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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/10/2022	11325350	P008EP.US (87942.0011)	7044

26582 7590 04/20/2022

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 176 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

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APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Danapak Flexibles A/S, Slagelse, DENMARK;

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Document Code:WFEE

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03/28/2022	16425067	$2,000.00

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method	Account Number
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

26582 7590 04/07/2022

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

EXAMINER
TISCHLER, FRANCES

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
04/07/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@hollandhart.com

Supplemental ***Notice of Allowability***	**Application No.** 16/425,067	**Applicant(s)** Johansen et al.	
	Examiner FRANCES TISCHLER	**Art Unit** 1765	**AIA (FITF) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 3/28/22.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1,3-8 and 10 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☑ All b) ☐ Some* c) ☐ None of the:

   1. ☑ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 3/28/22.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/FRANCES TISCHLER/
Primary Examiner, Art Unit 1765

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/425,067
Filing Date	May 29, 2019
First Named Inventor	Johansen et al.
Art Unit	1765
Examiner Name	Frances Tischler
Docket Number	P008EP.US (87942.0011)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	01	US 2014/0323996-A1	10-30-2014	Langer et al.	24 pgs.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Document Number Country Code[3] –Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	01	CN 103269698-A	08-28-2013	Acino AG	32 pgs.	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]

Examiner Signature	/FRANCES TISCHLER/	Date Considered	03/31/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 2

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Application Number	16/425,067
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First Named Inventor	Johansen et al.
Art Unit	1765
Examiner Name	Frances Tischler
Docket Number	P008EP.US (87942.0011)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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OR

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Steven A. Avena /	Date (YYYY-MM-DD)	2022-03-28
Name/Print	Steven A. Avena	Registration Number	75,211

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Document Code:WFEE

User :92866

Sale Accounting Date:03/31/2022

Sale Item Reference Number	Effective Date
16425067	03/28/2022

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
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Examiner Signature		Date Considered	

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Bibliographic data: CN103269698 (A) — 2013-08-28

Transdermal therapeutic system for administering an active substance

Inventor(s): SCHROEDER BRITTA; SCHURAD BJOERN; HAUSNER HEIKE ± (SCHROEDER BRITTA, ; SCHURAD BJOERN, ; HAUSNER HEIKE, ; 布丽塔·朗格尔, ; 比约恩·舒拉德, ; 海克·普林茨)

Applicant(s): ACINO AG ± (ACINO AG, ; 绿叶制药股份公司)

Classification: - **international:*A61K31/27; A61K9/00; A61K9/70***
- **cooperative:** **A61K31/27 (EP, CN, KR, US)**; **A61K47/32 (CN)**; **A61K9/70 (KR)**; **A61K9/7084 (EP, CN, US)**; **A61P17/00 (EP)**; **A61P25/16 (EP)**; **A61P25/28 (EP)**

Application number: CN20118059614 20111214 Global Dossier

Priority number (s): EP20100194968 20101214 ; WO2011EP72812 20111214

Also published as: CN103269698 (B) AU2011343363 (A1) AU2011343363 (B2) AU2017213569 (A1) AU2017213569 (B2) more

Abstract of CN103269698 (A)

The present invention relates to a transdermal therapeutic system for administering an active substance through the skin, said system being suitable for an application period of at least three days, comprising the layers arranged in the following order with respect to each other: a) a cover layer, b) an active substance layer comprising a polymer matrix containing the active substance, c) an adhesive layer comprising a contact adhesive, which consists of a mixture of one or more polyisobutylenes and one or more polybutenes, and d) a pull-off layer.

(19)中华人民共和国国家知识产权局

(12)发明专利申请

(10)申请公布号 CN 103269698 A
(43)申请公布日 2013.08.28

(21)申请号 201180059614.1

(22)申请日 2011.12.14

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(71)申请人 阿西诺股份公司
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(74)专利代理机构 北京集佳知识产权代理有限公司 11227
代理人 郑斌 彭鲲鹏

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A61K 31/27(2006.01)
A61K 9/00(2006.01)
A61K 9/70(2006.01)

权利要求书5页 说明书19页 附图6页

(54)发明名称

用于施用活性物质的经皮治疗系统

(57)摘要

本发明涉及用于通过皮肤施用活性物质的经皮治疗系统，所述系统适合用于至少三天的施用时期，其包含彼此按以下顺序排列的层：a)覆盖层，b)包含含有所述活性物质之聚合物基质的活性物质层，c)包含接触型粘合剂的粘合层，所述粘合剂由一种或更多种聚异丁烯和一种或更多种聚丁烯的混合物组成，以及d)拉脱层。

CN 103269698 A

1. 用于通过皮肤施用活性物质的经皮治疗系统，其包含彼此按以下顺序排列的层：

a) 覆盖层；

b) 活性物质层，其包含含有所述活性物质的聚合物基质；

c) 控制所述活性物质之释放的膜；

d) 包含接触型粘合剂的粘合层；和

e) 拉脱层；

其中所述活性物质是卡巴拉汀或其生理可相容的盐、水合物、溶剂合物或衍生物，其特征在于，所述聚合物基质的聚合物不包含任何游离羟基和游离羧基。

2. 根据权利要求 1 所述的经皮治疗系统，其特征在于，所述活性物质层不包含任何游离羟基和游离羧基。

3. 根据权利要求 1 或 2 所述的经皮治疗系统，其特征在于，其不包含任何生育酚。

4. 根据权利要求 1 至 3 中任一项所述的经皮治疗系统，其特征在于，其不包含任何选自生育酚、丁基羟基茴香醚和丁基羟基甲苯的抗氧化剂。

5. 根据权利要求 1 至 4 中任一项所述的经皮治疗系统，其特征在于，其不包含任何抗氧化剂。

6. 根据权利要求 1 至 5 中任一项所述的经皮治疗系统，其特征在于，所述接触型粘合剂包含聚异丁烯或数种聚异丁烯的混合物。

7. 根据权利要求 6 所述的经皮治疗系统，其特征在于，所述粘合层还包含聚丁烯或数种聚丁烯的混合物。

8. 根据权利要求 1 至 7 中任一项所述的经皮治疗系统，其中，基于所述粘合层的总重量，所述粘合层包含按重量计 98 至 100％的含有聚丁烯的所述接触型粘合剂和按重量计 0 至 2.0％的凝胶形成剂。

9. 根据权利要求 1 至 8 中任一项所述的经皮治疗系统，其用于时长至少为两天的施用。

10. 根据权利要求 1 至 9 中任一项所述的经皮治疗系统，其特征在于，所述接触型粘合剂由具有不同平均分子量的至少两种聚异丁烯和具有不同平均分子量的至少两种聚丁烯组成。

11. 根据权利要求 10 所述的经皮治疗系统，其特征在于，第一聚异丁烯聚合物具有约 40,000g/mol 的平均分子量 M_v，第二聚异丁烯聚合物具有约 400,000g/mol 的平均分子量 M_v。

12. 根据权利要求 10 至 11 中任一项所述的经皮治疗系统，其特征在于，第一聚丁烯聚合物具有 700 至 2,800g/mol 的平均分子量 M_n，第二聚丁烯聚合物具有 2,200 至 6,500g/mol 的平均分子量 M_n。

13. 根据权利要求 1 至 12 中任一项所述的经皮治疗系统，其中，基于所述活性物质层的总重量，所述活性物质层包含按重量计 30 至 50％的所述活性物质和按重量计 50 至 70％的所述聚合物基质。

14. 根据权利要求 1 至 13 中任一项所述的经皮治疗系统，其中所述活性物质层的所述聚合物基质包含不含游离羟基并且不含游离羧基的至少一种聚合物和 / 或共聚物，其选自聚丙烯酸酯、丙烯酸酯 - 乙酸乙烯酯共聚物、聚异丁烯、苯乙烯 - 丁二烯共聚物及其混合物。

15. 根据权利要求 1 至 14 中任一项所述的经皮治疗系统，其特征在于，所述 TTS 在至少 48 小时的时长中显示出所述活性物质的基本线性的渗透曲线。

16. 根据权利要求 1 至 15 中任一项所述的经皮治疗系统，其特征在于，所述控制所述活性物质之释放的膜基本由聚乙烯组成。

17. 用于通过皮肤施用活性物质的经皮治疗系统，其包含彼此按以下顺序排列的层：

a) 覆盖层；

b) 活性物质层，其包含含有所述活性物质的聚合物基质；

c) 粘合层，其包含 (1) 聚异丁烯或数种聚异丁烯的混合物和 (2) 聚丁烯或数种聚丁烯的混合物；和

d) 拉脱层。

18. 根据权利要求 17 所述的经皮治疗系统，其特征在于，所述粘合层包含具有不同平均分子量的至少两种聚异丁烯和具有不同平均分子量的至少两种聚丁烯。

19. 根据权利要求 18 所述的经皮治疗系统，其特征在于，第一聚异丁烯聚合物具有约 40,000g/mol 的平均分子量 M_v，第二聚异丁烯聚合物具有约 400,000g/mol 的平均分子量 M_v。

20. 根据权利要求 18 或 19 所述的经皮治疗系统，其特征在于，第一聚丁烯聚合物具有 700 至 2,800g/mol 的平均分子量 M_n，第二聚丁烯聚合物具有 2,200 至 6,500g/mol 的平均分子量 M_n。

21. 根据权利要求 17 至 20 中任一项所述的经皮治疗系统，其中，基于所述活性物质层的总重量，所述活性物质层包含按重量计 30 至 50％的所述活性物质和按重量计 50 至 70％的所述聚合物基质。

22. 根据权利要求 17 至 20 中任一项所述的经皮治疗系统，其特征在于，所述聚合物基质的聚合物不包含任何游离羟基和游离羧基。

23. 根据权利要求 22 所述的经皮治疗系统，其特征在于，所述活性物质层不包含任何游离羟基和游离羧基。

24. 根据权利要求 22 或 23 所述的经皮治疗系统，其特征在于，所述活性物质层的所述聚合物基质包含不含游离羟基并且不含游离羧基的至少一种聚合物和 / 或共聚物，其选自聚丙烯酸酯、丙烯酸酯 - 乙酸乙烯酯共聚物、聚异丁烯、苯乙烯 - 丁二烯共聚物及其混合物。

25. 根据权利要求 17 至 24 中任一项所述的经皮治疗系统，其特征在于，所述 TTS 在至少 48 小时中显示出所述活性物质的基本线性的渗透曲线。

26. 根据权利要求 17 至 25 中任一项所述的经皮治疗系统，其特征在于，将控制所述活性物质之释放的膜布置在所述活性物质层与所述粘合层之间。

27. 根据权利要求 26 所述的经皮治疗系统，其特征在于，所述控制所述活性物质之释放的膜基本由聚乙烯或聚乙烯和乙酸乙烯酯组成。

28. 根据权利要求 17 至 27 中任一项所述的经皮治疗系统，其特征在于，其不包含生育酚。

29. 根据权利要求 17 至 28 中任一项所述的经皮治疗系统，其特征在于，其不包含任何选自生育酚、丁基羟基茴香醚和丁基羟基甲苯的抗氧化剂。

30. 根据权利要求 17 至 29 中任一项所述的经皮治疗系统，其特征在于，其不包含任何抗氧化剂。

31. 用于通过皮肤施用活性物质的经皮治疗系统，其包含：

a) 覆盖层，

b) 所述覆盖层上的活性物质层，基于所述活性物质层的总重量，所述活性物质层包含按重量计 30 至 50％的活性物质和按重量计 50 至 70％的聚合物基质，其中所述聚合物基质基本由不含羟基并且不含羧基的丙烯酸酯聚合物组成，或者基本由不含羟基并且不含羧基的丙烯酸酯共聚物组成，并且其中所述活性物质是卡巴拉汀或其生理可相容的盐、水合物、溶剂合物或衍生物；

c) 所述活性物质层上的膜，其控制所述卡巴拉汀的释放；

d) 所述膜上的粘合层，其由按重量计 0 至 1％的二氧化硅和按重量计 99 至 100％的以下之混合物组成：具有约 40,000g/mol 之平均分子量 M_v 的聚异丁烯聚合物、具有约 400,000g/mol 之平均分子量 M_v 的聚异丁烯聚合物、具有约 2,500g/mol 之平均分子量 M_N 的聚丁烯聚合物和具有约 6,000g/mol 之平均分子量 M_N 的聚丁烯聚合物；以及

e) 所述粘合层上的拉脱层。

32. 用于通过皮肤施用活性物质的经皮治疗系统，其包含彼此按以下顺序排列的层：

a) 覆盖层；

b) 活性物质层，其包含含有所述活性物质的聚合物基质；

c) 控制所述活性物质之释放的膜；

d) 包含接触型粘合剂的粘合层；和

e) 拉脱层；

其中所述活性物质是卡巴拉汀或者其生理可相容的盐、水合物、溶剂合物或衍生物，其特征在于，所述经皮治疗系统不包含生育酚。

33. 根据权利要求 32 所述的经皮治疗系统，其特征在于，其不包含任何选自生育酚、丁基羟基茴香醚和丁基羟基甲苯的抗氧化剂。

34. 根据权利要求 33 所述的经皮治疗系统，其特征在于，其不包含任何抗氧化剂。

35. 根据权利要求 1 至 34 中任一项所述的经皮治疗系统，其特征在于，其适合用于在至少 2 天中的施用。

36. 根据权利要求 35 所述的经皮治疗系统，其特征在于，其适合用于在至少 3 天中的施用。

37. 根据权利要求 36 所述的经皮治疗系统，其特征在于，其适合用于在至少 4 天中的施用。

38. 根据权利要求 37 所述的经皮治疗系统，其特征在于，其适合用于在至少 5 天中的施用。

39. 根据权利要求 38 所述的经皮治疗系统，其特征在于，其适合用于在至少 6 天中的施用。

40. 根据权利要求 39 所述的经皮治疗系统，其特征在于，其适合用于在至少 7 天中的施用。

41. 根据权利要求 1 至 34 中任一项所述的经皮治疗系统，其特征在于，如通过体外皮肤渗透测试测量的，其在至少 48 小时的时长中显示出所述活性物质的基本线性的皮肤渗透。

42. 根据权利要求 41 所述的经皮治疗系统，其特征在于，如通过体外皮肤渗透测试测量的，其在至少 72 小时的时长中显示出所述活性物质的基本线性的皮肤渗透。

43. 根据权利要求 42 所述的经皮治疗系统，其特征在于，如通过体外皮肤渗透测试测

量的，其在至少 96 小时的时长中显示出所述活性物质的基本线性的皮肤渗透。

44. 根据权利要求 43 所述的经皮治疗系统，其特征在于，如通过体外皮肤渗透测试测量的，其在至少 120 小时的时长中显示出所述活性物质的基本线性的皮肤渗透。

45. 根据权利要求 44 所述的经皮治疗系统，其特征在于，如通过体外皮肤渗透测试测量的，其在至少 144 小时的时长中显示出所述活性物质的基本线性的皮肤渗透。

46. 根据权利要求 45 所述的经皮治疗系统，其特征在于，如通过体外皮肤渗透测试测量的，其在至少 168 小时的时长中显示出所述活性物质的基本线性的皮肤渗透。

47. 用于制备根据权利要求 1 至 46 中任一项的经皮系统的方法，其包括：

i) 制备包含所述活性物质层的组分，其包含所述覆盖层和所述活性物质层，所述活性物质层在所述覆盖层应面向皮肤的一侧上；

ii) 制备包含所述粘合层的组分，其包含所述拉脱层和所述拉脱层上的所述粘合层并任选地包含控制所述活性物质之释放的膜；

iii) 将 i) 和 ii) 的组分层压在彼此上，使得所述覆盖层和所述拉脱层在最终 TTS 的横截面中代表相反的最外层。

48. 根据权利要求 47 的方法，其包括：

i) 在所述覆盖层的应面向皮肤的一侧上应用形成所述活性物质层之组合物的薄膜并任选地随后干燥，并且任选地用控制所述活性物质之释放的所述膜进行衬垫，所述组合物任选地为在合适介质中的溶液或分散体的形式；

ii) 在所述拉脱层上应用形成所述粘合层之组合物的薄膜并任选地随后干燥，所述组合物任选地为在合适介质中的溶液或分散体的形式；以及

iii) 将 i) 和 ii) 的组分层压在彼此上，使得所述覆盖层和所述拉脱层在最终 TTS 的横截面中代表相反的最外层；

或者

i) 在硅化或涂布含氟聚合物的拉脱箔（“中间衬里”）上应用形成所述粘合层之组合物的薄膜并任选地随后干燥，并用所述覆盖层进行衬垫，所述组合物任选地为在合适介质中的溶液或分散体的形式；

ii) 将所述硅化的拉脱箔（“中间衬里”）拉脱，然后用所述控制所述活性物质之释放的膜进行衬垫；

iii) 在所述拉脱层上应用形成所述粘合层之组合物的薄膜并任选地随后干燥，所述组合物任选地为在合适介质中的溶液或分散体的形式；以及

iv) 将 ii) 和 iii) 的组分层压在彼此上，使得所述覆盖层和所述拉脱层在最终 TTS 的横截面中代表相反的最外层。

49. 根据权利要求 1 至 46 中任一项所述的经皮治疗系统，其用于在治疗阿尔茨海默病和帕金森痴呆中使用。

50. 根据权利要求 49 所述的用于使用的经皮治疗系统，其特征在于，使其在至少 48 小时的时长中施用。

51. 根据权利要求 50 所述的用于使用的经皮治疗系统，其特征在于，使其在至少 72 小时的时长中施用。

52. 根据权利要求 51 所述的用于使用的经皮治疗系统，其特征在于，使其在至少 96 小

时的时长中施用。

53. 根据权利要求 52 所述的用于使用的经皮治疗系统，其特征在于，使其在至少 120 小时的时长中施用。

54. 根据权利要求 53 所述的用于使用的经皮治疗系统，其特征在于，使其在至少 144 小时的时长中施用。

55. 根据权利要求 54 所述的用于使用的经皮治疗系统，其特征在于，使其在至少 168 小时的时长中施用。

56. 不含游离羟基并且不含游离羧基的聚合物或共聚物用于稳定 TTS 中卡巴拉汀的用途。

57. 不含游离羟基并且不含游离羧基的聚合物或共聚物用于降低 TTS 中卡巴拉汀之降解的用途。

58. 用于稳定 TTS 中卡巴拉汀的方法，其特征在于，将卡巴拉汀或其盐或溶剂合物嵌入不含游离羟基并且不含游离羧基的聚合物基质中。

59. 用于稳定 TTS 中卡巴拉汀的方法，其特征在于，将卡巴拉汀或其盐或溶剂合物引入不包含游离羟基并且不包含游离羧基的活性物质层中。

60. 用于降低 TTS 中卡巴拉汀之降解的方法，其特征在于，将卡巴拉汀或其盐或溶剂合物嵌入不含游离羟基并且不含游离羧基的聚合物基质中。

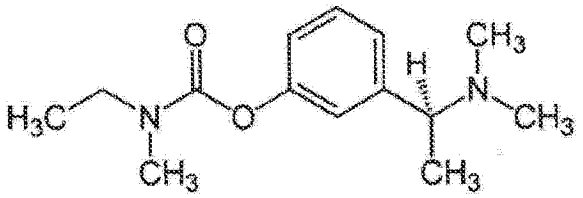
61. 用于降低 TTS 中卡巴拉汀之降解的方法，其特征在于，将卡巴拉汀或其盐或溶剂合物引入不包含游离羟基并且不包含游离羧基的活性物质层中。

用于施用活性物质的经皮治疗系统

[0001] 本申请的目的是用于经皮施用活性物质的系统，其适合用于数天的治疗施用时期，所述活性物质优选地为卡巴拉汀、其生理可相容的盐、水合物、溶剂合物或衍生物。

[0002] 卡巴拉汀是苯氨基甲酸酯，式 I 的 (S)-N- 乙基 -3-[(1- 二甲氨基）乙基]-N- 甲基 - 苯基 - 氨基甲酸酯。

[0003]



(I)

[0004] 它是作用于中枢神经系统的胆碱酯酶抑制剂，因此是用于治疗阿尔茨海默病和帕金森痴呆的活性物质。

[0005] 卡巴拉汀可以作为游离碱存在，但也作为酸加成盐、水合物、溶剂合物或作为其他衍生物存在。这些衍生物都包括在本发明名称“卡巴拉汀”中，除非另有所描述。

[0006] 施用卡巴拉汀的优选形式是以经皮 (transdermalen) 治疗系统的方式透皮 (perkutane) 施用，即经皮贴片。通常，经皮贴片是含有待递送之活性物质的小的自粘附绷带。这些绷带可具有多种形式和大小。最简单的类型是在载体（覆盖层）上包含活性物质储备物的粘合性整料 (Klebe-Monolith)。通常以可药用压敏粘合剂或接触型粘合剂中的活性物质之活性物质层的形式来形成该活性物质储备物并使其与皮肤区域接触，由此通过经皮扩散使活性物质递送至患者的身体。

[0007] 更复杂的贴片是具有活性物质储备物的多重层压物或贴片，其中可在活性物质层与皮肤之间布置另一粘合层。

[0008] 通过卡巴拉汀之经皮贴片的施用的一个形式已经在关于卡巴拉汀的基本专利 (GB2203040) 中描述。其中公开的经皮贴片由覆盖层和形成活性物质层的层组成。除了活性物质卡巴拉汀之外，在活性物质层中还包含亲水聚合物、非膨胀丙烯酸酯聚合物和增塑剂。

[0009] 在 GB2203040 公开之后，已经开发并描述了包含卡巴拉汀作为活性物质的另一些经皮治疗系统 (transdermale therapeutische systeme,TTS)。在 WO02/03969 中，描述了 TTS，其中含有活性物质的基质层还包含用于增加皮肤渗透性的高度分散的二氧化硅。

[0010] 在专利申请 WO2008/021113 和 EP2016939 中，有一些具有更复杂结构的公开的贴片，该结构旨在确保在长达七天的时长中施用不同活性物质。在含有活性物质的层与粘合层之间，这些贴片还包含控制活性物质之递送的膜。但是，在该贴片的活性物质层中存在游离羟基，这是因为在该活性物质层中包含多元醇。

[0011] 在 DE19918106 中，活性物质层包含具有丙烯酸或甲基丙烯酸单元的自粘合聚合物，所述单元具有确定含量的羧基以增加吸水能力以及酸性聚丙烯酸接触型粘合剂对潮湿的耐受性。

[0012] WO2007/064407A1 公开了实现在卡巴拉汀治疗中在粘合性质、耐受性和安全性之

方面的改善的具有基于硅酮之粘合层的 TTS。根据 WO2007/064407A1，特别优选的是，库层包含抗氧化剂（第 7 页，第 4 段）。因此，在实施例中所有的制剂均包含抗氧化剂维生素 E。其中使用的**Durotak®** 387-2353 是具有羧基的聚丙烯酸。根据 WO2007/064407A1，还认为库层包含作为渗透增强剂的多种物质，例如甘油、脂肪酸等（第 7 页，第 5 段）。这些物质常常包含游离羟基或羧基，其因此存在于库层的聚合物基质中。WO2007/064407A1 没有特别处理卡巴拉汀的稳定性。特别是，WO2007/064407A1 没有教导选择某些聚合物用于库层的聚合物基质以防止卡巴拉汀的降解。

[0013] US2008/0044461A1 公开了具有多奈哌齐的 TTS 制剂（参见实施例）。也提及了卡巴拉汀（权利要求 7）。US2008/0044461A1 没有公开任何具有聚合物基质的活性物质层。相反地，通过膜（所谓的膜贴片）而不是通过嵌入有活性物质的聚合物骨架（所谓的基质贴片）来控制释放。此外，US2008/0044461A1 的必要特征是库层包含凝胶形成剂和渗透增强剂（参见权利要求 1）。将醇类用作渗透增强剂（参见，[0053]）。将纤维素聚合物用作凝胶形成剂（参见，[0055]）。因此，渗透增强剂和凝胶形成剂均是 TTS 中存在于库层的具有游离羟基的化合物。

[0014] US2007/0259028A1 公开了具有多奈哌齐的 TTS 制剂（参见，实施例）。也提及了卡巴拉汀（权利要求 3）。US2007/0259028A1 的必要特征是库层包含多元醇，例如甘油。即，根据 US2007/0259028A1，在库层的聚合物基质中不可避免地存在游离羟基。

[0015] US2004/0086552A1 公开了具有可选自非常长的列表之活性物质的 TTS 制剂（参见 [0070] 至 [0095]）。公开了基质贴片和“膜贴片”二者（分别参见 [0057] 和 [0058]）。对于基质贴片，US2004/0086552A1 没有教导选择某些聚合物用于基质以稳定活性物质。

[0016] US6,689,379B1 公开了具有特定粘合层的 TTS 制剂。此外，卡巴拉汀作为可能的活性物质而被提及。优选地，认为活性物质层包含具有羟基的化合物（参见权利要求 10）。US6,689,379B1 没有教导选择某些聚合物用于库层的聚合物基质以防止卡巴拉汀的降解。

[0017] 但是，专利 EP1047409 报道了通过 TTS 施用卡巴拉汀的一般问题。已经发现，尤其在氧的存在下，活性物质易于分解。在 GB2203040 公开的经皮组合物中，卡巴拉汀分解，根据 EP1047409 中的公开内容也是如此，尽管形成了围绕活性物质的封闭聚合物基质以及组合物的气密包装。在 EP1047409 中，将抗氧化剂添加至药物组合物，解决了卡巴拉汀之低稳定性的问题。

[0018] 到目前为止，商业可获得的具有卡巴拉汀的 TTS 仅允许在 24 小时中的连续施用。本发明的一个目的是在延长的时间中控制释放。为了卡巴拉汀在更长的时间中的经皮施用，必须确保 (1) 保证活性物质卡巴拉汀的足够化学稳定性，(2) 保证该系统的足够物理稳定性（尤其在冷变形 (kalter fluss) 方面），以及 (3) 该系统在施用的时长中具有足够的粘合性。

[0019] 本发明的另一个目的是找到用于经皮施用的包含卡巴拉汀之治疗组合物，其适合用于数天的治疗施用时期。

[0020] 发明概述

[0021] 已经发现，如果活性物质层的聚合物基质不包含任何游离羟基或羧基，那么经皮贴片中的卡巴拉汀是足够稳定的。尤其，本发明是基于选择特定聚合物用于聚合物基质从而分别防止或最小化卡巴拉汀的降解。

[0022] 因此，本发明提供了足够稳定的包含卡巴拉汀的 TTS 以及用于产生其的方法。

[0023] 因此，本发明的第一方面是用于使卡巴拉汀施用数天之施用时期的 TTS，其包含以下组分：

[0024] a) 覆盖层，

[0025] b) 所述覆盖层上的活性物质层，其包含含有活性物质的聚合物基质，

[0026] c) 所述活性物质层上的膜，其控制卡巴拉汀的释放；

[0027] d) 所述膜上的粘合层，其包含接触型粘合剂；和

[0028] e) 所述粘合层上的拉脱层，

[0029] 其中，所述活性物质层的一种或更多种聚合物不包含任何游离羟基或羧基。

[0030] 此外，本发明提供了不含任何游离羟基或羧基的聚合物或共聚物在包含卡巴拉汀之 TTS 中的用途以及用于治疗阿尔茨海默病和帕金森痴呆的 TTS。

[0031] 虽然在 WO2008/021113 中将粘合材料聚异丁烯、聚丙烯酸酯和基于硅酮的粘合剂描述为同样适合，但是目前发现在粘合层中聚异丁烯更好地适合作为接触型粘合剂并且发现通过添加作为增粘剂的聚丁烯进一步改善了该粘合剂的性质。因此，本发明提供了包含活性物质并且具有改善的粘合性质的 TTS，以及用于产生其的方法。

[0032] 因此，本发明的第二方面是用于通过皮肤施用活性物质的经皮治疗系统，其包含彼此按以下顺序排列的层：

[0033] a) 覆盖层，

[0034] b) 活性物质层，包含含有所述活性物质的聚合物基质，

[0035] c) 粘合层，其包含 (1) 由聚异丁烯或数种聚异丁烯之混合物组成的接触型粘合剂，和 (2) 由聚丁烯或数种聚丁烯之混合物组成的粘合增强剂；以及

[0036] d) 拉脱层。

[0037] 本发明的第三方面是用于通过皮肤施用卡巴拉汀的 TTS，其包含覆盖层、包含所述卡巴拉汀的活性物质层、根据第二方面改善的粘合层和拉脱层，所述 TTS 用于在至少两天（例如两天或三天）的时长中施用卡巴拉汀，其中控制卡巴拉汀之释放的膜存在于所述活性物质层与所述粘合层之间。因此，本发明的第三方面是用于通过皮肤施用活性物质的经皮治疗系统，其包含彼此按以下顺序排列的层：

[0038] a) 覆盖层，

[0039] b) 活性物质层，包含含有活性物质的聚合物基质，

[0040] c) 控制所述卡巴拉汀之释放的膜；

[0041] d) 粘合层，其包含 (1) 由聚异丁烯或数种聚异丁烯之混合物组成的接触型粘合剂，和 (2) 由聚丁烯或数种聚丁烯之混合物组成的粘合增强剂；以及

[0042] e) 拉脱层。

[0043] 本发明的第四方面是用于通过皮肤施用卡巴拉汀的 TTS，其包含覆盖层、含有卡巴拉汀的活性物质层、根据第二方面改善的粘合层和拉脱层，其中所述活性物质层不含游离羟基或羧基。因此，本发明的第四方面是用于通过皮肤施用活性物质的经皮治疗系统，其包含彼此按以下顺序排列的层：

[0044] a) 覆盖层，

[0045] b) 活性物质层，包含含有所述活性物质的聚合物基质，

[0046] c) 粘合层，其包含 (1) 由聚异丁烯或数种聚异丁烯之混合物组成的接触型粘合剂，和 (2) 由聚丁烯或数种聚丁烯之混合物组成的粘合增强剂，以及

[0047] d) 拉脱层，

[0048] 其中，所述活性物质层的一种或更多种聚合物不包含任何游离羟基或羧基。

[0049] 本发明的第五方面是提供了用于通过皮肤施用卡巴拉汀的 TTS，其包含覆盖层、含有所述卡巴拉汀的活性物质层、根据本发明改善的的粘合层和拉脱层，其中至少所述活性物质层（但优选整个 TTS）不含抗氧化剂。因此，本发明的第五方面是用于通过皮肤施用活性物质的经皮治疗系统，其包含彼此按以下顺序排列的层：

[0050] a) 覆盖层，

[0051] b) 活性物质层，其包含含有所述活性物质的聚合物基质，

[0052] c) 粘合层，其包含 (1) 由聚异丁烯或数种聚异丁烯之混合物组成的接触型粘合剂，和 (2) 由聚丁烯或数种聚丁烯之混合物组成的粘合增强剂，以及

[0053] d) 拉脱层，

[0054] 其中，至少所述活性物质层（但优选整个 TTS）不含抗氧化剂。

[0055] 本发明的上述多个方面可任意地彼此组合。本发明的含义内的所述活性物质是卡巴拉汀或其生理可相容的盐、水合物、溶剂合物或衍生物。

[0056] 发明详述

[0057] 定义

[0058] 本发明的含义内的“抗氧化剂”是减慢、抑制、破坏和 / 或阻碍氧化过程的可药用化合物或组合物。特别是，抗氧化剂包括以下物质：生育酚及其酯、芝麻油的芝麻酚、安息香的苯甲酸松柏酯、去甲二氢愈创树脂和去甲二氢愈创木酸 (NDGA)、没食子酸酯（没食子酸甲酯、乙酯、丙酯、戊酯、丁酯、月桂酯等）、丁基羟基茴香醚 (BHT，也称为丁基对甲酚）；抗坏血酸及其盐和酯（例如棕榈酸抗坏血酸酯）、赤藻糖酸（异抗坏血酸）及其盐和酯、单硫代甘油、甲醛次硫酸钠、偏亚硫酸氢钠、亚硫酸氢钠、亚硫酸钠、偏亚硫酸氢钾、丁基羟基茴香醚、丁基羟基甲苯、丙酸。

[0059] 术语“生育酚”还包括生育酚酯。一种已知的生育酚是 α - 生育酚。术语“α - 生育酚”包括 α - 生育酚的酯（例如乙酸 α - 生育酚酯）。

[0060] “聚合物基质”是具有三维结构的固体或半固体组合物，其包括聚合物或聚合物的混合物。聚合物基质也称为聚合物骨架，这是因为通常由聚合物或聚合物的混合物提供三维骨架结构。可将其他物质（例如活性物质）嵌入聚合物基质中。优选地，将活性物质均匀分布在聚合物基质中。

[0061] 在下文中，更详细地描述根据本发明的 TTS 的特征，除非另有明确陈述，否则对于单个特征的各自解释是指本发明所有前述的方面。

[0062] 此外，本发明的前述方面可任意地与另一些优选实施方案联合。所以，例如在一个优选的 TTS 中，活性物质层不含生育酚，并且所述活性物质层之聚合物基质的一种或更多种聚合物不包含羟基或羧基。此外，在该实施方案中，控制卡巴拉汀之释放的膜优选地存在于活性物质层与粘合层之间，并且 TTS 适合用于至少两天、至少三天或至少四天（例如，两天至七天、三天至六天或四天至五天）的施用时期。

[0063] 在根据本发明的 TTS 中，活性物质卡巴拉汀是足够稳定的。“足够稳定”意指，基于

活性物质在制剂中的期望含量，在40℃和75％相对空气湿度下贮存一个月之后活性物质的杂质总体上不超过按重量计1％，优选不超过按重量计0.5％。在制剂中活性物质的杂质是活性物质卡巴拉汀的降解产物以及伴随活性物质被引入制剂的杂质（例如，痕量的来自活性物质之产生的中间产品）。

[0064] 可如实施例4中的描述分别测定杂质的稳定性和量。优选地，在40℃和75％相对空气湿度下贮存三个月之后分解产物／杂质的总含量低于按重量计1％，优选低于按重量计0.6％。还优选的是，在40℃和75％相对空气湿度下贮存六个月之后分解产物／杂质的总含量低于按重量计1％。还优选的是，在25℃和60％相对空气湿度下贮存一个月之后杂质的总含量低于按重量计0.25％。还优选的是，在25℃和60％相对空气湿度下贮存三个月之后和六个月之后杂质的总含量低于按重量计0.5％。对于“按重量计％”的杂质之信息总是指活性物质在制剂中的期望含量，除非另有所指。

[0065] 根据本发明的TTS的施用时期优选地为至少两天或至少三天。在一个特别的实施方案中，根据本发明的TTS适合用于2至4、2至5、2至6、2至7或3至8天的施用时间。

[0066] 优选地，活性物质层（更优选整个TTS）不含生育酚。在另一个实施方案中，活性物质层（优选整个TTS）不含生育酚并且不含丁基羟基茴香醚(BHT，也称为丁基对甲酚)。在另一个实施方案中，活性物质层（优选整个TTS）不含生育酚、不含丁基羟基茴香醚并且不含丁基羟基甲苯。在一个特定的实施方案中，活性物质层（优选整个TTS）不含以下的抗氧化剂：生育酚及其酯、芝麻油的芝麻酚、安息香的苯甲酸松柏酯、去甲二氢愈创树脂和去甲二氢愈创木酸(NDGA)、没食子酸酯（没食子酸甲酯、乙酯、丙酯、戊酯、丁酯、月桂酯等）、丁基羟基茴香醚(BHT、也称为丁基对甲酚)；抗坏血酸及其盐、棕榈酸抗坏血酸酯、赤藻糖酸（异抗坏血酸）及其盐、单硫代甘油、甲醛次硫酸钠、偏亚硫酸氢钠、亚硫酸氢钠、亚硫酸钠、偏亚硫酸氢钾、丁基羟基茴香醚、丁基羟基甲苯、丙酸。在一个特别的实施方案中，活性物质层（更优选整个TTS）完全不含抗氧化剂。

[0067] 但是，很可能的是，在本发明的TTS中，只要抗氧化剂对TTS的作用方式没有负面影响，就可存在抗氧化剂。这里应注意，对于稳定根据本发明的一个方面的卡巴拉汀，抗氧化剂不是必需的。但是，在根据本发明的TTS中，还可将抗氧化剂用于其他目的。因此，尽管不是优选的，但是根据本发明的TTS可能包含抗氧化剂，例如生育酚（如α-生育酚及其酯）、丁基羟基甲苯和丁基羟基茴香醚。

[0068] 在本发明之TTS中抗氧化剂的总量通常低于按重量计1％或低于按重量计0.1％，更优选低于按重量计0.05％，最优选低于按重量计0.01％，其各自基于总制剂的重量（在没有覆盖层和拉脱层的情况下）。

[0069] TTS的结构

[0070] 根据本发明的TTS的结构包含数层。覆盖层位于TTS在使用中远离皮肤的末端。活性物质层位于覆盖层使用中面向人皮肤的一侧。此外，粘合层位于活性物质层使用中面向人皮肤的一侧。在使用TTS之前，拉脱层位于粘合层使用中面向人皮肤的一侧，在将要使用TTS之前将拉脱层去除。优选地，控制活性物质之释放的膜存在于活性物质层与粘合层之间。

[0071] 根据本发明的TTS的面积没有特定限制。通常，该面积为约5～40cm^2，但完全可以更大或更小。

[0072] 在一个实施方案中，根据本发明的 TTS 的覆盖层之面积至少分别相当于活性物质层或粘合层之面积。但是，覆盖层之面积还可比活性物质层之面积大，使得其不但完全覆盖活性物质层，而且延伸超出活性物质层的边缘。但是，在这样的一个实施方案中，粘合层之面积应等于覆盖层之面积，或者覆盖层面向皮肤的一侧应具有另一个粘合层以确保使用中 TTS 面向皮肤的整个表面粘附至皮肤。在另一个实施方案中，覆盖层比活性物质层和 / 或粘合层之面积稍微小些。

[0073] 活性物质层

[0074] 根据本发明的 TTS 的活性物质层包含嵌入聚合物基质中的活性物质（优选卡巴拉汀）。根据本发明的第一方面，聚合物基质基本不包含含有游离羟基或游离羧基的聚合物或共聚物。优选地，聚合物基质基本不包含游离羟基并且不包含游离羧基。优选地，聚合物基质基本不包含游离氨基、不包含游离羟基并且不包含游离羧基。优选地，聚合物基质由基本不包含游离羟基并且不包含游离羧基的聚合物和 / 或共聚物形成。还更优选地，聚合物基质由不包含氨基、不包含游离羟基并且不包含游离羧基的聚合物和 / 或共聚物形成。

[0075] 形成聚合物基质的不含游离官能团的合适聚合物或共聚物特别是聚丙烯酸酯、丙烯酸酯 - 乙酸乙烯酯共聚物、聚异丁烯和苯乙烯 - 丁二烯共聚物，其可单独或作为共混物存在。

[0076] 作为基本不含有游离官能团的合适的聚丙烯酸酯，可使用基于丙烯酸酯和 / 或甲基丙烯酸酯的聚合物（均聚物、共聚物和嵌段共聚物）。作为在此用于产生合适聚丙烯酸酯的单体特别地可能为丙烯酸正丁酯、甲基丙烯酸正丁酯、丙烯酸乙酯、丙烯酸 2- 乙基己酯、甲基丙烯酸乙酯、丙烯酸甲酯、甲基丙烯酸甲酯、丙烯酸叔丁酯、丙烯酸伸丁酯、甲基丙烯酸叔丁酯、甲基丙烯酸环己酯、甲基丙烯酸 2- 乙基己酯、甲基丙烯酸异龙脑酯、甲基丙烯酸异丁酯、丙烯酸异丙酯、甲基丙烯酸异丙酯以及这些单体的混合物。这些单体分别是不含其他游离官能团的带有线性、支链或环状脂肪族 C_1-C_{12} 取代基的丙烯酸或甲基丙烯酸的酯。还可将乙酸乙烯酯连同用于产生聚丙烯酸酯的这些单体中的至少一个用作共聚单体。

[0077] 优选地，聚合物基质由基本不包含游离官能团的一种或更多种聚丙烯酸酯组成。更优选地，聚合物基质由通过丙烯酸酯和 / 或甲基丙烯酸酯之聚合而制备的聚丙烯酸酯组成。在一个特定的实施方案中，聚合物基质由通过丙烯酸酯和 / 或甲基丙烯酸酯之聚合而制备的聚丙烯酸酯组成，所述丙烯酸酯和 / 或甲基丙烯酸酯选自丙烯酸正丁酯、甲基丙烯酸正丁酯、丙烯酸乙酯、丙烯酸 2- 乙基己酯、甲基丙烯酸乙酯、丙烯酸甲酯、甲基丙烯酸甲酯、丙烯酸叔丁酯、丙烯酸伸丁酯、甲基丙烯酸叔丁酯、甲基丙烯酸环己酯、甲基丙烯酸 2- 乙基己酯、甲基丙烯酸异龙脑酯、甲基丙烯酸异丁酯、丙烯酸异丙酯、甲基丙烯酸异丙酯及其混合物。在另一个实施方案中，聚合物基质基本由通过丙烯酸酯和 / 或甲基丙烯酸酯与乙酸乙烯酯的共聚作用而制备的聚丙酸酯组成，其中所述丙烯酸酯和 / 或甲基丙烯酸酯选自丙烯酸正丁酯、甲基丙烯酸正丁酯、丙烯酸乙酯、丙烯酸 2- 乙基己酯、甲基丙烯酸乙酯、丙烯酸甲酯、甲基丙烯酸甲酯、丙烯酸叔丁酯、丙烯酸伸丁酯、甲基丙烯酸叔丁酯、甲基丙烯酸环己酯、甲基丙烯酸 2- 乙基己酯、甲基丙烯酸异龙脑酯、甲基丙烯酸异丁酯、丙烯酸异丙酯、甲基丙烯酸异丙酯及其混合物。

