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# United States Patent [19]

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Oshlack et al.

[45] Date of Patent: **Apr. 16, 1996**

[54] **CONTROLLED RELEASE OXYCODONE COMPOSITIONS**

5,266,331 11/1993 Oshlack et al. .... 424/468

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### [57] ABSTRACT

[21] Appl. No.: **467,584**

[22] Filed: **Jun. 6, 1995**

A method for substantially reducing the range in daily dosages required to control pain in approximately 90% of patients is disclosed whereby an oral solid controlled release dosage formulation having from about 10 to about 40 mg of oxycodone or a salt thereof is administered to a patient. The formulation provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e. every 12 hour) administration through steady-state conditions. Another embodiment is directed to a method for substantially reducing the range in daily dosages required to control pain in substantially all patients by administering an oral solid controlled release dosage formulation comprising up to about 160 mg of oxycodone or a salt thereof, such that a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions are achieved. Controlled release oxycodone formulations for achieving the above are also disclosed.

### Related U.S. Application Data

[60] Division of Ser. No. 81,302, Jun. 18, 1993, which is a continuation-in-part of Ser. No. 800,549, Nov. 27, 1991, Pat. No. 5,266,331.

[51] Int. Cl.<sup>6</sup> ..... **A61K 9/22; A61K 9/26**

[52] U.S. Cl. .... **424/468; 424/469; 424/470; 424/486; 424/487; 424/488; 424/494; 424/496; 424/497; 424/498; 424/501; 424/502; 424/495**

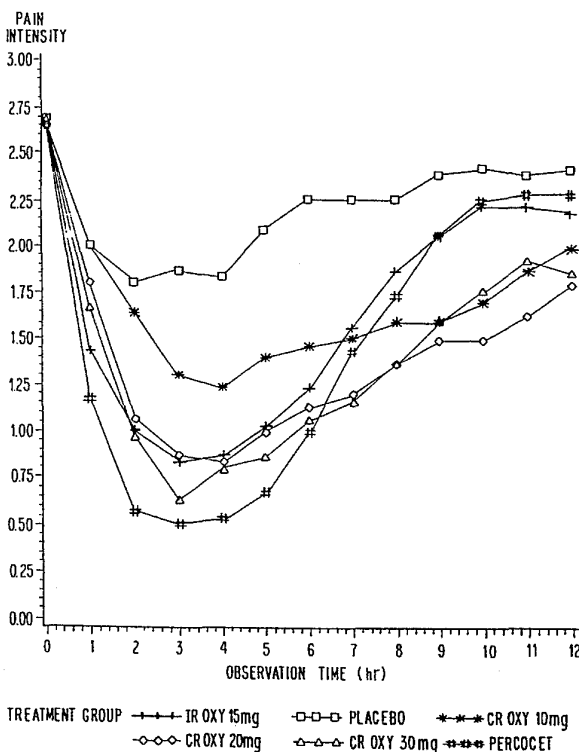
[58] Field of Search ..... **424/486, 464, 424/465, 468-469, 470, 487-488, 49-98, 494**

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**2 Claims, 5 Drawing Sheets**



