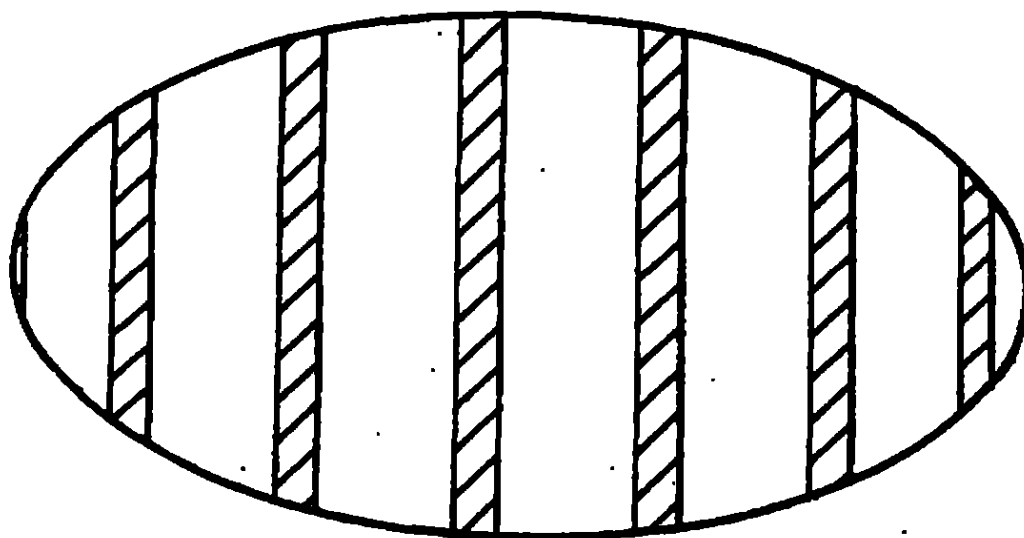
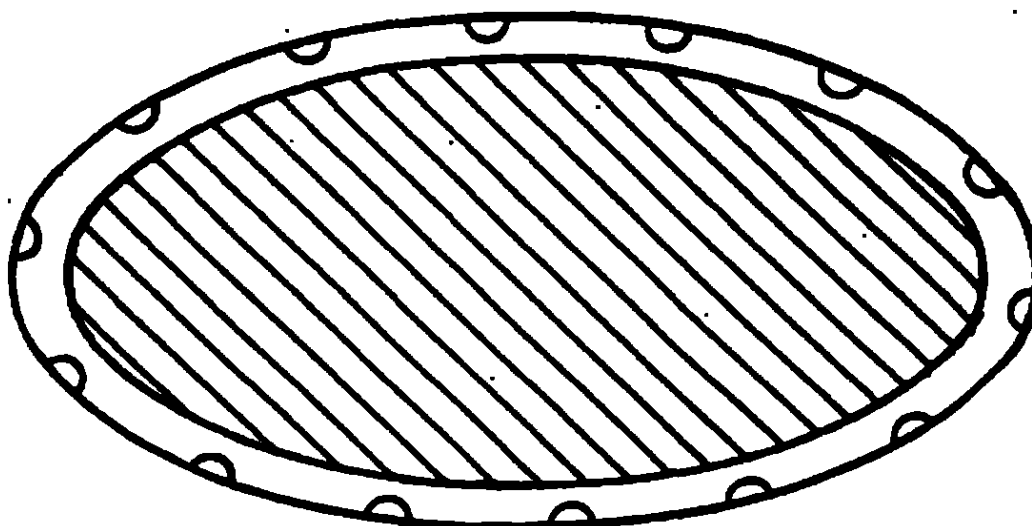


Fig. 10



UNITED STATES PATENT OFFICE

METHOD OF MAKING COLORED GELATIN CAPSULES

Frank E. Stirn, Pearl River, N. Y., assignor to American Cyanamid Company, New York, N. Y., a corporation of Maine

Application April 22, 1948, Serial No. 29,594

1 Claim. (Cl. 53-5)

My invention relates to improvements in gelatin capsules, particularly those which are formed from continuous strips of gelatin film, pertaining more particularly to methods of coloring of at least part of the surface of such capsules in such areas as may be considered desirable.

In the past soft gelatin capsules have been produced from gelatin film by stretching the film to a desired form and encapsulating therein the desired contents. It has been customary to form such gelatin capsules in some instances, in clear, colorless gelatin and in others from colored or pigmented gelatin as is desired for purposes of making the gelatin capsule more attractive. Such methods of coloring are described for example in the Patent No. 730,448 to Anthony M. Hanes. Additional methods are disclosed in the Patent No. 1,194,156 to H. H. Plantin, which again describes soft gelatin capsules being made from colored film, in this instance disclosing two different colors of film for different portions of the surface by making the capsule from two sheets of two different colors.

