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Case S-737-A Appl. No. 10/197,077

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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RAJENDRA K. JOSHI, ET AL.

APPL. NO.: 10/197,077

FILED: JULY 17, 2002

) GROUP ART UNIT: 1614

)EXAMINER: KEVIN E. WEDDINGTON

UTILIZATION OF DIALKYLFUMARATES

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

SUPPLEMENTAL AMENDMENT

Applicants desire to amend the above application by adding additional claims.

Amendments to the claims begin on page 2 hereof.

The Remarks commence on Page 7 hereof.

A Second Supplemental Information Disclosure Statement is also enclosed with the appropriate fee and a copy of the translated document referred to therein. Also enclosed is a paper authorizing the payment of the fee for the additional claims presented hereinafter.

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CERTIFICATE OF MAILING

I hereby certify that in accordance with standard business practice, this paper (along with any referred to as being attached or enclosed) is to be deposited on the date shown below with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

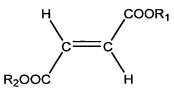
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elionah U.E Deborah A. Brouillette

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In the Claims:

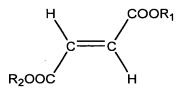
115. (New) A method for treating psoriasis comprising administering to a patient an effective amount of a pharmaceutical preparation which is in the form of microtablets or pellets and consists essentially of at least one dialkyl fumarate of the following formula



wherein R_1 and R_2 , which may be the same or different, independently represent a linear, branched or cyclic, saturated or unsaturated C_{1-20} alkyl radical which may be optionally substituted with halogen (Cl, F, I, Br), C_{1-4} alkoxy, nitro or cyano and optionally conventional excipients.

- 116. (New) A method as in claim 115, wherein said microtablets or pellets are contained in capsules.
- 117. (New) A method as in claim 115, wherein said preparation contains an amount between 10 and 300 mg of dimethyl fumarate.
- 118. (New) A method as in claim 115, wherein said preparation contains an amount of about 120 mg dimethyl fumarate.
- 119. (New) A method as in claim 115, wherein the size or mean diameter of said microtablets or pellets is in the range of 300 to 2000 μm.

- 120. (New) A method as in claim 115, wherein the size or mean diameter of said microtablets or pellets is about 2000 μm.
- 121. (New) A method as in claim 115, wherein said microtablets or pellets are entericcoated and contained in capsules, and wherein said pharmaceutical preparation consists essentially of dimethyl fumarate in an amount between 10 and 300 mg.
- 122. (New) A method as in claim 121, wherein said pharmaceutical preparation consists essentially of dimethyl fumarate in an amount of about 120 mg.
- 123. (New) A method as in claim 121, wherein the size or mean diameter of said microtablets or pellets is in the range of 300 to 2000 μm.
- 124. (New) A method for treating multiple sclerosis comprising administering to a patient an effective amount of a pharmaceutical preparation which consists essentially of at least one dialkyl fumarate of the following formula



wherein R_1 and R_2 , which may be the same or different, independently represent a linear, branched or cyclic, saturated or unsaturated C_{1-20} alkyl radical which may be optionally substituted with halogen (Cl, F, I, Br), C_{1-4} alkoxy, nitro or cyano and optionally conventional excipients.

125. (New) A method as in claim 124, wherein said pharmaceutical preparation is in the form of microtablets or pellets.

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- 126. (New) A method as in claim 125, wherein said microtablets or pellets are contained in capsules.
- 127. (New) A method as in claim 126, wherein said preparation contains an amount between 10 and 300 mg of dimethyl fumarate.
- 128. (New) A method as in claim 126, wherein said preparation contains an amount of about 120 mg dimethyl fumarate.
- 129. (New) A method as in claim 125, wherein the size or mean diameter of said microtablets or pellets is in the range of 300 to 2000 μm.
- 130. (New) A method as in claim 125, wherein the size or mean diameter of said microtablets or pellets is about 2000 μm.
- 131. (New) A method as in claim 125, wherein said microtablets or pellets are entericcoated and are contained in capsules, and wherein said pharmaceutical preparation consists essentially of dimethyl fumarate in an amount between 10 and 300 mg.
- 132. (New) A method as in claim 131, wherein said pharmaceutical preparation consists essentially of dimethyl fumarate in an amount of about 120 mg.
- 133. (New) A method as in claim 131, wherein the size or mean diameter of said microtablets or pellets is in the range of 300 to 2000 μm.
- 134. (New) A pharmaceutical preparation in the form of enteric-coated microtablets or pellets containing dimethyl fumarate in an amount effective for treating psoriasis.
- 135. (New) The preparation of claim 134, wherein the microtablets or pellets are contained in capsules.

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136. (New) The preparation of claim 135, wherein each capsule contains an amount between 10 and 300 mg of dimethyl fumarate.

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- 137. (New) The preparation of claim 135, wherein each capsule contains an amount of about 120 mg dimethyl fumarate.
- 138. (New) The preparation of claim 134, wherein the size or mean diameter of said microtablets or pellets is in the range of 300 to 2000 μm.
- 139. (New) The preparation of claim 134, wherein the size or mean diameter of said microtablets or pellets is about 2000 μm.
- 140. (New) The preparation of claim 134, wherein the microtablets or pellets contain dimethyl fumarate in an amount between 10 and 300 mg.
- 141. (New) The pharmaceutical preparation of claim 140, wherein the microtablets or pellets contain dimethyl fumarate in an amount of about 120 mg.
- 142. (New) The preparation of claim 140 wherein the size or mean diameter of said microtablets or pellets is in the range of 300 to 2000 μm.
- 143. (New) A pharmaceutical preparation consisting essentially of dimethyl fumarate in an amount effective for treating multiple sclerosis.
- 144. (New) The preparation of claim 143, wherein the preparation is in the form of entericcoated microtablets or pellets.
- 145. (New) The preparation of claim 144, wherein said microtablets or pellets are contained in capsules.

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