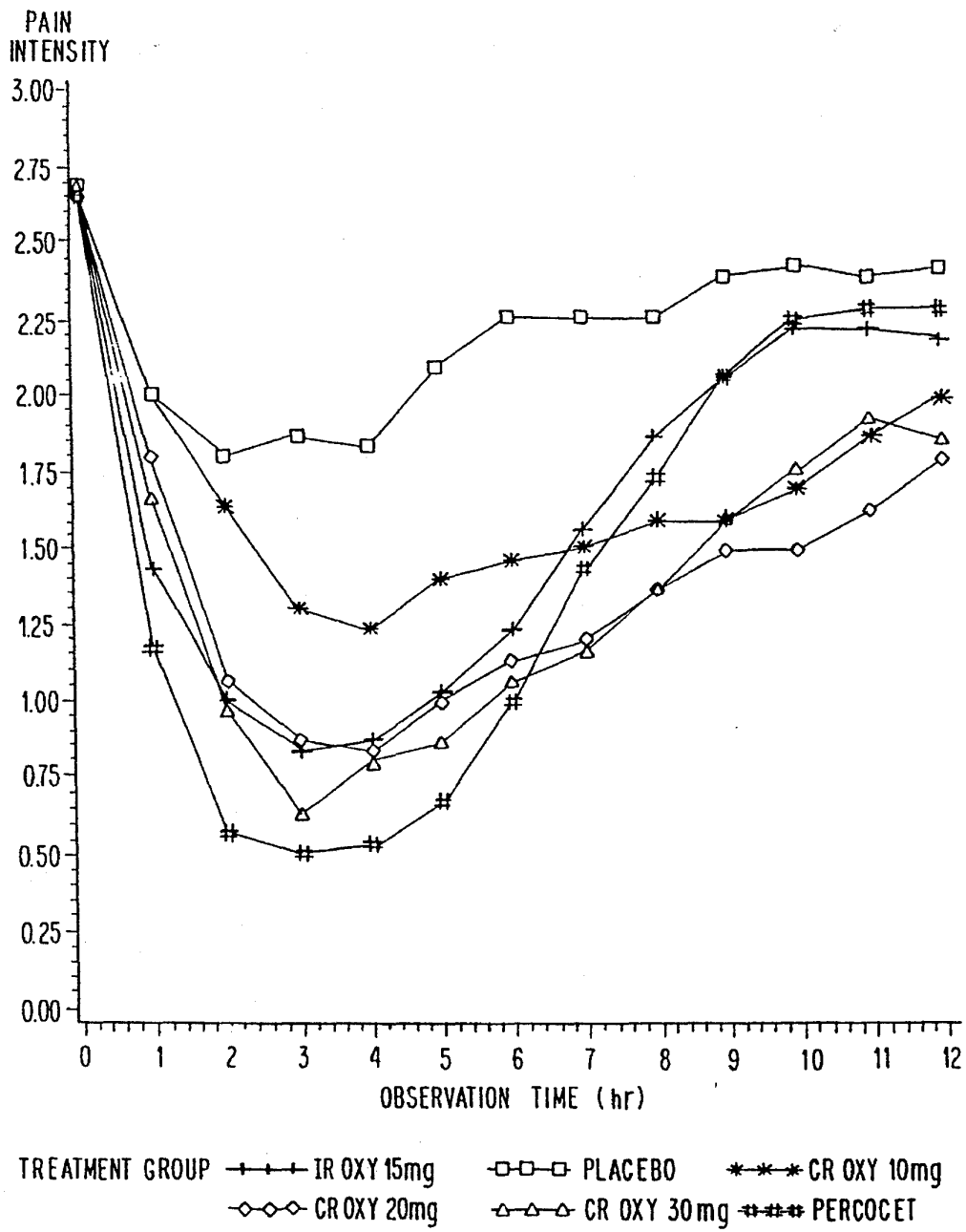


FIG. 1

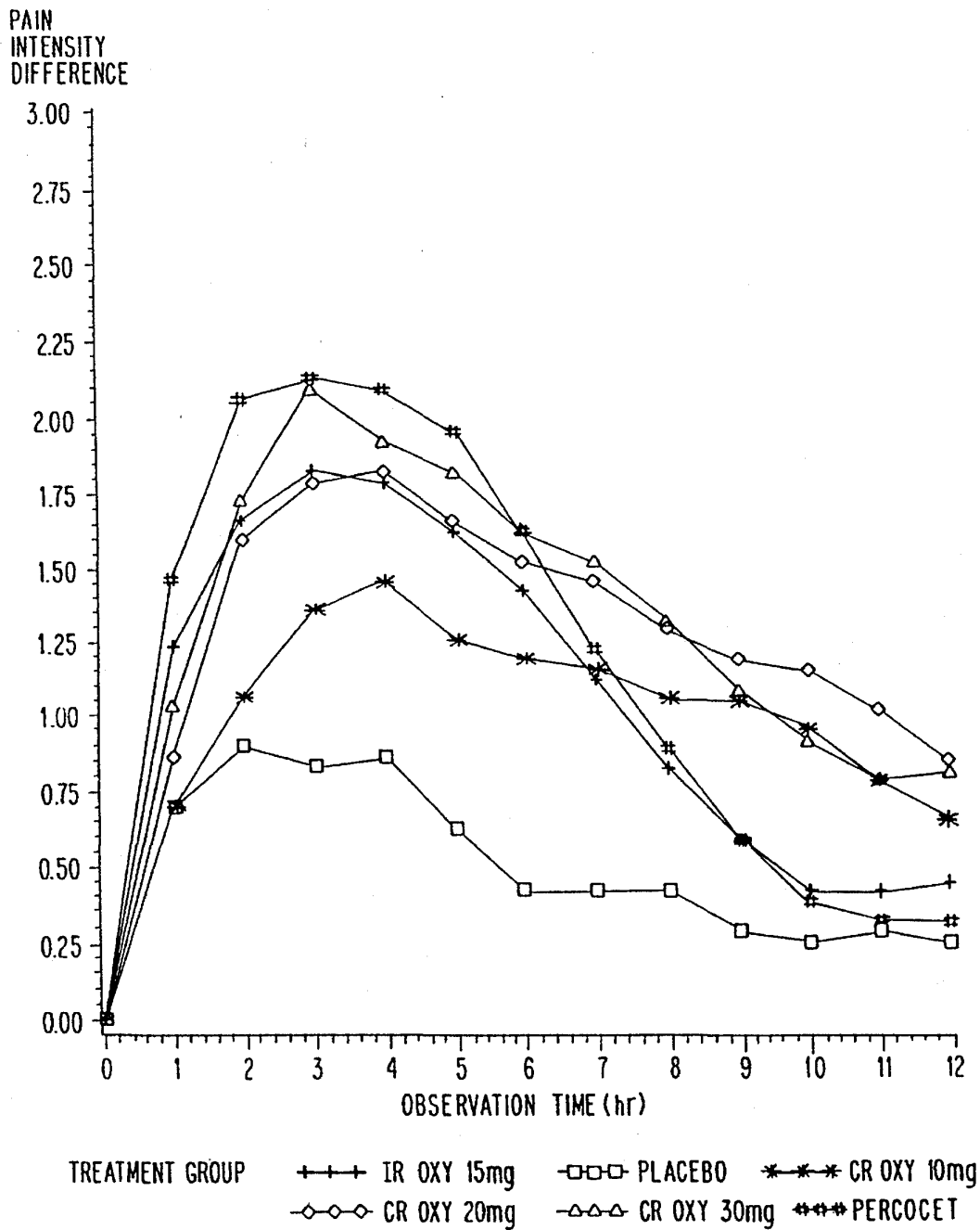


