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Attorney Docket No.: 064507-5014-US01

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Dated: 5/18/09
Signed: Candida Rubalcaba-Rivera
Candida Rubalcaba-Rivera

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Stephen J. BAKER, *et al.*

Application No.: 11/505,591

Filed: August 16, 2006

For: BORON-CONTAINING SMALL MOLECULES

Customer No.: 43850

Confirmation No.: 5739

Examiner: SHIAO, Rei Tsang

Art Unit: 1626

RESPONSE TO OFFICE ACTION

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

Madam:

In response to the Office Action dated January 27, 2009, please enter the following amendments and remarks.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application.

Listing of Claims:

1 **1.-120.** (Cancelled)

1 **121.** (Previously presented) A pharmaceutical formulation, comprising:

2 (a) 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole, or a salt thereof; and

3 (b) a pharmaceutically acceptable excipient

4 wherein said pharmaceutical formulation is for topical administration to an animal

5 suffering from an infection by a microorganism.

1 **122. – 192.** (Cancelled).

1 **193.** (Previously presented) The formulation of claim **121**, wherein said

2 formulation is a member selected from a lacquer, lotion, cream, gel, ointment and spray.

1 **194.** (Previously presented) The formulation of claim **121**, wherein said

2 formulation is a lacquer.

1 **195.** (Previously presented) The formulation of claim **121**, wherein said

2 formulation further comprises one or more members selected from an emulsifier, emollient,

3 antioxidant, preservative, chelating agent, neutralizing agent, viscosity increasing agent, nail

4 penetration enhancer, anti-inflammatory agent, vitamin, anti-aging agent, sunscreen and acne-

5 treating agent.

1 **196.** (Previously presented) The formulation of claim **121**, wherein said

2 formulation comprises one or more members selected from ethanol and propylene glycol.

1 **197.** (Previously presented) The formulation of claim **121**, comprising: about
2 propylene glycol:ethanol in a ratio of about 1:4, and about 1:10 wt/ volume of said 1,3-dihydro-
3 5-fluoro-1-hydroxy-2,1-benzoxaborole.

1 **198.** (Previously presented) The formulation of claim **121**, comprising: about
2 70% ethanol; about 20% poly(vinyl methyl ether-alt-maleic acid monobutyl ester) and about
3 10% of said 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole.

1 **199.** (Previously presented) The formulation of claim **121**, comprising: about
2 56% ethanol; about 14% water; about 15% poly(2-hydroxyethyl methacrylate); about 5% dibutyl
3 sebacate and about 10% of said 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole.

1 **200.** (Previously presented) The formulation of claim **121**, comprising: about
2 55% ethanol; about 15% ethyl acetate; about 15% poly(vinyl acetate); about 5% dibutyl sebacate
3 and about 10% 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole.

1 **201.** (Previously presented) The formulation of claim **121**, wherein said 1,3-
2 dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole is present in said formulation in a concentration
3 from about 0.5% to about 15% w/v.

1 **202.** (Previously presented) The formulation of claim **121**, wherein said 1,3-
2 dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole, or salt thereof, is present in a form which is a
3 member selected from a hydrate with water, a solvate with an alcohol, an adduct with an amino
4 compound, and an adduct with an acid.

1 **203.** (Previously presented) The formulation of claim **121**, wherein said
2 formulation is in a cosmetically effective amount.

1 **204.** (Previously presented) The formulation of claim **121**, wherein a site of said
2 topical administration is skin or nail or hair or skin surrounding the nail or skin surrounding the
3 hair.

1 **205.** (Previously presented) The formulation of claim **121**, wherein the
2 microorganism is a fungus or a yeast.

1 **206.** (Previously presented) The formulation of claim **205**, wherein said fungus
2 or yeast is a member selected from *Candida* species, *Trichophyton* species, *Microsporium*
3 species, *Aspergillus* species, *Cryptococcus* species, *Blastomyces* species, *Coccidioides* species,
4 *Histoplasma* species, *Paracoccidioides* species, *Phycomycetes* species, *Malassezia* species,
5 *Fusarium* species, *Epidermophyton* species, *Scytalidium* species, *Scopulariopsis* species,
6 *Alternaria* species, *Penicillium* species, *Phialophora* species, *Rhizopus* species, *Scedosporium*
7 species and *Zygomycetes* species.

1 **207.** (Previously presented) The formulation of claim **205**, wherein said fungus
2 or yeast is a member selected from *Aspergillus fumigatus*, *Blastomyces dermatitidis*, *Candida*
3 *albicans*, *Candida glabrata*, *Candida krusei*, *Cryptococcus neoformans*, *Candida parapsilosis*,
4 *Candida tropicalis*, *Coccidioides immitis*, *Epidermophyton floccosum*, *Fusarium solani*,
5 *Histoplasma capsulatum*, *Malassezia furfur*, *Malassezia pachydermatis*, *Malassezia sympodialis*,
6 *Microsporium audouinii*, *Microsporium canis*, *Microsporium gypseum*, *Paracoccidioides*
7 *brasiliensis*, *Trichophyton mentagrophytes*, *Trichophyton rubrum* and *Trichophyton tonsurans*.

1 **208.** (Previously presented) The formulation of claim **205**, wherein said fungus
2 or yeast is a member selected from *Trichophyton concentricum*, *Trichophyton violaceum*,
3 *Trichophyton schoenleinii*, *Trichophyton verrucosum*, *Trichophyton soudanense*, *Microsporium*
4 *gypseum*, *Microsporium equinum*, *Candida guilliermondii*, *Malassezia globosa*, *Malassezia*
5 *obtus*, *Malassezia restricta*, *Malassezia slooffiae* and *Aspergillus flavus*.

1 **209.** (Previously presented) The formulation of claim **205**, wherein said fungus
2 or yeast is a dermatophyte.

1 **210.** (Previously presented) The formulation of claim **205**, wherein said fungus
2 or yeast is a member selected from *Tinea unguium*, *Trichophyton rubrum* and *Trichophyton*
3 *mentagrophytes*.

1 **211.** (Previously presented) The formulation of claim **121**, wherein the infection
2 is a cutaneous infection.

1 **212.** (Previously presented) The formulation of claim **121**, wherein the infection
2 is a member selected from an ungual, periungual and subungual infection.

1 **213.** (Previously presented) The formulation of claim **121**, wherein the infection
2 is onychomycosis.

1 **214.** (Previously presented) The formulation of claim **121**, wherein the animal is
2 a human.

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