

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ALMIRALL, LLC  
Patent Owner.

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

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**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

**United States Patent**  
Warner et al.

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

7,531,698 B2 \* 5/2009 Villa et al.  
2010/029791 A1 2/2010 Morris  
2010/030031 A1 \* 5/2010 Datta

**FOREIGN PATENT DOCUMENTS**

WO 2006/088147 9/2006  
WO 2009/108147 A1 \* 9/2009  
WO 2010/046207 A1 \* 2/2011  
WO 2011/014627 A1 \* 2/2011  
WO 2011/014627 A1 \* 2/2011

**OTHER PUBLICATIONS**

Lubrizol (Publ.) "Viscosity of CARBOPOL Polymer Systems" [Retrieved Mar. 18, 2014]. Retrieved from <URL: <http://www.lubrizol.com/Life-Science/Doc/Viscosity%20of%20CARBOPOL%20Systems>> [Accessed on 03/18/2014].  
Duchow, Zofia D., et al. "Two Randomized Studies of the Efficacy and Safety of Dapsone Gel, 5% for the Treatment of Acne." *Journal of American Academy of Dermatology* 56(2): 267-274 (2007).  
Notifications of Transmittal of the International Search Report and Written Opinion of the International Searching Authority, International Application No. PCT/US 2011/014627, Nov. 18, 2011. Date of International Filing Date, Nov. 18, 2011. Date of Publication, Dec. 15, 2011.

\* cited by examiner

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

**ABSTRACT**

Dapsone and dapsones/dapsone 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 costy builder.

**6 Claims, 3 Drawing Sheets**

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.



## 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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