[0078] 特别优选由起始单体丙烯酸 2- 乙基己酯和乙酸乙烯酯制备的共聚物，例如，由各 50％起始单体丙烯酸 2- 乙基己酯和乙酸乙烯酯制备的丙烯酸酯 - 乙酸乙烯酯共聚物

(**Duro-Tak**® 87-4098)。还优选购自Henkel的丙烯酸酯聚合物**Duro-Tak**® 87-9088(也是不含游离官能团的丙烯酸酯聚合物)。在一个特别的实施方案中,将丙烯酸酯聚合物**Duro-Tak**® 87-900A或**Duro-Tak**® 87-9301用于聚合物基质。

[0079] 基于制备聚合物基质之单体的混合物,包含游离羟基或游离羧基之单体(例如,分别为带有官能团的丙烯酸、甲基丙烯酸以及丙烯酸或甲基丙烯酸的酯,特别是含有羟基的酯)的总比例低于按重量计1%,优选低于按重量计0.5%,更优选低于按重量计0.2%。在一个特定的实施方案中,所述单体的总比例低于按重量计0.1%。在一个特定实施方案中,在单体的混合物中不包含游离羟基并且不包含游离羧基。

[0080] 当然,已经在WO03/017988A1中描述了包含作为含有活性物质之聚合物基质的基本不含羟基和羧基之聚丙烯酸酯的TTS,但其没有与活性物质卡巴拉汀相关联。WO03/017988中所描述的目的是解决TTS之低活性物质利用的缺点。根据该公开内容,通过理想地不含羟基或羧基的聚合物基质解决了所述目的。在该印刷品中,没有提及活性物质卡巴拉汀,更不必说增强卡巴拉汀之稳定性的作用。

[0081] 根据本发明的一个方面,活性物质层基本不包含含有游离羟基或游离羧基的聚合物或共聚物。优选地,活性物质层基本不包含游离羟基并且不包含游离羧基。更优选地,活性物质基本不包含游离氨基、不包含游离羟基并且不包含游离羧基。在一个特定的实施方案中,同样地,粘合层基本不包含含有游离羟基或游离羧基的聚合物或共聚物。优选地,粘合层基本不包含游离羟基并且不包含游离羧基。更优选地,粘合层基本不包含游离氨基、不包含游离羟基并且不包含游离羧基。

[0082] 优选地,基于活性物质层的总重量,活性物质层包含按重量计30-50%的卡巴拉汀和按重量计50-70%的聚合物基质。在根据本发明的TTS的一个特别优选的实施方案中,活性物质层包含按重量计约40%的卡巴拉汀和按重量计约60%的聚合物基质。优选地,除了活性物质和聚合物基质之外,活性物质层不包含其他成分。但是,可能在活性物质层中另外地包含本领域已知的其他添加剂。因此,例如,在活性物质层中可另外地存在增塑剂或凝胶形成剂。

[0083] 卡巴拉汀的绝对量取决于不同的因素,特别是待使用的TTS的大小、基本重量和活性物质层中的活性物质浓度。经干燥的活性物质层基质的基本重量优选地为20-100g/m^2,更优选25-80g/m^2,并且还更优选30-70g/m^2。活性物质层可具有20-400μm或30-200μm或40-100μm的厚度(干厚度)。还可能是除了上文提及的那些之外的另一些厚度。中间膜(Zwischenmembran)

[0084] 优选地,根据本发明的一个方面处于活性物质层与粘合层之间并且控制活性物质之释放的膜(也称为"控制膜")由聚烯烃(例如聚丙烯(例如,**Celgard**® 2400))组成,或者特别优选由聚乙烯(例如,CoTran™9719或CoTranTM9720)组成,或者更优选由具有4.5%至19%之乙酸乙烯酯比例的聚乙烯(例如,CoTran™9707、CoTran™9702、CoTran™9728)组成。膜还可具有高达90%的孔隙率(例如**Solupor**® 10P05A、**Celgard**® 2400)。

[0085] 可使用多孔膜或相干膜(**kohärente** membranen)。

[0086] 多孔膜的孔隙率可高达约90%。优选的多孔膜的数据为:

[0087] **Solupor®** 10P05A(聚乙烯,孔隙率:83%,厚度:60μm)

[0088] **Celgard®** 2400(聚丙烯,孔隙率:41%,厚度:25μm)

[0089] 优选的相干膜的数据为:

[0090] CoTran™9719(聚乙烯,厚度:43.2μm)

[0091] CoTran™9720(聚乙烯,厚度:76.2μm)

[0092] CoTran™9707(具有4.5%乙酸乙烯酯的聚乙烯,厚度:50.8μm)

[0093] CoTran™9702(具有9.0%乙酸乙烯酯的聚乙烯,厚度:50.8μm)

[0094] CoTran™9728(具有19.0%乙酸乙烯酯的聚乙烯,厚度:50.8μm)

[0095] 通常,膜具有0.01至0.15mm的厚度。优选的膜厚度为0.025至0.080mm。

[0096] 根据本发明,优选使用具有约40至80μm之厚度的基本由聚乙烯组成的相干膜(例如,CoTran™9720)。根据本发明,还优选使用基本由具有约19.0%乙酸乙烯酯之聚乙烯组成的相干膜(例如,CoTran™9728)。根据本发明,最优选使用具有约40至50μm之厚度的基本由聚乙烯组成的相干膜(例如CoTran™9719)。

[0097] 膜是基本制剂成分,以确保活性物质在数天中的受控递送。尤其是,可通过膜中的乙酸乙烯酯比例来控制药物递送。

[0098] 粘合层

[0099] 优选地,根据本发明的TTS的粘合层包含作为接触型粘合剂的聚异丁烯和任选地用于改善粘合性的聚丁烯。聚异丁烯是不会固化的自粘附接触型粘合剂,因此在长时期内保持其粘合性质。优选地,使用作为混合物的具有不同平均分子量的聚异丁烯。可得到多种平均分子量的聚异丁烯。在本申请中与聚异丁烯相关的术语"平均分子量"是指所谓的粘度平均值M_v。在20℃下由聚异丁烯在异辛烷中之溶液的溶液粘度来测定粘度平均值M_v。作为测定设备,使用Ubbelohde粘度计。由以下方程计算粘度平均值M_v:

[0100]

$$M_V = \frac{0.65}{} \sqrt{\frac{J_0 \times 10^2}{3.06}}$$

[0101] 根据来自所测量之比粘度η_{SP}和溶液浓度的Schulz-Blaschke关系进行对于测定粘度平均值M_v所需要之固有粘度J_0的评估。

[0102] $J_0 = \eta_{sp}/c(1+0.31\times\eta_{sp})cm^3/g$(Schulze-Blaschke关系)

[0103] 比粘度$\eta_{SP} = t/t_0-1$,其中t和t_0分别是溶液或溶剂的流动时间(各自具有Hagenbach-Couette校准),并且c为以g/cm^3计的溶液浓度。任选地,可另外地考虑规定DIN53728。

[0104] 聚异丁烯的合适的平均分子量M_V例如为约40,000g/mol至约4,000,000g/mol。可能的混合物是(1)具有约40,000g/mol之平均分子量M_V的聚异丁烯(例如,**Oppanol®** B10,可购自BASF)和(2)具有超过约1,000,000g/mol之平均分子量M_V的聚异丁烯(z.B. **Oppanol®** B100,可购自BASF,具有约1,110,000g/mol之平均分子量)。将多种分子量以合适的比率进行混合例如以实现粘合层的期望性质,这是在技术人员的知识内的。

[0105] 粘合层中的聚异丁烯可具有这样的分子量分布,其具有30,000g/mol至100,000g/mol的第一相对最大值和300,000g/mol至500,000g/mol的第二相对最大值。

更优选地，第一相对最大值为 35,000g/mol 至 50,000g/mol 并且独立地第二相对最大值为 350,000g/mol 至 450,000g/mol。最优选地，第一相对最大值为约 40,000g/mol 并且独立地第二相对最大值为约 400,000g/mol。

[0106] 可通过将具有 30,000g/mol 至 100,000g/mol 之平均分子量 M_V 的第一聚异丁烯聚合物与具有 300,000g/mol 至 500,000g/mol 之平均分子量 M_V 的第二聚异丁烯聚合物相混合来获得接触型粘合剂的聚异丁烯混合物。优选地，第一聚异丁烯聚合物具有 35,000g/mol 至 50,000g/mol、最优选约 40,000g/mol 的平均分子量 M_V。优选地，第二聚异丁烯聚合物具有 350,000g/mol 至 450,000g/mol、最优选约 400,000g/mol 的平均分子量 M_V。

[0107] 最优选的混合物是 (1) 具有约 40,000g/mol 之平均分子量 M_V 的聚异丁烯（例如，**Oppanol**® B10SFN，可购自 BASF）和 (2) 具有约 400,000g/mol 之平均分子量 M_V 的聚异丁烯（例如，**Oppanol**® B50SF，可购自 BASF）。

[0108] 两种聚异丁烯聚合物在混合物中的比例可变。第一聚异丁烯聚合物与第二聚异丁烯聚合物在混合物中的重量比可以是 10 ：1 至 1 ：10，优选 2 ：1 至 1 ：2，最优选 3 ：2 至 2 ：3。在一些特别优选的实施方案中，接触型粘合剂的聚异丁烯聚合物由按重量计 40 至 60%**Oppanol**® B10（例如**Oppanol**® B10SFN）和按重量计 60 至 40%**Oppanol**® B50SF 组成。

[0109] 优选地，根据本发明改善的粘合层另外地包含聚丁烯。聚丁烯的合适平均分子量 M_N 例如为约 500 至 10,000g/mol。聚丁烯还优选地以不同平均分子量的混合物存在。优选的混合物为 (1) 具有约 900g/mol 之平均分子量 M_N 的聚丁烯（例如，**Indopol**® H-100，具有平均分子量 M_N = 910g/mol，可购自 Ineos）和 (2) 具有约 6,000g/mol 之平均分子量 M_N 的聚丁烯（例如，**Indopol**® H-18000，可购自 Ineos）。

[0110] 另一个优选的混合物为 (1) 具有约 900g/mol 之平均分子量 M_N 的聚丁烯（例如 **Indopol**® H-100，具有平均分子量 M_N = 910g/mol，可购自 Ineos）和 (2) 具有约 2,500g/mol 之平均分子量 M_N 的聚丁烯（例如**Indopol**® H-1900，可购自 Ineos）。

[0111] 特别优选的混合物为 (1) 具有约 2,500 之平均分子量 M_N 的聚丁烯（例如 **Indopol**® H-1900，可购自 Ineos）和 (2) 具有约 6,000g/mol 之平均分子量 M_N 的聚丁烯（例如**Indopol**® H-18000）。将多种分子量以合适的比率进行混合，使得在系统中实现粘合层在活性物质之粘合性和释放率方面的期望性质，这是在技术人员的知识内的。

[0112] 两种聚丁烯在粘合层中的比例可变。第一聚丁烯与第二聚丁烯的重量比优选为 2 ：1 至 1 ：2，最优选 3 ：2 至 2 ：3。在一个特别优选的实施方案中，粘合层中的聚丁烯聚合物由按重量计 40%的具有约 2,500g/mol 之平均分子量 M_N 的聚丁烯和按重量计约 60%的具有 6,000g/mol 之平均分子量 M_N 的聚丁烯组成。

[0113] “平均分子量 M_V”为数均摩尔质量并且可根据“美国标准”ASTMD3536-91 或 ASTM D5296-05 进行确定。

[0114] 根据本发明的改善的粘合层的成分（聚异丁烯和聚丁烯）优选地以 4 ：1 至 1 ：2、更优选 3 ：1 至 1 ：2 的重量比存在。例如，聚异丁烯和聚丁烯可以以约 1 ：1 的

重量比存在。在另一个实施方案中，聚异丁烯和聚丁烯以约 7 ： 3 的重量比存在。

[0115] 优选地，基于粘合层的总重量，粘合层包含按重量计约 10 至约 90%、优选按重量计约 25 至约 75%、最优选按重量计约 40 至约 70%的聚异丁烯（例如，按重量计约 50%或按重量计约 70%）。这些比例表明了聚异丁烯或聚异丁烯混合物在粘合层中的总含量。优选地，基于粘合层的总重量，粘合层还包含按重量计约 5 至约 80%、优选按重量计约 15 至约 60%、最优选按重量计约 25 至约 50%的聚丁烯（例如按重量计约 50%或按重量计约 30%）。这些比例分别表明了聚丁烯或聚丁烯混合物在粘合层中的总含量。

[0116] 在一个优选的实施方案中，粘合层不包含任何丙烯酸酯聚合物和丙烯酸酯共聚物。

[0117] 不特别地限制粘合层的厚度（干燥厚度）。其可以是约 10-300μm，或者 70-140μm。粘合层的绝对量可以是约 10-50g/m^2 或 20-40g/m^2，但不限于此。

[0118] 通常，粘合层包含按重量计 60-100%的接触型粘合剂（例如聚异丁烯）或接触型粘合剂之混合物，其分别包含粘合增强剂（例如聚丁烯）。粘合层的另一些可能的成分为增塑剂和凝胶形成剂。

[0119] 合适的增塑剂为本领域已知，并且这些优选地为矿物油、中性油、石蜡、亚麻籽油、棕榈酸辛酯、角鲨烯、角鲨烷、硅油、肉豆蔻酸异丁酯、异硬脂醇和 / 或油醇，更优选矿物油、中性油和 / 或石蜡。矿物油为无色透明烃类。将它们从在约 300℃以上沸腾的石油的蒸馏级分中回收并通过冷却从固体烃中释放出来。通过合适的分级，可回收这样的矿物油，其在体温（即在约 35-37℃）下为液体并且在低温下（特别是在低于 20℃的温度下）为固体。优选选择具有约 30-35℃之液化点的矿物油。特别地优选石蜡和矿物油，其对应于 Ph.Eur.6 和 / 或 USP32-NF27 的要求。

[0120] 通常，基于粘合层的总重量，增塑剂以按重量计 0-40%或按重量计 1-10%或按重量计 2-5%（例如按重量计 2%）的量在粘合层中存在。

[0121] 优选地，凝胶形成剂是具有微粒结构和在其表面上高浓度极性基团的凝胶形成剂。这些相应地引起朝向油的高界面张力，其通过颗粒本身之间的凝聚形成凝胶骨架而部分地被补偿。因此，总是油和骨架形成剂的表面之间的极性差异越大，凝胶骨架越坚固。根据本发明，优选使用高度分散的二氧化硅或热解硅酸作为凝胶形成剂。颗粒的大小优选地为纳米级并且例如为 400-1500nm，特别地为 500-1000nm。热解硅酸例如以名称 **CAB-O-SIL®** 销售并且是矿物油的已知增稠剂。合适的凝胶形成剂的另一个实例是皂土 (Bentonit)。还可使用已知作为凝胶形成剂的卡波姆钠 (Natriumcarbomer)。

[0122] 基于粘合层的重量，优选地以按重量计 0-4.0%、更优选按重量计 0.1-2.0%、仍更优选按重量计 0.5-2.0%的量使用凝胶形成剂。

[0123] 在根据本发明的 TTS 的一个特别优选的实施方案中，基于粘合层的总重量，粘合层由以下组成：按重量计 99.5%的具有不同分子量之聚异丁烯和具有不同分子量之聚丁烯的混合物以及按重量计 0.5%的凝胶形成剂（优选高度分散的二氧化硅或热解硅酸）。

[0124] 覆盖层

[0125] 优选地，根据本发明的 TTS 的覆盖层是闭塞的，其为末端。在一个优选的实施方案中，这样的覆盖层可由聚烯烃（特别是聚乙烯）或聚酯以及聚氨酯组成。还可优选地使用包含在互相的顶部布置之数种不同聚合物的层。合适的材料包括聚烯烃、玻璃

纸 (Zellophan)、乙酸纤维素、乙基纤维素、具有增塑剂的乙酸乙烯酯 - 氯乙烯共聚物、乙烯 - 乙酸乙烯酯共聚物、聚对苯二甲酸乙二醇酯、尼龙、聚乙烯、聚丙烯、聚偏二氯乙烯、乙烯 - 甲基丙烯酸酯共聚物、可任选被涂布的纸、纺织面料 (textile Gewebe)、铝箔和聚合物 - 金属复合材料。尤其优选聚酯箔，例如聚对苯二甲酸乙二醇酯箔。在本领域中，通常地，背衬层的厚度可以是例如 10μm 至 100μm，例如约 40μm（标称厚度）。尤其优选的是着色的 PE、PETP 和铝的复合箔。

[0126] 拉脱层

[0127] 根据本发明，在粘合层上存在拉脱层，也称为“离型衬里”。优选地，所述拉脱层由还可任选地被金属化的聚合物材料制备。优选使用的材料的实施例是聚氨酯、聚乙酸乙烯酯、聚偏二氯乙烯、聚丙烯、聚碳酸酯、聚苯乙烯、聚乙烯、聚对苯二甲酸乙二醇酯、聚对苯二甲酸丁二醇酯以及任选地用相应聚合物涂布表面的纸。优选地，其为在一侧或两侧上含氟聚合物涂布或硅化的拉脱层。特别优选常见的含氟聚合物涂布的或硅化的聚酯箔，例如一侧硅化的商品 Primeliner100μm 和 Perlasic LF75μm(Loparex, NL and Perlen Converting AG, Switzerland) 或者一侧涂布含氟聚合物的产品，例如 ScotchPak1022(3M Drug delivery)。

[0128] 其他方面和实施方案

[0129] 根据本发明的 TTS 的一个特别优选的实施方案是用于通过皮肤施用活性物质的 TTS，其包含：

[0130] a) 覆盖层，

[0131] b) 覆盖层上的活性物质层，基于活性物质层的总重量，其包含按重量计 30-50％的活性物质和按重量计 50-70％的聚合物基质，其中聚合物基质基本由不含羟基并且不含羧基的丙烯酸酯聚合物组成，或者基本由不含羟基并且不含羧基的丙烯酸酯共聚物组成，其中活性物质是卡巴拉汀或者其生理可相容的盐、水合物、溶剂合物或衍生物；

[0132] c) 活性物质层上的膜，其控制卡巴拉汀的释放；

[0133] d) 膜上的粘合层，其由按重量计 0-1％的二氧化硅和按重量计 99-100％的以下之混合物组成：具有约 40,000g/mol 之平均分子量 M_V 的聚异丁烯聚合物、具有约 400,000g/mol 之平均分子量 M_V 的聚异丁烯聚合物、具有约 2,500g/mol 之平均分子量 M_N 的聚丁烯聚合物和具有约 6,000g/mol 之平均分子量 M_N 的聚丁烯聚合物；以及

[0134] e) 粘合层上的拉脱层。

[0135] 特别地，在不含覆盖层和拉脱层的该实施方案的整个制剂中抗氧化剂的量按重量计低于 0.1％，优选低于 0.01％。

[0136] 在一个特别优选的实施方案中，根据本发明的 TTS 不含选自维生素 E 及其酯、丁基羟基甲苯和丁基羟基茴香醚的抗氧化剂。

[0137] 优选地，根据本发明的 TTS 具有基本线性的渗透曲线。在此，在至少 24 小时、优选至少 48 小时、更优选至少 72 小时、最优选至少 96 小时或至少 120 小时或至少 144 小时或至少 168 小时的时长中的渗透基本是线性的。可通过本领域技术人员已知的渗透测试本身来确定渗透作用，例如通过根据“OECD GUIDELINE FOR THE TESTING OF CHEMICALS. Skin Absorption :in vitro method”Test Guideline428. Adopted13April2004：1-8 的体外渗透测试。优选地，术语“基本线性”意指渗透速率（以每单位时间和单位面积渗透的量表示）

在长时间中没有显著变化，使得渗透曲线具有基本线性的进程。但是，特别在初始阶段，可发生所谓的潜伏期，其中渗透尚未具有恒定的渗透速率，此外，因很强的系统释出，渗透速率可能在非常迟的时间点降低。

[0138] 在一个特定的实施方案中，体内的平均释放速率为 0.1mg/ 天 /cm^2 至 2mg/ 天 /cm^2，优选 0.2mg/ 天 /cm^2 至 1mg/ 天 /cm^2 并且最优选至少 0.3mg/ 天 /cm^2。

[0139] 本发明的另一个方面是提供用于产生根据本发明的 TTS 的方法。本方法包括

[0140] i) 制备包含活性物质层的组分，其包含覆盖层和活性物质层，活性物质层在应是覆盖层面向皮肤之侧的一侧；

[0141] ii) 制备包含粘合层的组分，其包含拉脱层和拉脱层上的粘合层以及任选地控制活性物质之释放的膜；

[0142] iii) 将 i) 和 ii) 的组分层压在彼此上，使得覆盖层和拉脱层在最终 TTS 的横截面中代表相反的最外层。

[0143] 本方法的一个实施方案包括：

[0144] i) 在应是覆盖层面向皮肤之侧的一侧上应用形成活性物质层之组合物的薄膜并任选地随后干燥，并且任选地用控制活性物质之释放的膜进行衬垫，所述组合物任选地为在合适介质中的溶液或分散体的形式；

[0145] ii) 在拉脱层上应用形成粘合层之组合物的薄膜并任选地随后干燥，所述组合物任选地为在合适介质中的溶液或分散体的形式；以及

[0146] iii) 将 i) 和 ii) 的组分层压在彼此上，使得覆盖层和拉脱层在最终 TTS 的横截面中代表相反的最外层。

[0147] 本方法的另一个实施方案包括：

[0148] i) 在硅化拉脱箔（“中间衬里”）上应用形成活性物质层之组合物的薄膜并任选地随后干燥，并用覆盖层进行衬垫，所述组合物任选地为在合适介质中的溶液或分散体的形式；

[0149] ii) 将硅化拉脱箔（“中间衬里”）拉脱并用控制活性物质之释放的膜进行衬垫；

[0150] iii) 在拉脱层上应用形成粘合层之组合物的薄膜并任选地随后干燥，所述组合物任选地为在合适介质中的溶液或分散体的形式；以及

[0151] iv) 将 ii) 和 iii) 的组分层压在彼此上，使得覆盖层和拉脱层在最终 TTS 的横截面中代表相反的最外层。

[0152] 可通过以下进行优选 TTS 的制备：首先将用于活性物质层的组分（其分别为活性物质（优选卡巴拉汀）和基质形成聚合物或共聚物，或者其混合物）分别分散或溶解（除非聚合物已经溶解）在有机溶剂（例如庚烷或乙酸乙酯）中。通常，溶剂中已经存在基质形成聚合物或共聚物或者其混合物。在此，根据本发明，使用如上文定义的与根据本发明的 TTS 相关的聚合物和 / 或共聚物，其为不含羟基并且不含羧基的聚合物和 / 或共聚物。作为优选的上述聚合物基质的一些实施方案相应地适用于根据本发明的方法。在活性物质层的制备中，优选使用挥发性有机溶剂。之后，将所述混合物应用至作为均一层的覆盖层并干燥。如果要使用控制活性物质之释放的膜，那么活性物质层被干燥之后，可将其应用至与覆盖层相对的活性物质层的一侧，代替“中间衬里”。优选地，用于保护的活性物质层的组分配置有箔，优选硅化聚酯箔，也称为“中间衬里”，将其应用至与覆盖层相对的活性物质层的一

侧。可替换地或同等地，首先还可将混合物应用至“中间衬里”并干燥，随后将覆盖层应用至与“中间衬里”相对的活性物质层的一侧。在将要将活性物质层组分与含有粘合层之组分拼合在一起之前，除去“中间衬里”。任选地，拉脱“中间衬里”之后，在与粘合层进行拼合之前还可衬垫控制膜。

[0153] 在一个单独的步骤中，通过将形成接触型粘合剂的聚合物混合物（并溶解在有机溶剂中）（优选不同平均分子量的聚异丁烯）任选地与粘合增强剂、凝胶形成剂和/或增塑剂一起分散于有机溶剂（例如庚烷）中来制备粘合层。但是，优选的是，将接触型粘合剂及粘合增强剂和/或增塑剂溶解于有机溶剂中，随后将凝胶形成剂分散于该溶液中。之后，将所述混合物应用至拉脱薄膜并使其干燥。作为优选的上述粘合层的实施方案相应地适用于根据本发明的方法。

[0154] 随后将在这两个过程步骤中获得的组分一起层压，即优选地使粘合层直接施用至活性物质层。在使用膜的一些实施方案中，将粘合层应用至膜。随后，可由最终经层压的箔冲压出期望大小的片块并包装。

[0155] 在单个过程步骤中，通过使产物经受升高的温度（任选地另外使用部分真空）来除去使各个组分溶解或分散所需要的有机溶剂。

[0156] 本发明的另一个方面是不含氨基或羟基或羧基的聚合物或共聚物在包含卡巴拉汀之 TTS 中的用途，所述 TTS 适合用于至少两天或至少二天（例如，两天、三天、四天、五天、六天或七天）的施用时期。使用如上文定义的聚丙烯酸酯、丙烯酸酯 - 乙酸乙烯酯共聚物、聚异丁烯和苯乙烯 - 丁二烯共聚物是优选的。根据本发明，这些聚合物或共聚物表示活性物质层的聚合物基质，其中嵌入了活性物质卡巴拉汀。

[0157] 本发明的另一个方面是不含游离羟基并且不含游离羧基的聚合物或共聚物用于稳定 TTS 中卡巴拉汀或用于降低 TTS 中卡巴拉汀之降解的用途。本发明的另一个方面是不含游离氨基或游离羟基或游离羧基的聚合物或共聚物用于稳定 TTS 中卡巴拉汀或者用于降低 TTS 中卡巴拉汀之降解的用途。

[0158] 优选地，在根据本发明的用途中，使用不含氨基、不含羟基并且不含羧基的聚丙烯酸酯和聚丙烯酸酯共聚物，例如丙烯酸酯 - 乙酸乙烯酯共聚物。

[0159] 在根据本发明的用途的一个特别优选的实施方案中，使用丙烯酸酯 - 乙酸乙烯酯共聚物**Duro-Tak**® 87-4098。

[0160] 在根据本发明的用途的另一个特别优选的实施方案中，使用丙烯酸酯聚合物**Duro-Tak**® 87-9088。

[0161] 本发明的另一个方面是聚异丁烯和聚丁烯作为接触型粘合剂/粘合增强剂的独有成分在 TTS 之粘合层中的用途，所述 TTS 适合用于至少两天或至少三天的施用时期。在此，根据本发明的前述方面，聚异丁烯和聚丁烯优选地作为不同平均分子量之混合物存在。

[0162] 本发明的另一个方面是提供用于治疗阿尔茨海默病和帕金森痴呆的根据本发明的 TTS。在此，优选地制备的根据本发明的 TTS 用于至少两天或至少三天的施用时期。还可能是更长的施用时期。

[0163] 下文中，关于实验性实施例描述了根据本发明的 TTS 的一些优选实施方案并且在稳定性方面确定了其性质。

[0164] 附图 1-7 说明

[0165] 下文中，参数“n”表示导致平均结果而进行的测量之重复数目。

[0166] 图 1：具有膜的卡巴拉汀 TTS 的横截面示意图（非实际比例）。

[0167] 图 2：关于在 25℃ /60% r.h. 和 40℃ /75% r.h. 下贮存 9 周后活性物质层的最大冷变形的图 (n = 2)。

[0168] 图 3：关于根据实施例制备的粘合层之粘合性的图 (n = 3)。

[0169] 图 4：来自**Exelon®**的卡巴拉汀的体外渗透曲线 (n = 6)。

[0170] 图 5：来自具有或不具有膜之两层层压物的卡巴拉汀的体外渗透曲线 (n = 4)。

[0171] 图 6：来自具有基于聚丙烯酸酯粘合剂之粘合层的两层层压物的卡巴拉汀的体外渗透曲线 (n = 4)。

[0172] 图 7：与**Exelon®**相比来自具有不同膜和粘合层之两层层压物的卡巴拉汀的体外渗透曲线 (n ≥ 4)。

[0173] 图 8：来自具有不同膜之两层层压物的卡巴拉汀的体外渗透曲线 (n ≥ 4)。

[0174] 图 9：来自具有不同膜之两层层压物的卡巴拉汀的体外释放曲线 (n ≥ 4)。

实施例

[0175] 如下可更详细地描述在以下制剂实施例中使用的组分：

[0176] 表 1：制剂实施例之组分的总结

[0177]

组分名称	化学描述	功能
Duro-Tak® 87-4098	丙烯酸酯/乙酸乙烯酯共聚物	基质聚合物
Duro-Tak® 87-9088	丙烯酸酯共聚物	基质聚合物
Cab-O-Sil®	热解硅石	凝胶形成剂
Oppanol® B10	聚异丁烯 (M_V= 约 $4x10^4$ g/mol)	接触型粘合剂
Oppanol® B50 SF	聚异丁烯 (M_V= 约 $4x10^5$ g/mol)	接触型粘合剂
Indopol H-100, H-1900, H-6.000, H-18.000	聚丁烯 (M_N = 910, 2.500, 4.200 或 6.000 g/mol)	增粘剂
Eudragit® E100	丙烯酸酯共聚物	基质聚合物

[0178] 实施例 1

[0179] 不同活性物质层制剂的制备

[0180] 制备了包含卡巴拉汀基底的三种不同活性物质层制剂。表 2 中给出了不同制剂之成分的总结。

[0181] 表 2：使用的活性物质层

[0182]

装载物	活性物质层（R）	基质重量 mg/10cm²
010RIDTDS	40 % 卡巴拉汀； 60 % DT® 87-9088	64
011RIDTDS	40 % 卡巴拉汀； 60 % DT® 87-4098	62
012RIDTDS	40 % 卡巴拉汀； 60 % Eudragit® E100	54

[0183] 在图 2 中，给出了对于前述库制剂之物理稳定性（冷变形）的结果。具有**DT**® 87-9088(010RIDTDS) 的制剂在贮存 9 周后显示出最低的冷变形，因此其作为用于活性物质层之基质形成剂是特别合适的。

[0184] 实施例 2

[0185] 制备了六种不同的粘合层制剂。表 3 给出了不同制剂之成分的总结。

[0186] 表 3：使用的粘合层

[0187]

装载物	粘合层（A）	基质层 mg/10 cm²
019RIDTDS	17,91 % Oppanol® B10 SFN; 31,84 % Oppanol® B50SF; 29,85 % Indopol® H-100; 19,90 % Indopol® H-1900; 0,50 % Cab-O-Sil® M5P	30
005RIDTDS	24,88 % Oppanol® B10 SFN; 24,88 % Oppanol® B50SF; 24,88 % Indopol® H-100; 24,88 % Indopol® H-1900; 0,50 % Cab-O-Sil® M5P	32
013RIDTDS	24,88 % Oppanol® B10 SFN; 24,88 % Oppanol® B50SF; 24,88 % Indopol® H-100; 24,88 % Indopol® H-6000; 0,50 % Cab-O-Sil® M5P	32
014RIDTDS	24,88 % Oppanol® B10 SFN; 24,88 % Oppanol® B50SF; 24,88 % Indopol® H-100; 24,88 % Indopol® H-18000; 0,50 % Cab-O-Sil® M5P	30
015RIDTDS	29,85 % Oppanol® B10 SFN; 19,90 % Oppanol® B50SF; 19,90 % Indopol® H-1900; 29,85 % Indopol® H-18000; 0,50 % Cab-O-Sil® M5P	35
C006RIVTDS	64,5 % Oppanol® B10 SFN/B50SF (4/6); 35,0 % 石蜡； 0,5 % Cabo-O-Sil®	30

[0188] 在图 3 中，示出了所制备粘合层之粘合性的测量结果。这些示出，与使用石蜡相比，通过向**Oppanol**®粘合剂添加**Indopol**®，显著地改善了粘合性。还可通过特定选择所使用聚合物之分子量来进一步提高和控制粘合性。

[0189] 实施例 3

[0190] 最后，制备了六种不同装载物 (Chargen，charge) 的 TTS 制剂。表 4 对不同装载物的组成进行了总结。

[0191] 表 4：使用的装载物：

[0192]

装载物	活性物质层（R）	粘合层（A）	膜	基质重量 mg/10 cm²
015/017 RIDTDS（无膜）	40% 卡巴拉汀; 60% DT® 87-9088	29,65% Oppanol® B10 SFN 19,90% Oppanol® B50SF 19,90% Indopol® H-1900 29,85% Indopol® H-18000 0,50% Cap-O-Sil M5P	----	015RIDTDS (A): 35 017RIDTDS (R): 60
015/017 RIDTDS CoTran 9719	40% 卡巴拉汀; 60% DT® 87-9088	29,85% Oppanol® B10 SFN 19,90% Oppanol® B50SF 19,90% Indopol® H-1900 28,85% Indopol® H-18000 0,50% Cap-O-Sil M5P	CoTran™ 9719	015RIDTDS (A): 35 017RIDTDS (R): 60
009/010 RIDTDS Celgard 2400	40% 卡巴拉汀; 60% DT® 87-9088	10% 卡巴拉汀; 90% DT® 87-2516	Celgard® 2400	009RIDTDS (A): 33 010RIDTDS (R): 64
009/010 RIDTDS Solupor 10P05A	40% 卡巴拉汀; 60% DT® 87-9088	10% 卡巴拉汀; 90% DT® 87-2516	Solupor® 10P05A	009RIDTDS (A): 33 010RIDTDS (R): 64
029/030 RIDTDS Solupor 10P05A	40% 卡巴拉汀; 60% DT® 87-9088	20% Oppanol® B10 SFN 30% Oppanol® B50SF 30% Indopol® H-100 20% Indopol® H-1900	Solupor® 10P05A	029RIDTDS (A): 34 030RIDTDS (R): 61

[0193]

装载物	活性物质层（R）	粘合层（A）	膜	基质重量 mg/10 cm²
028/030 RIDTDS CoTran 9719	40% 卡巴拉汀; 60% DT® 87-9088	30% Oppanol® B10 SFN 20% Oppanol® B50SF 20% Indopol® H-1900 30% Indopol® H-18000	CoTran™ 9719	028RIDTDS (A): 28 030RIDTDS (R): 61
070/071 RIDTDS CoTran 9720	40% 卡巴拉汀; 60% DT® 87-9088	30% Oppanol® B10 SFN 20% Oppanol® B50SF 20% Indopol® H-1900 30% Indopol® H-18000	CoTran™ 9720	070RIDTDS (A): 30 071RIDTDS (R): 60

[0194] 制备方法

[0195] 1. 活性物质层的制备

[0196] 首先添加丙烯酸酯粘合剂，称重添加卡巴拉汀和乙酸乙酯。随后，通过搅拌器在足够的乙酸乙酯中使组分混合，使得形成可涂抹的均质涂层浆状物。

[0197] 将均质涂层浆状物作为薄薄膜施应用至硅化箔（“中间衬里”）。以 60℃ /20 分钟和 80℃ /5 分钟使基质薄膜干燥，随后用 PET 的覆盖层进行衬垫。

[0198] 随后，将“中间衬里”拉脱并且其衬垫了控制膜。

[0199] 2. 粘合层和整体层压物的制备

[0200] 将聚异丁烯粘合剂一起称重并混合。随后，搅拌下添加庚烷和**Cab-O-Sil®**并搅拌直到浆状物为均质。

[0201] 将浆状物作为薄薄膜应用至拉脱层（“离型衬里”），随后在 60℃ /20 分钟和 80℃ /5 分钟下除去溶剂。干燥后，层压物衬垫了活性物质层。

[0202] 由所获得的层压物冲压出合适大小的贴片。

[0203] 3. 体外小鼠皮肤渗透测试

[0204] 用表 4 的装载物和商品**Exelon®** TDS（单日制剂），进行体外小鼠皮肤渗透测试。

[0205] 图 4 至 7 给出了这些测试的结果。图 4 示出来自市售**Exelon®** TDS 之卡巴拉汀的渗透曲线。图 4 中的曲线痕迹清楚地显示了在 24 小时之后卡巴拉汀的递送速率已经显著降低。因此，该系统没有确保在超过 24 小时的施用时长中的连续并均一的活性物质递送。

[0206] 图 5 示出只有通过插入的膜才使在数天中的连续并均一的活性物质递送成为可能。

[0207] 与**Exelon®** TDS 的动力学相比，包含聚丙烯酸酯作为用于粘合层之基质形成剂的制剂装载物 009/010RIDTDS **Celgard®** 2400 和 009/010RIDTDS **Solupor®** 10P05A 出乎意料地具有相似的动力学（参照图 4 和 6）。这显示了来自聚丙烯酸酯的聚合物及其共聚物不适合作为用于粘合层的基质形成剂，这是因为即使在具有插入的膜的情况下它们也没有确保对活性物质递送在数天的施用时间内的足够控制。

[0208] 图 5 和 7 显示了，通过组合控制活性物质之释放的膜和基于聚异丁烯 / 聚丁烯混合物的粘合层，使经数天的时间间隔控制药物递送成为可能。

[0209] 图 8 显示了，用两种制剂“C008RIDTDS”和“070/071RIDTDS CoTran9720”，实现了在七天中的均一线性渗透曲线。因此，这些制剂特别适合作为 5 天贴片、6 天贴片和 7 天贴片。制剂“C008RIDTDS”来源于临床装载物，并且具有与实施例 4 中描述的制剂 I(060/062RIDTDS_Cotran9719) 相同的组成。

[0210] 4. 体外释放

[0211] 用根据 Ph. Eur. 5.0<2.9.4> 的“Disk assembly Method”测定体外释放。

[0212] 图 9 示出，制剂“C008RIDTDS”和“070/071RIDTDS CoTran9720”二者均表现出在至少七天中的活性物质的均一释放。

[0213] 实施例 4 ：稳定性测试

[0214] 根据上述方法，还制备了两种另外的制剂 ：

[0215] 表 5

[0216]

	制剂 I (060/062RIDTDS_Cotran9719)	制剂 II (058/062RIDTDS_Cotran9728)
活性物质层 60 g/m^2	卡巴拉汀 (40%) DT® 87-9088 (60%)	卡巴拉汀 (40%) DT® 87-9088 (60%)
膜	CoTran™ 9719	CoTran™ 9728
粘合层 30 g/m^2	Oppanol® B10 SFN (30%) Oppanol® B50 SF (20%) Indopol® H-1900 (20%) Indopol® H-18000 (30%)	Oppanol® B10 SFN (30%) Oppanol® B50 SF (40%) Indopol® H-1900 (30%)

[0217] 在铝复合箔的袋中密封经冲压的 TTS，分别在 25℃和 60％相对空气湿度下或在 40℃和 75％相对空气湿度下各自贮存至少一个月。随后，通过 HPLC 和 UV 吸收测定因卡巴拉汀之分解而形成的任选杂质含量。

[0218] 根据本发明的 TTS 显示出在数月内的极好的稳定性。贮存后，虽然活性物质层不包含任何抗氧化剂，但是仅鉴定出了非常低量的杂质 / 分解产物。这是通过使用不含羟基并且不含羧基的聚合物基质来实现的。

[0219]

在下表6中总结了该结果：

		温度	初始	1个月	2个月	3个月
	装载物	C/% r. h.				
纯度 n=3	060/062RIDTDS _CoTran9719	25 / 60	杂质1：0,04%（< RL）； 杂质4：0,02%（< RL）； 杂质5：0,05%（< RL）； → 总计：0,0%	杂质1：0,05%（< RL）； 杂质4：0,06%（< RL）； 杂质5：0,14%； → 总计：0,14%	杂质1：0,02%（< RL）； 杂质4：0,07%（< RL）； 杂质5：**0,18%** → 总计：0,18%	杂质1：0,02%（< RL）； **RRT=0,84**：0,01%（<RL）； 杂质2：0,02%（< RL）； 杂质4：0,06%（<RL）； 杂质5：**0,17%** → 总计：0,17%
		40 / 75		杂质1：0,04%（< RL）； **RRT=0,85**：0,06%（< RL）； 杂质2：0,02%（< RL）； 杂质4：**0,11%**； 杂质5：**0,23%** → 总计：0,34%		
	058/062RIDTDS _CoTran9728	25 / 60	杂质1：0,04%（< RL）； 杂质4：0,02%（< RL）； 杂质5：0,05%（< RL）； → 总计：0,0%	杂质1：0,05%（< RL）； 杂质4：0,05%（< RL）； 杂质5：0,15% → 总计：0,15%	杂质1：0,02%（< RL）； 杂质4：0,06%（< RL）； 杂质5：**0,18%** → 总计：0,18%	杂质1：0,02%（< RL）； **RRT=0,84**：0,02%（<RL）； 杂质2：0,02%（< RL）； 杂质4：0,09%（<RL）； 杂质5：**0,18%** → 总计：0,18%
		40 / 75		杂质1：0,05%（< RL）； **RRT=0,85**：0,04%（< RL）； 杂质2：0,03%（< RL）； 杂质4：0,09%（< RL）； 杂质5：**0,22%** → 总计：0,22%		

