

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC AND
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
Petitioners,

v.

ALMIRALL, LLC
Patent Owner.

Case IPR2018-00608
Patent No. 9,161,926 B2

PATENT OWNER'S DEMONSTRATIVE EXHIBITS

almirall



**AMNEAL PHARMACEUTICALS LLC and
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC**

v.

ALMIRALL, LLC

Case IPR2018-00608

Patent 9,161,926



J.S. Patent 9,161,926 - Claims

US9161926A

(10) Patent No.: US 9,161,926
(45) Date of Patent: Oct 14, 2014

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Primary Examiner—Leticia A. Boyda Dreger
(74) Attorney, Agent, or Firm—Lynn L. Witt, Joel B. German, Debra D. Conditio

(57)

ABSTRACT

Dapsone and dapsone/diethylene glycol compositions for treating a variety of dermatological conditions of this disclosure include dapsone in a polymer viscosity builder. Subject compositions effectively treat dermatological conditions of the polymer; viscosity builder provides additional benefits to the composition without a costy builder.

6 Claims, 3 Drawing Sheets

United States Patent
Warner et al.

(54) **TOPICAL DAPSONE AND DAPSONE/DAPLENE COMPOSITIONS AND METHODS FOR USE THEREOF**

(71) Applicant: Allergan, Inc., Irvine, CA (US)

(72) Inventors: Kevin S. Warner, Ashburn, CA (US);
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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 14/082,955

(22) Filed: Nov. 18, 2013

(65) Prior Publication Data
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Related U.S. Application Data
Provisional application No. 61/728,403, filed on Nov. 20, 2012, provisional application No. 61/770,768, filed on Feb. 28, 2013.

(51) Int. Cl.
A61K 31/02 (2006.01)
A61K 31/02 (2006.01)
A61K 9/00 (2006.01)

(52) U.S. Cl.
616/1592 (2013.01); A61K 9/0014 (2013.01); A61K 31/02 (2013.01)

(58) Field of Classification Search
CPC A61K 31/02 3/466
See application file for complete search history.

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What is claimed is:

1. A topical pharmaceutical composition comprising:
about 7.5% w/w dapsone;
about 30% w/w to about 40% w/w diethylene glycol mono-ethyl ether;
about 2% w/w to about 6% w/w of a polymeric viscosity builder consisting of acrylamide/sodium acryloyldimethyl taurate copolymer;
and water; wherein the composition does not comprise adapalene.

2. The composition of claim 1, wherein the diethylene glycol monoethyl ether is present at a concentration of about 30% w/w.

3. The composition of claim 1, wherein the polymeric viscosity builder is present at a concentration of about 4% w/w.

4. The composition of claim 1, further comprising methyl paraben.



J.S. Patent 9,161,926 - Claims

US909161926B2

(10) Patent No.: **US 9,161,926 B2**
 (45) Date of Patent: **Oct. 20, 2015**

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Primary Examiner—Leticia A. Boyda Draper
 (74) Attorney, Agent, or Firm—Larrin L. Wiley, Matthew D. German, Debra D. Conditio

ABSTRACT

Dapsone and dapsonolaldehyde compositions can be used for treating a variety of dermatological conditions. The compositions of this disclosure include dapsone and/or aldehyde in polymers viscosity builder. Subject compositions are used to treat dermatological conditions and improve the efficiency of pharmaceutical products applied to the skin of the polymer, viscosity builder provides composition with improved stability and shelf life. The compositions are used by other relative to compositions without the polymer viscosity builder.

6 Claims, 3 Drawing Sheets

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(2) United States Patent
 Warner et al.

(54) TOPICAL DAPSONE AND DAPSONOLALDEHYDE COMPOSITIONS AND METHODS FOR USE THEREOF

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(72) Inventors: Kevin S. Warner, Ashburn, CA (US);
 Aje P. Parshar, San Diego, CA (US);
 Vijaya Swaminathan, San Francisco, CA (US);
 Kevin Blum, San Francisco, CA (US)

(73) Assignee: Allergan, Inc., Irvine, CA (US)

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(51) Int. Cl. A61K 31/02 (2006.01)
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 A61K 9/00 (2006.01)

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(58) Field of Classification Search CPC: A61K 31/02 (2013.01); A61K 9/00 (2006.01); A61K 31/02 (2013.01)
 See application file for complete search history.

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5. A topical pharmaceutical composition comprising:
 about 7.5% w/w dapsone;
 about 30% w/w diethylene glycol monoethyl ether;
 about 4% w/w of a polymeric viscosity builder consisting of acrylamide/sodium acryloyldimethyl taurate copolymer;
 and water; wherein the composition does not comprise adapalene.

6. The composition of claim 5, further comprising methyl paraben.

Petitioners Have Not Proven Unpatentability



- Not credible that person of ordinary skill in the art as of 2012 would be motivated to formulate a novel dapsonone topical pharmaceutical composition
- Even assuming such motivation, no credible evidence of motivation in Garrett to develop a new topical pharmaceutical formulation of dapsonone
- Even accepting Garrett as a primary reference, no motivation to increase the concentration of dapsonone, let alone to choose a concentration of 7.5%
- Even assuming increase of dapsonone to 7.5%, no motivation to increase solvent to claimed concentrations
- Even assuming all of the above, no motivation to combine Garrett with Nadau-Fourcade or Bonacucina
 - No asserted reference discloses a polymeric viscosity builder consisting of A/SA copolymer in claimed concentration(s)

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