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Oppenheimer et al.

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(54) **METHODS AND COMPOSITIONS FOR THE TREATMENT OF METABOLIC DISORDERS**

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A61K 31/495 (2006.01)

(52) **U.S. Cl.** **514/249**; 514/250

(58) **Field of Classification Search** 514/183,
514/249, 250

See application file for complete search history.

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(57) **ABSTRACT**

The present invention is directed to a novel methods and compositions for the therapeutic intervention in hyperphenylalaninemia. More specifically, the specification describes methods and compositions for treating various types of phenylketonurias using compositions comprising BH4. Combination therapies of BH4 and other therapeutic regimens are contemplated.

46 Claims, 20 Drawing Sheets

Powder X-ray Diffraction Pattern of (6R)-L-erythro-Tetrahydrobiopterin Dihydrochloride Form B