RL = “报道极限”（检测极限）
RRT = 相对保留时间（HPLC）

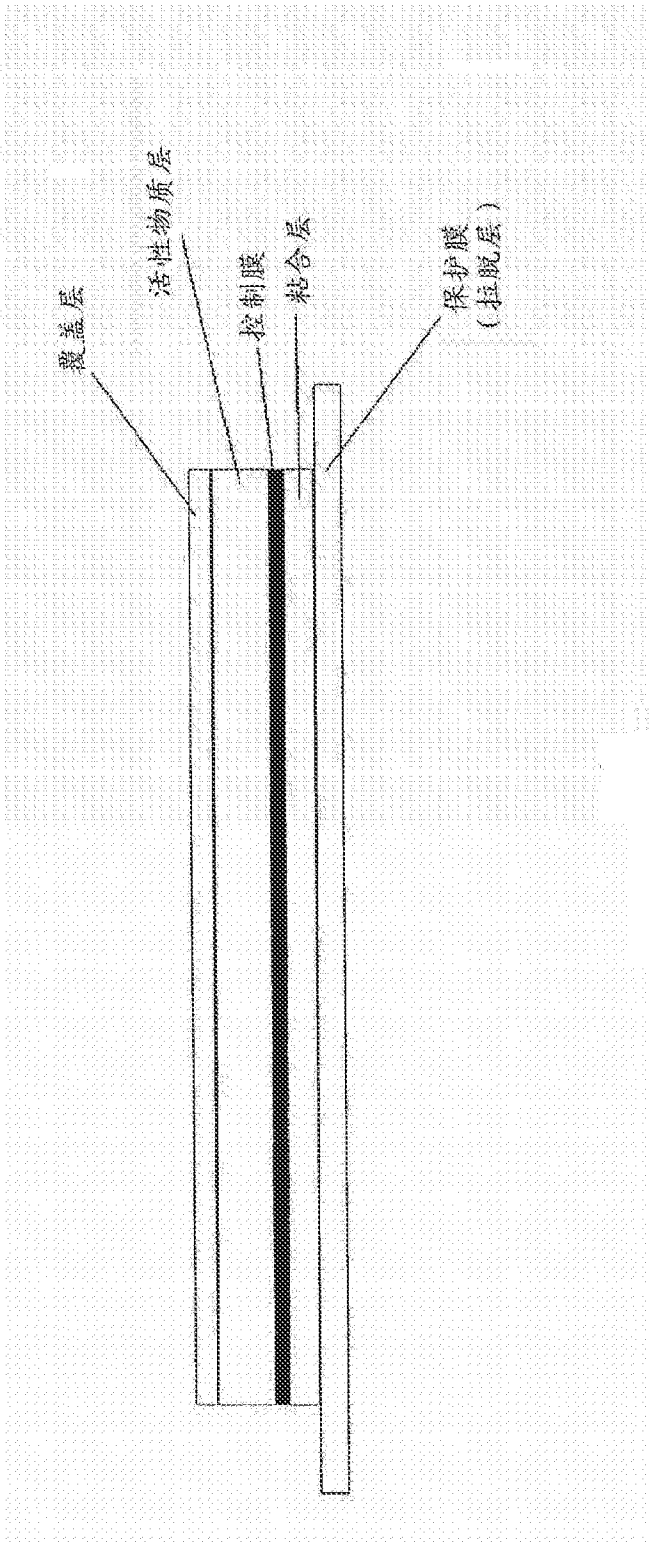


图 1

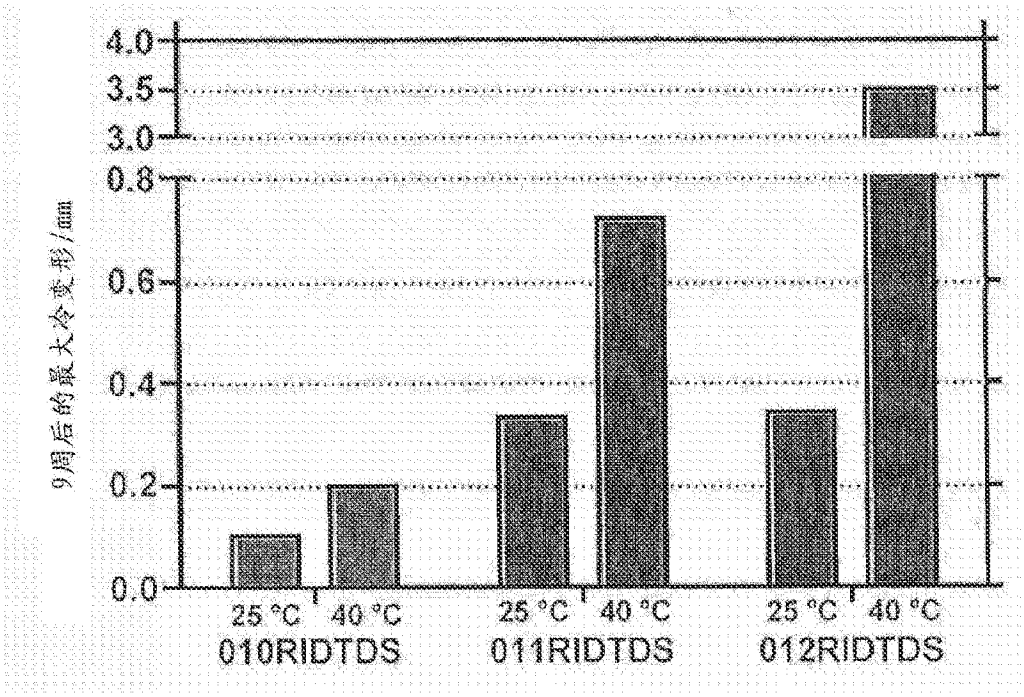

9周后的最大冷变形/mm
4.0
3.5
3.0
0.8
0.6
0.4
0.2
0.0
25 °C
40 °C
25 °C
40 °C
25 °C
40 °C
010RIDTDS
011RIDTDS
012RIDTDS

图 2

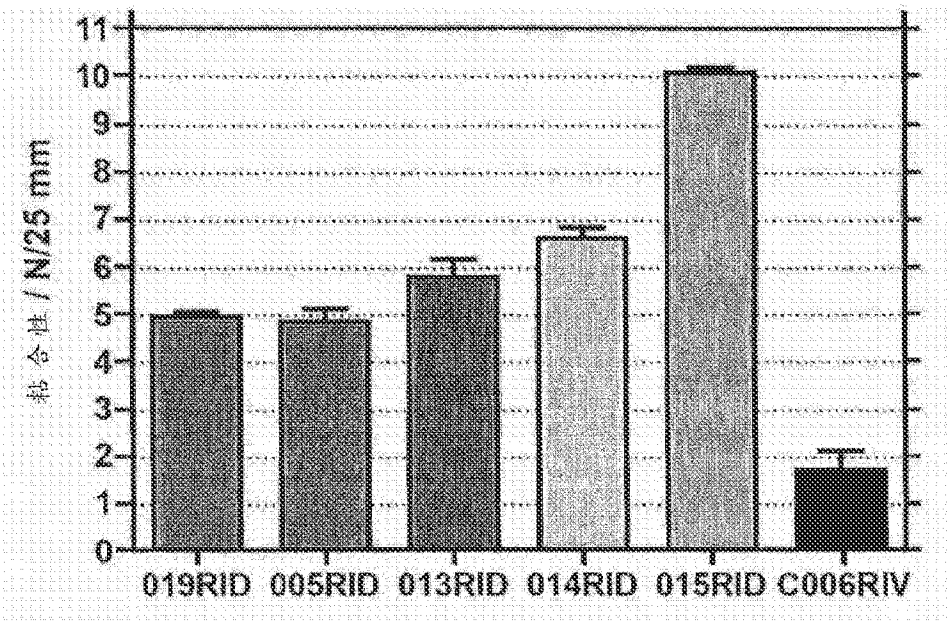

粘合性 / N/25 mm
11
10
9
8
7
6
5
4
3
2
1
0
019RID
005RID
013RID
014RID
015RID
C006RIV

图 3

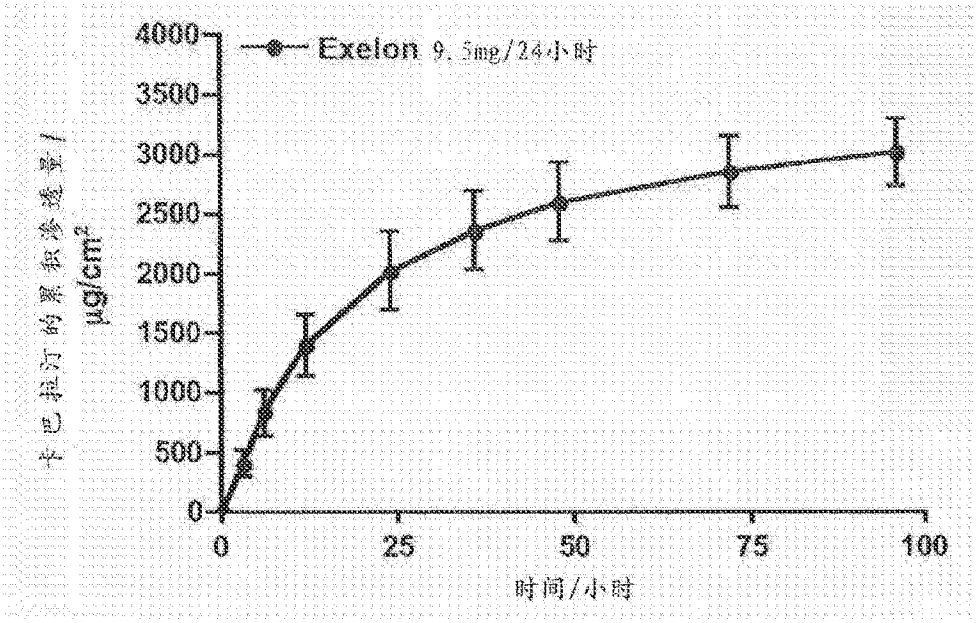

Exelon 9.5mg/24小时
卡巴拉汀的累积渗透量/ μg/cm²
4000
3500
3000
2500
2000
1500
1000
500
0
0
25
50
75
100
时间/小时

图 4

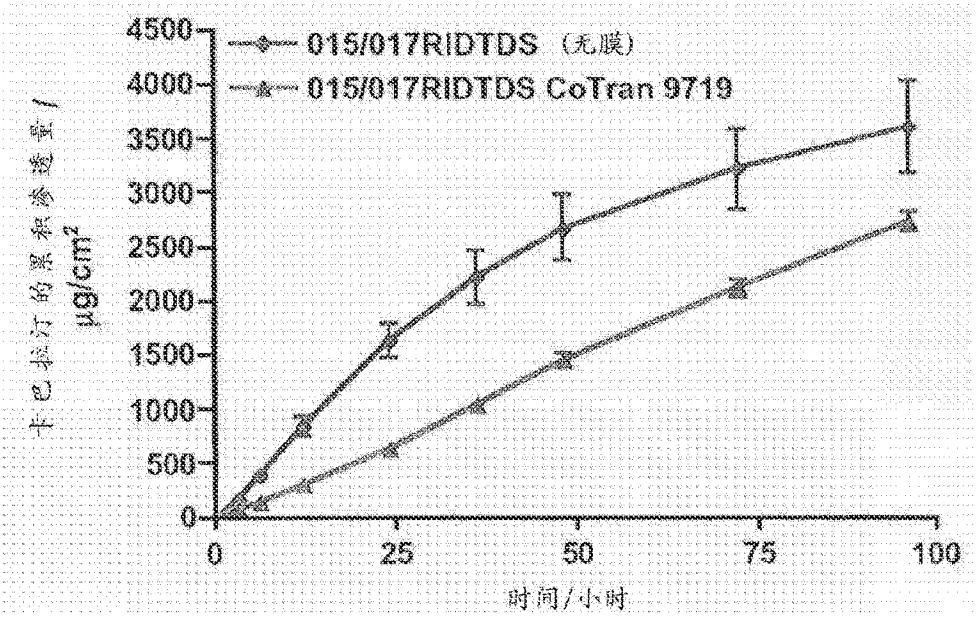

015/017RIDTDS (无膜)
015/017RIDTDS CoTran 9719
卡巴拉汀的累积渗透量/ μg/cm²
4500
4000
3500
3000
2500
2000
1500
1000
500
0
0
25
50
75
100
时间/小时

图 5

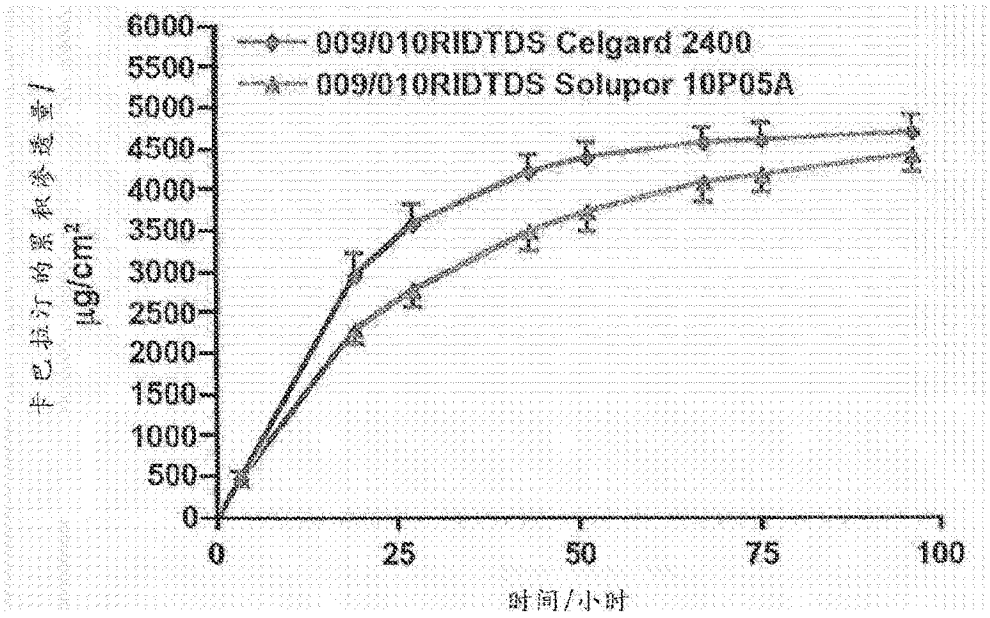

009/010RIDTDS Celgard 2400
009/010RIDTDS Solupor 10P05A
卡巴拉汀的累积渗透量 / μg/cm²
6000
5500
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
0
25
50
75
100
时间/小时

图 6

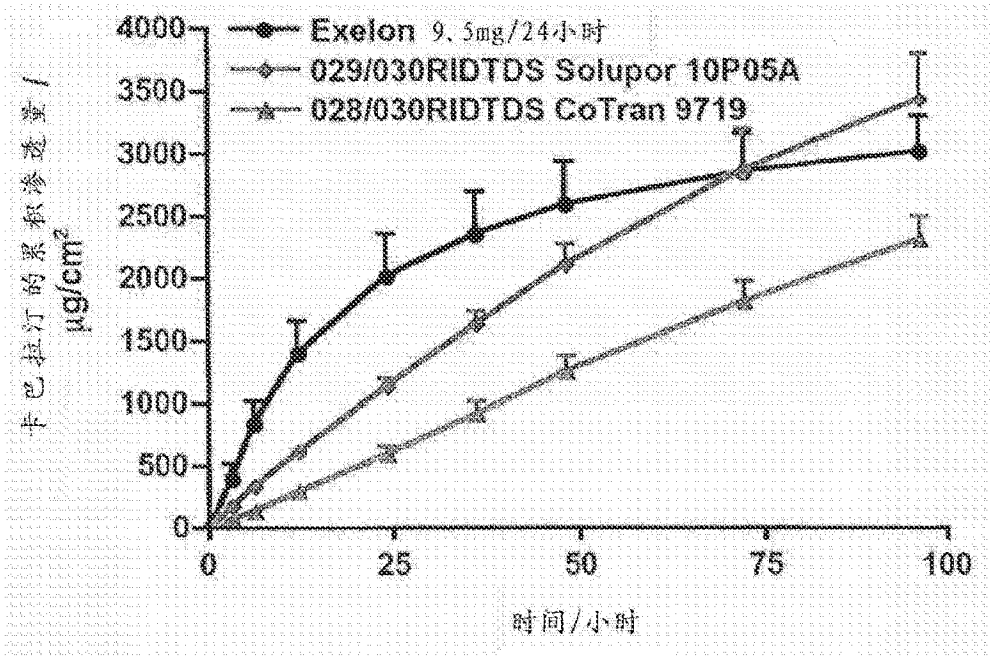

Exelon 9.5mg/24小时
029/030RIDTDS Solupor 10P05A
028/030RIDTDS CoTran 9719
卡巴拉汀的累积渗透量 / μg/cm²
4000
3500
3000
2500
2000
1500
1000
500
0
0
25
50
75
100
时间/小时

图 7

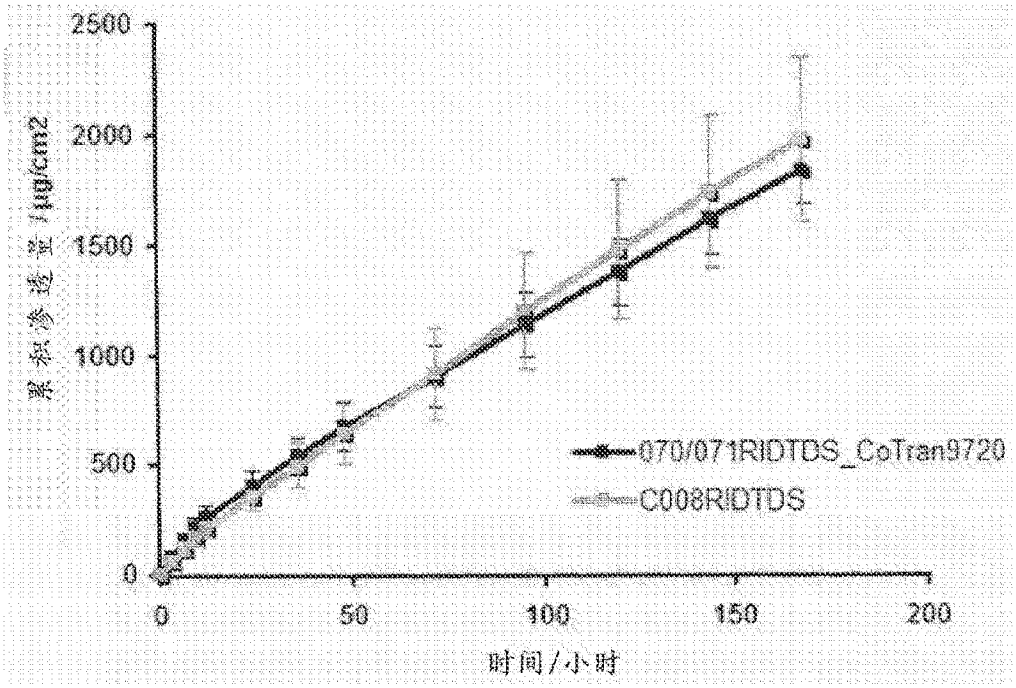

2500
2000
1500
1000
500
0
累积渗透量/μg/cm2
0
50
100
150
200
时间/小时
070/071RIDTDS_CoTran9720
C008RIDTDS

图 8

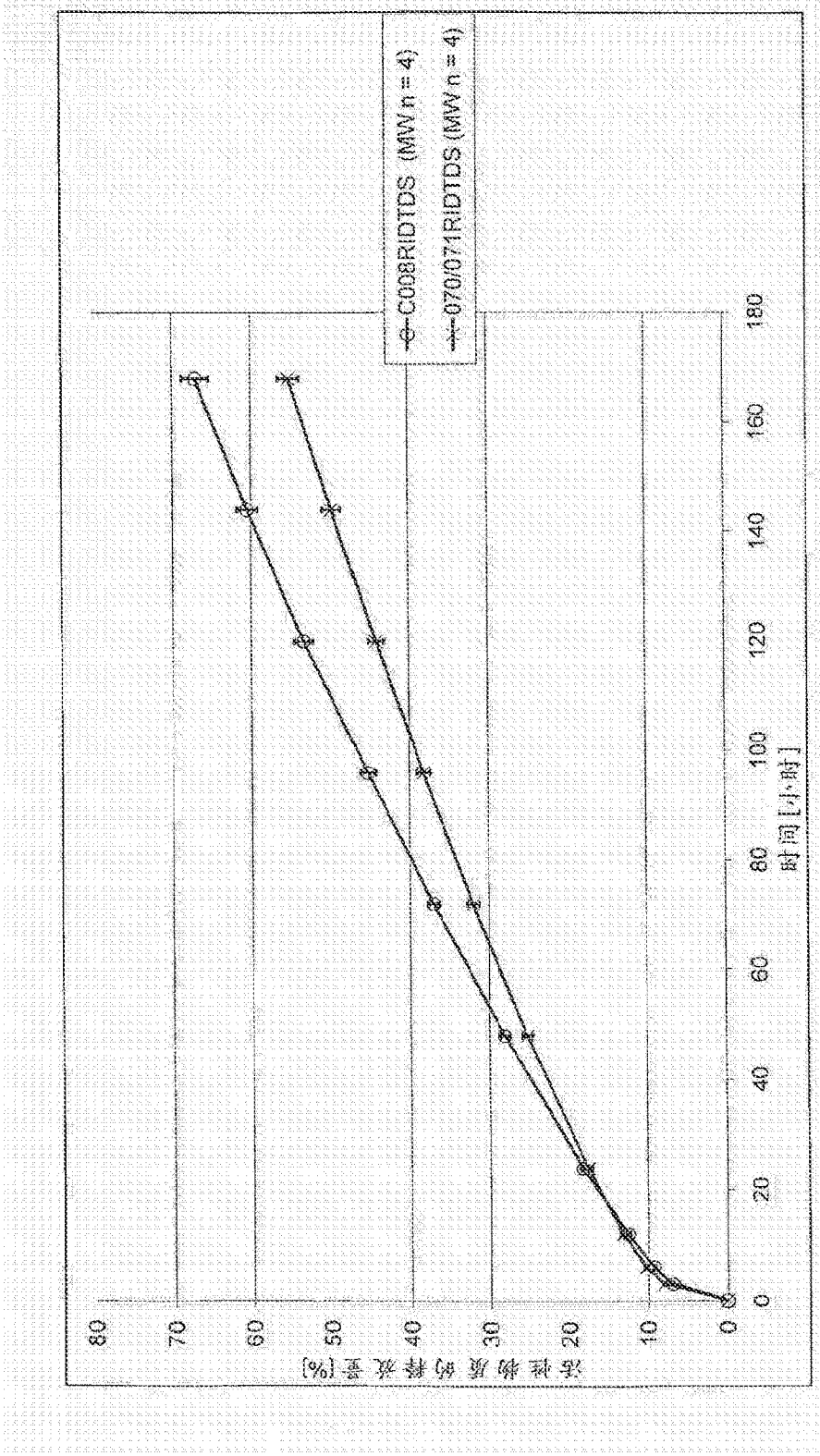

C008RIDTDS (MW n = 4)
070/071RIDTDS (MW n = 4)
活性物质的释放量[%]
时间[小时]
0
10
20
30
40
50
60
70
80
0
20
40
60
80
100
120
140
160
180

图 9

Doc Code: PET.AUTO Document Description: Petition automatically granted by EFS-Web	PTO/SB/140 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**PETITION TO WITHDRAW AN APPLICATION FROM ISSUE AFTER PAYMENT OF THE ISSUE FEE UNDER 37 CFR 1.313(c)**
Application Number	16425067
Filing Date	29-May-2019
First Named Inventor	Peter Johansen
Art Unit	1765
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)
Title	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

An application may be withdrawn from issue for further action upon petition by the applicant. To request that the Office withdraw an application from issue, applicant must file a petition under this section including the fee set forth in § 1.17(h) and a showing of good and sufficient reasons why withdrawal of the application from issue is necessary.

APPLICANT HEREBY PETITIONS TO WITHDRAW THIS APPLICATION FROM ISSUE UNDER 37 CFR 1.313(c).

A grantable petition requires the following items:
(1) Petition fee; and
(2) One of the following reasons:
(a) Unpatentability of one or more claims, which must be accompanied by an unequivocal statement that one or more claims are unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable;
(b) Consideration of a request for continued examination in compliance with § 1.114 (for a utility or plant application only); or
(c) Express abandonment of the application. Such express abandonment may be in favor of a continuing application, but not a CPA under 37 CFR 1.53(d).

Petition Fee

- ○ Small Entity
- ○ Micro Entity
- ◉ Regular Undiscounted

Reason for withdrawal from issue

◯ One or more claims are unpatentable ◉ Consideration of a request for continued examination (RCE) (List of Required Documents and Fees) ◯ Applicant hereby expressly abandons the instant application (any attorney/agent signing for this reason must have power of attorney pursuant to 37 CFR 1.32(b)).
RCE request,submission, and fee. ☐ I certify, in accordance with 37 CFR 1.4(d)(4) that : The RCE request ,submission, and fee have already been filed in the above-identified application on ☒ Are attached.
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who has been given power of attorney in this application. ◯ An attorney or agent registered to practice before the Patent and Trademark Office, acting in a representative capacity. ◯ A sole inventor ◯ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ◯ A joint inventor; all of whom are signing this e-petition

Signature	/Steven A. Avena/
Name	Steven A. Avena
Registration Number	75211

Electronic Patent Application Fee Transmittal

Application Number:	16425067
Filing Date:	29-May-2019
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Filer:	Steven Anthony Avena/Wendy Nishida
Attorney Docket Number:	P008EP.US (87942.0011)

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
PETITION FEE- 37 CFR 1.17(H) (GROUP III)	1464	1	140	140
RCE- 2ND AND SUBSEQUENT REQUEST	1820	1	2000	2000
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**2140**

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Decision Date : March 28, 2022

In re Application of :

Peter Johansen

DECISION ON PETITION

UNDER CFR 1.313(c)(2)

Application No : 16425067

Filed : 29-May-2019

Attorney Docket No : P008EP.US (87942.0011)

This is an electronic decision on the petition under 37 CFR 1.313(c)(2), filed March 28, 2022 , to withdraw the above-identified application from issue after payment of the issue fee.

The petition is **GRANTED.**

The above-identified application is withdrawn from issue for consideration of a submission under 37 CFR 1.114 (request for continued examination). See 37 CFR 1.313(c)(2).

Petitioner is advised that the issue fee paid in this application cannot be refunded. If, however, this application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.

Telephone inquiries concerning this decision should be directed to the Patent Electronic Business Center (EBC) at 866-217-9197.

This application file is being referred to Technology Center AU 1765 for processing of the request for continuing examination under 37 CFR 1.114 .

Office of Petitions

Electronic Acknowledgement Receipt

EFS ID:	45328908
Application Number:	16425067
International Application Number:	
Confirmation Number:	7044
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Customer Number:	26582
Filer:	Steven Anthony Avena/Wendy Nishida
Filer Authorized By:	Steven Anthony Avena
Attorney Docket Number:	P008EP.US (87942.0011)
Receipt Date:	28-MAR-2022
Filing Date:	29-MAY-2019
Time Stamp:	12:53:27
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$2140
RAM confirmation Number	E20223RC53214018
Deposit Account	082623
Authorized User	Wendy Nishida

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Quick Path Information Disclosure Statement	P008DanapakQPIDS.pdf	163766 c13ef6d1709d11b4826a79514e4a3b0331ef6f69	no	1
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	P008DanapakRCE.pdf	85260 acb32888cf5ee93b28970513d71211ec22a3cc5f	no	3
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
3		P008Danapak.pdf	12415121 eca40017978b9229cfe55626553a6a3f4ff2b56e	yes	36

Multipart Description/PDF files in .zip description

Document Description	Start	End
Transmittal Letter	1	2
Information Disclosure Statement (IDS) Form (SB08)	3	4
Foreign Reference	5	36

Warnings:					
Information:					
4	ePetition Request Form	petition-request.pdf	39969 5fa025473c88234173e5ee1e65ae2fd9917ff48b	no	2
Warnings:					
Information:					

5	Fee Worksheet (SB06)	fee-info.pdf	40466 faf4d8e9e52d053d14fbacc8efe72be60573383b	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	12744582

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: QPIDS.REQ
Document Description: QuickPath Information Disclosure Statement

PTO/SB/09 (09-18)

CERTIFICATION AND REQUEST FOR CONSIDERATION OF AN INFORMATION DISCLOSURE STATEMENT FILED AFTER PAYMENT OF THE ISSUE FEE UNDER THE QPIDS PROGRAM

Non-Provisional Application Number: 16/425,067	Filing Date: May 29, 2019
First Named Inventor: Johansen et al.	Title of Invention: FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

THE UNDERSIGNED HEREBY CERTIFIES AND REQUESTS THE FOLLOWING FOR THE ABOVE-IDENTIFIED APPLICATION.

1. Consideration is requested of the information disclosure statement (IDS) submitted herewith, which is being filed after payment of the issue fee.
2. Check the box next to the appropriate selection:

   ☑ Each item of information contained in the IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(1).

   OR

   ☐ No item of information contained in the IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(2).

   OR

   ☐ See attached certification statement in compliance with 37 CFR 1.97(e).
3. Please charge the IDS fee set forth in 37 CFR 1.17(p) to Deposit Account No. 08-2623.
4. A Petition to Withdraw from Issue After Payment of the Issue Fee (37 CFR 1.313(c)(2)), including the petition fee set forth in 37 CFR 1.17(h), is submitted herewith as a **Web-based ePetition**.
   WARNING: Do not submit the petition as a follow-on paper via EFS-Web. Submit the petition as a Web-based ePetition by signing on to EFS-Web as a registered user, selecting the radio button next to "Existing application/patent," and then selecting the radio button next to "ePetition (for automatic processing and immediate grant, if all petitions requirements are met)." Failure to use the Web-based ePetition interface will result in automatic entry of the RCE.
5. A request for continued examination (RCE) under 37 CFR 1.114 and the RCE fee under 37 CFR 1.17(e) are submitted herewith.
6. The RCE will be treated as a "conditional" RCE. In the event the examiner determines that any item of information contained in the IDS necessitates the reopening of prosecution in the application, the undersigned understands that (i) the RCE will be processed and treated as an RCE under 37 CFR 1.114 and therefore (ii) the IDS fee under 37 CFR 1.17(p) will be returned in accordance with 37 CFR 1.97(b)(4). In the event that no item of information in the IDS necessitates reopening prosecution, the undersigned understands that the RCE will not be processed and the RCE fee under 37 CFR 1.17(e) will be returned.
7. This certification and request is being filed as a **Web-based ePetition** and is not accompanied by an amendment to the application. Inclusion of an amendment will result in automatic entry of the RCE.

Signature /Steven A. Avena/	Date March 28, 2022
Name (Print/Typed) Steven A. Avena	Practitioner Registration Number (if applicable) 75211

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below.**

☐ *Total of _____ forms are submitted.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on March 28, 2022

HOLLAND & HART LLP

By: / Wendy Nishida /
Wendy Nishida

PATENT
Attorney Docket No.: P008EP.US (87942.0011)
Client Ref. No.: AWA#138787

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 7044
Johansen et al.	Examiner: Frances Tischler
Application No.: 16/425,067	Art Unit: 1765
Filed: May 29, 2019	**INFORMATION DISCLOSURE STATEMENT**
For: FILMS AND LAMINATES FOR USE IN PACKAGINE REACTIVE COMPOUNDS	
Customer No.: 26582	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Pursuant to the duty of disclosure set forth at 37 CFR §1.56 and the requirements for filing an Information Disclosure Statement set forth at 37 CFR §§1.97-1.98, enclosed is Form PTO/SB/08 (hereinafter "the Form") with a list of all items being submitted for consideration by the Office. A legible copy of each item listed in the Form that is not a U.S. patent or a published U.S. patent application, and not identified as being cumulative, is enclosed.

The disclosure of the remaining documents identified on the Form is not to be construed as an admission that any of the documents, alone or in any combination, is considered to be material to patentability as defined in 37 CFR §1.56(b). Moreover, the disclosure of these documents is not to be construed as an admission that any of the documents are prior art as to the above-identified application.

Applicants believe that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such a fee from the undersigned's

Deposit Account No. 08-2623. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

/ Steven A. Avena /

Steven A. Avena
Reg. No. 75,211

HOLLAND AND HART LLP
P.O. Box 11583
Salt Lake City, UT 84110
Tel: 303-473-2700
Fax: 303-473-2720

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26582 7590 02/07/2022

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Wendy Nishida	(Typed or printed name)
/Wendy Nishida/	(Signature)
March 25, 2022	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

TITLE OF INVENTION: FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/09/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
TISCHLER, FRANCES	1765	428-411100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 Holland & Hart LLP
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Danapak Flexibles A/S

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Slagelse, DENMARK

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 08-2623

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Steven A. Avena/ Date March 25, 2022

Typed or printed name Steven A. Avena Registration No. 75,211

Electronic Patent Application Fee Transmittal

Application Number:	16425067
Filing Date:	29-May-2019
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Filer:	Steven Anthony Avena/Wendy Nishida
Attorney Docket Number:	P008EP.US (87942.0011)

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1200**

Electronic Acknowledgement Receipt

EFS ID:	45318752
Application Number:	16425067
International Application Number:	
Confirmation Number:	7044
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Customer Number:	26582
Filer:	Steven Anthony Avena/Wendy Nishida
Filer Authorized By:	Steven Anthony Avena
Attorney Docket Number:	P008EP.US (87942.0011)
Receipt Date:	25-MAR-2022
Filing Date:	29-MAY-2019
Time Stamp:	14:12:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1200
RAM confirmation Number	E20223OE13160559
Deposit Account	082623
Authorized User	Wendy Nishida

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	P008Danapak.pdf	132026 88a0068d7f5eca6a28294fb363fdc6ba87f7784c	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37944 d0b1d7e0a106aa5f6867e480ac6a37ebb25e0758	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	169970		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26582 7590 02/07/2022

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

EXAMINER
TISCHLER, FRANCES

ART UNIT	PAPER NUMBER
1765	

DATE MAILED: 02/07/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

TITLE OF INVENTION: FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/09/2022

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26582 7590 02/07/2022

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

TITLE OF INVENTION: FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/09/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
TISCHLER, FRANCES	1765	428-411100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

26582 7590 02/07/2022

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

EXAMINER	
TISCHLER, FRANCES	
ART UNIT	PAPER NUMBER
1765	

DATE MAILED: 02/07/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/425,067	Applicant(s) Johansen et al.	
	Examiner FRANCES TISCHLER	Art Unit 1765	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 12/14/21.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1,3-8 and 10 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☑ All b) ☐ Some* c) ☐ None of the:

   1. ☑ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 12/22/21.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/FRANCES TISCHLER/
Primary Examiner, Art Unit 1765

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/21 has been entered.

Status of the Claims

Receipt is acknowledged of the Applicant's response filed on 11/14/21. Claims 1, 5, 6 and 10 have been amended. Claims 2 and 9 have been cancelled. Claims 11 – 20 are withdrawn due to a restriction requirement. Claims 1, 3 – 8 and 10 - 20 are now pending.

All outstanding objections and rejections, except for those maintained below, are withdrawn in light of applicant's amendments/remarks filed on 11/14/21.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Leah Villarreal on 12/22/21.

The application has been amended as follows:

Cancel claims 11 – 20 without prejudice.

REASONS FOR ALLOWANCE

Claims 1, 3 – 8 and 10 are allowed.

The following is an examiner's statement of reasons for allowance:

The present claims are allowable over the closest references of ADAMS (US 2005/0037162), of BOWEN et al (US 6,120,860) and of OSBORN et al (US 2015/0225151).

ADAMS discloses a laminate film that provides good oxygen barrier properties, wherein the film comprises several layers, including an aluminum base layer, a COC-containing contact layer, an EAA-containing tie layer, and several more layers, and wherein one or more layers comprise a filler. ADAMS discloses that the film is used for making cartons for orange juice or milk; failing to teach an aggressive chemical-

resistant film which is resistant to a chemical selected from nicotine, fentanyl, rivastigmine or lidocaine. ADAM gives an example of a tie loading of 14 lbs/3000 ft^2, which is equivalent to 70 g/m^2; failing to teach 3 – 9 g/m^2. ADAM fails to teach that the loading of the contact layer is one to three times that of the loading of the tie layer.

BOWEN discloses a package comprising a multilayer film, the film comprising a high barrier/base layer comprising nylon or aluminum, a flexible barrier comprising nylon, and a coextruded tie layer and a sealant/contact layer to coat the base layer or flexible barrier on one of its side and a tie and sealant layer on its other side. The contact layer comprises polyolefin polymers, polyolefin copolymers or ethylene vinyl acetate; failing to teach COC, polyamide or ethylene vinyl alcohol. BOWEN discloses that the film is used for making packages for containing organics such as amines, xylenes, toluene, epoxies, and the like, failing to teach aggressive chemicals selected explicitly from nicotine, fentanyl, rivastigmine or lidocaine. BOWEN fails to teach that the loading of the contact layer is one to three times that of the loading of the tie layer.

OSBORN discloses a multilayer packaging film used to contain nicotine or fentanyl comprising 8 layers which includes an oxygen resistant outer layer, one or more tie layers, and a sealant layer comprising EAA, LDPE and norbornene ethylene copolymer (COC) layers, wherein the COC layer is in direct contact with the pharmaceutical. OSBORN fails to teach that the tie layer and the contact layer are coextruded. OSBORN discloses an example wherein the COC has a thickness of 0.43 mil and the LDPE has a thickness of 0.65 mil. OSBORN fails to teach a loading for the

tie layer; or if the LDPE is considered a tie layer, then OSBORN fails to teach that the loading of the contact layer is one to three times that of the loading of the tie layer.

The closest prior art of record fails to teach or render obvious the claimed aggressive chemical-resistant film, wherein the film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine, said film comprising a base layer that is resistant to one or more of water or oxygen; a coextruded layer comprising a tie layer and a contact layer, wherein the contact layer consists of a cycloolefin copolymer (COC), a polyamide or an ethylene vinyl alcohol; wherein the tie layer has a loading in the range of 3 to 9 g/m^2; and wherein the loading of the contact layer = x * (the loading of the tie layer), with x being 1-3.

Applicant further shows unexpected results in the uptake of the active pharmaceutical ingredient when the loading of the contact layer is greater than the loading of the tie layer.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FRANCES TISCHLER whose telephone number is (571)270-5458. The examiner can normally be reached on Monday-Friday, 8:00 AM - 8:00 PM EST, midday flex.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/FRANCES TISCHLER/
Primary Examiner, Art Unit 1765

Examiner-Initiated Interview Summary	Application No. 16/425,067	Applicant(s) Johansen et al.		
	Examiner FRANCES TISCHLER	Art Unit 1765	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
FRANCES TISCHLER	Primary Examiner	Telephonic
Leah Villareal	Attorney of Record	

Date of Interview: 22 December 2021

Issues Discussed:

Other

Discussed the withdrawn claims. Authorization for examiner's amendment.

