Freedom to Operate
We provide you with qualitative information

Report

Patent examiner: Carollina Gómez Lagerlòf

Our ref: 999000
Date of search: 29 April 2016
Your ref: Ref test 000
Freedom to Operate (FTO) – We provide you with qualitative information

A freedom to operate search provides a good indication of the risk of infringement of existing patents. The search report is the result of your request and the search itself which performed by one or several patent examiners. An FTO search carried out by PRV InterPat primarily focuses on patents in Europe and the United States.

Please note that we do not state an opinion regarding the risk of infringement.

The report contains categorized citations and comments over the parts that the patent examiner finds relevant, to state the opinion about the risk of infringement.

An important part of the evaluation process of a patent is to be able to secure the legal status and the geographical area. The patent references in the report contain links to the database Espacenet, where such information can be found. We can also upon request provide you with the references in Excel-format.

Patent Family Search – additional service

There is also a possibility to use our information specialists to make the Patent family search for you. You will get a report showing a clear overview of the status and geographical coverage over the patent in question and where obvious information is missing the legal status will, if possible, be confirmed.

To perform this search as cost effective as possible you choose the patents that are of particular interest to you and then order a Patent family search on these. If you wish to complement a FTO search with a Patent family search reduced rates are available.

Scope of the search

In agreement with the customer, the search has focused on the following:

The search relates to a ointment comprising a vitamin D compound, preferably calcipotriene, a corticosteroid, preferably betamethasone, and an additive, for the use in the treatment of psoriasis.

Only patent which are potentially valid in Europe are of interest to the customer. Therefore, in agreement with the customer, the search has been limited to WO, EP, FR, DE and GB documents published 1996 or later. No non-patent literature has been included in the search.

Search history
IPC:
A61K 31/58 Compounds containing cyclopenta[a]hydrophenanthrene ring systems; Derivatives thereof, e.g. steroids containing heterocyclic rings, e.g. aldosterone, danazol, stanozolol, pancuronium, digitogenin
A61K 31/59 Compounds containing 9,10-seco-cyclopenta[a]hydro-phenanthrene ring systems.

Search words (truncations are not included, for the sake of clarity):
Vitamin D, calcipotriene, calcipotriol, CAS rn: 112965-21-6
Corticosteroid, betamethasone, CAS rn 378-44-9
Psoriasis, ointment, topical

Summary of the result
The patent examiner’s comments:
The search revealed a number of documents which could be of particular interest to study and analyse further. These documents are labeled with “1”.
As agreed with the customer, other documents which are possibly relevant are also included for further analysis. These documents, which are labeled “2” in the list belowed, are topical composition but not ointments.

The following databases have been used:
STN: Registry file. Caplus
WPI, Epodoc

Result
The documents are categorized by the patent examiner according to the following codes:
1= Documents of particular relevance
2= Documents of possible relevance
However, please note that the patent examiner do not state an opinion regarding the risk of infringement.
## Patent Literature - overview

<table>
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<tr>
<th>Aspect</th>
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## Patent literature - details

Follow the links in the patent numbers to original documents on Espacenet, where legal status and patent family information (INPADOC) is also available (in the left-hand menu).

### 1

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**Applicant**

LEO PHARM PROD AS; LEO PHARM PROD LTD; LEO PHARMA AS

**Title** [retrieved from database]

Dermal composition useful for treating psoriasis and related skin disorders comprises vitamin D or vitamin D analogue and corticosteroid

**Comments**

[Publication date: 2012-05-30+02:00 Oldest priority date: ]

A composition comprising a vitamin D analog and at least one corticosteroid. See the claims
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**Applicant**
BRINKMAN H; CARBOL J; MUNRO J; TOLMAR INC

**Title** [retrieved from database]
Composition useful for treating a dermatologic condition e.g. psoriasis vulgaris comprises corticosteroid; vitamin D analog; and acylated glycerol

**Comments**
[Publication date: 2010-11-11+01:00 Oldest priority date: ]
A composition comprising a corticosteroid, a vitamin D analog and a acylated glycerol.
See the claims

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**Applicant**
JO S H; MEXMED HOLDINGS INC; NEXMED HOLDINGS INC; PAN J; WANG Y; WEI W S

**Title** [retrieved from database]
Ointment for treating psoriasis, comprises vitamin D compound, corticosteroid and alkylamino substituted alkyl carboxylic ester; in petrolatum carrier, and optionally contains mineral oil or tocopherol

**Comments**
[Publication date: 2010-04-08+02:00 Oldest priority date: ]
A storage stable ointment comprising a vitamin D analog, acorticosteroid and a carboxylic ester.
See claim 1

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**Applicant**
LEO PHARMA AS

**Title** [retrieved from database]
Pharmaceutical composition useful for prevention/treatment of e.g. acne comprises corticosteroid incorporated as solid solution/ dispersion in lipid nanoparticles, where nanoparticles are solid and comprises first lipid and surfactant
A composition comprising a corticosteroid and vitamin D in a lipid dispersion. 
See claims 1, 8-9 and 17-18

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**Applicant**
CADILA HEALTHCARE LTD

**Title** [retrieved from database]
Composition, useful for treating psoriasis, comprises nano-size droplets of antipsoriatic agents or their salts or esters

**Comments**

A stable topical medicinal composition comprising one or more anti-psoriatic agents. 
Betamethasone and calcipotriene are mentioned as alternatives. See claim 5

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**Applicant**
TEVA PHARM IND LTD; TEVA PHARM USA INC; TEVA PHARMA; COHEN R; FOX M

**Title** [retrieved from database]
Topical use pharmaceutical composition useful for treating psoriasis comprises vitamin D-containing compounds comprising calcipotriene anhydrate, corticosteroid compounds comprising betamethasone dipropionate and solvent

**Comments**

A pharmaceutical composition for topical use comprising at least one vitamin D-containing compound as a corticosteroid. See claims 1-8 and 31

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Applicant
LEO PHARMA AS

Title [retrieved from database]
Sprayable, anhydrous topical composition, useful for treating dermatological
diseases including psoriasis, pustulosis palmoplantaris, ichthyosis, dermatitis,
rosacea and acne, comprises vitamin D derivative or analogue and corticosteroid

Comments
[Publication date: 2011-12-15+01:00 Oldest priority date: ]
A pharmaceutical spray comprising a vitamin D analogue and corticosteroid.
See claims 1-4.

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Applicant
LEO PHARMA AS

Title [retrieved from database]
Topical composition for treating e.g. acne comprises homogenous mixture of vitamin D
or analogue in dissolved form; and a solvent mixture containing fatty acid ester,
fatty alkyl ether and pyrrolidone based lipophilic penetration enhancer

Comments
[Publication date: 2011-06-30+02:00 Oldest priority date: ]
A topical composition comprising a vitamin D derivative in a solvent mixture.
Betamethasone can be an additional ingredient in the composition.
See claims 1, 25 and 28
PRV InterPat aims to carry out all requests accurately and thoroughly, but due to the extensive amount of information involved we cannot guarantee that the results are always exhaustive.

PRV InterPat is bound to observe professional secrecy with regard to every search request, as well as the search result. This directive is supported by chapter 31, §12 of the Swedish Secrecy Act (2009:400). Documentation is delivered exclusively to the client, and may not be cited as a hindrance to novelty in a subsequent application.

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