My invention relates to a very simple and more convenient method of forming capsules which comprises casting the gelatin in any convenient manner, of any convenient color, as may be desired, and treating the film after having been cast, but preferably before the capsule formation, with a soluble dye in a suitable solvent whereby the surface only of desired portions of the gelatin film is colored in accordance with the operator's choice to form capsules in which various portions may be colored. It is convenient by my method to form capsules in which the two different portions of gelatin strip from which the capsule is formed are differently colored, but additionally, it is possible by my method to form capsules in which trade names or identifying marks may be placed on the surface of the capsules for purposes of identifications of origin, giving information to the physician or patient, or such other purposes as may be deemed desirable or necessary.

The methods of forming the gelatin film and the methods of encapsulating material in the formed films are not a part of the present invention and may be in accordance with conventional practice or in accordance with such novel procedures as are described in the patent application of Frank E. Stirn and Arthur S. Taylor entitled "Method and Machine for Making Capsules" Serial No. 16,954, filed March 23, 1948.

As described in that patent application gelatin films may be cast in which titanium dioxide pigment or other pigment is present to render the

film opaque and in which a suitable dye may be dissolved so as to color the film throughout to a uniform density as may be desired. Additionally this base film may have a desired flavor or odor imparted thereto by the addition to the gelatin mixture of suitable essential oils or other aromatic materials.

The method of treating such a film and further objects of my invention will become obvious from the following description, accompanying drawings and appended claims.

Figure 1 is a side elevation of a coloring roll stack which may be used in accordance with this invention to color a gelatin film.

Figure 2 is a front view of the roll stack in section, showing the gelatin film passing thereover, taken along line 2-2 of Figure 1.

Figure 3 is a view of a contacting roll certain portions of the surface of which are raised to give selective coloring to the gelatin film.

Figure 4 is a view of a typical capsule showing one-half of the capsule being colored differently than the remainder.

Figure 5 shows a capsule, the entire surface of which is colored.

Figure 6 is a figure of a capsule showing a portion of the gelatin capsule which does not have a surface dye thereon, and the remainder dyed with a striped pattern.

Figure 7 is a gelatin capsule a portion of the surface of which is so colored as to show a desired inscription, as for example that produced by the roller of Figure 3.

Different methods of forming the gelatin film can be used in connection with my method of coloring. There is shown, accordingly, only a portion of the gelatin film 11, as it is fed from a conveyor feed belt 12, over a dyeing assembly 13 to a take-up roller 14. The conveyor feed belt and take-up roller are not part of this invention and are shown diagrammatically only as they may be any of those previously known.

For my purpose of dyeing the film it is necessary that a dye roll mechanism be used such that a sufficient and not excess portion of dye is continuously transmitted to the gelatin film continuously and uniformly.

In such traditional printing procedures as are used in printing paper webs; as for example a newspaper; it is customary to transfer ink from an inking roll to a type surface and from there to the paper, with the paper at the time of printing being pressed firmly against the surface of the type by some form of backing roll. Such a form of backing roll would not be satisfactory

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Jan. 6, 1953

F. E. STIRN

2,624,163

METHOD OF MAKING COLORED GELATIN CAPSULES

Filed April 22, 1948

Fig. 1.