/FRANCES TISCHLER/ Primary Examiner, Art Unit 1765	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61K31/167 OR A61K31/27 OR A61K31/4468 OR A61K31/465 OR A61K9/0014 OR A61K9/7084 OR B32B15/08 OR B32B15/082 OR B32B15/085 OR B32B15/20 OR B32B2255/10 OR B32B2255/20 OR B32B2307/718 OR B32B2307/7244 OR B32B2307/7246 OR B32B2307/7265 OR B32B2439/46 OR B32B2439/80 OR B32B2556/00 OR B32B27/08 OR B32B27/283 OR B32B27/30 OR B32B27/304 OR B32B27/306 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/02 OR B65D65/40	05/25/2021	/FT/
updated search	08/17/2021	/FT/
updated search	12/22/2021	/FT/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

Search Notes		
Search Notes	**Date**	**Examiner**
East text search; inventor and company search; classification search, codes shown above; combination of East text search and classification search; combination of East text search and inventor search; combination of East text search and company search; considered/examined all IDS; searched google scholar and google patent and IP.com; search terms included, for instance: cycloolefin or COC or (cyclic adj olefin) or polyamide or (ethylene adj vinyl adj alcohol) or EVA) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride)	05/25/2021	/FT/
updated search	08/17/2021	/FT/
updated search	12/22/2021	/FT/

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
	see search above; interference search	12/22/2021	/FT/

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	**Art Unit**
	FRANCES TISCHLER	1765

CPC						
Symbol					**Type**	**Version**
B32B	/	15	/	085	F	2013-01-01
A61K	/	9	/	0014	I	2013-01-01
A61K	/	9	/	7084	I	2013-01-01
A61K	/	31	/	167	I	2013-01-01
A61K	/	31	/	27	I	2013-01-01
A61K	/	31	/	4468	I	2013-01-01
A61K	/	31	/	465	I	2013-01-01
B32B	/	27	/	30	I	2013-01-01
B32B	/	27	/	325	I	2013-01-01
B32B	/	37	/	02	I	2013-01-01
B65D	/	65	/	40	I	2013-01-01
B32B	/	2307	/	7244	A	2013-01-01
B32B	/	2307	/	7265	A	2013-01-01
B32B	/	2439	/	46	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	8	
/FRANCES TISCHLER/ Primary Examiner, Art Unit 1765	22 December 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	fig 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	**Art Unit**
	FRANCES TISCHLER	1765

INTERNATIONAL CLASSIFICATION				
CLAIMED				
B32B15/085	/	15	/	085

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner) (Date)		**Total Claims Allowed:** 8	
/FRANCES TISCHLER/ Primary Examiner, Art Unit 1765 (Primary Examiner)	22 December 2021 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure fig 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	**Art Unit**
	FRANCES TISCHLER	1765

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	8	10		19										
	2		11		20										
2	3		12												
3	4		13												
4	5		14												
5	6		15												
6	7		16												
7	8		17												
	9		18												

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	8	
/FRANCES TISCHLER/ Primary Examiner, Art Unit 1765	22 December 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	fig 1

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	02/02/2021	05/25/2021	08/17/2021	12/22/2021					
1	1	÷	✓	✓	=					
	2	÷	✓	✓	-					
2	3	÷	✓	✓	=					
3	4	÷	✓	✓	=					
4	5	÷	✓	✓	=					
5	6	÷	✓	✓	=					
6	7	÷	✓	✓	=					
7	8	÷	✓	✓	=					
	9	÷	✓	✓	-					
8	10	÷	✓	✓	=					
	11	÷	N	N	-					
	12	÷	N	N	-					
	13	÷	N	N	-					
	14	÷	N	N	-					
	15	÷	N	N	-					
	16	÷	N	N	-					
	17	÷	N	N	-					
	18	÷	N	N	-					
	19	÷	N	N	-					
	20	÷	N	N	-					

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"20200047461".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/12/22 18:50
S1	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 17:13
S2	1	"6120860".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:07
S4	1	"20040234790".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:10
S5	1	"20050106344".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:11
S6	1	"6790496".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:12
S7	1	"20050037162".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:47
S8	302	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:50
S9	3	((("DANAPAK") near3 ("FLEXIBLES") near3 ("A/S"))).AS,AANM.	USPAT	NEAR	ON	2021/01/31 19:50
S10	142	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:51
S11	350,512	(B05D1/265 OR B32B15/082 OR B32B15/20 OR B32B1/00 OR B32B2250/05 OR B32B2307/714 OR B32B2307/7244 OR B32B2307/7265 OR B32B2323/00 OR B32B2398/20 OR B32B2439/00 OR B32B27/08 OR B32B27/306 OR B32B27/308 OR B32B27/32 OR B32B27/325 OR	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:53

		B32B27/34 OR B32B27/36 OR B32B37/153 OR B32B7/12).CPC.				
S12	22	(cycloolefin or COC) and (base adj layer) and (tie adj layer) and (contact adj layer) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:55
S13	14	("20090208685" | "20110158564" | "20150225151" | "20160325534" | "20170158400" | "5613958" | "6670423" | "6891018" | "6921563" | "8703283" | "8722164" | "9452593" | "9487918" | "9663281").PN.	US-PGPUB; USPAT	NEAR	ON	2021/01/31 19:57
S14	1	"20160325534".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:58
S15	0	S12 and S14	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S16	0	S12 and S13	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S17	3	S12 and S8	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S18	3	S12 and S10	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S19	21	S12 and S11	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:01
S20	0	S12 and S2	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S21	0	S12 and S3	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S22	0	S12 and S4	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S23	0	S12 and S5	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S24	0	S12 and S6	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02

S25	0	S12 and S7	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S26	25	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 08:55
S27	1	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:20
S28	302	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S29	3	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)) and S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S30	142	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S31	4	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)) and S30	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S32	1	"20200047461".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/02/02 04:37
S33	14	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic) and load$5	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:38

S34	457,500	(A61K31/167 OR A61K31/27 OR A61K31/4468 OR A61K31/465 OR A61K9/0014 OR A61K9/7084 OR B32B15/08 OR B32B15/082 OR B32B15/085 OR B32B15/20 OR B32B2255/10 OR B32B2255/20 OR B32B2307/718 OR B32B2307/7244 OR B32B2307/7246 OR B32B2307/7265 OR B32B2439/46 OR B32B2439/80 OR B32B2556/00 OR B32B27/08 OR B32B27/283 OR B32B27/30 OR B32B27/304 OR B32B27/306 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/02 OR B65D65/40).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S35	25	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S36	17	S34 and S35	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S37	33	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/25 08:59
S38	74	(cycloolefin or COC or (cyclic adj olefin) or polyamide or (ethylene adj vinyl adj alcohol) or EVA) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/25 09:00
S39	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/05/25 17:49

S40	313	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/08/17 20:39
S41	149	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/08/17 20:39
S42	22	(cycloolefin or COC) and (base adj layer) and (tie adj layer) and (contact adj layer) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/08/17 20:39
S43	3	S42 and S40	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/08/17 20:39
S44	3	S42 and S41	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/08/17 20:39
S45	1	"20200047461".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/08/20 07:31
S46	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/11/10 10:54
S47	53	(cycloolefin or COC or polyamide or EVA or (ethylene adj vinyl adj alcohol)) and (base adj layer) and ((tie or adhesive) adj layer) and (contact adj layer) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/12/21 17:52
S48	1	"20150225151".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/12/21 18:31

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S49	239	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT	NEAR	ON	2021/12/21 17:50

S50	18	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT	NEAR	ON	2021/12/21 17:50
S51	88,381	(A61K31/167 OR A61K31/27 OR A61K31/4468 OR A61K31/465 OR A61K9/0014 OR A61K9/7084 OR B32B15/08 OR B32B15/082 OR B32B15/085 OR B32B15/20 OR B32B2255/10 OR B32B2255/20 OR B32B2307/718 OR B32B2307/7244 OR B32B2307/7246 OR B32B2307/7265 OR B32B2439/46 OR B32B2439/80 OR B32B2556/00 OR B32B27/08 OR B32B27/283 OR B32B27/30 OR B32B27/304 OR B32B27/306 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/02 OR B65D65/40).CPC.	US-PGPUB; USPAT	NEAR	ON	2021/12/21 17:50
S52	50	(cycloolefin or COC or polyamide or EVA or (ethylene adj vinyl adj alcohol)) and (base adj layer) and ((tie or adhesive) adj layer) and (contact adj layer) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT	NEAR	ON	2021/12/21 17:53
S53	3	S52 and S49	US-PGPUB; USPAT	NEAR	ON	2021/12/21 17:54
S54	3	S52 and S50	US-PGPUB; USPAT	NEAR	ON	2021/12/21 17:54
S55	24	S52 and S51	US-PGPUB; USPAT	NEAR	ON	2021/12/21 17:54
S56	3	((cycloolefin or COC or polyamide or EVA or (ethylene adj vinyl adj alcohol)) and (base adj layer) and ((tie or adhesive) adj layer) and (contact adj layer) and coextrud$5).clm.	US-PGPUB; USPAT	NEAR	ON	2021/12/22 14:44
S57	66	((cycloolefin or COC or polyamide or EVA or (ethylene adj vinyl adj alcohol)) and (base adj layer) and ((tie or adhesive) adj layer) and (contact adj layer) and coextrud$5)	US-PGPUB; USPAT	NEAR	ON	2021/12/22 14:45
S58	239	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT	NEAR	ON	2021/12/22 14:45
S59	3	S57 and S58	US-PGPUB; USPAT	NEAR	ON	2021/12/22 14:45
S60	18	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT	NEAR	ON	2021/12/22 14:45

S61	3	S57 and S60	US-PGPUB; USPAT	NEAR	ON	2021/12/22 14:45

12/22/2021 6:59:31 PM
C:\Users\ftischler\Documents\EAST\Workspaces\16425067.wsp

Bibliographic Data

Application No: 16/425,067

Foreign Priority claimed: (•) Yes ( ) No

35 USC 119 (a-d) conditions met: [✓] Yes [ ] No [ ] Met After Allowance

Verified and Acknowledged: /FRANCES TISCHLER/ Examiner's Signature [ ] Initials

Title: FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
05/29/2019	428	1765	P008EP.US (87942.0011)
RULE			

APPLICANTS

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Lars Christensen, Slagelse, DENMARK

Torben Fogtmann, Nyborg, DENMARK

CONTINUING DATA

FOREIGN APPLICATIONS

EPO EP18187923.0 08/08/2018

IF REQUIRED, FOREIGN LICENSE GRANTED**

06/05/2019

STATE OR COUNTRY

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FILING FEE RECEIVED

$1,880

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/425,067	Filing Date 05/29/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	12/14/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ROSALIND A BALL/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/30EFS (02-18)
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	16/425,067	Filing Date	2019-05-29	Docket Number (if applicable)	P008EP.US (87942.0011)	Art Unit	1765
First Named Inventor	Johansen et al.			Examiner Name	Frances Tischler		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 082623

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/ Paul M. Schramm /	Date (YYYY-MM-DD)	2021-12-14
Name	Paul M. Schramm	Registration Number	62050

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 7044
Johansen et al.	Examiner: Frances Tischler
For: IMPROVED FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS	Art Unit: 1765
Application No.: 16/425,067	**AMENDMENT WITH REQUEST FOR CONTINUED EXAMINATION (RCE)**
Filed: May 29, 2019	**CERTIFICATE OF TRANSMISSION** I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on: December 14, 2021.
Docket No.: P008EP.US (87942.0011)	By: / Wendy Nishida / Wendy Nishida
Customer No.: 26582	

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the final Office Action dated August 25, 2021 and the Advisory Action dated December 1, 2021, please enter the following amendments and remarks:

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

Amendments to the Claims

1. (Currently Amended) A**n aggressive chemical-resistant** laminate film comprising:

a base layer, wherein the base layer is one or more of water or oxygen resistant; and

a co-extrusion layer, the co-extrusion layer comprising a tie layer and a contact layer, wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof;

wherein a total loading of the tie layer is in the range of 3-9 g/m2 and wherein a loading of the contact layer is:

loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3**, wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine**.

2. (Canceled)

3. (Original) The laminate film according to claim 1, wherein x is in the range of 1.33 to 2.75.

4. (Original) The laminate film according to claim 1, wherein the tie layer is a multilayered tie layer comprising at least two layers.

5. (Currently Amended) The laminate film according to claim **[[1]] 4**, wherein at least one layer of **[[a]] the** multilayered tie layer is made from a material selected from the group consisting of: ethylene methacrylic acid, ethylene acrylic acid, **a** terpolymer of ethylene, acrylic ester, and maleic anhydride, **[[or]]** a terpolymer of ethylene, butyl acrylate, **and** maleic anhydride, or combinations thereof.

6. (Currently Amended) The laminate film according to claim **[[1]] 4**, wherein a second layer of **[[a]] the** multilayered tie layer comprises a material selected from the

group consisting of ethylene methacrylic acid, low-density polyethylene, ethylene methyl acrylate, ethylene butyl acrylate, ethylene ethyl acrylate, a terpolymer of ethylene, acrylic ester, and maleic anhydride, **[[or]]** a terpolymer of ethylene, butyl acrylate, and maleic anhydride, ethylene acrylic acid, or combinations thereof.

7. (Original) The laminate film according to claim 1, wherein the tie layer consists of two layers, a first tie layer and a second tie layer.

8. (Original) The laminate film according to claim 7, wherein a loading ratio of the first tie layer to the second tie layer is approximately 1:1.

9. (Canceled)

10. (Currently Amended) The laminate film according to claim 1, wherein the base layer is selected from the group consisting of a metal foil and a polymer made of **a** polyamide, silicon, **[[or]]** aluminiumoxide coated polyesters and fluoropolymers, or a combination thereof.

11. (Withdrawn) A packaging for packing a composition said packaging comprising:

a first outer layer made of a mechanically wear resistant material;

a laminate film comprising a base layer and a co-extrusion layer;

wherein the base layer is one or more of water resistant or oxygen resistant;

wherein the co-extrusion layer comprise a tie layer and a contact layer, a total loading of the tie layer is in the range of 3-9 g/m2, and a loading of the contact layer is loadingcontact=x*loadingtie, where loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 0.8 to 3;

wherein the base layer side of the film is facing the first outer layer.

12. (Withdrawn) The packaging according to claim 11, wherein x is in the range of 1 to 3.

13. (Withdrawn) The packaging according to claim 12, wherein x is in the range of 1.33 to 2.75.

14. (Withdrawn) The packaging according to claim 11, wherein the laminate encloses a composition comprising a compound selected from the group consisting of: nicotine, rivastigmine, fentanyl, lidocaine, or a combination thereof.

15. (Withdrawn) The packaging according to claim 11, wherein the composition is a patch.

16. (Withdrawn) A method for providing a laminate film, said method comprising the steps of:

providing a base layer, wherein the base layer is one or more of: water resistant or oxygen resistant;

coextruding a layer comprising a tie layer and a contact layer to provide a co-extrusion layer,

coating the co-extrusion layer to the base layer; and

curing the co-extrusion layer coated to the base layer to provide the laminate film,

wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof; and

wherein the total loading of the tie layer is 3 to 9 g/m2 and wherein the loading of the contact layer is:

loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and where x is in the range of 0.8 to 3.

17. (Withdrawn) The method according to claim 16, wherein x is in the range of 1 to 3.

18. (Withdrawn) The method according to claim 16, wherein the tie layer is multilayered and wherein all the layers of the multilayered tie layer are coextruded with the contact layer.

19. (Withdrawn) The method according to claim 18, wherein a total loading of the multilayered tie layer and contact layer is less than 40 g/m2.

20. (Withdrawn) The method according to claim 16, wherein the co-extrusion is performed at a temperature of 240 - 330°C.

REMARKS

Status of the Claims

Before this Amendment, claims 1–10 were present for examination and claims 11–20 were withdrawn from consideration. In this Amendment: claims 1, 5, 6, and 10 are amended; claims 2 and 9 are canceled without prejudice or disclaimer; and no new claims are added. Therefore, claims 1, 3–8, and 10 are present for examination, and claim 1 is the independent claim. Support for the amendments to the claims may be found throughout the Specification as filed including at least at Paragraphs [0017], [0021], [0049], [0078], [0088], [0181], [0188], [0189], [0207], and [0209]–[0211]. No new matter is added with these amendments.

In the final Office Action dated August 25, 2021 ("Office Action"): claims 5, 6, and 10 were rejected under 35 U.S.C. § 112(b) as being indefinite; claims 2 and 9 were rejected under 35 U.S.C. § 112(d) as being of improper dependent form; and claims 1–10 were rejected under 35 U.S.C. § 103 over U.S. Patent Publication No. 2005/0037162 to Adams ("Adams"). Applicant respectfully requests reconsideration. In the Advisory Action dated December 1, 2021, the claims were further rejected in view of U.S. Patent No. 6,120,860 to Bowen et al. ("Bowen").

Examiner Interview

Applicant thanks Examiner Tischler for granting a telephone interview with Applicant's representatives on November 10, 2021.

During the interview, Applicant's representatives discussed the claimed features of "wherein a total loading of the tie layer is in the range of 3-9 g/m2 and wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3" in light of the Paragraphs [0181], [0188], [0189], [0207], and [0209]–[0211] of the Application showing of criticality. The claimed features were also contrasted with those of the references cited in the standing rejection of the claims. Examiner Tischler acknowledged distinctions between the pending claims and the cited references, and agreed to reconsider the claims in view of the discussion.

Applicant thanks Examiner Tischler for the courtesies extended during the interview

35 U.S.C. § 112(b)

The Office Action rejected claims 5, 6, and 10 under 35 U.S.C. § 112(b) as being allegedly indefinite.

Regarding claim 5, the Office Action alleges that "it is unclear if the multilayered tie layer is in addition to the tie layer of claim 1 or if the tie layer of claim 1 is comprised of multilayer." See Office Action, p. 3. Further, the Office Action alleges that "it is assumed that Applicant means to claim that the combinations thereof means that one can combine any one of the listed compounds/polymers." Id. Without conceding the assertion that claim 5 is indefinite, Applicant has amended the claim to recite, in part, "[t]he laminate film according to claim 4 . . . the multilayered tie layer is made from . . . a terpolymer of ethylene, acrylic ester, and maleic anhydride, a terpolymer of ethylene, butyl acrylate, and maleic anhydride, or combinations thereof."

Regarding claim 6, the Office Action alleges that "it is unclear if the multilayered tie layer is in addition to the tie layer of claim 1 or if the tie layer of claim 1 is comprised of multilayer." Id. Further, the Office Action alleges that "it is assumed that Applicant means to claim that the combinations thereof means that one can combine any one of the listed compounds/polymers." Id. Without conceding the assertion that claim 6 is indefinite, Applicant has amended the claim to recite, in part, "[t]he laminate film according to claim 4 . . . the multilayered tie layer is made from . . . a terpolymer of ethylene, acrylic ester, and maleic anhydride, a terpolymer of ethylene, butyl acrylate, and maleic anhydride, ethylene acrylic acid, or combinations thereof."

Regarding claim 10, the Office Action alleges that "it is unclear which polymers are actually part of the group." Id. Without conceding the assertion that claim 10 is indefinite, Applicant has amended the claim to recite, in part, "wherein the base layer is selected from the group consisting of a metal foil and a polymer made of a polyamide, silicon, aluminiumoxide coated polyesters and fluoropolymers, or a combination thereof."

Accordingly, Applicant requests that the rejection of claims 5, 6, and 10 under 35 U.S.C. § 112(b) be withdrawn.

35 U.S.C. § 112(d)

The Office Action rejected claims 2 and 9 under 35 U.S.C. 112(d) as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends.

Regarding claim 2, the Office Action alleges that the limitation "x is in the range of 1 to 3" fails to further limit the subject matter of the claim upon which it depends. *See id.* at p. 4. Regarding claim 9, the Office Action alleges that the limitation "wherein x is in the range of 1.33 to 2.75" is a repeat of claim 3. *Id.*

Without conceding the assertion of the rejection, Applicant notes that claims 2 and 9 are canceled by this Amendment.

Accordingly, Applicant requests that the rejection of claims 2 and 9 under 35 U.S.C. § 112(d) be withdrawn.

35 U.S.C. § 103

The Office Action rejected claims 1–10 under 35 U.S.C. § 103 over Adams.

Factual findings made by the Office are the "necessary underpinnings to establish obviousness." MPEP § 2141(II). The Office must set forth "the relevant teachings of the prior art relied upon." MPEP § 2142. In *KSR International Co. v. Teleflex Inc.*, the Supreme Court noted that the analysis supporting a rejection under 35 U.S.C. § 103 must be made explicit. *See* 550 U.S. 398, 418 (2007); MPEP § 2142. "[O]bviousness [also] requires a suggestion of all limitations in a claim." *In re Wada and Murphy*, Appeal 2007-3733 (citing *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)).

Independent Claim 1

Without conceding the merits of the rejection of independent claim 1 under 35 U.S.C. § 103—and solely to expedite prosecution—Applicant has amended independent claim 1. For example, independent claim 1 has been amended to recite, in part, "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine."

Specifically, Adams does not teach or suggest "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1.

Adams is generally directed to "a laminate structure having improved resistance to the migration of essential oils, aromas and flavors and improved oxygen barriers characteristics for beverage packing." Adams, Abstract. Adams describes that "the peel oil concentrations determined on cartons in duplicate for each filler loading percent and storage time clearly demonstrate the reduction in absorption of peel oil as loading increased." *Id.*, ¶ [0040]. Adams further describes that "since the orange juice was used for all cartons (i.e., equal oil concentrations), the initial absorption rate of peel oil is, therefore, greatest for lowest addition level." *Id.*, ¶ [0042]. However, cartons containing orange juice is not the same as "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1.

Rather, Adams describes that "the laminate structure of the invention can be used in laminates comprising a coated paperboard substrate for use in the production of containers and cartons for products such as juices, punches, milk and other beverages." *Id.*, ¶ [0011]. However, juices, punches, milk and other beverages are not the same as and do not teach or suggest "a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine" much less "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1. Therefore, Adams does not teach or suggest "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1.

Further, Bowen does not teach or suggest all the features of amended independent claim 1. Bowen is generally directed to "multilayer film structures and packages." Bowen, Abstract. Bowen describes that "EVA/tie/nylon/tie/EVA or, more generally, sealant/tie/nylon/tie/sealant . . . can be formed as a coextrusion which is then adhered to the second layer element." *Id.*, col. 4, ll. 47-50. Bowen further describes that "nylon acts as a good barrier for containing organic products such as solvents, e.g., amines, within the package." *Id.*, col. 5, ll. 29-30. However,

organic products such as solvents are not the same as and do not teach or suggest "a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine" much less "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1. Therefore, Bowen does not teach or suggest "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1.

Bowen further describes that "the adhesive layers can consist of a plurality of layers , , , [where] suitable materials for adhesive or tie layers can include, by way of example . . . ethylene acrylic acid (EAA), ethylene vinyl acetate (EVA)." *Id.*, col. 3, ll. 52-60. However ethylene vinyl ***acetate*** is not the same as and does not teach or suggest "an ethylene vinyl alcohol" much less "wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof," as recited in amended independent claim 1 (emphasis added). Therefore, Bowen does not teach or suggest all the features of amended independent claim 1.

Thus, Adams and Bowen do not teach or suggest "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1.

In addition, Adams does not teach or suggest "wherein a total loading of the tie layer is in the range of 3-9 g/m2" and "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1. The Office Action concedes, and Applicant agrees, that Adams is silent regarding the loading value of the tie layer and the equation that compares it with the load value of the contact layer. *See* Office Action, p. 5.

Instead the Office Action states that "merely selecting proportions and ranges in not patentable absent a showing of criticality." *Id.* The Office Action further states that "Applicant is asked to show that the claimed loading of the tie layer (3-9 g/m2) and its relationship to the loading of the contact layer (i.e., wherein x=1-3) is critical or provides for unexpected results."

Id. Applicant submits that the loading value of the tie layer and the equation that compares it with the load value of the contact layer is critical and the current application provides support for unexpected results in at least Paragraphs [0181], [0188], [0189], [0207], and [0209]–[0211] of the Application, among other sections.

In one example, Table 3 of the Application shows and related portions describe that "testing with nicotine as API [active pharmaceutical ingredient], the following was found re the laminates performance." Application-as-filed, ¶ [0181]. That is, Table 3 shows that Laminate #3 in which the Tie 1 loading (e.g., 18 g/m2) is greater than contact loading (e.g., 12 g/m2) results in a "not ok" API uptake. *See id.* In addition, Table 3 shows that laminates #1 and #2 include a loading of the tie layer to be less than the contact loading which results in an "ok" API uptake. *Id.* Table 5 further illustrates the ranges of the tie layer and contact layer and the effect on usability in light of the sum of mechanical strength tests. *Id.*, ¶ [0207]. Therefore, the current application shows that the claimed loading of the tie layer (3-9 g/m2) and its relationship to the loading of the contact layer (i.e., wherein x=1-3) is critical or provides for unexpected results.

Further, Adams does not teach or suggest that the thickness of the tie layer and/or contact layer is important for API uptake much less disclose what mechanical stress parameters are important and how these interplay with the loadings. Rather, Adams describes that "the peel oil concentrations determined on cartons in duplicate for each filler loading percent and storage time clearly demonstrate the reduction in absorption of peel oil as loading increased." Adams, ¶ [0040]. That is, Adams describes that increasing an amount of filler gives the lowest absorption of peel oil. However, Adams fails to teach or suggest the importance of the relationship between the tie layer and the contact layer and how the relationship is important for API uptake.

Further, Bowen does not teach or suggest "wherein a total loading of the tie layer is in the range of 3-9 g/m2" and "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1. That is, Bowen is silent regarding the loading value of the tie layer and the equation that compares it with the load value of the contact layer.

In addition, Bowen does not teach or suggest that the thickness of the tie layer and/or contact layer is important for API uptake much less disclose what mechanical stress parameters are important and how these interplay with the loadings. Rather, Bowen describes that "it is important that layers of the first layer element, the layers of the second layer element and the first and second layer elements themselves be well bonded." *Id.*, col. 6, ll. 63-65. That is, Bowen describes that the importance of the bonding between layers but does not teach or suggest how the thickness of the tie layer and/or contact layer is important for API uptake. Therefore, Bowen fails to teach or suggest the importance of the relationship between the thickness of the tie layer and the thickness of the contact layer and how the relationship is important for API uptake.

Therefore, Adams and Bowen do not teach or suggest "wherein a total loading of the tie layer is in the range of 3-9 g/m^2" much less "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1. That is, Adams and Bowen do not teach or suggest that the loading of the tie layer and its relationship to the loading of the contact layer is important much less that that the relationship to the loading of the contact layer is important for API and/or mechanical strength tests.

Because Adams and Bowen do not teach or suggest all the features of amended claim 1, the loading value of the tie layer and the equation that compares it with the load value of the contact layer cannot be inherently the same as claimed. Accordingly, the Office Action has failed to establish a *prima facie* case of obviousness for the claimed loading value of the tie layer and the equation that compares it with the load value of the contact layer in view of Adams and Bowen.

Therefore, for at least these reasons, amended independent claim 1 is allowable over any combination of Adams and Bowen.

Accordingly, Applicant requests that the rejection of independent claim 1 under 35 U.S.C. § 103 be withdrawn.

Dependent Claims 3–8 and 10

Dependent claims 3–8 and 10 each depend from independent claim 1, and are therefore allowable for at least the same reasons that independent claim 1 is allowable.

Accordingly, for at least these reasons, Applicant requests that the rejection of dependent claims 3–8 and 10 under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is therefore respectfully requested.

The Commissioner is authorized to charge any fees or underpayments that may be due with this response, or credit any overpayments, to Deposit Account No. 08-2623.

If the Examiner believes a telephone conference would expedite prosecution of this Application, please call the undersigned at (303) 473-2700.

Respectfully submitted,

By: / Paul M. Schramm /
Paul M. Schramm
Reg. No. 62,050

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Electronic Patent Application Fee Transmittal

Application Number:	16425067
Filing Date:	29-May-2019
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Filer:	Paul M. Schramm/Wendy Nishida
Attorney Docket Number:	P008EP.US (87942.0011)

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	1251	1	220	220
Miscellaneous:				
RCE- 1ST REQUEST	1801	1	1360	1360
		Total in USD ($)		**1580**

Electronic Acknowledgement Receipt

EFS ID:	44509713
Application Number:	16425067
International Application Number:	
Confirmation Number:	7044
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Customer Number:	26582
Filer:	Paul M. Schramm/Wendy Nishida
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P008EP.US (87942.0011)
Receipt Date:	14-DEC-2021
Filing Date:	29-MAY-2019
Time Stamp:	12:45:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1580
RAM confirmation Number	E2021BDC46133887
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P008Danapak.pdf	442692 5e9fc886a672240ea9a45fe04842c7cfb38e0f65	yes	15

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Request for Continued Examination (RCE)	1	2
	Amendment Copy Claims/Response to Suggested Claims	3	3
	Claims	4	7
	Applicant Arguments/Remarks Made in an Amendment	8	15

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	40979 09e57cfc0090b99ef439b5ab59a1cf7fd7aae74a	no	2

Warnings:

Information:

Total Files Size (in bytes):	483671

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

26582 7590 12/01/2021

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

EXAMINER	
TISCHLER, FRANCES	

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
12/01/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@hollandhart.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 16/425,067	**Applicant(s)** Johansen et al.	
	Examiner FRANCES TISCHLER	**Art Unit** 1765	**AIA (FITF) Status** Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 November 2021 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☑ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☑ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: See Continuation Sheet (See 37CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicants reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☑ For purposes of appeal, the proposed amendment(s):(a) ☑ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☑ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☑ Other: PTO-413; PTO-2323.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:1,3-8 and 10.
    Claim(s) withdrawn from consideration:11-20.

/FRANCES TISCHLER/ Primary Examiner, Art Unit 1765	

Continuation of 3 and 12. NOTE:

Claim 1 has been amended to recite that the laminate film is an aggressive chemical-resistant laminate film which is resistant to nicotine, fentanyl, rivastigmine or lidocaine. Applicant has also provided new arguments of unexpected results that have not been previously made of record.

The amendments and remarks overcome the rejection in the final office action. However, the Examiner was not able to make a definitive determination of the patentability of the claims based upon a limited update search and additional consideration within the time authorized for the pilot program.

Examiner-Initiated Interview Summary	**Application No.** 16/425,067	**Applicant(s)** Johansen et al.		
	Examiner FRANCES TISCHLER	**Art Unit** 1765	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
FRANCES TISCHLER	Primary Examiner	Telephonic
Paul Schramm	Attorney of Record	

Date of Interview: 27 November 2021

Issues Discussed:

Other

The Examiner informed Applicant by voice mail that the amendments to claim 1 (now reciting an aggressive chemical-resistant laminate film which is resistant to nicotine, fentanyl, rivastigmine or lidocaine) raises new issues, but would overcome the rejection in the final office action. However, the Examiner was not able to make a definite determination of the patentability of the claims based upon the limited update search and additional consideration within the time authorized for the pilot program. BOWEN et al (USA 6,120,860), for instance, disclose a multilayer laminate film for holding aggressive organics.

/FRANCES TISCHLER/ Primary Examiner, Art Unit 1765	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

AFCP 2.0 Decision

Application No.	Applicant(s)	
16/425,067	Johansen et al.	
Examiner	**Art Unit**	**AIA (FITF) Status**
FRANCES TISCHLER	1765	Yes

This is in response to the After Final Consideration Pilot request filed 18 November 2021.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ The request is not the first proper AFCP 2.0 request submitted in response to the most recent final rejection.

   ☐ Other: _____

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☐ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action . See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☑ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other: _____

   Examiner Note: Please attach an interview summary when necessary as described above.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DO NOT ENTER: /F.T./ 11/27/2021

In re application of:	Confirmation No.: 7044
Johansen et al.	Examiner: Frances Tischler
For: IMPROVED FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS	Art Unit: 1765
Application No.: 16/425,067	**AMENDMENT AFTER FINAL**
Filed: May 29, 2019	**CERTIFICATE OF TRANSMISSION** I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on: November 18, 2021.
Docket No.: P008EP.US (87942.0011)	By: / Wendy Nishida / Wendy Nishida
Customer No.: 26582	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the final Office Action dated August 25, 2021, please enter the following amendments and remarks:

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
P008EP.US (87942.0011)	16/425,067	May 29, 2019
First Named Inventor:	**Title:**	
Johansen et al.	IMPROVED FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
   - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
   - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
     - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
     - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
       - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
       - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/ Paul M. Schramm /	November 18, 2021
Name (Print/Typed) Paul M. Schramm	Practitioner Registration No. 62,050

***Note**: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.*

☐ * Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 7044
Johansen et al.	Examiner: Frances Tischler
For: IMPROVED FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS	Art Unit: 1765
	AMENDMENT AFTER FINAL
Application No.: 16/425,067	**CERTIFICATE OF TRANSMISSION** I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on: November 18, 2021.
Filed: May 29, 2019	
Docket No.: P008EP.US (87942.0011)	By: / Wendy Nishida / Wendy Nishida
Customer No.: 26582	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the final Office Action dated August 25, 2021, please enter the following amendments and remarks:

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

Amendments to the Claims

Please enter the following amendments to the claims:

1. (Currently Amended) A**n aggressive chemical-resistant** laminate film comprising:

a base layer, wherein the base layer is one or more of water or oxygen resistant; and

a co-extrusion layer, the co-extrusion layer comprising a tie layer and a contact layer, wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof;

wherein a total loading of the tie layer is in the range of 3-9 g/m2 and wherein a loading of the contact layer is:

loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3**, wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine**.

2. (Canceled)

3. (Original) The laminate film according to claim 1, wherein x is in the range of 1.33 to 2.75.

4. (Original) The laminate film according to claim 1, wherein the tie layer is a multilayered tie layer comprising at least two layers.

5. (Currently Amended) The laminate film according to claim **[[1]] 4**, wherein at least one layer of **[[a]] the** multilayered tie layer is made from a material selected from the group consisting of: ethylene methacrylic acid, ethylene acrylic acid, **a** terpolymer of ethylene, acrylic ester, and maleic anhydride, **[[or]]** a terpolymer of ethylene, butyl acrylate, **and** maleic anhydride, or combinations thereof.

6. (Currently Amended) The laminate film according to claim **[[1]] 4**, wherein a second layer of **[[a]] the** multilayered tie layer comprises a material selected from the

group consisting of ethylene methacrylic acid, low-density polyethylene, ethylene methyl acrylate, ethylene butyl acrylate, ethylene ethyl acrylate, a terpolymer of ethylene, acrylic ester, and maleic anhydride, **[[or]]** a terpolymer of ethylene, butyl acrylate, and maleic anhydride, ethylene acrylic acid, or combinations thereof.

7. (Original) The laminate film according to claim 1, wherein the tie layer consists of two layers, a first tie layer and a second tie layer.

8. (Original) The laminate film according to claim 7, wherein a loading ratio of the first tie layer to the second tie layer is approximately 1:1.

9. (Canceled)

10. (Currently Amended) The laminate film according to claim 1, wherein the base layer is selected from the group consisting of a metal foil and a polymer made of **a** polyamide, silicon, **[[or]]** aluminiumoxide coated polyesters and fluoropolymers, or a combination thereof.

11. (Withdrawn) A packaging for packing a composition said packaging comprising:

a first outer layer made of a mechanically wear resistant material;

a laminate film comprising a base layer and a co-extrusion layer;

wherein the base layer is one or more of water resistant or oxygen resistant;

wherein the co-extrusion layer comprise a tie layer and a contact layer, a total loading of the tie layer is in the range of 3-9 g/m2, and a loading of the contact layer is loadingcontact=x*loadingtie, where loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 0.8 to 3;

wherein the base layer side of the film is facing the first outer layer.

12. (Withdrawn) The packaging according to claim 11, wherein x is in the range of 1 to 3.

13. (Withdrawn) The packaging according to claim 12, wherein x is in the range of 1.33 to 2.75.

14. (Withdrawn) The packaging according to claim 11, wherein the laminate encloses a composition comprising a compound selected from the group consisting of: nicotine, rivastigmine, fentanyl, lidocaine, or a combination thereof.

15. (Withdrawn) The packaging according to claim 11, wherein the composition is a patch.

16. (Withdrawn) A method for providing a laminate film, said method comprising the steps of:

providing a base layer, wherein the base layer is one or more of: water resistant or oxygen resistant;

coextruding a layer comprising a tie layer and a contact layer to provide a co-extrusion layer,

coating the co-extrusion layer to the base layer; and

curing the co-extrusion layer coated to the base layer to provide the laminate film,

wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof; and

wherein the total loading of the tie layer is 3 to 9 g/m2 and wherein the loading of the contact layer is:

loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and where x is in the range of 0.8 to 3.

17. (Withdrawn) The method according to claim 16, wherein x is in the range of 1 to 3.

18. (Withdrawn) The method according to claim 16, wherein the tie layer is multilayered and wherein all the layers of the multilayered tie layer are coextruded with the contact layer.

19. (Withdrawn) The method according to claim 18, wherein a total loading of the multilayered tie layer and contact layer is less than 40 g/m2.

20. (Withdrawn) The method according to claim 16, wherein the co-extrusion is performed at a temperature of 240 - 330°C.

REMARKS

Status of the Claims

Before this Amendment, claims 1–10 were present for examination and claims 11–20 were withdrawn from consideration. In this Amendment: claims 1, 5, 6, and 10 are amended; claims 2 and 9 are canceled without prejudice or disclaimer; and no new claims are added. Therefore, claims 1, 3–8, and 10 are present for examination, and claim 1 is the independent claim. Support for the amendments to the claims may be found throughout the Specification as filed including at least at Paragraphs [0017], [0021], [0049], [0078], [0088], [0181], [0188], [0189], [0207], and [0209]–[0211]. No new matter is added with these amendments.

In the final Office Action dated August 25, 2021 ("Office Action"): claims 5, 6, and 10 were rejected under 35 U.S.C. § 112(b) as being indefinite; claims 2 and 9 were rejected under 35 U.S.C. § 112(d) as being of improper dependent form; and claims 1–10 were rejected under 35 U.S.C. § 103 over U.S. Patent Publication No. 2005/0037162 to Adams ("Adams"). Applicant respectfully requests reconsideration.

Examiner Interview

Applicant thanks Examiner Tischler for granting a telephone interview with Applicant's representatives on November 10, 2021.

During the interview, Applicant's representatives discussed the claimed features of "wherein a total loading of the tie layer is in the range of 3-9 g/m2 and wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3" in light of the Paragraphs [0181], [0188], [0189], [0207], and [0209]–[0211] of the Application showing of criticality. The claimed features were also contrasted with those of the references cited in the standing rejection of the claims. Examiner Tischler acknowledged distinctions between the pending claims and the cited references, and agreed to reconsider the claims in view of the discussion.

Applicant thanks Examiner Tischler for the courtesies extended during the interview.

After Final Consideration Pilot 2.0 (AFCP 2.0)

Applicant respectfully submits that the above amendments to the claims place the application in condition for allowance. Further, the amendments can be determined to place the application in condition for allowance with only a limited amount of further searching or consideration. Therefore, Applicant requests that the Office consider these amendments under the AFCP 2.0. If the Office declines the request to consider this response under the AFCP 2.0, Applicant respectfully requests that the Office notify Applicant of this decision.

35 U.S.C. § 112(b)

The Office Action rejected claims 5, 6, and 10 under 35 U.S.C. § 112(b) as being allegedly indefinite.

Regarding claim 5, the Office Action alleges that "it is unclear if the multilayered tie layer is in addition to the tie layer of claim 1 or if the tie layer of claim 1 is comprised of multilayer." *See* Office Action, p. 3. Further, the Office Action alleges that "it is assumed that Applicant means to claim that the combinations thereof means that one can combine any one of the listed compounds/polymers." *Id.* Without conceding the assertion that claim 5 is indefinite, Applicant has amended the claim to recite, in part, "[t]he laminate film according to claim 4 . . . the multilayered tie layer is made from . . . a terpolymer of ethylene, acrylic ester, and maleic anhydride, a terpolymer of ethylene, butyl acrylate, and maleic anhydride, or combinations thereof."

Regarding claim 6, the Office Action alleges that "it is unclear if the multilayered tie layer is in addition to the tie layer of claim 1 or if the tie layer of claim 1 is comprised of multilayer." *Id.* Further, the Office Action alleges that "it is assumed that Applicant means to claim that the combinations thereof means that one can combine any one of the listed compounds/polymers." *Id.* Without conceding the assertion that claim 6 is indefinite, Applicant has amended the claim to recite, in part, "[t]he laminate film according to claim 4 . . . the multilayered tie layer is made from . . . a terpolymer of ethylene, acrylic ester, and maleic anhydride, a terpolymer of ethylene, butyl acrylate, and maleic anhydride, ethylene acrylic acid, or combinations thereof."

Regarding claim 10, the Office Action alleges that "it is unclear which polymers are actually part of the group." *Id.* Without conceding the assertion that claim 10 is indefinite, Applicant has amended the claim to recite, in part, "wherein the base layer is selected from the group consisting of a metal foil and a polymer made of a polyamide, silicon, aluminiumoxide coated polyesters and fluoropolymers, or a combination thereof."

Accordingly, Applicant requests that the rejection of claims 5, 6, and 10 under 35 U.S.C. § 112(b) be withdrawn.

35 U.S.C. § 112(d)

The Office Action rejected claims 2 and 9 under 35 U.S.C. 112(d) as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends.

Regarding claim 2, the Office Action alleges that the limitation "x is in the range of 1 to 3" fails to further limit the subject matter of the claim upon which it depends. *See id.* at p. 4. Regarding claim 9, the Office Action alleges that the limitation "wherein x is in the range of 1.33 to 2.75" is a repeat of claim 3. *Id.*

Without conceding the assertion of the rejection, Applicant notes that claims 2 and 9 are canceled by this Amendment.

Accordingly, Applicant requests that the rejection of claims 2 and 9 under 35 U.S.C. § 112(d) be withdrawn.

35 U.S.C. § 103

The Office Action rejected claims 1–10 under 35 U.S.C. § 103 over Adams.

Factual findings made by the Office are the "necessary underpinnings to establish obviousness." MPEP § 2141(II). The Office must set forth "the relevant teachings of the prior art relied upon." MPEP § 2142. In *KSR International Co. v. Teleflex Inc.*, the Supreme Court noted that the analysis supporting a rejection under 35 U.S.C. § 103 must be made explicit. *See* 550 U.S. 398, 418 (2007); MPEP § 2142. "[O]bviousness [also] requires a suggestion of all limitations in a claim." *In re Wada and Murphy*, Appeal 2007-3733 (citing *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)).

Independent Claim 1

Without conceding the merits of the rejection of independent claim 1 under 35 U.S.C. § 103—and solely to expedite prosecution—Applicant has amended independent claim 1. For example, independent claim 1 has been amended to recite, in part, "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine."

Specifically, Adams does not teach or suggest "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1.

Adams is generally directed to "a laminate structure having improved resistance to the migration of essential oils, aromas and flavors and improved oxygen barriers characteristics for beverage packing." Adams, Abstract. Adams describes that "the peel oil concentrations determined on cartons in duplicate for each filler loading percent and storage time clearly demonstrate the reduction in absorption of peel oil as loading increased." *Id.*, ¶ [0040]. Adams further describes that "since the orange juice was used for all cartons (i.e., equal oil concentrations), the initial absorption rate of peel oil is, therefore, greatest for lowest addition level." *Id.*, ¶ [0042]. However, cartons containing orange juice is not the same as "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1.

Rather, Adams describes that "the laminate structure of the invention can be used in laminates comprising a coated paperboard substrate for use in the production of containers and cartons for products such as juices, punches, milk and other beverages." *Id.*, ¶ [0011]. However, juices, punches, milk and other beverages are not the same as and do not teach or suggest "a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine" much less "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1. Therefore, Adams does not teach or suggest "wherein the aggressive chemical-resistant laminate film is resistant to a chemical selected from nicotine, fentanyl, rivastigmine, or lidocaine," as recited in amended independent claim 1.

In addition, Adams does not teach or suggest "wherein a total loading of the tie layer is in the range of 3-9 g/m2" and "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1. The Office Action concedes, and Applicant agrees, that Adams is silent regarding the loading value of the tie layer and the equation that compares it with the load value of the contact layer. *See* Office Action, p. 5.

Instead the Office Action states that "merely selecting proportions and ranges in not patentable absent a showing of criticality." *Id.* The Office Action further states that "Applicant is asked to show that the claimed loading of the tie layer (3-9 g/m2) and its relationship to the loading of the contact layer (i.e., wherein x=1-3) is critical or provides for unexpected results." *Id.* Applicant submits that the loading value of the tie layer and the equation that compares it with the load value of the contact layer is critical and the current application provides support for unexpected results in at least Paragraphs [0181], [0188], [0189], [0207], and [0209]–[0211] of the Application, among other sections.

In one example, Table 3 of the Application shows and related portions describe that "testing with nicotine as API [active pharmaceutical ingredient], the following was found re the laminates performance." Application-as-filed, ¶ [0181]. That is, Table 3 shows that Laminate #3 in which the Tie 1 loading (e.g., 18 g/m2) is greater than contact loading (e.g., 12 g/m2) results in a "not ok" API uptake. *See id.* In addition, Table 3 shows that laminates #1 and #2 include a loading of the tie layer to be less than the contact loading which results in an "ok" API uptake. *Id.* Table 5 further illustrates the ranges of the tie layer and contact layer and the effect on usability in light of the sum of mechanical strength tests. *Id.*, ¶ [0207]. Therefore, the current application shows that the claimed loading of the tie layer (3-9 g/m2) and its relationship to the loading of the contact layer (i.e., wherein x=1-3) is critical or provides for unexpected results.

Further, Adams does not teach or suggest that the thickness of the tie layer and/or contact layer is important for API uptake much less disclose what mechanical stress parameters are important and how these interplay with the loadings. Rather, Adams describes that "the peel oil concentrations determined on cartons in duplicate for each filler loading percent and storage time

clearly demonstrate the reduction in absorption of peel oil as loading increased." Adams, ¶ [0040]. That is, Adams describes that increasing an amount of filler gives the lowest absorption of peel oil. However, Adams fails to teach or suggest the importance of the relationship between the tie layer and the contact layer and how the relationship is important for API uptake.

Therefore, Adams does not teach or suggest "wherein a total loading of the tie layer is in the range of 3-9 g/m^2" much less "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1. That is, Adams does not teach or suggest that the loading of the tie layer and its relationship to the loading of the contact layer is important much less that that the relationship to the loading of the contact layer is important for API and/or mechanical strength tests.

Because Adams does not teach or suggest all the features of amended claim 1, the loading value of the tie layer and the equation that compares it with the load value of the contact layer cannot be inherently the same as claimed. Accordingly, the Office Action has failed to establish a *prima facie* case of obviousness for the claimed loading value of the tie layer and the equation that compares it with the load value of the contact layer in view of Adams.

Therefore, for at least these reasons, amended independent claim 1 is allowable over any combination of Adams.

Accordingly, Applicant requests that the rejection of independent claim 1 under 35 U.S.C. § 103 be withdrawn.

Dependent Claims 3–8 and 10

Dependent claims 3–8 and 10 each depend from independent claim 1, and are therefore allowable for at least the same reasons that independent claim 1 is allowable.

Accordingly, for at least these reasons, Applicant requests that the rejection of dependent claims 3–8 and 10 under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is therefore respectfully requested.

The Commissioner is authorized to charge any fees or underpayments that may be due with this response, or credit any overpayments, to Deposit Account No. 08-2623.

If the Examiner believes a telephone conference would expedite prosecution of this Application, please call the undersigned at (303) 473-2700.

Respectfully submitted,

By: / Paul M. Schramm /
Paul M. Schramm
Reg. No. 62,050

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Salt Lake City, Utah 84147
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Electronic Acknowledgement Receipt

EFS ID:	44320715
Application Number:	16425067
International Application Number:	
Confirmation Number:	7044
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Customer Number:	26582
Filer:	Paul M. Schramm/Wendy Nishida
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P008EP.US (87942.0011)
Receipt Date:	18-NOV-2021
Filing Date:	29-MAY-2019
Time Stamp:	17:27:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P008Danapak.pdf	229115 02f039a9db95d108ecd255eb8e0cb9c229e2a2b3	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	After Final Consideration Program Request	1	1
	Response After Final Action	2	2
	Claims	3	6
	Applicant Arguments/Remarks Made in an Amendment	7	13
Warnings:			
Information:			
	Total Files Size (in bytes):	229115	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/425,067	Filing Date 05/29/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	11/18/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 18	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/DENISE HOPKINS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

26582 7590 11/16/2021

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

EXAMINER
TISCHLER, FRANCES

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
11/16/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@hollandhart.com

Applicant-Initiated Interview Summary	**Application No.** 16/425,067	**Applicant(s)** Johansen et al.		
	Examiner FRANCES TISCHLER	**Art Unit** 1765	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
FRANCES TISCHLER	Primary Examiner	Telephonic
LEah Villarreal	Attorney of Record	

Date of Interview: 10 November 2021

Issues Discussed:

Proposed Amendment(s)

Discussed the importance of the contact layer having a greater loading than the tie layer by 1-3:1 and the importance of the total loading to be in the range of 3-9 g/m2, given that the film is used as packaging for reactive compounds.
Discussed amending claim 1 to recite that he film is an aggressive chemical resistant film, the chemical being selected from nicotine, fentanyl, rivastigamine or lidoncaine.
Applicant will respond with amendments/remarks in writing.

/FRANCES TISCHLER/ Primary Examiner, Art Unit 1765	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

26582 7590 08/25/2021

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Salt Lake City, UT 84147

EXAMINER
TISCHLER, FRANCES

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
08/25/2021	ELECTRONIC

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patentdocket@hollandhart.com

Office Action Summary	Application No. 16/425,067	Applicant(s) Johansen et al.	
	Examiner FRANCES TISCHLER	Art Unit 1765	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 8/13/21.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) 11-20 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-10 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 8/13/21.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Status of the Claims

Receipt is acknowledged of the Applicant's response filed on 8/13/21. Claims 1, 5, 6, 9 and 10 have been amended. Claims 11 – 20 are withdrawn due to a restriction requirement. Claims 1 - 10 are now pending.

All outstanding objections and rejections, except for those maintained below, are withdrawn in light of applicant's amendments/remarks filed on 8/13/21.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Terminal Disclaimer

The Terminal Disclaimers have been received and entered.

Claim Rejections - 35 USC § 112

Claims 5, 6 and 10 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Regarding Claim 5: Claim 5 has been amended to read "wherein at least one layer of a multilayered tie layer is made from…" However, claim 1 recites "a tie layer". It is, therefore, unclear if the multilayered tie layer is in addition to the tie layer of claim 1 or if the tie layer of claim 1 is comprised of multiplayers. Note that claim 4 recites the tie layer is a multilayered tie layer. Maybe claim 5 is meant to depend from claim 4.

Regarding Claim 6: The same argument applies to claim 6.

Regarding Claim 5: Claim 5 has been amended to read "…a material selected from the group consisting of: ethylene methacrylic acid, ethylene acrylic acid, terpolymer of ethylene, acrylic ester, and maleic anhydride, **or** a terpolymer of ethylene, butyl acrylate, maleic anhydride, **or** combinations thereof". The "or combinations thereof" seems to belong to the second terpolymer since there is no "and" between the butyl acrylate **and** maleic anhydride to delineate what the terpolymer is made of. However, a terpolymer is necessarily made of 3 monomers, so one cannot have a combination thereof for the terpolymer. Therefore, it is assumed that Applicant means to claim that the combination thereof means that one can combine any one of the listed compounds/polymers. Additionally, the "or" before the "terpolymer of ethylene, butyl acrylate…" should be removed.

Regarding Claim 6: Similarly in claims 6, the "or" before the "terpolymer of ethylene, butyl acrylate…" should be removed.

Regarding Claim 10: Claim 10 has been amended to recite "the group consisting of a metal foil **and** a polymer made of polyamide, silicon, **or** aluminiumoxide coated polyesters **and** fluoropolymers, **or** a combination thereof". Similarly to claim 5, it is unclear which polymers are actually part of the group.

The following is a quotation of 35 U.S.C. 112(d):

> (d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claims 2 and 9 are rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.

Regarding Claim 2: Claim 2 recites that x is in the range of 1 – 3, but claim 1 has been amended to read that x is in the range of 1 - 3.

Regarding Claim 9: Claim 9 has been amended to depend from claim 1, but now it is a repeat of claim 3.

Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 103

Claims 1 – 10 are rejected under 35 U.S.C. 103 as being unpatentable over ADAMS (US 2005/0037162).

Claims 1 - 3, 5, 6 and 9 - 10: ADAMS discloses (see entire document) a laminate film that provides good oxygen barrier properties ([0004]) [as claimed] comprising:

providing a base layer, referred to as a functional barrier layer, comprising aluminum, polyamide or PET ([0019]) [also reading on the claimed resistant to water or oxygen, since they are the same layer as claim 10];

coextruded layers ([0028], [0044], [0045], figures), wherein the coextruded layers comprise one or more adhesive tie layers and contact layers, wherein the tie layer is selected from ethylene acrylic acid (EAA) [as per claims 5 and 6], and the contact layer is selected from cycloolefin copolymer (COC) [as per claim 1] ([0023], [0024], [0030], table in [0034]), claims 7, 10, 14) [as claimed].

ADAMS discloses an example of the tie layer loading at 14 lbs/3000 ft^2 ([0037]), failing to teach 3-9 g/m^2; and regarding the amendment for the range of x from 0.8-3 to a range of 1-3, ADAMS example shows of a ratio of 12:14, or 0.85:1, failing to teach 1-3.

However, it has been settled that:

merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971); and

where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the instant case, one of ordinary skill in the art would know to vary the process parameters depending on the desired thickness of the film which depends on the desired end-use of the product, or the desired weight of the layers which also depends on the desired end-use of the

product, wherein ADAMS discloses an example of coating weights for the various layers ([0037]), discloses that constant loading levels are achieved even if one would add fillers to a layer ([0043]), and discloses different end-uses for the laminate film, including laminates that provides oxygen barrier for beverage packaging, laminates that have resistance to migration of essential oils, to flavors, or to aromas, and laminates that minimize scalping (abstract, [0001], [0004]), all of which affect the loading, to achieve ADAMS' stated objective of making a film comprising a base layer and coextruded tie and contact layers that provides for good packaging, and have thus arrived at the claimed loading.

Claims 4 and 7: ADAMS discloses one or more tie layers (figures 3-4, [0024], examples H and I in paragraph [0034]).

Claims 5 – 6: ADAMS discloses few contact layers to choose from comprising linear polyolefins or cyclic olefin copolymer ([0023]) and few tie layers to choose from comprising ethylene acrylic acid, polyolefins and vinyl acetate ([0024], claim 10). It would be obvious to one skilled in the art to choose from ADAMS' small list of tie polymers and contact polymers the combination that produces ADAMS' stated objective of making a film comprising a base layer, and tie and contact layers that provides for good packaging with good oxygen barrier and is effective in minimizing scalping ([0004]), and have thus arrived at the claimed combination of COC of claim 1 and the acrylic acids of claims 5-6.

Claim 8: Since ADAMS discloses one or more tie layers and gives an example of ethylene acrylic acid for either or both layers, then the loading ratio between them is necessarily 1:1.

Response to Arguments

Applicant's arguments filed 8/13/21 have been fully considered but they are not persuasive.

Applicant submits that ADAMS teaches away from the claimed loading values and equations, as per the example in paragraph [0037] of ADAMS.

Applicant's argument is not convincing:

Although the weight of ADAMS' tie layer in the example is not the claimed weight and the relationship between it and the contact layer is only close to the claimed ratio (0.87 vs the claimed 1), it is not inventive to discover the optimum or workable ranges. ADAMS discloses several end-uses for the laminate, each use can have layers of different weights/loads/thicknesses, which can be achieved by routine experimentation.

Additionally, merely selecting proportions and ranges is not patentable - absent a showing of criticality. Applicant is asked to show that the claimed loading of the tie layer (3-9 g/m^2) and its relationship to the loading of the contact layer (i.e.wherein x=1-3) is critical or provides for unexpected results.

Applicant submits that the tie layer and outermost polyolefin layer are not coextruded in structures E, F and G in ADAMS.

Applicant's argument is not convincing. ADAMS explicitly discloses that the tie layer and other layers can be achieved by coextrusion (see [0028], [0045]).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FRANCES TISCHLER whose telephone number is (571)270-5458. The examiner can normally be reached on Monday-Friday, 8:00 AM - 8:00 PM EST, midday flex.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/FRANCES TISCHLER/
Primary Examiner, Art Unit 1765

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	02/02/2021	05/25/2021	08/17/2021						
	1	÷	✓	✓						
	2	÷	✓	✓						
	3	÷	✓	✓						
	4	÷	✓	✓						
	5	÷	✓	✓						
	6	÷	✓	✓						
	7	÷	✓	✓						
	8	÷	✓	✓						
	9	÷	✓	✓						
	10	÷	✓	✓						
	11	÷	N	N						
	12	÷	N	N						
	13	÷	N	N						
	14	÷	N	N						
	15	÷	N	N						
	16	÷	N	N						
	17	÷	N	N						
	18	÷	N	N						
	19	÷	N	N						
	20	÷	N	N						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61K31/167 OR A61K31/27 OR A61K31/4468 OR A61K31/465 OR A61K9/0014 OR A61K9/7084 OR B32B15/08 OR B32B15/082 OR B32B15/085 OR B32B15/20 OR B32B2255/10 OR B32B2255/20 OR B32B2307/718 OR B32B2307/7244 OR B32B2307/7246 OR B32B2307/7265 OR B32B2439/46 OR B32B2439/80 OR B32B2556/00 OR B32B27/08 OR B32B27/283 OR B32B27/30 OR B32B27/304 OR B32B27/306 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/02 OR B65D65/40	05/25/2021	/FT/
updated search	08/17/2021	/FT/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

Search Notes		
Search Notes	**Date**	**Examiner**
East text search; inventor and company search; classification search, codes shown above; combination of East text search and classification search; combination of East text search and inventor search; combination of East text search and company search; considered/examined all IDS; searched google scholar and google patent and IP.com; search terms included, for instance: cycloolefin or COC or (cyclic adj olefin) or polyamide or (ethylene adj vinyl adj alcohol) or EVA) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride)	05/25/2021	/FT/
updated search	08/17/2021	/FT/

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/425,067
Filing Date	May 29, 2019
First Named Inventor	Johansen et al.
Art Unit	1765
Examiner Name	Frances Tischler
Docket Number	P008EP.US (87942.0011)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Document Number Country Code[3] –Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	19	EP 0245921-A2	11-19-1987	International Paper Company	10 pgs.	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]

Examiner Signature	/FRANCES TISCHLER/	Date Considered	08/17/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 2.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Office, U.S. patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /F.T./

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	2

Complete if Known	
Application Number	16/425,067
Filing Date	May 29, 2019
First Named Inventor	Johansen et al.
Art Unit	1765
Examiner Name	Frances Tischler
Docket Number	P008EP.US (87942.0011)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Steven A. Avena /	Date (YYYY-MM-DD)	2021-08-13
Name/Print	Steven A. Avena	Registration Number	75,211

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /F.T./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 17:13
S2	1	"6120860".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:07
S4	1	"20040234790".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:10
S5	1	"20050106344".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:11
S6	1	"6790496".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:12
S7	1	"20050037162".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:47
S8	302	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:50
S9	3	((("DANAPAK") near3 ("FLEXIBLES") near3 ("A/S"))).AS,AANM.	USPAT	NEAR	ON	2021/01/31 19:50
S10	142	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:51
S11	350,512	(B05D1/265 OR B32B15/082 OR B32B15/20 OR B32B1/00 OR B32B2250/05 OR B32B2307/714 OR B32B2307/7244 OR B32B2307/7265 OR B32B2323/00 OR B32B2398/20 OR B32B2439/00 OR B32B27/08 OR B32B27/306 OR B32B27/308 OR B32B27/32 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/153 OR B32B7/12).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:53

S12	22	(cycloolefin or COC) and (base adj layer) and (tie adj layer) and (contact adj layer) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:55
S13	14	("20090208685" | "20110158564" | "20150225151" | "20160325534" | "20170158400" | "5613958" | "6670423" | "6891018" | "6921563" | "8703283" | "8722164" | "9452593" | "9487918" | "9663281").PN.	US-PGPUB; USPAT	NEAR	ON	2021/01/31 19:57
S14	1	"20160325534".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:58
S15	0	S12 and S14	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S16	0	S12 and S13	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S17	3	S12 and S8	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S18	3	S12 and S10	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S19	21	S12 and S11	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:01
S20	0	S12 and S2	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S21	0	S12 and S3	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S22	0	S12 and S4	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S23	0	S12 and S5	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S24	0	S12 and S6	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02

S25	0	S12 and S7	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S26	25	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 08:55
S27	1	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:20
S28	302	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S29	3	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)) and S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S30	142	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S31	4	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)) and S30	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S32	1	"20200047461".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/02/02 04:37
S33	14	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic) and load$5	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:38

S34	457,500	(A61K31/167 OR A61K31/27 OR A61K31/4468 OR A61K31/465 OR A61K9/0014 OR A61K9/7084 OR B32B15/08 OR B32B15/082 OR B32B15/085 OR B32B15/20 OR B32B2255/10 OR B32B2255/20 OR B32B2307/718 OR B32B2307/7244 OR B32B2307/7246 OR B32B2307/7265 OR B32B2439/46 OR B32B2439/80 OR B32B2556/00 OR B32B27/08 OR B32B27/283 OR B32B27/30 OR B32B27/304 OR B32B27/306 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/02 OR B65D65/40).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S35	25	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S36	17	S34 and S35	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S37	33	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/25 08:59
S38	74	(cycloolefin or COC or (cyclic adj olefin) or polyamide or (ethylene adj vinyl adj alcohol) or EVA) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/25 09:00
S39	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/05/25 17:49

S40	313	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/08/17 20:39
S41	149	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/08/17 20:39
S42	22	(cycloolefin or COC) and (base adj layer) and (tie adj layer) and (contact adj layer) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/08/17 20:39
S43	3	S42 and S40	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/08/17 20:39
S44	3	S42 and S41	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/08/17 20:39
S45	1	"20200047461".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/08/20 07:31

EAST Search History (Interference)

<This search history is empty>

8/20/2021 7:32:51 PM
C:\Users\ftischler\Documents\EAST\Workspaces\16425067.wsp

Application Number * 16/425,067 *	Application/Control No. 16/425,067	Applicant(s)/Patent under Reexamination Johansen et al.	
	Examiner TISCHLER, FRANCES	Art Unit 1765	

Document Code - DISQ	Internal Document - DO NOT MAIL

TERMINAL DISCLAIMER	☑ APPROVED	☐ DISAPPROVED
Date Filed: 13 August 2021	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

/TRINA STEPTOE/

Technology Center: OPLC

Telephone: (571)272-2577

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/425,067	Filing Date 05/29/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

	(Column 1)	(Column 2)			
FOR	NUMBER FILED	NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	08/13/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/BRENDA MURPHY/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 7044
Johansen et al.	Examiner: Frances Tischler
For: IMPROVED FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS	Art Unit: 1765
	AMENDMENT
Application No.: 16/425,067	**CERTIFICATE OF TRANSMISSION** I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on: August 13, 2021.
Filed: May 29, 2019	
Docket No.: P008EP.US (87942.0011)	By: / Wendy Nishida / Wendy Nishida
Customer No.: 26582	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the non-final Office Action dated June 1, 2021, please enter the following amendments and remarks:

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

Amendments to the Claims

Please enter the following amendments to the claims:

1. (Currently Amended) A laminate film comprising:

a base layer, wherein the base layer is one or more of water or oxygen resistant; and

a co-extrusion layer, the co-extrusion layer comprising a tie layer and a contact layer, wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof;

wherein a total loading of the tie layer is in the range of 3-9 g/m2 and wherein a loading of the contact layer is:

loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of **[[0.8]]** **1** to 3.

2. (Original) The laminate film according to claim 1, wherein x is in the range of 1 to 3.

3. (Original) The laminate film according to claim 1, wherein x is in the range of 1.33 to 2.75.

4. (Original) The laminate film according to claim 1, wherein the tie layer is a multilayered tie layer comprising at least two layers.

5. (Currently Amended) The laminate film according to claim 1, wherein at least one layer of **[[the]]** **a** multilayered tie layer is made from a material selected from the group consisting of: ethylene methacrylic acid, ethylene acrylic acid, terpolymer of ethylene, acrylic ester, and maleic anhydride, ~~**preferably**~~ **or a terpolymer of** ethylene, butyl acrylate, maleic anhydride, or **[[a]]** combination**s** thereof.

6. (Currently Amended) The laminate film according to claim 1, wherein a second layer of **[[the]]** **a** multilayered tie layer comprises a material selected from the group consisting of ethylene methacrylic acid, low-density polyethylene, ethylene methyl acrylate, ethylene butyl acrylate, ethylene ethyl acrylate, a terpolymer of ethylene, acrylic ester, and

maleic anhydride, ~~**preferably**~~ **or a terpolymer of** ethylene, butyl acrylate, and maleic anhydride, ethylene acrylic acid, or **[[a]]** combination**s** thereof.

7. (Original) The laminate film according to claim 1, wherein the tie layer consists of two layers, a first tie layer and a second tie layer.

8. (Original) The laminate film according to claim 7, wherein a loading ratio of the first tie layer to the second tie layer is approximately 1:1.

9. (Currently Amended) The laminate **film** according to claim **[[7]] 1**, wherein x is in the range of 1.33 to 2.75.

10. (Currently Amended) **[[A]] The** laminate film according to claim 1, wherein the base layer is selected from the group consisting of a metal foil**[[,]] and** a polymer **made of polyamide, silicon, or aluminiumoxide coated polyesters and[[, a]]** fluoropolymer**s**, or a combination thereof.

11. (Withdrawn) A packaging for packing a composition said packaging comprising:

a first outer layer made of a mechanically wear resistant material;

a laminate film comprising a base layer and a co-extrusion layer;

wherein the base layer is one or more of water resistant or oxygen resistant;

wherein the co-extrusion layer comprise a tie layer and a contact layer, a total loading of the tie layer is in the range of 3-9 g/m2, and a loading of the contact layer is loadingcontact=x*loadingtie, where loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 0.8 to 3;

wherein the base layer side of the film is facing the first outer layer.

12. (Withdrawn) The packaging according to claim 11, wherein x is in the range of 1 to 3.

13. (Withdrawn) The packaging according to claim 12, wherein x is in the range of 1.33 to 2.75.

14. (Withdrawn) The packaging according to claim 11, wherein the laminate encloses a composition comprising a compound selected from the group consisting of: nicotine, rivastigmine, fentanyl, lidocaine, or a combination thereof.

15. (Withdrawn) The packaging according to claim 11, wherein the composition is a patch.

16. (Withdrawn) A method for providing a laminate film, said method comprising the steps of:

providing a base layer, wherein the base layer is one or more of: water resistant or oxygen resistant;

coextruding a layer comprising a tie layer and a contact layer to provide a co-extrusion layer,

coating the co-extrusion layer to the base layer; and

curing the co-extrusion layer coated to the base layer to provide the laminate film,

wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof; and

wherein the total loading of the tie layer is 3 to 9 g/m2 and wherein the loading of the contact layer is:

loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and where x is in the range of 0.8 to 3.

17. (Withdrawn) The method according to claim 16, wherein x is in the range of 1 to 3.

18. (Withdrawn) The method according to claim 16, wherein the tie layer is multilayered and wherein all the layers of the multilayered tie layer are coextruded with the contact layer.

19. (Withdrawn) The method according to claim 18, wherein a total loading of the multilayered tie layer and contact layer is less than 40 g/m2.

20. (Withdrawn) The method according to claim 16, wherein the co-extrusion is performed at a temperature of 240 - 330°C.

REMARKS

Status of the Claims

Before this Amendment, claims 1–10 were present for examination and claims 11–20 were withdrawn from consideration. In this Amendment: claims 1, 5, 6, 9, and 10 are amended; no claims are canceled; and no new claims are added. Therefore, claims 1–10 are present for examination, and claim 1 is the independent claim. Support for the amendments to the claims may be found throughout the Specification as filed including at least at Paragraphs [0017], [0049], and [0088]. No new matter is added with these amendments.

In the non-final Office Action dated June 1, 2021 ("Office Action"): claims 5, 6, and 9 were rejected under 35 U.S.C. § 112(b) as being indefinite; claims 1–10 were rejected under 35 U.S.C. § 103 over U.S. Patent Publication No. 2005/0037162 to Adams ("Adams"); claims 1–10 were rejected under 35 U.S.C. § 103 over U.S. Patent No. 6,120,860 to Bowen et al. ("Bowen"); claims 1–10 were rejected for non-statutory double patenting over U.S. Patent No. 16,835,018 to Christensen et al. ("Christensen1"); claims 1–10 were rejected for (statutory/non-statutory) double patenting over U.S. Patent No. 16,780,999 to Gu et al. ("Gu"); and claims 9 and 10 were objected to for certain informalities. Applicant respectfully requests reconsideration.

Double Patenting

It appears that the Office Action incorrectly listed U.S. Patent Application No. 16,780,999 to Gu et al. ("Gu") instead of U.S. Patent Application No. 15,780,999 to Christensen et al. ("Christensen2"). Without conceding the merits of the rejection—and solely to expedite prosecution—Applicant has addressed the rejection in view of Christensen1 and Christensen2. The Office Action rejected claims 1–10 on the ground of non-statutory obviousness-type double patenting over claims 1–20 of Christensen1 and claims 1–36 of Christensen2. *See* Office Action, pp. 9 and 10. The Office Action states that the filing of a terminal disclaimer would overcome the double patenting rejection. *See id*, p. 9.

Applicant has submitted an electronic terminal disclaimer with this response. Applicant submits this terminal disclaimer to expedite allowance of the pending claims and does not concede the merits of the double patenting rejection or any determination regarding whether

claims 1–10 are patentably distinct over claims 1–20 of Christensen1 and claims 1–36 of Christensen2.

Applicant believes that the terminal disclaimer overcomes the double patenting rejection, and accordingly requests that the double patenting rejection of claims 1–10 be withdrawn.

Objections to the Claims

The Office Action objected to claims 9 and 10 for certain informalities. *See* Office Action, p. 2.

Regarding claim 9, Applicant has amended the claim to recite, in part, "[t]he laminate film." Regarding claim 10, Applicant has amended the claim to recite, in part, "[t]he laminate film according to claim 1."

Accordingly, Applicant requests that the objection to the claims be withdrawn.

35 U.S.C. § 112(b)

The Office Action rejected claims 5, 6, and 9 under 35 U.S.C. § 112(b) as being allegedly indefinite.

Regarding claims 5 and 6, the Office Action alleges that the term "preferably" renders the claims indefinite. *See* Office Action, p. 3. Without conceding the assertion that claims 5 and 6 are indefinite, Applicant has amended the claims to recite, in part, "ethylene methacrylic acid, ethylene acrylic acid, terpolymer of ethylene, acrylic ester, and maleic anhydride, or a terpolymer of ethylene, butyl acrylate, maleic anhydride, or combinations thereof."

Regarding claim 9, the Office Action alleges that "it is unclear if the value of x in claim 9 refers to one tie layer and which one or to both tie layers and if both tie layers have the same x value." *Id.* Without conceding the assertion that claim 9 indefinite, Applicant has amended the claim to recite, in part, "[t]he laminate film according to claim 1."

Accordingly, Applicant requests that the rejection of claims 5, 6, and 9 under 35 U.S.C. § 112(b) be withdrawn.

35 U.S.C. § 102 & § 103

The Office Action rejected claims 1–10 under 35 U.S.C. § 102 over Adams or alternatively, under 35 U.S.C. § 103 over Adams. The Office Action further rejected claims 1–10 under 35 U.S.C. § 102 over Bowen or alternatively, under 35 U.S.C. § 103 over Bowen.

Factual findings made by the Office are the "necessary underpinnings to establish obviousness." MPEP § 2141(II). The Office must set forth "the relevant teachings of the prior art relied upon." MPEP § 2142. In *KSR International Co. v. Teleflex Inc.*, the Supreme Court noted that the analysis supporting a rejection under 35 U.S.C. § 103 must be made explicit. *See* 550 U.S. 398, 418 (2007); MPEP § 2142. "[O]bviousness [also] requires a suggestion of all limitations in a claim." *In re Wada and Murphy*, Appeal 2007-3733 (citing *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)).

Independent Claim 1

Without conceding the merits of the rejection of independent claim 1 under 35 U.S.C. § 102 and § 103—and solely to expedite prosecution—Applicant has amended independent claim 1. For example, independent claim 1 has been amended to recite, in part, "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3."

Specifically, Adams does not disclose "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in amended independent claim 1 (emphasis added).

Adams is generally directed to "a laminate structure having improved resistance to the migration of essential oils, aromas and flavors and improved oxygen barriers characteristics for beverage packing." Adams, Abstract. However, Adams does not disclose "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1. The Office Action concedes, and Applicant agrees, that Adams is

silent regarding the loading value of the tie layer and the equation that compares it with the load value of the contact layer. *See* Office Action, p. 5.

Instead the Office Action states that "since Adams discloses the claimed laminate film and the claimed layers comprising COC and EAA, their loading values are inherently the same as claimed." *Id.* The Office Action, however, does not provide explicit analysis to support why the features of independent claim 1 can be ignored, let alone establish (or even argue) that the loading value of the tie layer and the equation that compares it with the load value of the contact layer are inherently the same as claimed. Applicant submits that the assertion that the loading value of the tie layer and the equation that compares it with the load value of the contact layer are inherently the same as claimed is inapplicable in the current application.

The Office bears the initial burden to develop reasons supporting a reliance on inherency. *See MPEP* 2112 (IV). To satisfy this burden, the Office must identify some basis or articulate some reasoning at least tending to show that allegedly inherent subject matter inevitability flows from cited art (e.g., Adams). Indeed, the MPEP expressly instructs that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

However, the Office Action fails to include rationale or evidence at least tending to show that the features of the loading value of the tie layer and the equation that compares it with the load value of the contact layer can be inherently the same as claimed. In addition, because Adams does not disclose all the features of amended claim 1, the loading value of the tie layer and the equation that compares it with the load value of the contact layer cannot be inherently the same as claimed. Thus, for at least the foregoing reasons, the assertion that the loading value of the tie layer and the equation that compares it with the load value of the contact layer are inherently the same as claimed is inapplicable in the current application. Accordingly, the Office Action has failed to establish a *prima facie* case of obviousness for the claimed loading value of the tie layer and the equation that compares it with the load value of the contact layer in view of Adams.

In addition, because Adams teaches away from such loading values and equation, the loading value of the tie layer and the equation that compares it with the load value of the contact layer cannot be inherently the same as claimed. In one example, Adams describes that the tie layer includes a target coating weight of 14 lbs/3,000 ft^2. *See* Adams, ¶ [0037]. That is, Adams describes a target coating weight of a tie layer to be about 70 g/m^2. Adams further describes that "the LDPE layer was extrusion coated on the paperboard[, and] the polyamide and tie layer were then deposited as a coextrusion coating to the paperboard and the polyolefin containing filler [i.e., the food contact layer], then applied over the tie layer." *Id.*, ¶ [0037]. However, the tie layer that includes a target coating weight of 14 lbs/3,000 ft^2 is not the same as "wherein a total loading of the tie layer is in the range of 3-9 g/m^2," as recited in independent claim 1. It therefore follows that Adams does not disclose "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1. Rather, because Adams is directed towards a target coating weight of a tie layer greater than a loading in the range of 3 to 9 g/m^2, Adams teaches away from such loading values. That is, Adams discloses a target coating weight different than the claimed loading value of the application.

In other examples, Adams describes in structures E., F., and G. that the outer most polyolefin layer is without filler, but all examples then have an adjacent polyolefin layer with filler. Furthermore, the tie layer and the outermost polyolefin layer are not coextruded. *See id.* at ¶ [0034]. Therefore Adams does not disclose "a co-extrusion layer, the co-extrusion layer comprising a tie layer and a contact layer" much less "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1. Accordingly, Adams does not disclose "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1, nor are the target coating weight values of Adams inherently the same as the loading values and the equation that compares with the load values of the contact layer as claimed.

Therefore, for at least these reasons, amended independent claim 1 is allowable over Adams.

In addition, Bowen does not disclose "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in amended independent claim 1.

Bowen is generally directed to "multilayer film structures and packages." Bowen, Abstract. However, the Office Action concedes, and Applicant agrees, that Bowen is silent regarding the loading value of the tie layer and the equation that compares it with the load value of the contact layer. *See* Office Action, p. 7.

Instead the Office Action states that "since Bowen discloses the claimed laminate film and the claimed layers comprising EVA and EAA, their loading values are inherently the same as claimed." *Id.* The Office Action, however, does not provide explicit analysis to support why the features of independent claim 1 can be ignored, let alone establish (or even argue) that the loading value of the tie layer and the equation that compares it with the load value of the contact layer are inherently the same as claimed. Applicant submits that the assertion that the loading value of the tie layer and the equation that compares it with the load value of the contact layer are inherently the same as claimed is inapplicable in the current application.

The Office bears the initial burden to develop reasons supporting a reliance on inherency. *See MPEP* 2112 (IV). To satisfy this burden, the Office must identify some basis or articulate some reasoning at least tending to show that allegedly inherent subject matter inevitability flows from cited art (e.g., Bowen). Indeed, the MPEP expressly instructs that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

However, Office Action fails to include rationale or evidence at least tending to show that the feature of the loading value of the tie layer and the equation that compares it with the load value of the contact layer can be inherently the same as claimed. In addition, because Bowen does not disclose all the features of amended claim 1, the loading value of the tie layer and the

equation that compares it with the load value of the contact layer cannot be inherently the same as claimed. Thus, for at least the foregoing reasons, the assertion that the loading value of the tie layer and the equation that compares it with the load value of the contact layer are inherently the same as claimed is inapplicable in the current application. Accordingly, the Office Action has failed to establish a *prima facie* case of obviousness for the claimed loading value of the tie layer and the equation that compares it with the load value of the contact layer in view of Bowen.

In addition, because Bowen teaches away from such loading values and equation, the loading value of the tie layer and the equation that compares it with the load value of the contact layer cannot be inherently the same as claimed. The Office Action states that "Bowen discloses that the sealant or contact layer is selected from EVA . . . [reading on claimed ethylene vinyl alcohol]." *See* Office Action, p. 7. Bowen describes that "suitable materials for adhesive . . . can include . . . ethylene vinyl acetate (EVA)." Bowen, col. 3, ll. 59-60. However, ethylene vinyl acetate (EVA) is not the same as ethylene vinyl alcohol. Therefore, Bowen does not disclose "wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof" much less "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited independent claim 1, nor is the contact layer of Bowen inherently the same as the contact layer as claimed.

In other examples, Bowen describes that the coextrusion layer of Example 1 that is coated to the base layer (e.g., barrier layer) is not a coextruded contact and tie layer but rather an EVA/tie/PA/tie/EVA layer. *See id.* at col. 7, l. 6. Bowen further describes that "a 2.5 mil blown coextrusion of the type employed in Example 1 was adhered to a second layer element." *Id.*, col. 7, l. 27-28. However, Bowen does not disclose "a co-extrusion layer, the co-extrusion layer comprising a tie layer and a contact layer" much less "wherein a loading of the contact layer is loadingcontact=x*loadingtie, wherein loadingcontact is the loading of the contact layer, loadingtie is the total loading of the tie layer, and x is in the range of 1 to 3," as recited in independent claim 1, nor is the coextrusion layer thickness value of Bowen inherently the same

as the loading values and the equation that compares with the load values of the contact layer as claimed.

Therefore, for at least these reasons, amended independent claim 1 is allowable over Bowen.

In addition, Applicant submits that it would have not been obvious to combine the teachings of Adams and Bowen. Specifically, a person of ordinary skill would not reasonably expect the films of Bowen to work when replacing the sealant layers of Bowen with polymers mentioned in Adams because Bowen is directed at aggressive solvents which is something very different from food/juices of Adams. In one example, Bowen describes that "the high barrier material provides an effective barrier between the outside atmosphere and the product within the package." *Id.*, col. 5, ll. 19-20. Bowen further describes that "nylon acts as a good barrier for containing organic products such as solvents, e.g., amines, within the package." *Id.*, col. 5, ll. 29-30. That is, Bowen describes that nylon is the flexible barrier rather than an olefin or olefin-based material of the sealant layer. Therefore, a person of ordinary skill cannot conclude from Adams and Bowen that the sealant layer of Bowen is the layer capable for conferring for the given properties sought in the different applications. Further, the combination of elements yields unpredictable results (e.g., unpredictable behavior). Thus, it would not have been obvious to replace an olefin of the sealant layer of Bowen with a cycloolefin copolymer of Adams because it is the combination of layers (e.g., including nylon of the flexible barrier) that contributes to the given barrier properties within the package of Bowen. Therefore, Applicant submits that it would have not been obvious to combine the teachings of Adams and Bowen.

Accordingly, Applicant requests that the rejection of independent claim 1 under 35 U.S.C. § 102 and § 103 be withdrawn.

Dependent Claims 2–10

Dependent claims 2–10 each depend from independent claim 1, and are therefore allowable for at least the same reasons that independent claim 1 is allowable.

Accordingly, for at least these reasons, Applicant requests that the rejection of dependent claims 2–10 under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is therefore respectfully requested.

The Commissioner is authorized to charge any fees or underpayments that may be due with this response, or credit any overpayments, to Deposit Account No. 08-2623.

If the Examiner believes a telephone conference would expedite prosecution of this Application, please call the undersigned at (303) 473-2700.

Respectfully submitted,

By: / Steven A. Avena /
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I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on August 13, 2021

HOLLAND & HART LLP

By: / Wendy Nishida /
Wendy Nishida

PATENT
Attorney Docket No.: P008EP.US (87942.0011)
Client Ref. No.: AWA#138787

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Johansen et al.

Application No.: 16/425,067

Filed: May 29, 2019

For: FILMS AND LAMINATES FOR USE IN PACKAGINE REACTIVE COMPOUNDS

Customer No.: 26582

Confirmation No.: 7044

Examiner: Frances Tischler

Art Unit: 1765

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Pursuant to the duty of disclosure set forth at 37 CFR §1.56 and the requirements for filing an Information Disclosure Statement set forth at 37 CFR §§1.97-1.98, enclosed is Form PTO/SB/08 (hereinafter "the Form") with a list of all items being submitted for consideration by the Office. A legible copy of each item listed in the Form that is not a U.S. patent or a published U.S. patent application, and not identified as being cumulative, is enclosed.

The disclosure of the remaining documents identified on the Form is not to be construed as an admission that any of the documents, alone or in any combination, is considered to be material to patentability as defined in 37 CFR §1.56(b). Moreover, the disclosure of these documents is not to be construed as an admission that any of the documents are prior art as to the above-identified application.

Applicants believe that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such a fee from the undersigned's

Deposit Account No. 08-2623. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

/ Steven A. Avena /

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	16/425,067
Filing Date	May 29, 2019
First Named Inventor	Johansen et al.
Art Unit	1765
Examiner Name	Frances Tischler
Docket Number	P008EP.US (87942.0011)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Document Number Country Code[3] –Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	19	EP 0245921-A2	11-19-1987	International Paper Company	10 pgs.	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 2.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Office, U.S. patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

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Sheet 2 of 2

Complete if Known	
Application Number	16/425,067
Filing Date	May 29, 2019
First Named Inventor	Johansen et al.
Art Unit	1765
Examiner Name	Frances Tischler
Docket Number	P008EP.US (87942.0011)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Steven A. Avena /	Date (YYYY-MM-DD)	2021-08-13
Name/Print	Steven A. Avena	Registration Number	75,211

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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(54) **heat sealable barrier material for improved juice packaging.**

(57) The present invention relates to an improved container for citrus juices and other liquids. The container utilizes a paperboard barrier laminate (34, 36, 38, 40) for the containment of essential oils and the prevention of losses of Vitamin C. Also disclosed is a process of making the laminate. The laminate makes use of a layer (40) of a heat-sealable ethylene vinyl alcohol copolymer to enhance the barrier properties of the laminate.

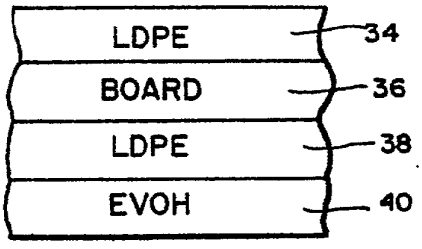


FIG. 5.