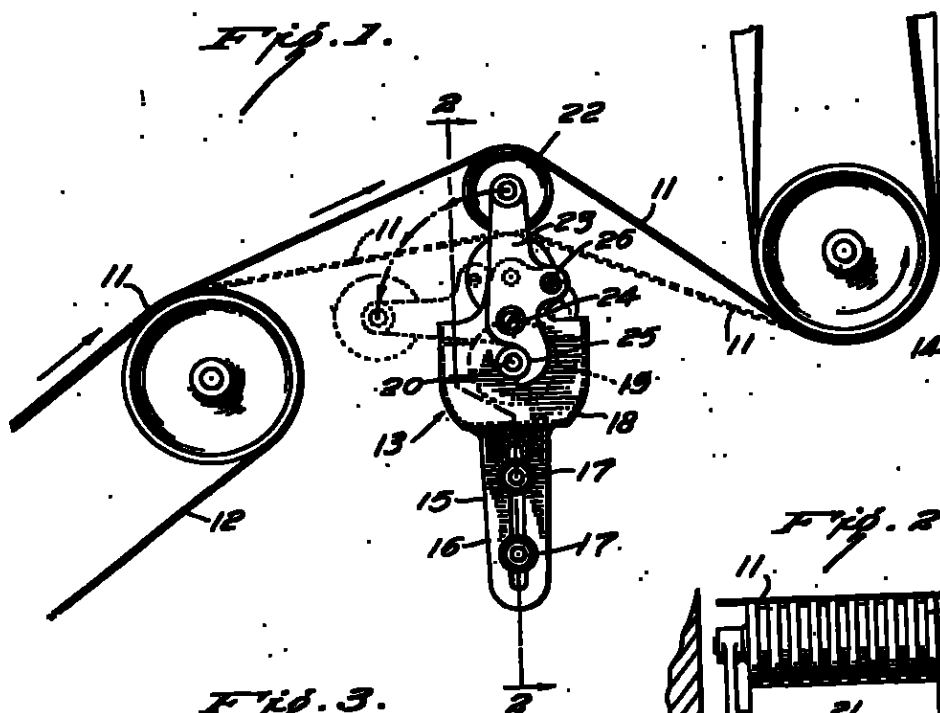


Fig. 3.



Fig. 2.

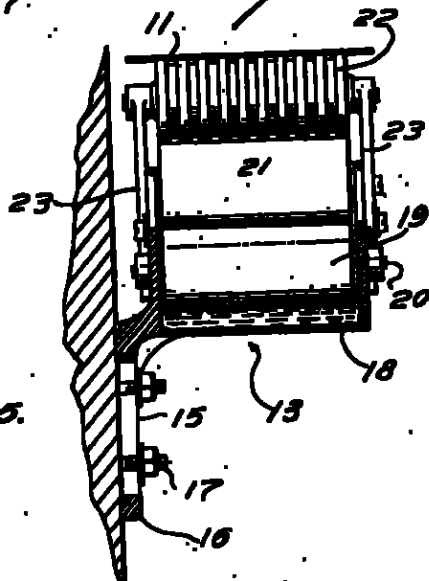


Fig. 4.



Fig. 5.



Fig. 6.



Fig. 7.



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BY
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ATTORNEY

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ship in the capsule forming disc whereby capsules were formed with the trade insignia uniformly printed in red on a green background and accurately registered on the surface of the filled gelatin capsules.

Example 7

10 A 1% solution of "F, D. and C Red No. 3" in ethylalcohol was substituted but the apparatus otherwise operated the same as in Example 1. A rather light color coat was formed, but entirely uniform and satisfactory for purposes where pale colors are desired.

Discussion

18" A 1% solution of "F, D and C Green No. 1" was prepared in isopropyl alcohol and placed in the dye trough with the gelatin film contacting the transfer roll. The gelatin film was inverted by running over a pair of rolls, having a half twist and an additional coloring mechanism was placed in contact with what was to form the internal surface of the capsule. In this trough was placed a solution of 5% "F, D and C Red No. 3" in tertiary butyl alcohol, with the strip then fed to the capsule forming machine. An embossed roll was used in this second machine with the name of the maker thereon. Capsules were formed with a comparatively smooth, uniform dye coat on the outside which effectively concealed the dye insignia on the inside of the capsule. The capsules could be identified as to origin by slicing them in two and reading the name of the maker on the internal surface.

35 In general, it will be found that the dyes will print evenly and uniformly. However, with certain gelatin formulations particularly those in which an unusually high percentage of a plasticizer such as glycerine is used, the dyes will exhibit a tendency to bleed after the printing, perhaps because such plasticizer acts as a solvent for the dye and permits it to run. Under such circumstances, a dye must be selected such that due to its lower solubility in glycerine it will not bleed to an undesirable extent. With the harder formulations, such as are preferred for the powder filled capsules, such troubles with bleeding are not normally encountered, and clear, sharp lines are the rule. If a high oil content is present in the capsule, with a high glycerine content, it will be found that the oil remains in place, but if a low glycerine mix is used, some of the oil may tend to penetrate the gelatin, and in such cases, it may be desirable to coat the inside of the capsule with an impervious coating such as a resin to prevent the oil from blurring the color lines.

Other dyes may be used. The publication of the Federal Security Agency, Food and Drug Administration, Service and Regulatory Announcements, Coal Tar Color Regulations list such acceptable colors. For those skilled in the art the dye index lists the colors of the dyes, the solvents in which they dissolve, whether or not they are water compatible and their toxicity. Any dye which is acceptable from the standpoint of toxicity and which meets solubility characteristics is acceptable and may normally be readily selected from the dye indices without the necessity of experimentation. It is desirable that the dyes be at least somewhat water soluble so that they will go into the gelatin film more readily and will not tend to cake on the surface thereof. The number, the depth, and configuration of dye patterns may be varied in accordance with the choice of