EP 0 245 921 A2

HEAT SEALABLE BARRIER MATERIAL FOR IMPROVED JUICE PACKAGING

BACKGROUND OF THE INVENTION

The invention relates to heat-sealable barrier laminates for the containment of essential oils and the prevention of loss of Vitamin C in paperboard cartons, as well as to a process for making such laminates. More particularly, this invention relates to barrier laminates which are comprised of an improved heat-sealable product contact material which does not absorb or transmit flavor or odor ingredients of citrus and other juices.

Heat-sealable low-density polyethylenes are well known to be components of current paperboard citrus juice cartons which provide little barrier to absorption and/or transmission of citrus juice essential flavor/aroma oils. Additionally, it is well known that impermeable materials such as aluminum foil, polar materials such as: polyamides, polyethylene terephthalates, polyvinylidene chlorides, polyvinyl chlorides, etc., and highly crystalline non-polar materials such as high-density polyethylene and polypropylene provide varying degrees of barrier to the absorption and/or transmission of non-polar citrus juice flavor oils such as d-limonene, et al. However, these materials could not be substituted for low density polyethylene since they lacked the requisite heat-sealability over a practical temperature range, necessary FDA clearance for direct contact to foods, stress cracking resistance and cutability during the scoring, and/or die cutting conversion processes. Due to the failures of these impermeable materials, past efforts have concentrated on using a combination of these flavor-oil resistant materials with low density polyethylene as the heat-sealable component.

The existing commercial structure for a paperboard carton for juice and similar products has utilized an easily heat-sealable barrier laminate composed of paperboard sandwiched between two layers of low density polyethylene (LDPE). The LDPE is an inexpensive heat-sealable moisture barrier. The conventional structure falters in that the LDPE layer absorbs the essential oils of the juice after short periods of time causing integrity decay of heat seals, stress cracking of the layer and allows transmission of the essential oils into the paperboard and to the atmosphere. Additionally, the conventional structure provides virtually no barrier resistance to oxygen causing the juice to lose Vitamin C in large amounts.

One other conventional structure adds two additional layers to the structure identified above, namely a foil layer and an additional LDPE layer. The expensive foil layer increases barrier resistance to the flow of oxygen, while the additional LDPE allows for ultimate heat-sealability of the laminate. The improved conventional structure has poor barrier properties relating to the absorption of essential oils and aromas, since the interior contacting layer is still LDPE.

The object of the present invention is to produce an improved juice packaging heat-sealable laminate material which does not absorb or transmit flavor/odor ingredients of citrus and other juices.

SUMMARY OF THE INVENTION

The preferred embodiment of the present invention reveals a heat-sealable barrier laminate providing a substantial barrier to the loss of Vitamin C and an almost complete barrier to the loss of essential flavor oils over the shelf life period of the carton (six weeks) and far beyond the six week period as well. The preferred embodiment comprises from the outer surface to the inner surface contacting the essential oils and/or flavors: an exterior layer of a low density polyethylene, a paperboard substrate, an interior layer of a low density polyethylene and a layer of ethylene vinyl alcohol copolymer (EVOH) coated onto the interior layer of the low density polyethylene, in contact with the juice rendering the laminate heat-sealable.

The cartons constructed of the laminate of the present invention enable significant flavor oil retention of the citrus juice contained, and also significant prevention of loss of Vitamin C, resulting in a significant extension of the shelf life thereof and permits replacement of the costly aluminum foil barrier.

The preferred EVOH is sold under the product name Eval EP resins and is available from Eval Company of America.

The present invention has produced a suitable container which has excellent barrier properties utilizing a laminate which can be heat-sealed with its exterior and interior layers being a non-polar constituent (LDPE) and a polar constituent (EVOH) from front to back. The conventional theories have been that the laminate could not be heat-selaed on conventional apparatus at practical temperatures without having non-polar constituents on its ends. The liquid juice components are insoluble in the polar EVOH material, preventing flavor oil absorption and resulting swelling, stress cracking, and plasticization, heat seal degradation as occurs with LDPE as the contact layer.

The preferred laminate of the present invention not only exhibits significant barrier properties to extend the shelf life of the juice, but the laminate is produced using conventional extrusion equipment.

Stepwise, the paperboard is flame treated both sides, a layer of molten LDPE is placed onto the paperboard substrate by extrusion coating, the newly formed layer of LDPE is then corona discharge treated or flame treated in preparation for heat-sealing later in the process.

Secondly, the web is turned over and a layer of LDPE is extrusion coated onto the other exposed side of the paperboard substrate. This layer is also corona discharge treated or flame treated to facilitate adhesion to a subsequent EVOH layer.

Thirdly, a molten layer of EVOH is extrusion coated onto the interior layer of LDPE. The completed laminate can now be heat-sealed from front to back (LDPE to EVOH) at conventional temperatures (250°F to 500°F).

The newly formed laminate can then be scored, cut into blanks, folded and side-seam heat-sealed thereon for transport.

Once transported, the prepared blanks can be placed onto conventional equipment, such as a PurePak® machine made by Ex-Cell-O. The blanks are heat-sealed at the bottom, filled and heat-sealed at the top by the PurePak® machine to complete the filled carton.

The barrier laminate produced by the present invention not only exhibits excellent barrier properties and can be easily constructed but also meets FDA approval for use in food packaging. Eval Company of America's Eval EP is FDA approved for direct food contact and the preferred EVOH of the invention. Other EVOH's which heat seal at low temperatures (250°F to 500°F) and which can be cut on conventional machinery could also be used as the contacting barrier.

Thus, until the advent of the present invention no suitable containers for the containment of citrus juices have been developed which retain the advantages of using paperboard as the base material and is an FDA approved heat-sealable barrier laminate which is economical and can be formed using conventional extrusion coating equipment.

The present invention described herein is particularly useful as a paperboard laminate employed in the manufacture of citrus juice or other liquid containers. Such containers which make use of a heat-seal for seaming and closing such as folding boxes, square or rectangular containers or cartons, or even cylindrical tubes.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional elevation of an existing commercial structure of a laminate;

FIG. 2 is a cross-sectional elevation of an existing commercial structure of a laminate;

FIG. 3 is a cross-sectional elevation of an existing commercial structure of a laminate;

FIG. 4 is a cross-sectional elevation of an existing commercial structure of a laminate;

FIG. 5 is a cross-sectional elevation of the preferred embodiment of the laminate of the present invention;

FIG. 6 is a cross-sectional elevation of an alternate embodiment of the laminate of the present invention;

FIG. 7 is a cross-sectional elevation of an alternate embodiment of the laminate of the present invention;

FIG. 8 is block diagram representing the process for making the preferred embodiment of the laminate of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The existing commercial structure for a paperboard carton for juice and similar products has made use of an easily heat-sealed barrier laminate composed of paperboard 4 (FIG. 1) sandwiched between two layers of low density polyethylene (LDPE) 2, 6. The LDPE is an inexpensive heat-sealable material which acts only to a limited extent as a moisture barrier to prevent loss of essential oils (flavor) and aroma. The problem encountered with conventional laminate structure has been that the essential oils of the juice (namely - D Limonene) has, after short periods of time, been absorbed into the LDPE layer causing heat seal decay, stress cracking, and swelling while stripping the juice of the essential oils. Additionally, the conventional structure (FIG 1) provides virtually no barrier resistance to oxygen which causes the juice to lose Vitamin C in great quantities after a relatively short period of time. To illustrate, the conventional paperboard ½ gallon juice carton will lose 60.5% of its essential oil (D-Limonene) and 84.5% of its Vitamin C content in a storage period of six weeks (SEE TABLE 1).

One conventional existing paperboard carton (FIG. 2) utilizes two additional layers in addition to the layers disclosed in FIG. 1 to add greater barrier resistance to the passage of oxygen and resultant loss of Vitamin C. Aluminum foil 14 has been added to the laminate structure to increase the barrier's resistance to the flow of oxygen. The additional layer of LDPE 16 is needed to allow the laminate to be heat-sealed from front to back with the exterior LDPE 8 layer. The structure of the barrier laminate (FIG. 2) has poor barrier properties relating to the absorption of essential oils and aromas, since the heat-sealable contacting layer is still low density polyethylene. The shelf storage life of the juice carton made up of the barrier laminate of FIG. 2 still exhibits a percentage loss of essential oils (D-Limonene) of 35.5%, while greatly improving its barrier properties with respect to the percentage loss of Vitamin C, 24% (See Table 1). The addition of the foil layer allows the laminate to exhibit excellent O_2 barrier properties. Although, the use of a foil layer is extremely beneficial, the increased expense makes the use of foil economically less desirable.

FIGS. 3 and 4 disclose structures of barrier laminates described in U.S. Patent 4,513,036. FIG. 3 discloses a barrier laminate comprising a sandwich of LDPE 18-paperboard 20-High Density Polyethylene (HDPE) 22-LDPE 24. The laminate disclosed exhibits large losses of essential oils during its shelf life of six weeks, namely 60.5%, while also exhibiting large losses of Vitamin C during the six week period 87% (see Table 1). The economics and ease of fabrication of the laminates of FIG. 3 are outweighed by the poor barrier properties exhibited.

FIG. 4 discloses the preferred embodiment of U.S. Patent 4,513,036, namely a barrier laminate comprising LDPE 26-Paperboard 28-Polypropylene 30-LDPE 32. The additional polypropylene layer 30 adds to the barrier properties at relatively low additional costs. The barrier properties still are extremely deficient in its resistance to the passage of oxygen and its loss of Vitamin C, namely 71% after six weeks. The polypropylene laminate structure loses 39.5% of its essential oils (D-Limonene) after six weeks (see Table 1).

Both embodiments disclosed in the patent cited above do not adequately preserve the flavor/aroma and Vitamin C content of the juice. The structure of the existing commercial constructions have all faced the same problem due to the necessity for heat sealing the seams and closures while forming the carton blank and while filling the cartons with juice or the like. The necessity of forming a heat seal from the front to the back of the laminate has resulted in the use of an exterior layer of LDPE and an interior layer of LDPE, both non-polar compounds which exhibit excellent heat-sealing characteristics to one another (see FIGS. 1-4).

Referring to FIG. 5, the preferred embodiment of the laminate of the present invention is shown as comprising a paperboard substrate 36 which is most suitably high-grade paperboard stock, for example, 282 lb. Milk Carton Board, to which is applied on both sides a coating of low density polyethylene (LDPE) 34, 38 in a coating weight ranging from about 5 to about 40 pounds per ream. Any commercial extrusion coating grade LDPE is suitable for use herein. On the back or interior portion of the laminate, namely onto LDPE layer 38 is applied a layer of EVOH 40. The EVOH being a heat-sealable layer composed of Eval Company of America's Eval EP resins.

Referring now to FIG. 8, wherein a block diagram discloses the method of forming the heat-sealable barrier laminate of Figure 5.

The laminate can be easily fabricated. In Step A, the paperboard is flame treated two sides. Step B, a molten layer of the LDPE 34 is extrusion coated onto the paperboard substrate 36. Step C, the LDPE layer 34 is corona discharge or flame treated in preparation for subsequent heat-sealing Step D, the web is turned over to facilitate Step E, which has a layer of molten LDPE 38 extrusion coated onto the paperboard substrate 36. Step F, LDPE layer 38 is corona discharge treated to facilitate the adhesion of a subsequent EVOH coating, and lastly, Step G, a layer of EVOH 40 is extrusion coated onto LDPE layer 38 to complete the sandwich.

Referring now to FIG. 6, an alternate embodiment of the laminate of the present invention is shown. The embodiment adds an additional barrier layer which not only provides total containment of flavor oils, but also provides significant containment of Vitamin C. In this alternate embodiment, the paperboard substrate 44, is extrusion coated on the external surface thereof with a coating of heat-sealable LDPE 42. On the internal surface of the paperboard substrate 44 is applied a coating of LDPE 46. Overlying the LDPE web 46 is a layer of an oxygen barrier material 48. The oxygen barrier material can be any of the following group: foil, polyacrylonitrile or its copolymers, polyethylene terephthalate or its copolymers, polyvinylidene chloride or its copolymers, polyamide or its copolymers, polyvinyl alcohols or its copolymers, polyvinyl chloride or its copolymers or an additional layer of EVOH. Overlying the barrier material is a layer of heat-sealable EVOH 50 which will ultimately form the internal surface of the container constructed therefrom.

To enhance the adhesion of the additional barrier layer 48 to the LDPE layer 46 and the EVOH layer 50, additional tie layers 47, 49 can be interposed therebetween. Adhesives which are extrudable or coextrudable, such as Dupont's CXA series or recent vintage Plexars® from Norchem are suitable choices. When using ethylene vinyl alochol (EVOH) as both an oxygen barrier 48 and a heat seal layer 50 in FIG. 6, tie layer 47 can be eliminated by coextrusion coating an EVOH 48/tie layer 49/EVOH 50 composite extrudate onto LDPE layer 46 which has been previously flame or corona treated.

FIG. 7 reflects an embodiment similar to that of FIG. 5. Replacing the outer layer of a heat-sealable LDPE 34, is a blend layer 52 of EVOH and LDPE. The blend is made up of between five (5) to thirty (30) percent EVOH and the rest being LDPE. The laminate is comprised from outside to inside: LDPE/EVOH Blend 52-PAPERBOARD SUBSTRATE 54-LDPE 56-EVOH 58. The advantage of the LDPE/EVOH blend layer is that it eliminates the need for extensive surface treatment prior to heat sealing.

Although specific coating techniques have been described, any appropriate technique for applying the layers onto the paperboard substrate can be suitably employed, such as extrusion, coextrusion, or adhesive lamination or single and/or multilayer films to paperboard to achieve the stated inventions of this patent.

The unique barrier effect provided by the laminate of the present invention to the % loss of essential oils and to the % loss of Vitamin C is clearly demonstrated by the following example outlined in Table 1.

Standard ½ gallon juice containers were prepared and filled with juice. A typical essential oil in the juice was d-limonene. The filled cartons were stored for a test period of six weeks after which the juice was analyzed to determine the percentage loss by weight of the essential oil d-limonene and the percentage loss by weight of Vitamin C.

The six cartons tested were those shown in FIGS. 1-6 and described herein.

TABLE 1

Test Sample ½ Gallon Juice Container	% Loss of Essential Oil	% Loss of Vitamin C
LDPE-BOARD-LDPE (FIG. 1)	60.5	84
LDPE-BOARD-LDPE-FOIL-LDPE (FIG. 2)	35.5	24
LDPE-BOARD-HDPE-LDPE (FIG. 3)	60.5	87
LDPE-BOARD-POLYPROPYLENE-LDPE (FIG. 4)	39.5	71
LDPE-BOARD-LDPE-EVOH (FIG. 5)	0*	30
LDPE-BOARD-LDPE-EVOH-Tie Layer-EVOH (FIG. 6 with tie layer)	0*	24

*Less than one percent

It can be clearly seen that the container prepared from a laminate of the present invention provides an almost complete barrier to the loss of essential oils far greater than has been present in existing structures comprising LDPE heat seal layers. Additionally, the oxygen passage or percentage loss of Vitamin C has been greatly reduced over all prior laminates not containing aluminum foil.

The effectiveness of the laminate of the present invention as a barrier to migration of essential oils and flavors, as well as a barrier to a loss of Vitamin C permits a significant extension of shelf life of containers constructed therefrom.

Claims

1. A container for liquids containing essential oils and/or flavors, said container constructed from a laminate comprising:

a) a paperboard substrate;

b) an outer layer of 1) a heat-sealable low density polyethylene polymer or 2) a blend of low density polyethylene polymer and ethylene vinyl alcohol copolymer coated on said outer surface of said paperboard substrate;

c) an inner layer of a heat-sealable low density polyethylene polymer coated on said inner surface of said paperboard substrate; and

d) a layer of a heat-sealable ethylene vinyl alcohol copolymer which can heat-seal on conventional equipment at temperatures ranging from 250°F - 500°F coated on said outer surface of said inner layer of said polyethylene polymer.

2. The container as claimed in claim 1 wherein said outer layer is a low density polyethylene polymer which is corona discharge treated to enhance heat-sealability of said laminate.

3. The container as claimed in claim 2 wherein said outer layer of a low density polyethylene polymer is flame treated to enhance heat-sealability of said laminate.

4. The container as claimed in claim 2 wherein said surface of said inner layer of said heat-sealable low density polyethylene polymer is corona discharge treated to enhance adhesion of said heat-sealable EVOH layer.

5. The container as claimed in claim 3 wherein said surface of said inner layer of said heat-sealable low density polyethylene polymer is flame treated to enhance adhesion of said heat-sealable EVOH layer.

6. The container according to claim 1 characterized by the fact that the outer layer b) is a heat-sealable low density polyethylene polymer coated on said outer surface of said paperboard substrate, and additionally comprises:

an oxygen barrier material layer coated on said outer surface of said inner layer of said polyethylene polymer;

a tie layer of a heat-sealable low density polyethylene polymer coated on said outer surface of said oxygen barrier materials; and

a heat-sealable layer of an ethylene vinyl alcohol copolymer coated on said outer surface of said tie layer.

7. The container as claimed in claim 6 wherein said oxygen barrier material layer is an ethylene vinyl alcohol copolymer.

8. The container as claimed in claim 6 wherein said oxygen barrier material layer is a polyvinyl alcohol.

9. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of aluminum foil.

10. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of polyethylene terephthalate.

11. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of glycol modified polyethylene terephthalate.

12. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of acid modified polyethylene terephthalate.

13. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of polyvinylidene chloride.

14. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of vinylidine chloride copolymer.

15. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of polyvinyl chloride polymer.

16. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of vinyl chloride copolymer.

17. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of polyamide.

18. The container as claimed in claim 6 wherein said oxygen barrier material layer is a layer of polyamide copolymers.

19. The container as claimed in claim 6 wherein said outer layer of said low density polyethylene polymer is corona discharge treated to enhance heat-sealability of said laminate.

20. The container as claimed in claim 6 wherein said outer layer of said low density polyethylene polymer is flame treated to enhance heat-sealability of said laminate.

21. The container as claimed in claim 19 wherein said inner layer of said low-density polyethylene polymer is corona discharge treated to enhance adhesion of said subsequent heat-sealable EVOH coating.

22. The container is claimed in claim 20 wherein said inner layer of said low-density polyethylene polymer is flame treated to enhance adhesion of said subsequent heat-sealable EVOH coating.

23. The container according to claim 1 characterized by the fact that the outer layer b) is a heat-sealable ethylene vinyl alcohol copolymer/low density polyethylene blend coated on said outer surface of said paperboard substrate.

24. The container as claimed in claim 23 wherein said surface of said inner layer of said heat-sealable low density polyethylene polymer is corona discharge treated to enhance adhesion of said heat-sealable EVOH layer.

25. The container as claimed in claim 23 wherein said surface of said inner layer of said heat-sealable low density polyethylene polymer is flame treated to enhance adhesion of said heat-sealable EVOH layer.

26. A process for improving the resistance of paperboard to the migration of essential oils and/or flavorings, said process comprising the steps of:

a) extrusion coating an outer layer of a low density polyethylene polymer onto said outer surface of said paperboard;

b) corona discharge treating or flame treating said outer layer of low density polyethylene polymer;

c) extrusion coating an inner layer of a low density polyethylene polymer onto said inner surface of said paperboard;

d) corona discharge treating or flame treating said inner layer of low density polyethylene polymer; and

e) extrusion coating a layer of 1) a heat-sealable ethylene vinyl alcohol copolymer or 2) coextrusion coating a three layer (ethylene vinyl alcohol/tie layer/ethylene vinyl alcohol) composite extrudate onto said surface of said inner layer of low density polyethylene polymer.

FIG. 1.

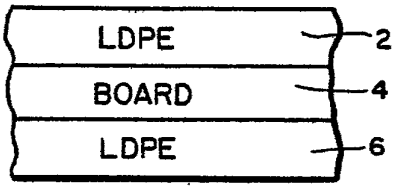
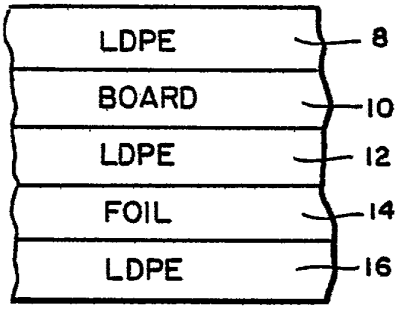


FIG. 2.



EXISTING COMMERCIAL STRUCTURES

FIG. 3.

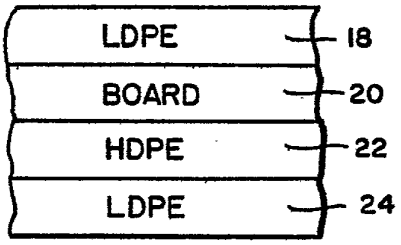
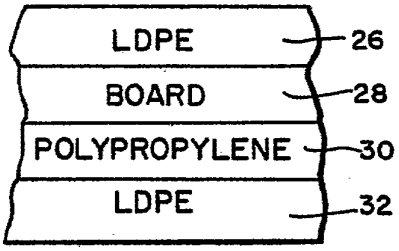


FIG. 4.



CHAMPION PATENT

FIG. 5.

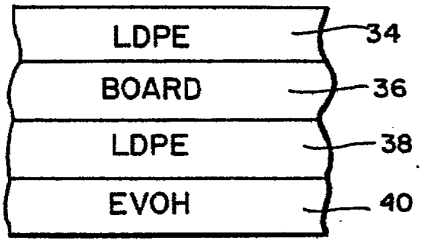


FIG. 6.

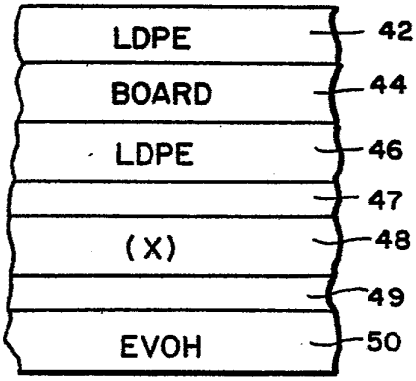
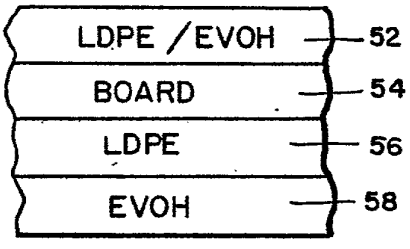


FIG. 7.



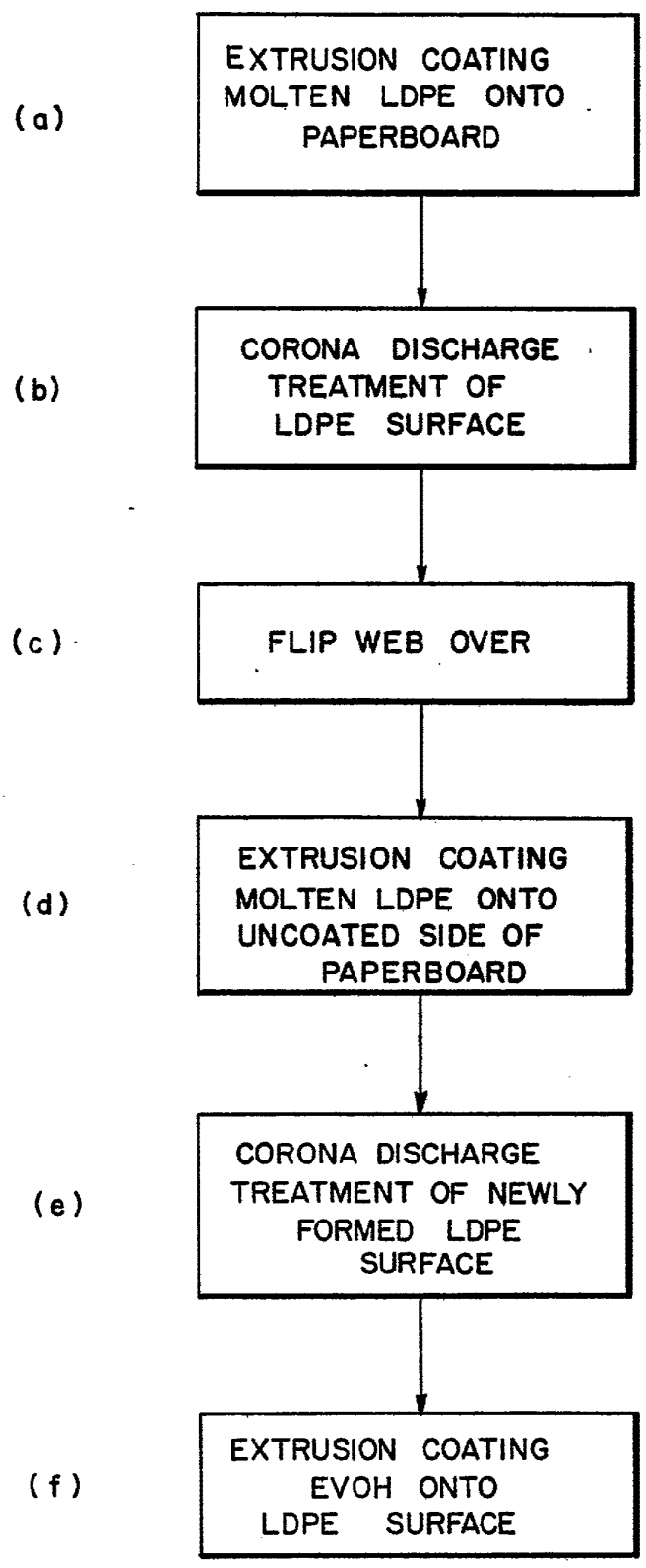

(a)
EXTRUSION COATING MOLTEN LDPE ONTO PAPERBOARD
(b)
CORONA DISCHARGE TREATMENT OF LDPE SURFACE
(c)
FLIP WEB OVER
(d)
EXTRUSION COATING MOLTEN LDPE ONTO UNCOATED SIDE OF PAPERBOARD
(e)
CORONA DISCHARGE TREATMENT OF NEWLY FORMED LDPE SURFACE
(f)
EXTRUSION COATING EVOH ONTO LDPE SURFACE

FIG. 8.

Electronic Acknowledgement Receipt

EFS ID:	43491882
Application Number:	16425067
International Application Number:	
Confirmation Number:	7044
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Customer Number:	26582
Filer:	Steven Anthony Avena/Wendy Nishida
Filer Authorized By:	Steven Anthony Avena
Attorney Docket Number:	P008EP.US (87942.0011)
Receipt Date:	13-AUG-2021
Filing Date:	29-MAY-2019
Time Stamp:	12:22:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P008Danapak.pdf	141184 24520b7418d611a930628d0280289a2a00542df9	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	14

Warnings:					
Information:					
2		P008DanapakIDS.pdf	727102 976fc45d55a2aff596624b90ffc7e91eed3dfda3	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	2
	Information Disclosure Statement (IDS) Form (SB08)	3	4
	Foreign Reference	5	14

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/25 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION**
Application Number	16425067
Filing Date	29-May-2019
First Named Inventor	Peter Johansen
Attorney Docket Number	P008EP.US (87942.0011)
Title of Invention	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Danapak Flexibles A/S	100%

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

15780999 filed on 06/01/2018

16835018 filed on 03/30/2020

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○	I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

○ Small Entity

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I hereby 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 Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 75211

○ A sole inventor

○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

○ A joint inventor; all of whom are signing this request

Signature	/Steven A. Avena/
Name	Steven A. Avena

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	16425067
Filing Date:	29-May-2019
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Filer:	Steven Anthony Avena/Wendy Nishida
Attorney Docket Number:	P008EP.US (87942.0011)

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
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Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16425067

Filing Date: 29-May-2019

Applicant/Patent under Reexamination: Johansen

Electronic Terminal Disclaimer filed on August 13, 2021

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This patent is subject to a terminal disclaimer

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Electronic Acknowledgement Receipt

EFS ID:	43491819
Application Number:	16425067
International Application Number:	
Confirmation Number:	7044
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Customer Number:	26582
Filer:	Steven Anthony Avena/Wendy Nishida
Filer Authorized By:	Steven Anthony Avena
Attorney Docket Number:	P008EP.US (87942.0011)
Receipt Date:	13-AUG-2021
Filing Date:	29-MAY-2019
Time Stamp:	12:21:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$170
RAM confirmation Number	E20218CC21483535
Deposit Account	082623
Authorized User	Wendy Nishida

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	44708 c37016b909aea9f479e9b88ab88dadebbbcab277	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37928 09097da1c9718c754b742d22af1d0ff24b509df6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	82636		

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New Applications Under 35 U.S.C. 111

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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Courtesy Reminder for
Application Serial No: 16/425,067

Attorney Docket No: P008EP.US (87942.0011)
Customer Number: 26582
Date of Electronic Notification: 06/01/2021

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

26582 7590 06/01/2021

Holland & Hart LLP
PO Box 11583
Salt Lake City, UT 84147

EXAMINER
TISCHLER, FRANCES

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
06/01/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@hollandhart.com

Office Action Summary	Application No. 16/425,067	Applicant(s) Johansen et al.	
	Examiner FRANCES TISCHLER	Art Unit 1765	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 5/19/21.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) 11-20 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-10 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 11/15/19,6/1/20.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1 – 10, in the reply filed on 5/19/21 is acknowledged.

Claim Objections

Claims 9 – 10 are objected to because of the following informalities:

Claim 9 recites "The laminate according…" but should be "The laminate film according…".

Claim 10 recites "A laminate film according to claim 1" but should be "The laminate film according to claim 1"…" Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

Claims 5 – 6 and 9 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Regarding claims 5 and 6, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 9 recites a range for the value of x, wherein the equation comprising x is found in claim 1 and wherein the equation is a comparison between the loading values of the tie layer with the contact layer. However, claim 9 depend from claim 7 which recites that the tie layer consists of two layers. So it is unclear if the value of x in claim 9 refers to one tie layer and which one or to both tie layers and if both tie layers have the same x value.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claims 1 - 10 are rejected under 35 U.S.C. 102(a)(1) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over ADAMS (US 2005/0037162).

Claims 1 - 3, 5, 6 and 9 - 10: ADAMS discloses (see entire document) a laminate film that provides good oxygen barrier properties ([0004]) [as claimed] comprising:

providing a base layer, referred to as a functional barrier layer, comprising aluminum, polyamide or PET ([0019]) [also reading on the claimed resistant to water or oxygen, since they are the same layer as claim 10];

coextruded layers ([0028], [0044], [0045], figures), wherein the coextruded layers comprise one or more adhesive tie layers and contact layers, wherein the tie layer is selected from ethylene acrylic acid (EAA) [as per claims 5 and 6], and the contact layer is selected from cycloolefin copolymer (COC) [as per claim 1] ([0023], [0024], [0030], table in [0034]), claims 7, 10, 14) [as claimed].

ADAMS is silent regarding the loading value of the tie layer and the equation that compares it with the load value of the contact layer.

However, since ADAMS discloses the claimed laminate film and the claimed layers comprising COC and EAA, their loading values are inherently the same as claimed. Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." See MPEP 2112.01. Since the PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

Alternatively, one of ordinary skill in the art would know to vary the process parameters such as the temperature in the extruder, the degree of dryness of the polymers upon extrusion, the thickness of the film, etc., wherein ADAMS discloses target coating weights for the various layers ([0037]) and discloses that constant loading levels are achieved even if one would add fillers to a layer ([0043]), all of which may affect the loading, to achieve ADAMS' stated objective of making a film comprising a base layer and coextruded tie and contact layers that provides for good packaging with good oxygen barrier and is effective in minimizing scalping ([0004]), and have thus arrived at the claimed loading.

Claims 4 and 7: ADAMS discloses one or more tie layers (figures 3-4, [0024], examples H and I in paragraph [0034]).

Claims 5 – 6: ADAMS discloses few contact layers to choose from comprising linear polyolefins or cyclic olefin copolymer ([0023]) and few tie layers to choose from comprising ethylene acrylic acid, polyolefins and vinyl acetate ([0024], claim 10). If the genus is small, if one can at once envisage each member of the group, then it is anticipated. *In re Petering 301 F.2d 676, 681 (CCPA 1962).* Alternately, it would be obvious to one skilled in the art to choose from ADAMS' small list of tie polymers and contact polymers the combination that produces ADAMS' stated objective of making a film comprising a base layer, and tie and contact layers that provides for good packaging with good oxygen barrier and is effective in minimizing scalping ([0004]), and have thus arrived at the claimed combination of COC of claim 1 and the acrylic acids of claims 5-6.

Claim 8: Since ADAMS discloses one or more tie layers and gives an example of ethylene acrylic acid for either or both layers, then the loading ratio between them is necessarily 1:1.

Claims 1 - 10 are rejected under 35 U.S.C. 102(a)(1) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over BOWEN et al (US 6,120,860).

Claims 1 – 3, 5 – 6 and 9 - 10: BOWEN discloses (see entire document) a multilayer laminate film comprising a base layer and a coextrusion layer comprising a tie layer and a sealant layer that coats the base layer (abstract, 4:49-50). The film structure has superior properties for holding aggressive organics, wherein the film comprises high barrier materials (2:48-3:7).

The laminate comprises a first and second layer which can have additional layers (3:40-44).

The high barrier material is aluminum or nylon (4:10-16) [thus reading on the claimed water or oxygen resistant base layer, noting that they are the same materials of claim 10], and further discloses that the high barrier prevents water or moisture to contact the product in the package (5:15-32) [meeting the claimed water resistant layer].

The adhesive or tie layer consists of a plurality of layers and is chosen from preferably ethylene acrylic acid (EAA) (3:52-4:10, 4:51-63) [as claimed].

BOWEN discloses that the sealant or contact layer is selected from EVA (4:32-42) [reading on the claimed ethylene vinyl alcohol].

The layers are coextruded and adhered to the core layer (4:49-51).

BOWEN is silent regarding the loading value of the tie layer and the equation that compares it with the load value of the contact layer.

However, since BOWEN discloses the claimed laminate film and the claimed layers comprising EVA and EAA, their loading values are inherently the same as claimed. Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." See MPEP 2112.01. Since the PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

Alternatively, one of ordinary skill in the art would know to vary the process parameters such as the temperature in the extruder, the degree of dryness of the polymers upon extrusion, the thickness of the film, etc., wherein BOWEN discloses that the layers can be oriented or not (5:55-59), can be laminated, extruded, coextruded, blown extruded extrusion coated, etc., can be made by different apparatuses (6:27-40), and the layers can vary in thickness from 2.0 to 20 mils (6:40-62), all of which may affect the loading, and have thus arrived at the claimed loading.

Claims 4 and 7: BOWEN discloses a plurality of tie layers (3:52-54).

Claims 5 – 6: BOWEN discloses a few contact layers to choose from and a few tie layers to choose from. If the genus is small, if one can at once envisage each member of the group, then it is anticipated. *In re Petering 301 F.2d 676, 681 (CCPA 1962).* Alternately, it would be obvious to one skilled in the art to choose from BOWEN's small list of tie polymers and contact polymers the combination that produces BOWEN's stated objective of making a film comprising a base layer, and tie and contact layers that provides for a structure that has superior properties for holding aggressive organics, and wherein the film comprises high barrier materials, and have thus arrived at the claimed combination of EVA of claim 1 and the acrylic acids of claims 5-6.

Claim 8: Since BOWEN discloses a plurality of tie layers and gives an example of ethylene acrylic acid for either or both layers, then the loading ratio between them is necessarily 1:1.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 - 10 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 - 20 of copending Application No. 16/835,018 (reference application).

Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of claims recite the same invention with obvious variants in the language. For instance, '018 recites that the loading of the contact layer is 4 – 20 g/m^2 and that of the tie layer is 7 – 20 g/m^2 while in the present claims the loading is claimed as an equation between the loading of the contact layer and the tie layer.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claims 1 – 10 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 - 36 of copending Application No. 16/780,999 (reference application).

Although the claims at issue are not identical, they are not patentably distinct from each other because '999 recites a relative energy difference value for the contact layer while the present claims are more broadly silent regarding this value, thus fully encompassing '999.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FRANCES TISCHLER whose telephone number is (571)270-5458. The examiner can normally be reached on Monday-Friday, 8:00 AM - 8:00 PM EST, midday flex.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/FRANCES TISCHLER/
Primary Examiner, Art Unit 1765

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61K31/167 OR A61K31/27 OR A61K31/4468 OR A61K31/465 OR A61K9/0014 OR A61K9/7084 OR B32B15/08 OR B32B15/082 OR B32B15/085 OR B32B15/20 OR B32B2255/10 OR B32B2255/20 OR B32B2307/718 OR B32B2307/7244 OR B32B2307/7246 OR B32B2307/7265 OR B32B2439/46 OR B32B2439/80 OR B32B2556/00 OR B32B27/08 OR B32B27/283 OR B32B27/30 OR B32B27/304 OR B32B27/306 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/02 OR B65D65/40	05/25/2021	/FT/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

Search Notes		
Search Notes	**Date**	**Examiner**
East text search; inventor and company search; classification search, codes shown above; combination of East text search and classification search; combination of East text search and inventor search; combination of East text search and company search; considered/examined all IDS; searched google scholar and google patent and IP.com; search terms included, for instance: cycloolefin or COC or (cyclic adj olefin) or polyamide or (ethylene adj vinyl adj alcohol) or EVA) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride)	05/25/2021	/FT/

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	02/02/2021	05/25/2021							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
	4	÷	✓							
	5	÷	✓							
	6	÷	✓							
	7	÷	✓							
	8	÷	✓							
	9	÷	✓							
	10	÷	✓							
	11	÷	N							
	12	÷	N							
	13	÷	N							
	14	÷	N							
	15	÷	N							
	16	÷	N							
	17	÷	N							
	18	÷	N							
	19	÷	N							
	20	÷	N							

Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	1787
Examiner Name	Callie E. Shosho
Attorney Docket Number	P008EP.US (87942.0011)

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	20160325534-A1	11-10-2016	Hu et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	002	WO-2017114922-A1	07-06-2017	Danapak Flexibles A/S		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	05/25/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /F.T./

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	1787
Examiner Name	Callie E. Shosho
Attorney Docket Number	P008EP.US (87942.0011)

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
			☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	05/25/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /F.T./

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	1787
Examiner Name	Callie E. Shosho
Attorney Docket Number	P008EP.US (87942.0011)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul M. Schramm/	Date (YYYY-MM-DD)	2020-06-01
Name/Print	Paul M. Schramm	Registration Number	62,050

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Bibliographic Data

Application No: 16/425,067

Foreign Priority claimed: (•) Yes ( ) No

35 USC 119 (a-d) conditions met: [✓] Yes [ ] No [ ] Met After Allowance

Verified and Acknowledged: /FRANCES TISCHLER/ Examiner's Signature [ ] Initials

Title: FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
05/29/2019	428	1765	P008EP.US (87942.0011)
RULE			

APPLICANTS

Danapak Flexibles A/S, Slagelse, DENMARK

INVENTORS

Peter Johansen, Odense C, DENMARK

Lars Christensen, Slagelse, DENMARK

Torben Fogtmann, Nyborg, DENMARK

CONTINUING DATA

FOREIGN APPLICATIONS

EPO EP18187923.0 08/08/2018

IF REQUIRED, FOREIGN LICENSE GRANTED**

06/05/2019

STATE OR COUNTRY

DENMARK

ADDRESS

Holland & Hart LLP

PO Box 11583

Salt Lake City, UT 84147

UNITED STATES

FILING FEE RECEIVED

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	20040234790-A1	11-25-2004	Smith et al.	
	002	20050037162-A1	02-17-2005	Adams	
	003	20050112337-A1	05-26-2005	Jester	
	004	20090208685-A1	08-20-2009	Rivers et al.	
	005	20110158564-A1	06-30-2011	Krumme	
	006	20150225151-A1	08-13-2015	Osborn et al.	
	007	20170158400-A1	06-08-2017	Priscal et al.	
	008	5613958-A	03-25-1997	Kochinke et al.	
	009	6120860-A	09-19-2000	Bowen et al.	
	010	6670423-B2	12-30-2003	Hausmann	
	011	6891018-B2	05-10-2005	Murakami et al.	
	012	6921563-B2	07-26-2005	Goerlitz et al.	
	013	8703283-B2	04-22-2014	Goerlitz et al.	
	014	8722164-B2	05-13-2014	Bekele et al.	
	015	9452593-B2	09-27-2016	Tatarka et al.	
	016	9487918-B2	08-25-2016	Geerdinck et al.	
	017	9663281-B2	05-30-2017	Hall et al.	

Examiner Signature	/FRANCES TISCHLER/	Date Considered	05/25/2021

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Sheet 2 of 8

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Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	018	BR-102015012729-A2	01-17-2017	Bemis Co. Inc.		☒
	019	DE-102012113026-A1	06-26-2014	SCHOTT AG		☒
	020	DE-102013113718 A1	06-11-2015	Buergofol GmbH		☒
	021	DE-202008017320-U1	05-28-2009	Alcan Technology & Management AG		☐
	022	EP-1364777-B1	08-03-2005	Ticona GmbH		☐
	023	EP-1475228-B1	07-26-2017	Mitsubishi Polyester Film GmbH		☒
	024	EP-1525092-B1	05-23-2007	Cryovac, Inc.		☐
	025	EP-1769908-A1	04-04-2007	Safta S.p.A		☐
	026	EP-1775122-B1	09-03-2014	Curwood, Inc.		☐
	027	EP-2349867-B1	10-11-2017	Cryovac, Inc.		☐
	028	EP-2907769-B1	09-27-2017	BPI.FORMIPAC		☐
	029	EP-2939667-A1	11-04-2015	NIPRO Patch Co., Ltd.		☐
	030	EP-2986450-B1	01-30-2019	Goglio S.p.A.		☐
	031	EP-3000750-A1	03-30-2016	Fujimori Kogyo Co., Ltd.		☐
	032	EP-3112384-B1	07-18-2018	SABIC Global Technologies B.V.		☐
	033	EP-3144127-B1	01-31-2018	SCHOTT Schweiz AG		☒
	034	EP-3210907-B1	07-17-2019	Kyodo Printing Co., Ltd.		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	05/25/2021

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	035	EP-3360530-A1	08-15-2018	Mitsubishi Gas Chemical Company, Inc.		☐
	036	WO-1991009731-A1	07-11-1991	ALZA Corporation		☐
	037	WO-1995007816-A1	03-23-1995	The Dow Chemical Company		☐
	038	WO-2000044559-A1	08-03-2000	Pharmacia & Upjohn AB		☐
	039	WO-2001064786-A1	09-07-2001	Ticona GmbH		☒
	040	WO-2005037539-A1	04-28-2005	E.I. Dupot de Nemours and Company		☐
	041	WO-2005097486-A1	10-20-2005	Curwood, Inc.		☐
	042	WO-2010047906-A1	04-29-2010	ExxonMobil Oil Company		☐
	043	WO-2010075946-A1	07-08-2010	Huhtamaki Forcchheim		☒
	044	WO-20121192271A1	09-13-2012	Surface Medical Inc.		☐
	045	WO-2013004243-A1	01-10-2013	Fertin Pharma A/S		☐
	046	WO-2013028398-A1	02-28-2013	Avery Dennison Corporation		☐
	047	WO-2013034273-A1	03-14-2013	Siegfried Ltd.		☐
	048	WO-2013116445-A1	08-08-2013	E.I. Dupont de Nemours and Company		☐
	049	WO-2014023995-A1	02-13-2014	Probiotical S.p.A.		☐
	050	WO-2015097208-A1	07-02-2015	Solvay Specialty Polymers Italy S.p.A.		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	05/25/2021

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Sheet 4 of 8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

FOREIGN PATENT DOCUMENTS

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	051	WO-2015118215-A1	08-13-2015	Tampereen Patenttitoimisto Oy		☐
	052	WO-2015123211-A1	08-20-2015	Bemis Company, Inc.		☐
	053	WO-2015174502-A1	11-19-2015	Nichiban Co., Ltd.		☒
	054	WO-2015187173-A1	12-10-2015	Perfecseal, Inc.		☐
	055	WO-2015187174-A1	12-10-2015	Perfecseal, Inc.		☐
	056	WO-2015199637-A1	12-30-2015	Perfecseal, Inc.		☐
	057	WO-2016076844-A1	05-19-2016	Bemis Company, Inc.		☐
	058	WO-2016164794-A1	10-13-2016	PolyOne Corporation		☐
	059	WO-2016190081-A1	12-01-2016	Dexerials Corporation		☒
	060	WO-2016194555-A1	12-08-2016	Polyplastics Co., Ltd.		☒
	061	WO-2016200363-A1	12-15-2016	Bemis Company, Inc.		☐
	062	WO-2017034560-A1	03-02-2017	Bemis Company, Inc.		☐
	063	WO-2017063087-A1	04-20-2017	Macro Technology Inc.		☐
	064	WO-2017087032-A1	05-26-2017	SiO2 Medical Products, Inc.		☐
	065	WO-2017100182-A1	06-15-2017	Bemis Company, Inc.		☐
	066	WO-2017100358-A1	06-15-2017	Bemis Company, Inc.		☐
	067	WO-2017189836-A1	11-02-2017	Cryovac, Inc.		☐
	068	WO-2017217989-A1	12-21-2017	Bemis Company, Inc.		☐
	069	WO-2018028996-A1	02-15-2018	Clariant International Ltd.		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	05/25/2021

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Sheet 5 of 8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
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	070	WO-2018041320-A2	03-08-2018	Coloplast A/S		☐
	071	WO-2018222864-A1	12-06-2018	Bay Materials, LLC		☐
	072	WO-2018231219-A1	12-20-2018	Bemis Company, Inc.		☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	05/25/2021

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Sheet 6 of 8

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First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	073	DATABASE WPI Week 201579, Derwent Publications Ltd., London, GB; AN 2015-71769A, XP002759263; 2 pgs.	☐

Examiner Signature	/FRANCES TISCHLER/	Date Considered	05/25/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /F.T./

Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	7	of	8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul M. Schramm/	Date (YYYY-MM-DD)	2019-11-15
Name/Print	Paul M. Schramm	Registration Number	62,050

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /F.T./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /F.T./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/05/25 17:49
S1	1	"20200223185".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 17:13
S2	1	"6120860".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:07
S4	1	"20040234790".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:10
S5	1	"20050106344".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:11
S6	1	"6790496".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:12
S7	1	"20050037162".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:47
S8	302	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:50
S9	3	((("DANAPAK") near3 ("FLEXIBLES") near3 ("A/S"))).AS,AANM.	USPAT	NEAR	ON	2021/01/31 19:50
S10	142	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:51
S11	350,512	(B05D1/265 OR B32B15/082 OR B32B15/20 OR B32B1/00 OR B32B2250/05 OR B32B2307/714 OR B32B2307/7244 OR B32B2307/7265 OR B32B2323/00 OR B32B2398/20 OR B32B2439/00 OR B32B27/08 OR B32B27/306 OR B32B27/308 OR B32B27/32 OR B32B27/325 OR	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:53

		B32B27/34 OR B32B27/36 OR B32B37/153 OR B32B7/12).CPC.				
S12	22	(cycloolefin or COC) and (base adj layer) and (tie adj layer) and (contact adj layer) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/01/31 19:55
S13	14	("20090208685" | "20110158564" | "20150225151" | "20160325534" | "20170158400" | "5613958" | "6670423" | "6891018" | "6921563" | "8703283" | "8722164" | "9452593" | "9487918" | "9663281").PN.	US-PGPUB; USPAT	NEAR	ON	2021/01/31 19:57
S14	1	"20160325534".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:58
S15	0	S12 and S14	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S16	0	S12 and S13	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S17	3	S12 and S8	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S18	3	S12 and S10	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 19:59
S19	21	S12 and S11	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:01
S20	0	S12 and S2	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S21	0	S12 and S3	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S22	0	S12 and S4	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S23	0	S12 and S5	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S24	0	S12 and S6	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02

S25	0	S12 and S7	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/01/31 20:02
S26	25	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 08:55
S27	1	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:20
S28	302	((("CHRISTENSEN") near3 ("Lars")) OR (("JOHANSEN") near3 ("Peter")) OR (("FOGTMANN") near3 ("Torben"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S29	3	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)) and S28	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S30	142	(("DANAPAK") near3 ("FLEXIBLES")).AS,AANM.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S31	4	((cycloolefin or COC) and layer and coextrud$5 and (ethylene adj acrylic)) and S30	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/01 13:21
S32	1	"20200047461".pn.	US-PGPUB; USPAT; USOCR	NEAR	ON	2021/02/02 04:37
S33	14	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic) and load$5	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:38

S34	457,500	(A61K31/167 OR A61K31/27 OR A61K31/4468 OR A61K31/465 OR A61K9/0014 OR A61K9/7084 OR B32B15/08 OR B32B15/082 OR B32B15/085 OR B32B15/20 OR B32B2255/10 OR B32B2255/20 OR B32B2307/718 OR B32B2307/7244 OR B32B2307/7246 OR B32B2307/7265 OR B32B2439/46 OR B32B2439/80 OR B32B2556/00 OR B32B27/08 OR B32B27/283 OR B32B27/30 OR B32B27/304 OR B32B27/306 OR B32B27/325 OR B32B27/34 OR B32B27/36 OR B32B37/02 OR B65D65/40).CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S35	25	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and (ethylene adj acrylic)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S36	17	S34 and S35	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/02/02 04:52
S37	33	(cycloolefin or COC) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/25 08:59
S38	74	(cycloolefin or COC or (cyclic adj olefin) or polyamide or (ethylene adj vinyl adj alcohol) or EVA) and (base adj layer) and ((tie adj layer) or (adhesive adj layer) or (sealant) or (sealing adj layer) or (sealant adj layer)) and ((contact adj layer) or (flexible adj layer)) and coextrud$5 and ((ethylene adj acrylic) or ethylene or (butyl adj acrylate) or (maleic adj anhydride))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	NEAR	ON	2021/05/25 09:00

EAST Search History (Interference)

<This search history is empty>

5/25/2021 7:17:23 PM
C:\Users\ftischler\Documents\EAST\Workspaces\16425067.wsp

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/425,067	Filing Date 05/29/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	05/19/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/KAREN T WASHINGTON/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 7044
Johansen et al.	Examiner: Frances Tischler
For: IMPROVED FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS	Art Unit: 1765
Application No.: 16/425,067	**RESPONSE TO RESTRICTION REQUIREMENT**
Filed: May 29, 2019	**CERTIFICATE OF TRANSMISSION** I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on: May 19, 2021.
Docket No.: P008EP.US (87942.0011)	By: / Wendy Nishida / Wendy Nishida
Customer No.: 26582	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the restriction requirement dated February 19, 2021, please enter the following remarks:

A Listing of the Claims begins on page 2.

Remarks begin on page 6.

Electronic Patent Application Fee Transmittal

Application Number:	16425067
Filing Date:	29-May-2019
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Filer:	Paul M. Schramm/Wendy Nishida
Attorney Docket Number:	P008EP.US (87942.0011)

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	1251	1	220	220
Miscellaneous:				
			Total in USD ($)	**220**

Electronic Acknowledgement Receipt

EFS ID:	42769949
Application Number:	16425067
International Application Number:	
Confirmation Number:	7044
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Customer Number:	26582
Filer:	Paul M. Schramm/Wendy Nishida
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P008EP.US (87942.0011)
Receipt Date:	19-MAY-2021
Filing Date:	29-MAY-2019
Time Stamp:	19:41:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$220
RAM confirmation Number	E20215IJ42032013
Deposit Account	082623
Authorized User	Wendy Nishida

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P008Danapak.pdf	100813 5a1b2c15db3d9a68f7df23656fe130ec5c45489f	yes	7
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Applicant Arguments/Remarks Made in an Amendment		6	7	
	Claims		2	5	
	Response to Election / Restriction Filed		1	1	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30995 815e9cb3e81daaf0f9b96024e04c2ec1fa50f2ab	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	131808		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

REMARKS

The Office Action dated February 19, 2021 ("Restriction Requirement") requested restriction of the claims to one of the following groups:

- Group I Claims 1–10;
- Group II Claims 11–15; and
- Group III Claims 16–20.

Restriction Requirement

In response, Applicant hereby elects claims 1–10 of Group I, without traverse, for examination on the merits.

Applicant files this response solely to facilitate prosecution. As such, Applicant reserves the right to pursue claims of broader or similar scope as originally filed in this application, a continuation application, or other application after allowance of the present application. Any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter.

CONCLUSION

Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is therefore respectfully requested.

The Commissioner is authorized to charge any fees or underpayments that may be due with this response, or credit any overpayments, to Deposit Account No. 08-2623.

If the Examiner believes a telephone conference would expedite prosecution of this Application, please call the undersigned at (303) 473-2700.

Respectfully submitted,

By: / Paul M. Schramm /
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Listing of Claims

1. (Original) A laminate film comprising:

a base layer, wherein the base layer is one or more of water or oxygen resistant; and

a co-extrusion layer, the co-extrusion layer comprising a tie layer and a contact layer, wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof;

wherein a total loading of the tie layer is in the range of 3-9 g/m^2 and wherein a loading of the contact layer is:

$loading_{contact}=x*loading_{tie}$, wherein $loading_{contact}$ is the loading of the contact layer, $loading_{tie}$ is the total loading of the tie layer, and x is in the range of 0.8 to 3.

2. (Original) The laminate film according to claim 1, wherein x is in the range of 1 to 3.

3. (Original) The laminate film according to claim 1, wherein x is in the range of 1.33 to 2.75.

4. (Original) The laminate film according to claim 1, wherein the tie layer is a multilayered tie layer comprising at least two layers.

5. (Original) The laminate film according to claim 1, wherein at least one layer of the multilayered tie layer is made from a material selected from the group consisting of: ethylene methacrylic acid, ethylene acrylic acid, terpolymer of ethylene, acrylic ester, and maleic anhydride, preferably ethylene, butyl acrylate, maleic anhydride, or a combination thereof.

6. (Original) The laminate film according to claim 1, wherein a second layer of the multilayered tie layer comprises a material selected from the group consisting of ethylene methacrylic acid, low-density polyethylene, ethylene methyl acrylate, ethylene butyl acrylate, ethylene ethyl acrylate, a terpolymer of ethylene, acrylic ester, and maleic anhydride, preferably

ethylene, butyl acrylate, and maleic anhydride, ethylene acrylic acid, or a combination thereof.

7. (Original) The laminate film according to claim 1, wherein the tie layer consists of two layers, a first tie layer and a second tie layer.

8. (Original) The laminate film according to claim 7, wherein a loading ratio of the first tie layer to the second tie layer is approximately 1:1.

9. (Original) The laminate according to claim 7, wherein x is in the range of 1.33 to 2.75.

10. (Original) A laminate film according to claim 1, wherein the base layer is selected from the group consisting of a metal foil, a polymer, a fluoropolymer, or a combination thereof.

11. (Withdrawn) A packaging for packing a composition said packaging comprising:

a first outer layer made of a mechanically wear resistant material;

a laminate film comprising a base layer and a co-extrusion layer;

wherein the base layer is one or more of water resistant or oxygen resistant;

wherein the co-extrusion layer comprise a tie layer and a contact layer, a total loading of the tie layer is in the range of 3-9 g/m^2, and a loading of the contact layer is $loading_{contact}=x*loading_{tie}$, where $loading_{contact}$ is the loading of the contact layer, $loading_{tie}$ is the total loading of the tie layer, and x is in the range of 0.8 to 3;

wherein the base layer side of the film is facing the first outer layer.

12. (Withdrawn) The packaging according to claim 11, wherein x is in the range of 1 to 3.

13. (Withdrawn) The packaging according to claim 12, wherein x is in the range of 1.33 to 2.75.

14. (Withdrawn) The packaging according to claim 11, wherein the laminate encloses a composition comprising a compound selected from the group consisting of: nicotine, rivastigmine, fentanyl, lidocaine, or a combination thereof.

15. (Withdrawn) The packaging according to claim 11, wherein the composition is a patch.

16. (Withdrawn) A method for providing a laminate film, said method comprising the steps of:

providing a base layer, wherein the base layer is one or more of: water resistant or oxygen resistant;

coextruding a layer comprising a tie layer and a contact layer to provide a co-extrusion layer,

coating the co-extrusion layer to the base layer; and

curing the co-extrusion layer coated to the base layer to provide the laminate film,

wherein the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, an ethylene vinyl alcohol, or a combination thereof; and

wherein the total loading of the tie layer is 3 to 9 g/m^2 and wherein the loading of the contact layer is:

$loading_{contact}=x*loading_{tie}$, wherein $loading_{contact}$ is the loading of the contact layer, $loading_{tie}$ is the total loading of the tie layer, and where x is in the range of 0.8 to 3.

17. (Withdrawn) The method according to claim 16, wherein x is in the range of 1 to 3.

18. (Withdrawn) The method according to claim 16, wherein the tie layer is multilayered and wherein all the layers of the multilayered tie layer are coextruded with the contact layer.

19. (Withdrawn) The method according to claim 18, wherein a total loading of the multilayered tie layer and contact layer is less than 40 g/m^2.

20. (Withdrawn) The method according to claim 16, wherein the co-extrusion is performed at a temperature of 240 - 330°C.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)	7044

26582 7590 02/19/2021

HOLLAND & HART, LLP
222 South Main Street, Suite 2200
P.O. Box 11583
SALT LAKE CITY, UT 84147

EXAMINER	
TISCHLER, FRANCES	

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
02/19/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@hollandhart.com

Office Action Summary	Application No. 16/425,067	Applicant(s) Johansen et al.	
	Examiner FRANCES TISCHLER	Art Unit 1765	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 6/1/20.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☐ Claim(s) _____ is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☑ Claim(s) 1-20 are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 10, drawn to a laminate film, classified in B32B9/00.

II. Claims 11 - 15, drawn to a packaging for packing a composition, classified in B65D65/40.

III. Claims 16 - 20, drawn to a method for providing a laminate film, classified in B32B37/00.

The inventions are independent or distinct, each from the other because:

Inventions I and II are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, and effect since one group is drawn to a film while the other group is drawn a separate invention comprising a package that is used for packing a composition. Furthermore,

the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make another and materially different product, such as polyester films.

Inventions II and III are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, Group III is drawn to a process of making a film while Group II is drawn to a package.

Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be

maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FRANCES TISCHLER whose telephone number is (571)270-5458. The examiner can normally be reached on Monday-Friday, 8:00 AM - 8:00 PM EST, midday flex.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/FRANCES TISCHLER/
Primary Examiner, Art Unit 1765

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/425,067	Johansen et al.
	Examiner	Art Unit
	FRANCES TISCHLER	1765

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant					☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE								
Final	Original	02/02/2021								
	1	÷								
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	3	÷								
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	1787
Examiner Name	Callie E. Shosho
Attorney Docket Number	P008EP.US (87942.0011)

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	20160325534-A1	11-10-2016	Hu et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	002	WO-2017114922-A1	07-06-2017	Danapak Flexibles A/S		☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Sheet 2 of 4

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First Named Inventor	Johansen et al.
Art Unit	1787
Examiner Name	Callie E. Shosho
Attorney Docket Number	P008EP.US (87942.0011)

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
			☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
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Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	1787
Examiner Name	Callie E. Shosho
Attorney Docket Number	P008EP.US (87942.0011)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul M. Schramm/	Date (YYYY-MM-DD)	2020-06-01
Name/Print	Paul M. Schramm	Registration Number	62,050

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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(54) Title: A METHOD FOR PROVIDING A CHEMICAL RESISTANT FILM

(57) Abstract: The present invention relates to a method for providing an extreme chemical resistant film whereby a tie layer and a contact layer are coextruded with a base layer, such as a metal foil, as well as films and laminates obtained by the method and uses of the films and laminates to pack aggressive chemical substances such as nicotine, lidocaine, fentanyl and rivastigmine.

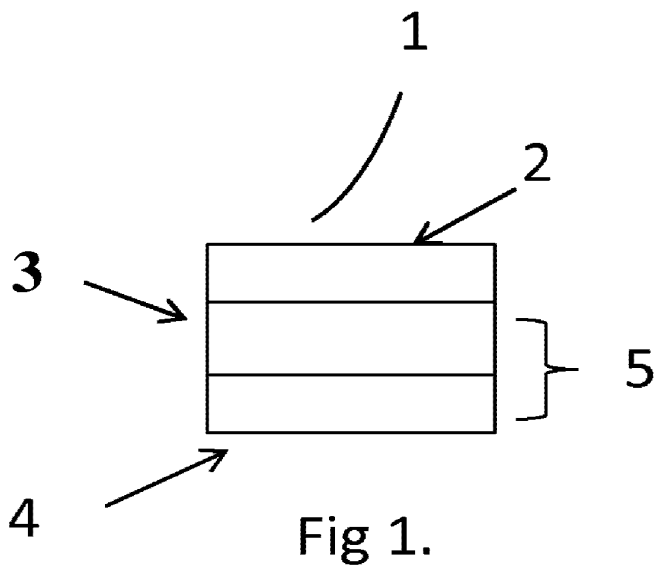


Fig 1.

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A METHOD FOR PROVIDING A CHEMICAL RESISTANT FILM

The present invention relates to a method for providing an extreme chemical resistant film whereby a tie layer and a contact layer are coextruded with a base layer, such as a metal foil, as well as films and laminates obtained by the method and uses of the films and laminates to wrap aggressive chemical substances such as nicotine, fentanyl, lidocaine and rivastigmine.

Background of the invention

In the pharmaceutical industry substances, including highly aggressive substances such as nicotine, fentanyl, rivastigmine and lidocaine, are packed as tablets in inhalers, patches etc. resulting in special requirements for the packing, laminate, or film for sealing these substances in order to ensure that no adverse degradation takes place.

One common example is the problem relating to the packaging of nicotine, in particular as nicotine patches, because nicotine is highly aggressive towards its environment and highly volatile. These properties are problematic for the consumer safety and product durability if not addressed, because it is important that the amount of nicotine in, for example a tablet, gum or a patch is stable and complies with the product specification. Further, it is important to avoid adverse reactions between the packaging and the pharmaceutical substance. Additionally, from a business perspective a long stable shelf time is highly desirable. Thus, the chemical requirements of a packaging, film or laminate are typically:

- Resistance towards highly aggressive substances such as nicotine.
- Inert properties for ensuring that chemical compounds do not migrate from the exterior environment of for example a laminate, through the laminate getting into contact with a sealed substance;
- Possibly ensuring that the packaging is child proof to increase safety of potentially hazardous compounds.

A known polymer that fulfils the requirements of extreme chemical resistance and inert properties is a polyactyllonitrile (PAN) based film, which is sold for example as resins under the trademark Barex®, which is manufactured *i.a.* by the company Ineos. Barex® is widely used and approved for

drugs and food applications and is used because it is a good barrier towards oxygen, nitrogen and carbon dioxide compared to other common polymers, and because it has excellent chemical resistance towards different functional groups such as hydrocarbons, ketones, esters, alcohols, bases and acids and/or pharmaceuticals such as nicotine. Furthermore, extruded Barex® resin is heat stable and therefore weldable at a temperature around 160 - 220°C, which makes it possible to use in flexible packagings. However, Barex® is sold at a high prize due to the difficulties in the production and subsequent extrusion to film resulting in a high loss of material. Furthermore, the water and oxygen resistance of Barex® is not satisfactory for all purposes.

Another solution can be found in WO 00/44559 disclosing a material for packaging nicotine containing products (e.g. patches, tablets, lozenges, nasal spray), wherein the material comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers. Further, it is disclosed that a polymeric film is combined with other barrier materials in a laminate to further improve the barrier characteristic of the laminate. The preferred material for a laminate is aluminium due to its good oxygen and water barrier properties.

In addition to the barrier properties, in particular for pharmaceuticals, it is important that the concentration of the substances is stable and reliable, which also poses requirements of the packaging and laminates in terms of inertness and permeability.

Hence, given the increased market and demands for packagings, there is an instant need for finding solutions for packaging, of in particular highly aggressive substances and pharmaceuticals, which fulfil all the requirements while still being economical.

Summary of the invention

With this background it is an object of the present invention to provide solutions that meet one or more of the needs described above, that is, *i.a.* provide impermeability and inertness to a packaging. Furthermore, it is an object to provide a laminate that is weldable at temperatures suitable for the manufacture of flexible wrappings, such as for use in preparing packagings for patches. It is a further object to provide methods and products that

are cost efficient without compromising the quality of the products.

Accordingly, in a first aspect this is solved by a method for providing, e.g. an aggressive chemical resistant, film, said method comprising the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide the, e.g. aggressive chemical resistant, film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards an aggressive chemical of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred between 1 to 2.

It has surprisingly been found that when coextruding the tie layer and the contact layer according to the invention, the respective layers can be thinner while maintaining the overall mechanical and chemical robustness of the final film and laminates and wrappings made with the film. The coextrusion also results in a better adherence of the various layers resulting in a homogonous film in which the layers do not separate.

While it was previously believed that usable polymers should be hydrophobic (in order to repel water from the surroundings), the present inventors have found that by providing the film according to the invention where the coextrusion layer comprises a tie layer and a contact layer, and where the contact layer comprises a polymer having a relative energy difference (RED) value in the range 0.8 to 10 relative to the aggressive substance, it has surprisingly turned out that the desired effect of the laminate being inert to aggressive compounds, such as nicotine, rivastigmine and lidocaine, while still providing a barrier to external factors such as water/moist and oxygen, is obtained.

A polymer candidate for use as a contact layer in the present invention is selected by calculating the RED value, which is generally used to predict the solubility of a polymer in a particular solvent, or the compatibility of

two polymers in a blend. In the present invention the RED values for various polymer/solvent systems have been calculated, wherein the polymer is the polymer forming the contact layer, and the solvent is an aggressive chemical substance such as nicotine, rivastigmine, fentanyl and lidocaine etc.

The RED value for the polymer and the aggressive chemical substance is calculated by using the theory of the Hansen solubility Parameters (HSP), which is described in CM. Hansen : "Hansen Solubility Parameters, A User's Handbook", CRC Press, Boca Raton, 1999.

The HSP system between the polymer and the aggressive chemical substance is described by parameters set up in a 3 dimensional coordinate system :

— δ_D for dispersion cohesion energy
— $\delta\rho$ for dipolar cohesion energy
— δ_H for hydrogen bonding cohesion energy

The HSP distance, Ra, between polymer and the aggressive chemical substance is given by:

$$Ra^2 = 4(\Delta\ \delta_D)^2 + \Delta\ \delta\rho^2 + \Delta\ \delta_H{}^2$$

The Δ indicates the difference in the given parameter for the aggressive substance and the polymer.

The relation between the HSP distance, Ra and RED is given as:

$$RED = Ra/Ro$$

Where Ro is the interaction radius, which determines the radius of the sphere in Hansen space, and the center are the three Hansen parameters. All values are calculated or determined with empiric data and it is known to the person skilled in the art how to calculate the values.

The obtained RED value indicates whether or not the polymer is likely to dissolve in the aggressive chemical substance or not:

RED < 1 the polymer and the aggressive chemical substance will dissolve
RED = 1 the polymer and the aggressive chemical substance will partially dissolve
RED > 1 the polymer and the aggressive chemical substance will not dissolve

The resulting RED value is used to give an indication of the likelihood of dissolution or not.

All values can be calculated using the Hansen Solubility Parameter in Practice by (HSPiP) Software, commercially available at http://hansen-solubility.com.

Contact layer polymers according to the invention surprisingly turned out to have a RED value in the range from 0.8 and higher, preferably, 0.8 to 10 and more preferred 0.8 to 5 and most preferred 1 to 2. It is highly unexpected that polymers which in theory range from being soluble to insoluble with an aggressive substance to be packed fulfill the requirements set for films according to the invention as is supported by the examples provided here with.

The base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluro polymers.

According to the invention water and/or oxygen resistance is preferably encompassing materials having an oxygen transfer rate (OTR) equal to or below 1 $cm^3/m^2/24hr/bar$ according to ASTM standard D3985 at 23°C and 0% RH and/or water (or moisture) vapor transfer rate (WVTR) equal to or below 1 $g/m^2/24hr$ according to ASTM standard F1249 at 38°C and 90%RH, preferably both the WVTR and the OTR are below 0.01 $g/m^2/24hr$ or 0.01 $cm^3/m^2/24hr/bar$ respectively.

According to the invention, the base layer of the film is selected to provide a number of properties to the film and a laminate and packaging comprising the film. The base layer may give desired barrier and support properties to the final laminate. Furthermore, the base layer may in one embodiment be a gas and water impermeable base layer, more preferably a water and/or oxygen resistant base layer.

In embodiments where the contact layer is hygroscopic the base layer is preferably made of a metal foil, preferably aluminum.

Aluminum is price competitive, a superior barrier of all gases and moisture and furthermore similar to other metal-like materials aluminium has good dead-fold properties, i.e. it does not unfold once folded, it reflects radiant heat, and gives a decorative appeal to laminates and packages.

According to the invention the tie layer is selected to provide sufficient adhesion between the base layer and the coextrusion layer. The tie lay-

er may give melt strength and support the coextrusion coating of both the tie layer and the contact layer. It is preferred that the melting profile of the tie layer polymers and the contact layer polymers are in the same range to provide optimal films that do not separate. Preferably both layers comprise polymers that melt at the operating temperature of the process of the invention and even more preferred the melting profiles (i.e. melting points) should differ with less than 30°C, preferably with 0-15°C, such as 5-15°C.

In one embodiment the tie layer is made of 1, 2, 3, 4 or 5 layers. In this way, the properties of the film and resulting laminates and packagings may be improved to accommodate the specific chemical and physical properties of the contact layer and/or the base layer.

In a further embodiment all the layers are coextruded with the contact layer for a simplified processing and for ensuring homogeneity of the layers.

In a further embodiment the tie layer is constituted of one layer where the layer is made of a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride. Most preferably the tie layer has a melting profile similar to that of the contact layer.

According to the invention the contact layer must be chemically resistant to the aggressive substance and excipient if present ultimately to be packed. Further it must show an extreme low absorption of the aggressive substances migrating through the film or laminate. The degree of absorption for a given substances is typically dictated by the manufacturer of the substance but often the accepted values lie in the range of 0 to 1 % (w/w). For some products up to 10 % (W/W) is acceptable typically for products with a low initial API content. The absorption is calculated as the weight of API in packaging relative to the initial weight of the API in the commercial product.

Hence, in the context of the present invention aggressive chemical resistant film means that no more than 1% of the original amount of API to be packaged (or sometimes no more than 10%) is migrated into the packaging material after 24 weeks. Typically, the degree of uptake is complete after 12 weeks or less.

In one preferred embodiment the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer (COC), a polyamide (PA), or, an ethylene vinyl alcohol (EVOH).

In a further embodiment the tie layer and contact layer comprise the same polymer, such as a cyclic olefin copolymer (COC), a polyamide (PA), or, an ethylene vinyl alcohol (EVOH) the latter being particularly preferred.

The HSP and RED Values calculated using http://hansen-solubility.com, mentioned above resulted in the following values for the preferred polymers according to the invention using lidocaine/rivastigmine as solvent (API) :

Table 1: HSP and RED values for preferred polymers according to the invention

Polymer	D	P	H	RED value (chi)
Lidocaine/ Rivastigmine	18.1	8.2	6.1	-
PA 66	16	11	24	1.72
COC	18	3	2	1.32
EVOH	20.5	10.5	12.3	1.12

It has surprisingly been shown that when the contact layer comprises any of the polymers from the group above, having a relatively low RED (i.e. between 1 and 2) value a chemical resistant film and also laminate may be obtained even though the mentioned polymers chemically represent different polymer types. Tests have shown that the resistance of laminates in which the film is coated with the preferred polymers shows results unexpectedly superior to those of laminates coated/laminated with Barex®.

EVOH is normally used in laminates due to the superior oxygen barrier properties of EVOH. However, EVOH is known to be very hydrophilic and hydroscopic (i.e. has a high WVTR), hence it is surprising that a EVOH polymer is usable in the context of the present invention where water resistance is a desired property. Also, PA has typically been used in laminates due to the superior mechanical properties like tear strength or as a barrier. As for EVOH it is unexpected that PA may be used as a contact layer and/or co-extrusion layer (i.e tie and contact layer) for providing a chemical resistant film due to the hydrophilic nature of PA.

Because of the hydrophilic nature of PA and EVOH, in a preferred embodiment, the film obtained according to the invention may be tightly packed in a moisture barrier, in particular if it has to be stored. The film or laminate according to the invention may be packed immediately after manufacture of the chemical resistant film or laminate and should be kept safely packed until further use, for example in a packing line.

COC has not previously been recognized as being suitable for extrusion coating and for the production of heat sealable laminates. Without the wish to be bound by any theory this is believed to be due to the stress which the polymer is subjected to during an extrusion process. The stress causes irregular heating and melting within the COC, resulting in the final film or laminate to be unacceptable from a visual point of view for use in various packaging industries. Hence, it is very surprising that the inventors of the present invention have succeeded in providing a coextrusion layer comprising COC as a contact layer for sealing aggressive substances. The inventors have found that an improved processing of COC is obtained when COC is coextruded with a tie layer having a glass transition temperature higher than or equal to that of a COC polymer such as a terpolymer of ethylene, acrylic ester and maleic anhydride. In another embodiment of the invention the tie layer has a melting point that differs from COC with 30°C or less, preferably with 0-15°C, such as 5-15°C.

In a further embodiment, the melting point of the tie layer is at least the same as COC, preferably 5 to 30 °C higher, more preferably 15 to 30 °C higher than COC.

To obtain a satisfactory coextrusion layer it is important that the polymer constituting a contact layer and a copolymer constituting a tie layer are compatible with respect to the melting characteristic of the polymers and the copolymer. As an effect of having been able to process a chemical resistant laminate with a coextrusion layer laminated to a base layer, thin laminates may be obtained, and generally improved process ability during the manufacture of the laminates or wrappings are achieved.

Consequently, in one embodiment the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m2 and/or the contact layer has a loading in the range of 4 to 20 g/m2 and the loading of the laminate is not more than 40 g/m2.

In terms of the invention loading means the amount of polymer left, in the layer when the film has dried.

In a particular embodiment the contact layer of the coextrusion layer is made from a blend of at least two polymers. Using blends can be a means for reducing the costs and for adapting the physical and chemical properties of the co-extrusion process, such as reducing or increasing the melting temperature to comply with the profile of the tie layer(s) and the polarity of the blend to improve the adhesion properties of the layers and hence the robustness of the final product.

In a preferred embodiment the contact layer consists of one polymer type. Experiments showed that using one type of polymer resulted in improved resistance of the film and laminate towards the chemical substance to be packed.

According to an embodiment, in any of the blends or homo layers at least one of or all the polymer(s) forming the contact layer of the coextrusion layer is a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol. Each of the polymers are commercial available for example under the tradenames EVAL® C109B sold by Kuraray, Selar PA 3426 R sold by Dupont®, 6013M-07 sold by Topas®.

In one embodiment the cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol makes up at least 50% w/w of the blend, preferably at least 60% w/w, more preferably at least 80% w/w, most preferably at least 95% w/w.

The adhering of step iv) preferably occurs instantly for example by cooling the co-extrudate in cooling cylinders during the lamination process.

According to the invention a chemical resistant film has various applications. In an embodiment of the invention, the film is used to wrap a composition comprising a chemical selected from nicotine, fentanyl, lidocine and rivastigmine.

In a particular embodiment of the invention, wherein the composition is provided as a patch, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/- 10% in comparison to a Barex® patch as index 100.

In a further aspect of the invention an aggressive chemical resistant film is provided, said film comprising at least a base layer, which is water

and/or oxygen resistant, and a coextrusion layer, wherein the coextrusion layer comprises a tie layer and a contact layer, and whereby the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2. Films according to the invention are resistant to aggressive chemical substances.

the term "aggressive chemical resistant film" means a film which when in contact with an aggressive substance does not allow more than 10 %, such as 5% w/w or 1.5% w/w based on the nomial content of the aggressive chemical to migrate to the packaging material.

In one embodiment the base layer, which is water and/or oxygen resistant, is selected from the group consisting of metal foil, preferably aluminum foil, polymers, polyamide, polyvinylidene chloride, silicium oxide coated polyesters, and/or fluropolymers.

In a further embodiment the tie layer is constituted of one layer and wherein the layer is a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride.

In a particular embodiment the contact layer comprises or is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

In yet an embodiment the tie layer and the contact layer is the same material.

In a further embodiment the film is heat sealable. A heat sealable film or laminate is a laminate that is capable of sealing to itself during heat sealing without creating any deformation of films or laminates, which is highly undesired, especially, during the final wrapping of the product. The deformation is undesirable in relation to quality assurance, where any deformation must be noted and explained, which is highly labor intensive. Furthermore, the legislation in many countries is very strict. Hence, film and/or laminates with any deformation are not allowable for packing active ingredients.

In yet another aspect the invention relates to a laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;

- an aggressive chemical resistant film as described above comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer said coextrusion layer comprising a tie layer wherein the base layer side of the film is facing the first outer layer.

In one embodiment the first outer layer may be made from a material selected from but not limited to paper, polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets, or combinations. It is preferred that the first outer layer is a combination of materials when polyester based sheets are used.

In an embodiment the first outer layer and the film are laminated to provide the packaging in one piece. Laminating the first outer layer to the film provides a strong laminate, which is easy to wrap, and, it is ensured that the individual parts of the laminate do not fall apart.

In another embodiment the laminate further comprises a second outer layer facing the exterior side of the first outer layer, preferably the second outer layer is a paper layer. The paper layer is typically printed with the name, color and/or logo of the product and manufacturer of the product. It is also contemplated that the first outer layer is printed.

It is also contemplated that an adhesive agent may be applied between the second and first outer layers. The adhesive layer may be the same or different from the tie layer. Additional suitable adhesives are adhesives approved for use in packaging products for human use and are well known to the skilled person. A suitable adhesive may be selected from but is not limited to polyurethane based adhesives, epoxy based adhesives, or acrylic based adhesives.

The laminate of the present invention must be inert and impermeable to the aggressive chemical substance which the laminate is wrapped around. Hence, in an embodiment of the invention a maximum of 10%, preferably a maximum of 5%, even more preferably a maximum of 1.5%, most preferably a maximum 0.5% of the aggressive chemical is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

In a further embodiment the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl and lidocaine. These compounds are known as aggressive chemicals/compounds and re-

quire specialized packaging.

Hence, the invention also contemplates an aggressive chemical substance packed in a laminate or packaging as explained above and a method for providing the packaging the chemical substance, said method comprising the steps of:

a) providing a base layer

b) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

c) coating the coextrusion layer to the base layer;

d) allowing the coextrusion layer coated to the base layer to adhere to the base layer to provide a chemical resistant film comprising the tie layer and the contact layer formed as an coextrusion layer coated to the base layer;

e) providing a highly aggressive substance to the contact layer side of the film; and

f) sealing the chemical resistant film, preferably by heat sealing, in such a way to provide a hollow interior space for sealing the highly aggressive substance, said hollow space having an interior side and an exterior side, wherein the interior side of the film is the contact layer of the coextrusion layer and the exterior side of the film is the base layer.

In a preferred embodiment the highly aggressive substance is selected from the group consisting of nicotine, lidocaine, rivastigmine, and fentanyl.

It is also contemplated that a first outer layer may be applied to the film; the first outer layer is made of a mechanically wear resistant material and typically serves to protect from children being able to break the sealed film, laminate or wrapping.

A packaging should preferably comply with International standards such as 16 CFR §1700.20 (for USA) and ISO 8317 (2003) corresponding to DIN EN ISO 8317 (2004) (for Europe).

A "packaging" is in the context of the invention intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate

It is also contemplated that a second outer layer may be applied to the film and/or laminate; the second outer layer is typically a paper layer.

The paper layer is typically printed with the logo or colors etc. of the supplier of the product. The second outer layer is preferably applied when there is a first outer layer.

It is contemplated that the first and/or second outer layer is laminated to the film before steps e) and f) for example in one combined coextrusion and laminating step.

In yet another aspect, the invention provides the use of a polymer having a RED value of > 0.8, preferably having a RED value in the range of 0.8 to 10, more preferred 0.8 to 5, and most preferred 1 to 2 as a contact layer for providing chemical resistance to a film, wherein the film comprises a base layer which is water and/or oxygen resistant coated to a, optionally co-extruded, layer comprising a tie layer and the contact layer.

In a further embodiment the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

Specific films according to the invention comprise but are not limited to base layer/tie-layer/contact-layer (the latter two coextruded) EAA/PE/COC, EAA/EMA/COC, EAA/terpolymer/COC, terpolymer/PE/COC, EAA/terpolymer/EVOH, EAA/terpolymer/PA, or EAA/PA.

Specific films according to the invention that are resistant to nicotine comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%, Al/EVOH/EVOH, AL/EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride.

In a further embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to nicotine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

Specific films according to the invention resistant to rivastigmine

comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%, Al/EVOH/EVOH, AL/EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride.

In a further embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to rivagstigmine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

Specific films according to the invention resistant to lidocaine comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%, Al/EVOH/EVOH, AL/terpolymer of EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride

In a further embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to lidocaine and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

Specific films according to the invention resistant to fentanyl comprise but are not limited to base layer/tie-layer/contact layer (the latter two coextruded) Al/EAA/PA, Al/terpolymer of EAE and maleic anhydride/EVOH 60% and PE 40%, Al/terpolymer of EAE and maleic anhydride/EVOH 100%,

Al/EVOH/EVOH, AL/terpolymer of EAE and maleic anhydride/COC.

In an embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is COC and the base layer is aluminium, the tie-layer is preferably a terpolymer of ethylene, acrylic ester and maleic anhydride

In a further embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is PA and the base layer is aluminium, the tie-layer is preferably a copolymer of ethylene and acrylic acid.

In yet another embodiment of the invention, wherein the film is resistant to fentanyl and the contact layer is EVOH and the base layer is aluminium, the tie-layer is preferably EVOH and/or a terpolymer of ethylene, acrylic ester and maleic anhydride.

The invention should not be restricted to the above combinations. Further combinations are within the scope of the invention.

In another aspect of the invention is provided a method for providing an aggressive chemical resistant film said film being resistant to nicotine, rivastigmine and/or and lidocaine, and wherein said method comprises the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards nicotine, rivastigmine and/or lidocaine of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

It has surprisingly been shown that films provided from polymers having a red value between 0.8 and 10 relative to rivastigmine, lidocaine and/or nicotine and coextruded as stipulated above have superior resistance to said chemical substances.

In a further aspect of the invention is provided a method for provid-

ing an aggressive chemical resistant film against nicotine, rivastigmine and/or and lidocaine, said method comprising the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

It has surprisingly been shown that polymers of cyclic olefin copolymer, polyamide and ethylene vinyl alcohol, when coextruded, provide a resistant film, which performs at least as well as films known in the prior art for packaging compunds such as nicotine, lidocaine and rivastigmine.

Conveniently, the polymers used in the present invention have the advantage of being easy accessible thereby providing a more cost efficient production.

Figures

Figures 1 is a cross section of an embodiment of a chemical resistant film according to the invention

Figure 2 is a cross section of another embodiment of a chemical resistant film according to the invention.

Figure **3** is a cross section of a laminate according to the invention.

Figure 4 shows the results of an absorption study of rivastigmine as API wrapped in laminates according to the invention as compared to a commercial available laminate with the commercial available polymer film Barex® after storing for 2, 4, 8 and 12 weeks at 40°C.

Figure **5** shows the amount of licodaine remaining in a patch after **7** days at 40°C for embodiments of the laminate according to the invention and in comparison, with a commercial available Barex® laminate.

Detailed description

The invention will now be described in greater details. Each specific

embodiment and variation of features applies equally to each aspect of the invention unless specifically stated otherwise.

The film, laminate and packaging according to the present invention is intended to be used in packaging highly aggressive substances such as nicotine, rivastigmine, fentanyl or lidocaine, however, the invention should not be limited to these specific substances.

The term "film" according to the invention contemplates a product comprising a base layer coated with a coextrusion layer comprising a tie layer and a contact layer or a base layer laminated with a tie layer and a contact layer.

Where the contact layer is laminated, for example using an EVOH film, the contact layer and tie layer may be either coextruded, or, the contact film layer may be laminated to the base layer optionally with an intermediate tie layer or the tie and contact layers may be the same material.

The term "laminate" according to the invention contemplates the film to which a further layer is laminated, such as a first outer layer.

A "packaging" is in the context of the invention intended to mean a film or laminate used to pack a substance. Packaging may be used interchangeably for film or laminate.

The term "highly aggressive substance" should be understood as a substance which is both very reactive with metals, acids, bases or functional groups such as ketones, alcohols, hydro carbons and/or esters, and/or, volatile but also easily migrates through barriers. Similarly, the term "aggressive chemical resistant film" means a film which when in contact with an aggressive substance does not allow more than 1.5 % w/w of nominal content to migrate to the packaging material or that 90-110% w/w of the aggressive chemical substance remains in the product when compared to Barex® as index 100.

Therefore, the films, laminates or packagings applicable for packing highly aggressive substances should have both chemical-resistant properties but also limit the migration of the aggressive substance through the film, laminate or packaging. The aggressive substance according to the invention is also or alternatively susceptible to degradation when exposed to ambient conditions, such as oxygen and water, it is volatile and able to migrate or a combination. Specifically, the aggressive substance is selected from but not

limited to nicotine, oils, such as spearmint and peppermint oil, licodaine, fentanyl or rivastigmine.

The term "oxygen and water resistant" as used in the context of the present invention contemplates material for which the oxygen transfer rate (OTR) and/or water vapor transfer rate (WVTR) is no more than 1 preferably no more than 0.1 as also indicated above. The term WVTR may also be referred to as the moisture vapor transfer rate (MVTR). WVTR and MVTR are equivalent.

The term "mechanically wear resistant layer" as used for the first outer layer in the context of the present invention should be a material which is suitable for the manufacture of a flexible packaging. The mechanically wear resistant layer may be chosen from materials such as polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets or combinations.

Further, the mechanically wear resistant material can be provided as a film that is biaxially oriented to give the film higher seal strength. The term "biaxial oriented" should be understood such that the provided polymer film has been stretched in both a longitudinal and a transverse direction during manufacturing.

The term "exterior side" should be understood in its broadest term. The term exterior environment is used for defining the direction opposite of the side that is facing the highly aggressive substance to be sealed by a laminate or packaging of the present invention. This means that the term exterior environment is independent on whether additional layers are coated, laminated or otherwise attached to the film. Thus, the word is used for specifying which direction a side of a layer is facing.

The various embodiments of the invention will now be illustrated with references to the figures and examples.

With reference to figure 1 a film of the invention will now be described in greater detail. The extreme chemical resistant film, 1, is obtained by providing a base layer, 2. A coextrusion layer, 5, comprising a tie layer, 3, and a contact layer, 4, is coated to one side of the base layer, 2, according to the method of the invention and is allowed to adhere. The base layer, 2, and the coextrusion layer, 5, define the film according to all the aspects of the invention. Consequently, the film is provided with a base layer side, 2, and a

coextrusion layer side 5, wherein the base layer side, 2, is intended for facing the exterior environment and the coextrusion layer side, 5, is intended for facing the highly aggressive substance to be sealed.

The coextrusion layer may be coated to the aluminium layer by a co-extrusion system generally known in the art to provide the coextrusion layer coated on the first side of the aluminum layer. The coextrusion layer may be applied in an amount of 7-40 g/m3. After coating of the aluminium layer and subsequently cooling, the coextrusion layer is adhered to the side of the tie layer facing away from the aggressive chemical substance.

The coextrusion is preferably performed at a temperature of 240-330°C, more preferred 270 - 300°C and the speed of the application/coating is in the range of 150 to 600 m/min. The equipment suitable for extruding and laminating films and laminates according to the invention may be obtained from Bobst.

When using coextrusion, it is possible to obtain a multi layer which is thinner than multilayer layers provided by sequential film application techniques without compromising the extreme chemical resistance properties of the first laminate. Hence, the present invention does not only provide an extreme chemical resistance laminate, and packaging comprising the same but at the same time the manufacturing process is more cost effective since less polymer, forming the contact layer, has to be used.

Another embodiment of a film in which the tie layer comprises two layers is illustrated in figure 2. The extreme chemical resistant film, 1, is obtained by providing a base layer, 2. The coextrusion layer, 5, comprises a tie layer, 3, comprising a first layer, 3a, and a second layer, 3b, and a contact layer 4. The coextrusion layer is coated onto one side of the base layer, 2, according to the method of the invention and is allowed to dry.

In the embodiment illustrated, the tie layer, 3, comprises two layers. These layers may be made of EAA as the first layer, 3a, and polyethylene (PE) as the second layer, 3b, where the first layer of EAA faces the base layer and second layer of the PE faces the contact layer, 4.

The extreme chemical resistant film according to the invention is intended for use as a component of a packaging suitable for sealing a highly aggressive substance. The film may constitute the packing itself.

To further improve the mechanical wear resistance of the film a first

outer layer may be laminated to the base layer side of the film or simply be wrapped around the film to provide a laminate. Hence, in figure 3 is illustrated a cross section of an embodiment of a laminate according to the invention, 12, comprising a first outer layer, 21, a base layer, 22, and a coextrusion layer, 25. The first outer layer, 21 and the base layer side, 22, may be laminated together before, during or after the coextrusion layer 25 is applied/coated to the base layer.

The first outer layer, 21, is a mechanically wear resistant layer which adds safety properties to the wrapping ensuring that the wrapping is not inadvertently opened. Hence, the outer layer can also be seen as a child proof layer meaning that the layer is made of a material and is sealable in such a way that it is difficult for children to open. Additionally, the outer layer may be provided with a second outer layer, 20.

The second outer layer, 20, is typically a paper layer, wherein the paper layer is facing the exterior environment; the exterior facing side of the second layer may be printed as desired. The second outer layer, such as the paper layer is added to improve the stiffness of the packaging in addition to providing a printing platform.

Furthermore, it is within the inventive concept of the present invention that an adhesive agent is applied between the first outer layer and the base layer and/or between the first outer layer and the second outer layer. The obtained packaging may then be assembled in such a way that the various layers do not part during handling, printing and/or packaging of the substance to be packed.

After production, the film, laminate or packaging may be stored as rolls ready for use in further lamination or packaging of the aggressive substance to be packed.

In use, the packaging is sealed around the substance to be packed so that the contact layer of the coextrusion layer faces the interior side and the substance, and, the base layer, first outer layer or second outer layer, as applicable, face the exterior side, so as to create a hollow interior for containing the, substance, such as the aggressive substance.

The sealing of the packaging is achieved in such way that the contact layer of the coextrusion layer is facing the aggressive substance so that the remaining part of the package is protected by the contact layer of the coex-

trusion layer. In this way, the aggressive substance is encompassed by the inner side of packaging and will therefore only have direct contact with the contact layer of the coextrusion layer.

In general, the order in which the different layers of the packaging according to the invention are applied to the base layer is flexible. Hence, the first outer layer may be applied before the coextrusion layer and the other way around. The order depends on which production line is suitable in a specific situation.

In more details the packaging according to the present invention may in one embodiment be manufactured by obtaining a film comprising a base layer, such as an aluminum layer and a coextrusion layer comprising a biopolymer of ethylene and acrylic acid as a tie layer and EVOH as the contact layer coated to the aluminium as described above. The base layer side of the film may then be provided with an adhesive agent and subsequently laminated to a biaxial orientated PET-film which is the first outer layer, i.e. the mechanically wear resistant layer. The PET-film is further provided with an adhesive agent on the exterior side of the mechanically wear resistant layer and is subsequently laminated to a paper layer for providing the final packaging.

An aggressive substance, such as but not limited to lidocaine, is placed on the contact layer side of the laminate which is welded around the substance, such as to form a pouch with an inner side and an outer side. Accordingly, the interior of the pouch consists of the coextrusion layer, where the contact layer of EVOH facing the aggressive substance thereby protects the rest of the provided packaging and the exterior side is the paper layer.

In general, the lamination procedure for laminating the mechanically wear resistant or paper layer to each other or to the base layer is routine procedure for the person skilled in the art.

According to all aspects of the invention the base layer may be selected from but not limited to a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluro polymers, such as commercial Alu foil from e.g. Hydro, or AlOx coated PET films obtainable from e.g. Toray Films Europe, or SiOx coated PET films obtainable from e.g. Celplast under the tradename Ceramis.

According to all aspects of the invention the tie layer may be made of a material selected from but not limited to a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride, such as the commercial product Lotader® 3410 sold by Arkema or Nucrel® 0609HSA sold by Dupont®

According to all aspects of the invention the contact layer may be made of a material selected from cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol or mixtures thereof, such as the commercial products EVAL® C109B sold by Kuraray, Selar PA 3426 R sold by Dupont® or COC 6013M-07, COC 8007F-600, or 9506F500 sold by Topas® or EVOH obtainable from Nippon Gohsei under the tradename Soarnel.

According to all aspects of the invention the first outer layer may be made of a material selected from paper, polyethylene or polyamide based sheets, ortho-phthalaldehyde based sheets, or polyester based sheets, or combinations, such as the commercial product F-PAP sold by Flexpet.

The invention will now be illustrated in more details with reference to the following non limiting examples.

RED Calculation

Determination of the HSP values and interaction radius for nicotine, rivastigmine, fentanyl and lidocaine requires that the solubility of the drug is evaluated against at least 16 solvents having a range of polar and hydrogen bonding properties. The methodology of determining HSP values, interaction radius and RED values are described in CM. Hansen : "Hansen Solubility Parameters, A User's Handbook", CRC Press, 2007, Second Edition and exemplified in EP 2 895 531.

Typical solvents used to determine the HSP may be but is not limited to the solvents present in table 2.

Table 2: Typical solvents used to determine the HSP of a polymer or substance of interest.

Typical solvents used in Determining of HSP of rivagstigmine, lidocaine, fentanyl and nicotine	
Chemical name	Trade Designation or Alternate Name
Acetonitrile	Acetonitrile
Ethylene glycol n-Butyl Ether	Butyl CELLOSOLVE™ Glycol Ether
Dibutyl Ether	Dibutyl Ether
Dimethyl Formamide	Dimethyl Formamide
Dimethyl Sulfoxide	Dimethyl Sulfoxide
Methanol	Methyl alcohol
2-Butanone	Methyl Ethyl Ketone
4-Methyl-2-pentanone	Methyl Isobutyl Ketone
n-Butyl Acetate	n-Butyl Acetate
n-Heptane	n-Heptane
1-Propanol	n-Propyl Alcohol
o-Dichlorobenzene	1,2-Dichlorobenzene
Tetrahydrofuran	Tetrahydrofuran
Toluene	Methylbenzene
Propylene Carbonate	Propylene Carbonate
Water	Water

For assessing the solubility of Rivastigmine, Lidocaine, fentanyl and nicotine in the solvents an experimental measurement is performed. The solubility is assesed based on the visual observation of 0.5 g of the chemical substance in a vial with 5 cm^3 solvent at room temperature. The vial is capped with a polyethylene-lined lid and labeled with the solvent loaded. The vials are placed in a vial shaker at low speed at room temperature. After 24 hours, the samples are removed from the vial shaker, and allowed to sit for 30 min before they are visually rated. The rating is performed by giving each solvent a score being 0 for insoluble and 1 for soluble. The numerical ratings are then entered into the HSPiP software program to obtain the HSP (Hansen solubility parameters). R (radius) values for the compound of relevance, e.g. nicotine, rivastigmine, fentanyl and/or lidocaine is inserted, and a report is

generated. The report lists the final parameters and R values calculated for nicotine, rivastigmine, fentanyl and/or lidocaine. The report also lists the solvents used in the evaluation, their HSP values (taken from a database), the rating of the visual observations, and their RED values with a specific polymer of interest.

Example 1- performance of a laminate according to the invention compared to a commercially used laminate

A study was conducted to evaluate the performance of four laminates according to the present invention as compared to a commercially available laminate product comprising Barex® as the contact layer.

The wrappings according to the invention were compared to the performance of a Barex® laminate currently used in the field.

The test is a resistance test, wherein the migration of rivastigmine to the laminates is evaluated.

Table 3: The composition of the 6 wrappings was a follows, laminates 1 to 5 are laminates according to the invention

	Adhesive/Polymer layer Coextrusion layer	Base layer	First outer layer	Second Outer layer
Commercially used Barex® laminate (prior art)	Adhesive/ Barex® film	Al	PET	Paper
Laminate 1	Tie layer: Bipolymer of ethylene and acrylic acid (Nucrel 0609 HAS) Contact layer: PA (Selar PA 3426R)	Al	PET	
Laminate 2	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: EVOH 60% (EVAL C109B) and PE 40%	Al	PET	
Laminate 3	Tie and contact layer: EvOH film (EVAL C109B)	Al	PET	
Laminate 4	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: EVOH 100% (EVAL C109B)	Al	PE	PET
Laminate 5	Tie layer: Terpolymer of ethylene, acrylic ester and maleic anhydride (Lotader 3410) Contact layer: COC	Al	PE	PET

*Between the paper/PET, PET/Al, and Al/EVOH film layers an adhesive was applied.

Laminates 1 to 5 were obtained according to the method of the invention. For laminates 1, 2, 4 and 5 a coextrusion layer was coated to the base layer and in laminate 3 the combined tie and contact layer was laminated to the base layer. For the co-extrusion layers, the loading of the tie layers was between 4-18 g/m^2 and the loading of the contact layer was 8-12 g/m^2.

The resulting laminates were wrapped around a patch containing rivastigmine as API and the migration of the API to the packaging material/wrapping was measured after 2, 4, 8 and 12 weeks at 40 °C. The API in the wrapping was measured by extracting the packaging and analysing the amount of API therein using Mass spectrometry.

The Rivastigmine patches tested were commercially available patches originally containing 9.5 mg API/patch.

The results are shown in figure 4 illustrating the resulting migration of rivastigmine (weight API extracted from the laminate) to the laminate in percentage of the content of the original patches of 9.5 mg.

The columns are denoted 1, 2, 3 and 4 respectively to the order they are shown from left to right in figure 4. Hence column 1 (furthest to the left) for each contact layer polymer used shows the results for the 6 laminates after two weeks. Column 2 shows the results for the 6 laminates after four weeks. Column 3 shows the results for the 6 laminates after 8 weeks, and column 4 shows the results for the 6 laminates after 12 weeks.

The Barex® laminate is a reference known for applicability in the art and comparison were made for evaluating the properties of the laminates according to present invention.

From the figure it is clear that the results for laminates according to the invention obtained by coextrusion of either of EVOH, PA, or COC as well as laminating EVOH provides for an improved chemical resistant laminate compared to the commercially used Barex® laminate, meaning that less migration occurs.

Also, a contact layer, illustrated as laminate 2, of a blend of EVOH and PE was prepared and tested. Though the properties of this blend with rivastigmine as API resulted in a higher migration of the API than Barex®, the rate is still below the limit demanded in the industry and hence, it illustrates that blends as provided in laminate 2 are usable alternatives to

Barex® as well. Surprisingly though the tie/contact layer made of 100% EVOH was markedly superior to the blend.

Also, a contact layer, illustrated as laminate 3, a film of EVOH laminated to aluminum was prepared and tested. Surprisingly, it was shown that the use of EVOH in the form of a film laminated to aluminum provided a chemical resistant laminate.

Example 2 - stability test of a chemical substance wrapped in laminates according to the invention and wrapped in a prior art product using Barex®

Similar to the test described in example 1, laminates according to the invention were prepared as outlined in table 4 below. A lidocaine patch containing 40 mg lidocaine was wrapped in the pouch, packaged and stored at 40°C for seven days.

Table 4 : Packagings for lidocaine stability test.

	Barex Commercially used Barex® laminate (prior art)	COC coex same as laminate 5 of example 1	Coex EVOH same as laminate 4 of example 1

Stability of the API is important to ensure that the dose indicated on the packaging is correct. A value of 90% - 110% of the original dose after one week when stored at 40°C using Barex® as index 100 is considered acceptable. Figure 5 illustrates the results of the test where the y-axis indicates the weight decrease of the two laminates according to the invention using Barex as index 100.

As can be seen from figure 5, both inventive laminates have a lower value than the index 100 Barex® comparative product, however with a value within the acceptable limits. The lower %value of the laminates according to the invention indicates that more lidocaine has disappeared from the patch.

C L A I M S

1. A method for providing a, e.g. aggressive chemical resistant, film, said method comprising the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer; and,

wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards an aggressive chemical of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

2. A method according to claim 1, wherein the base layer, which is water and/or oxygen resistant, is selected from the group consisting of a metal foil, preferably aluminum foil, a polymer, such as a polymer made from polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluro polymers.

3. A method according to any one of the claims 1 to 2, wherein the tie layer is made of 1, 2, 3, 4 or 5 layers.

4. A method according to claim 3, wherein all the layers of the tie layer are coextruded with the contact layer.

5. A method according any one of the preceding claims, wherein the tie layer is constituted of one layer and wherein the layer is a copolymer made of a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a terpolymer comprising ethylene, acrylic ester and a third polymer, which third polymer is preferably a glycidyl methacrylate, and more preferably a maleic anhydride.

6. A method according to any one of the claims 1 to 4, wherein the tie layer comprises at least two layers, and wherein the first layer comprises a copolymer according to claim 5 and the at least second or more layer(s) comprises a material selected from EEA, PE, EMA, EAA or a combination.

7. A method according to any one of the preceding claims, wherein

the contact layer comprises a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

8. A method according to anyone of the preceding claims wherein the contact layer is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

9. A method according to anyone of the preceding claims, wherein the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m^2 and/or the contact layer has a loading in the range of 4 to 20 g/m^2 and the loading of the film is not more than 40 g/m^2.

10. A method according to any of the preceding claims, wherein the film is used to wrap a composition comprising a chemical selected from nicotine, lidocine and rivastigmine

11. A method according to claim 10, wherein the composition is a patch.

12. A method according to claim 10 or 11, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/-10% in comparison to a Barex® patch as index 100.

13. An aggressive chemical resistant film comprising at least a base layer, which is water and/or oxygen resistant, and a coextrusion layer, wherein the coextrusion layer comprises a tie layer and a contact layer, and wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

14. A film according to claim 13, wherein the base layer, which is water and/or oxygen resistant, is selected from the group consisting of metal foil, preferably aluminum foil, polymers, such as polyamide, polyvinylidene chloride, silicium or aluminium oxide coated polyesters, and/or fluropolymers; and/or

the tie layer is constituted of one layer and wherein the layer is made of a copolymer, said copolymer comprising a material selected from a copolymer of ethylene and acrylic acid, ethylene and methacrylic acid and a third polymer, which third polymer is preferably made of a material selected from glycidyl methacrylate, and more preferably maleic anhydride; and/or

wherein the contact layer comprises or is a polymer selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

15. A film according to claims 13 or 14, wherein the tie layer or plurality of layers constituting the tie layer, has a loading in the range of 7 to 20 g/m^2 and/or the contact layer has a loading in the range of 4 to 20 g/m^2 and the loading of the film is not more than 40 g/m^2.

16. A laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;

- an aggressive chemical resistant film according to any of claims 13 to 15, said film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, where the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value based on Hansens Solubility parameter (HSP) in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2; and, where the base layer side of the film is facing the first outer layer.

17. A laminate according to claim 16, wherein the laminate further comprises a second outer layer facing the exterior side of the outer layer, preferably the second outer layer is a paper layer.

18. A laminate according to any of the claims 16 to 17, wherein the laminate encloses a compound selected from the group consisting of nicotine, rivastigmine, fentanyl and lidocaine.

19. A laminate according to claim 16, 17, and 18, wherein the laminate is heat sealable.

20. A laminate according to claim 16 to 19, wherein a maximum of 10%, preferably a maximum of 5%, even more preferably a maximum of 2% of the active ingredient is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

21. An aggressive chemical substance packed in a heat sealable laminate, said heat sealable laminate comprising

- a first outer layer made of a mechanically wear resistant material;

- an aggressive chemical resistant film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextru-

sion layer comprising a tie layer and a contact layer, wherein the base layer side of the film is facing the outer layer; and, wherein the contact layer comprises a polymer having a RED value of > 0.8, more preferred a RED value based on Hansens Solubility parameter (HSP) in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

22. Use of a polymer having a RED value based on Hansens Solubility parameter (HSP) of > 0.8, preferably having a RED value in the range of 0.8 to 10, more preferred 0.8 to 5, and most preferred 1 to 2 as a contact layer for providing chemical resistance to a film, wherein the film comprises a base layer which is water and/or oxygen resistant, said film is coated to a, optionally coextruded, layer comprising a tie layer and the contact layer.

23. Use according to claim 22, wherein the polymer is selected from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

24. A method for providing an aggressive chemical resistant film said film being resistant against nicotine, rivastigmine, fentanyl and/or lidocaine, and wherein said method comprises the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer having a RED value based on Hansens Solubility parameter (HSP) towards nicotine, rivastigmine, fentanyl and/or lidocaine of > 0.8, more preferred a RED value in the range of 0.8 to 10, even more preferred 0.8 to 5, and most preferred 1 to 2.

25. A method for providing an aggressive chemical resistant film said film being resistant against nicotine, rivastigmine, fentanyl and/or and lidocaine, and wherein said method comprises the steps of:

i) providing a base layer, which is water and/or oxygen resistant;

ii) coextruding a layer comprising a tie layer and a contact layer to provide a coextrusion layer;

iii) coating the coextrusion layer to the base layer;

iv) allowing the coextrusion layer coated to the base layer to adhere to provide the aggressive chemical resistant film comprising the tie layer and the contact layer formed as a coextrusion layer coated to the base layer, wherein the tie layer comprises at least one layer and wherein the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

26. A method according to claim 25, wherein the film is used to wrap a composition comprising a chemical selected from nicotine, lidocaine, fentanyl and rivastigmine

27. A method according to claim 26, wherein the composition is a patch.

28. A method according to claim 26 and 27, the amount of the aggressive chemical substance remaining at day 0 after storage for at least 7 days at 40°C is a maximum +/-10% in comparison to a Barex® patch as index 100.

29 A laminate for packing an aggressive chemical substance said laminate comprising at least

- a first outer layer made of a mechanically wear resistant material;
- an aggressive chemical resistant film according to claim 25, said film comprising a base layer, which is water and/or oxygen resistant and a coextrusion layer, said coextrusion layer comprising a tie layer and a contact layer, where the contact layer comprises a polymer from the group consisting of a cyclic olefin copolymer, a polyamide, or, an ethylene vinyl alcohol.

30. A laminate according to claim 29, wherein the laminate is wrapped around a composition comprising the aggressive chemical substance and wherein a maximum of 10% w/w, preferably a maximum of 5% w/w, even more preferably a maximum of 1.5% w/w, most preferably a maximum of 0.5% w/w of the aggressive chemical substance based on nominal content is migrated into the laminate at day 0 after 12 weeks of storage at 40 °C.

31. A laminate according to claim 30, wherein the aggressive chemical substance is selected from the group consisting of rivastigmine, lidocain, fentanyl and nicotine.

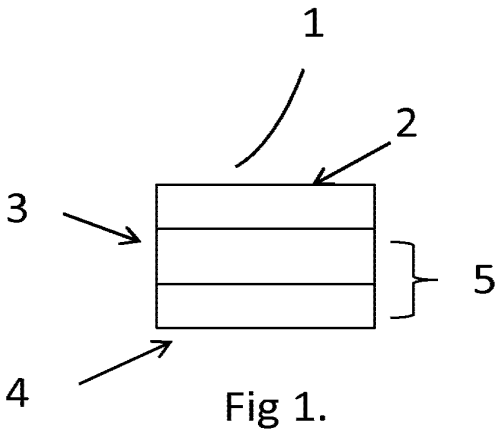


Fig 1.

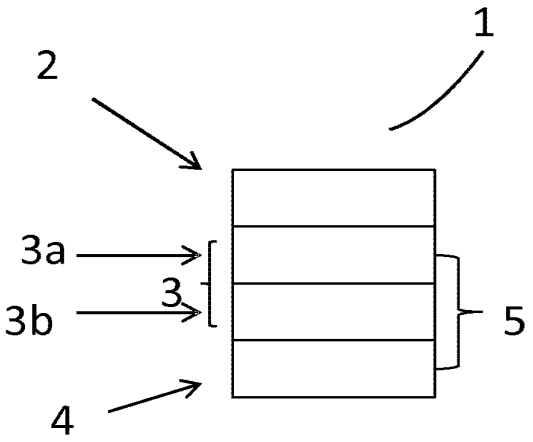


Fig. 2

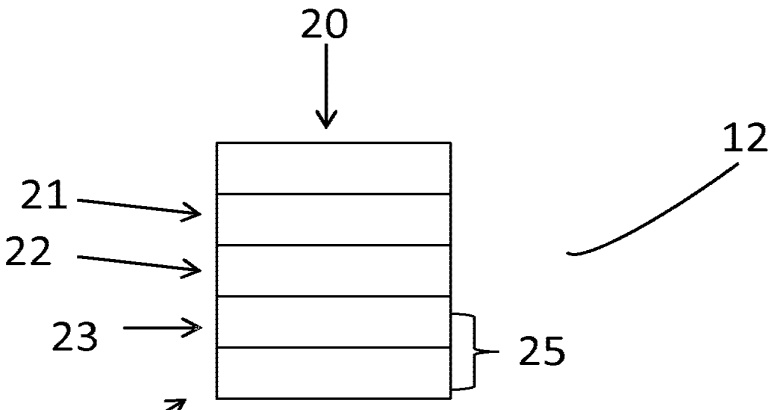


Fig. 3

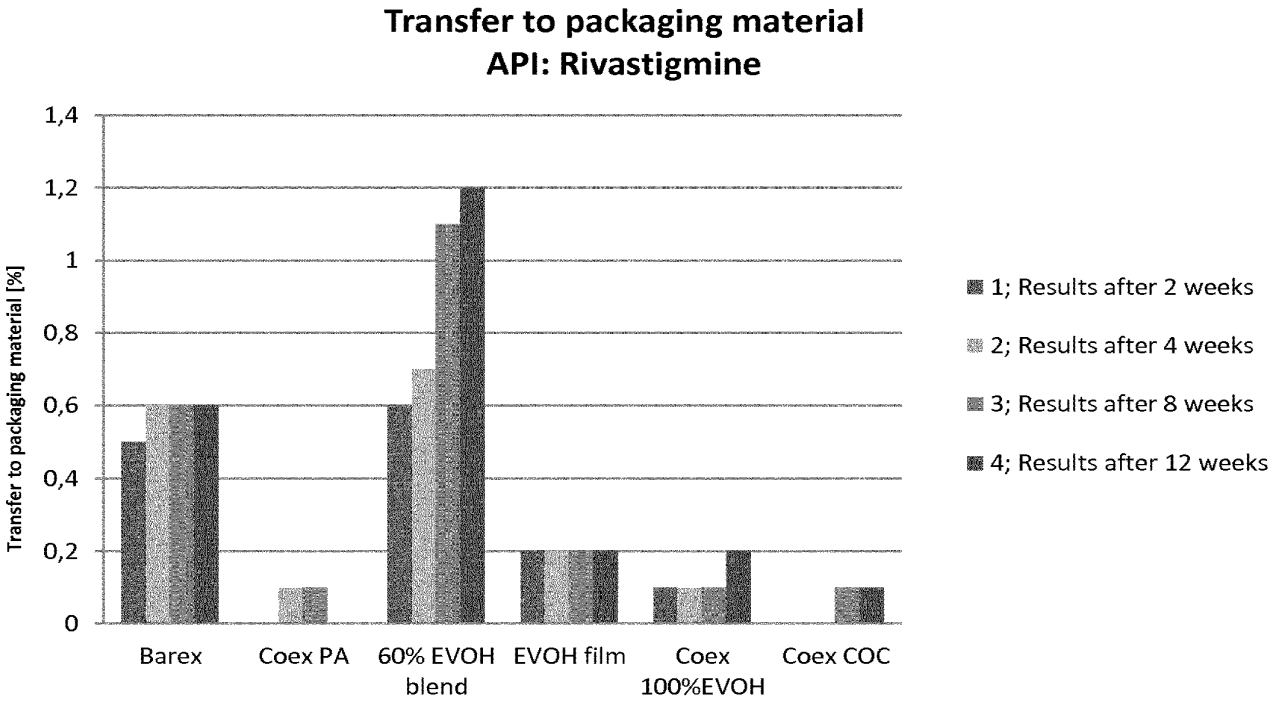

Transfer to packaging material
API: Rivastigmine
Transfer to packaging material [%]
1,4
1,2
1
0,8
0,6
0,4
0,2
0
Barex
Coex PA
60% EVOH blend
EVOH film
Coex 100%EVOH
Coex COC
1; Results after 2 weeks
2; Results after 4 weeks
3; Results after 8 weeks
4; Results after 12 weeks

Fig. 4

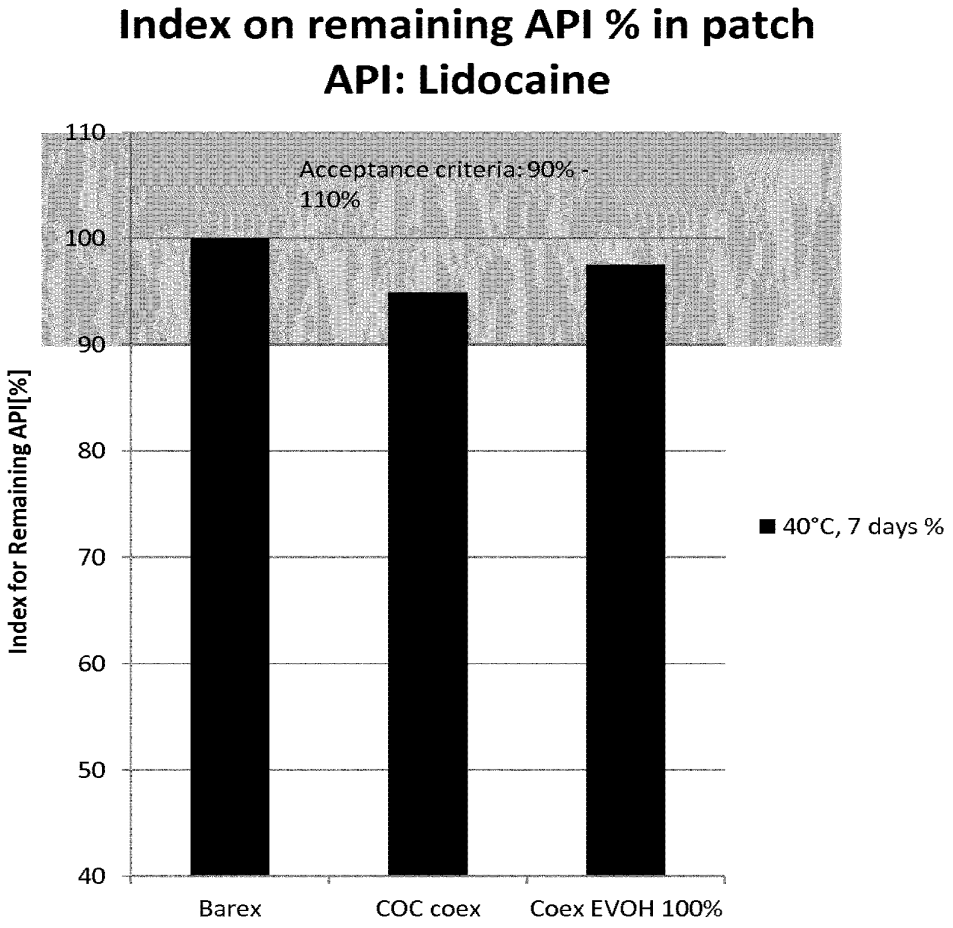

Index on remaining API % in patch
API: Lidocaine
Acceptance criteria: 90% - 110%
Index for Remaining API[%]
110
100
90
80
70
60
50
40
Barex
COC coex
Coex EVOH 100%
40°C, 7 days %

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/082876

A. CLASSIFICATION OF SUBJECT MATTER
INV. B32B7/12 B32B15/08 B32B15/082 B32B15/085 B32B15/20
B32B27/08 B32B27/30 B32B27/32 B32B27/36
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
B32B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 120 860 A (BOWEN WILLIAM E [US] ET AL) 19 September 2000 (2000-09-19) column 2, line 24 - column 3, line 8 page 3, line 30 - page 5, line 14 page 5, line 33 - line 44 page 6, line 27 - line 40; claims	1-31
X	US 2005/037162 A1 (ADAMS JOHN PETER [US]) 17 February 2005 (2005-02-17) figures paragraphs [0028] , [0045] sample E; page 3; table claim	1-31

-/- .

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 March 2017	30/03/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Mazet, Jean-Frangoi s

1

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/082876

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/234790 A1 (SMITH WILLIAM STUART [US] ET AL) 25 November 2004 (2004-11-25) figure 1 paragraphs [0004] , [0005] claims	1-31
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/082876

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/082876

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
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		ZA	9010132	B	30-10-1991

Electronic Acknowledgement Receipt

EFS ID:	39590206
Application Number:	16425067
International Application Number:	
Confirmation Number:	7044
Title of Invention:	FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS
First Named Inventor/Applicant Name:	Peter Johansen
Customer Number:	26582
Filer:	Paul M. Schramm/Sherry Soares
Filer Authorized By:	Paul M. Schramm
Attorney Docket Number:	P008EP.US (87942.0011)
Receipt Date:	01-JUN-2020
Filing Date:	29-MAY-2019
Time Stamp:	17:56:18
Application Type:	Utility under 35 USC 111(a)

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	Transmittal Letter		1	2	
	Information Disclosure Statement (IDS) Form (SB08)		3	6	
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Information:					
2	Foreign Reference	FR_WO2017114922A1_Danapak_41pgs.pdf	587640 047a961734e446a896d8aca5076ad079d0dbfba1	no	41
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Johansen et al. Application No.: 16/425,067 Filed: May 29, 2019 For: FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS Docket No.: P008EP.US (87942.0011) Customer No.: 26582	Confirmation No.: 7044 Examiner: Callie E. Shosho Art Unit: 1787 **INFORMATION DISCLOSURE STATEMENT** **CERTIFICATE OF TRANSMISSION** I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on June 1, 2020. By: /Sherry Soares/ Sherry Soares

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Respectfully submitted,

/Paul M. Schramm/

Paul M. Schramm
Reg. No. 62,050

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/425,067	05/29/2019	Peter Johansen	P008EP.US (87942.0011)

CONFIRMATION NO. 7044

26582
HOLLAND & HART, LLP
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SALT LAKE CITY, UT 84147

PUBLICATION NOTICE

OC000000114703808

Title:FILMS AND LAMINATES FOR USE IN PACKAGING REACTIVE COMPOUNDS

Publication No.US-2020-0047461-A1
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Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	001	20040234790-A1	11-25-2004	Smith et al.	
	002	20050037162-A1	02-17-2005	Adams	
	003	20050112337-A1	05-26-2005	Jester	
	004	20090208685-A1	08-20-2009	Rivers et al.	
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	014	8722164-B2	05-13-2014	Bekele et al.	
	015	9452593-B2	09-27-2016	Tatarka et al.	
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Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
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	019	DE-102012113026-A1	06-26-2014	SCHOTT AG		☒
	020	DE-102013113718 A1	06-11-2015	Buergofol GmbH		☒
	021	DE-202008017320-U1	05-28-2009	Alcan Technology & Management AG		☐
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	034	EP-3210907-B1	07-17-2019	Kyodo Printing Co., Ltd.		☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	035	EP-3360530-A1	08-15-2018	Mitsubishi Gas Chemical Company, Inc.		☐
	036	WO-1991009731-A1	07-11-1991	ALZA Corporation		☐
	037	WO-1995007816-A1	03-23-1995	The Dow Chemical Company		☐
	038	WO-2000044559-A1	08-03-2000	Pharmacia & Upjohn AB		☐
	039	WO-2001064786-A1	09-07-2001	Ticona GmbH		☒
	040	WO-2005037539-A1	04-28-2005	E.I. Dupot de Nemours and Company		☐
	041	WO-2005097486-A1	10-20-2005	Curwood, Inc.		☐
	042	WO-2010047906-A1	04-29-2010	ExxonMobil Oil Company		☐
	043	WO-2010075946-A1	07-08-2010	Huhtamaki Forcchheim		☒
	044	WO-20121192271A1	09-13-2012	Surface Medical Inc.		☐
	045	WO-2013004243-A1	01-10-2013	Fertin Pharma A/S		☐
	046	WO-2013028398-A1	02-28-2013	Avery Dennison Corporation		☐
	047	WO-2013034273-A1	03-14-2013	Siegfried Ltd.		☐
	048	WO-2013116445-A1	08-08-2013	E.I. Dupont de Nemours and Company		☐
	049	WO-2014023995-A1	02-13-2014	Probiotical S.p.A.		☐
	050	WO-2015097208-A1	07-02-2015	Solvay Specialty Polymers Italy S.p.A.		☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

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	051	WO-2015118215-A1	08-13-2015	Tampereen Patenttitoimisto Oy		☐
	052	WO-2015123211-A1	08-20-2015	Bemis Company, Inc.		☐
	053	WO-2015174502-A1	11-19-2015	Nichiban Co., Ltd.		☒
	054	WO-2015187173-A1	12-10-2015	Perfecseal, Inc.		☐
	055	WO-2015187174-A1	12-10-2015	Perfecseal, Inc.		☐
	056	WO-2015199637-A1	12-30-2015	Perfecseal, Inc.		☐
	057	WO-2016076844-A1	05-19-2016	Bemis Company, Inc.		☐
	058	WO-2016164794-A1	10-13-2016	PolyOne Corporation		☐
	059	WO-2016190081-A1	12-01-2016	Dexerials Corporation		☒
	060	WO-2016194555-A1	12-08-2016	Polyplastics Co., Ltd.		☒
	061	WO-2016200363-A1	12-15-2016	Bemis Company, Inc.		☐
	062	WO-2017034560-A1	03-02-2017	Bemis Company, Inc.		☐
	063	WO-2017063087-A1	04-20-2017	Macro Technology Inc.		☐
	064	WO-2017087032-A1	05-26-2017	SiO2 Medical Products, Inc.		☐
	065	WO-2017100182-A1	06-15-2017	Bemis Company, Inc.		☐
	066	WO-2017100358-A1	06-15-2017	Bemis Company, Inc.		☐
	067	WO-2017189836-A1	11-02-2017	Cryovac, Inc.		☐
	068	WO-2017217989-A1	12-21-2017	Bemis Company, Inc.		☐
	069	WO-2018028996-A1	02-15-2018	Clariant International Ltd.		☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	070	WO-2018041320-A2	03-08-2018	Coloplast A/S		☐
	071	WO-2018222864-A1	12-06-2018	Bay Materials, LLC		☐
	072	WO-2018231219-A1	12-20-2018	Bemis Company, Inc.		☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T[2]
	073	DATABASE WPI Week 201579, Derwent Publications Ltd., London, GB; AN 2015-71769A, XP002759263; 2 pgs.	☐

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	7	of	8

Complete if Known	
Application Number	16/425,067
Filing Date	05-29-2019
First Named Inventor	Johansen et al.
Art Unit	3736
Examiner Name	
Attorney Docket Number	P008EP.US (87942.0011)

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul M. Schramm/	Date (YYYY-MM-DD)	2019-11-15
Name/Print	Paul M. Schramm	Registration Number	62,050

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.