FIG.2

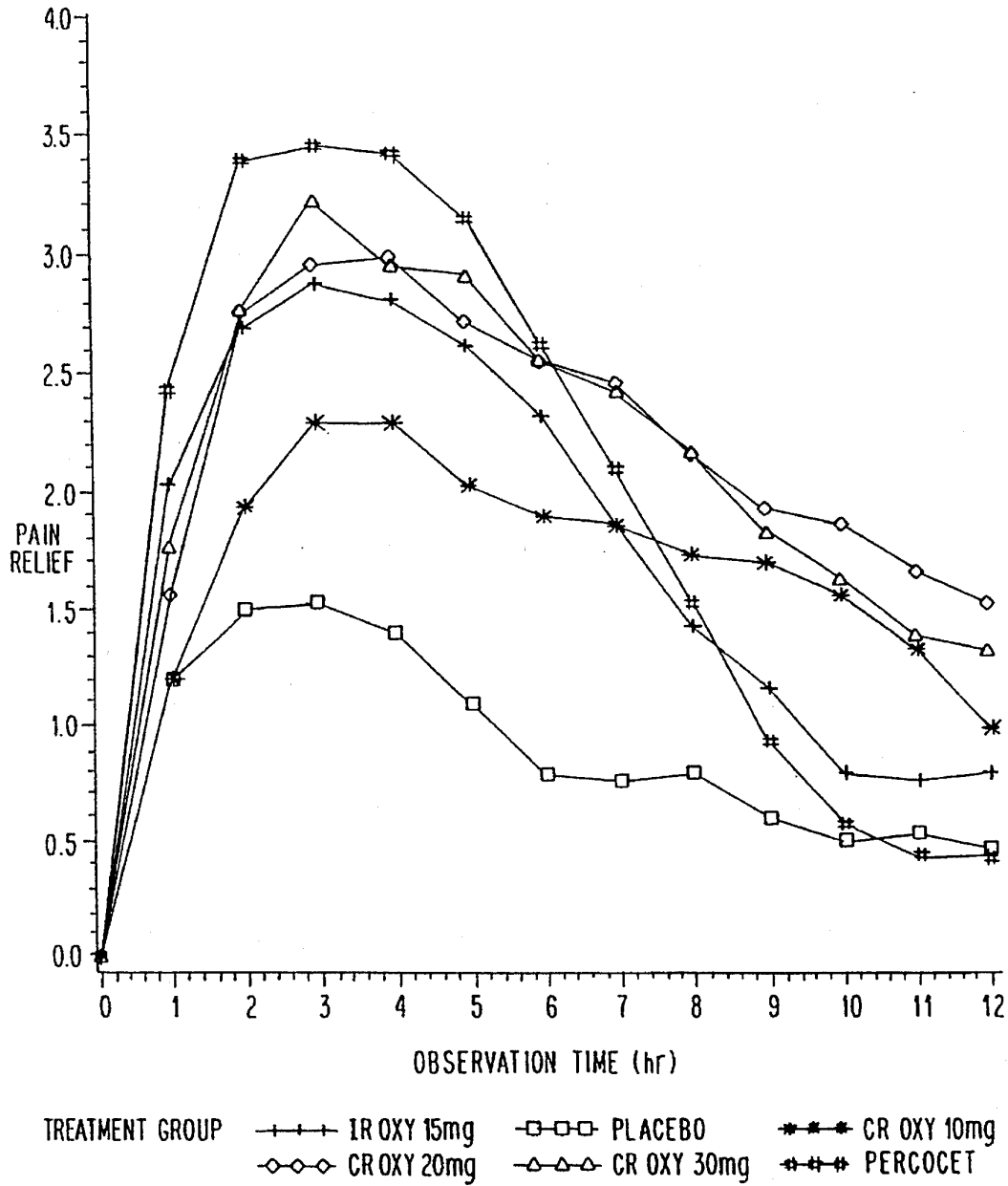


FIG. 3

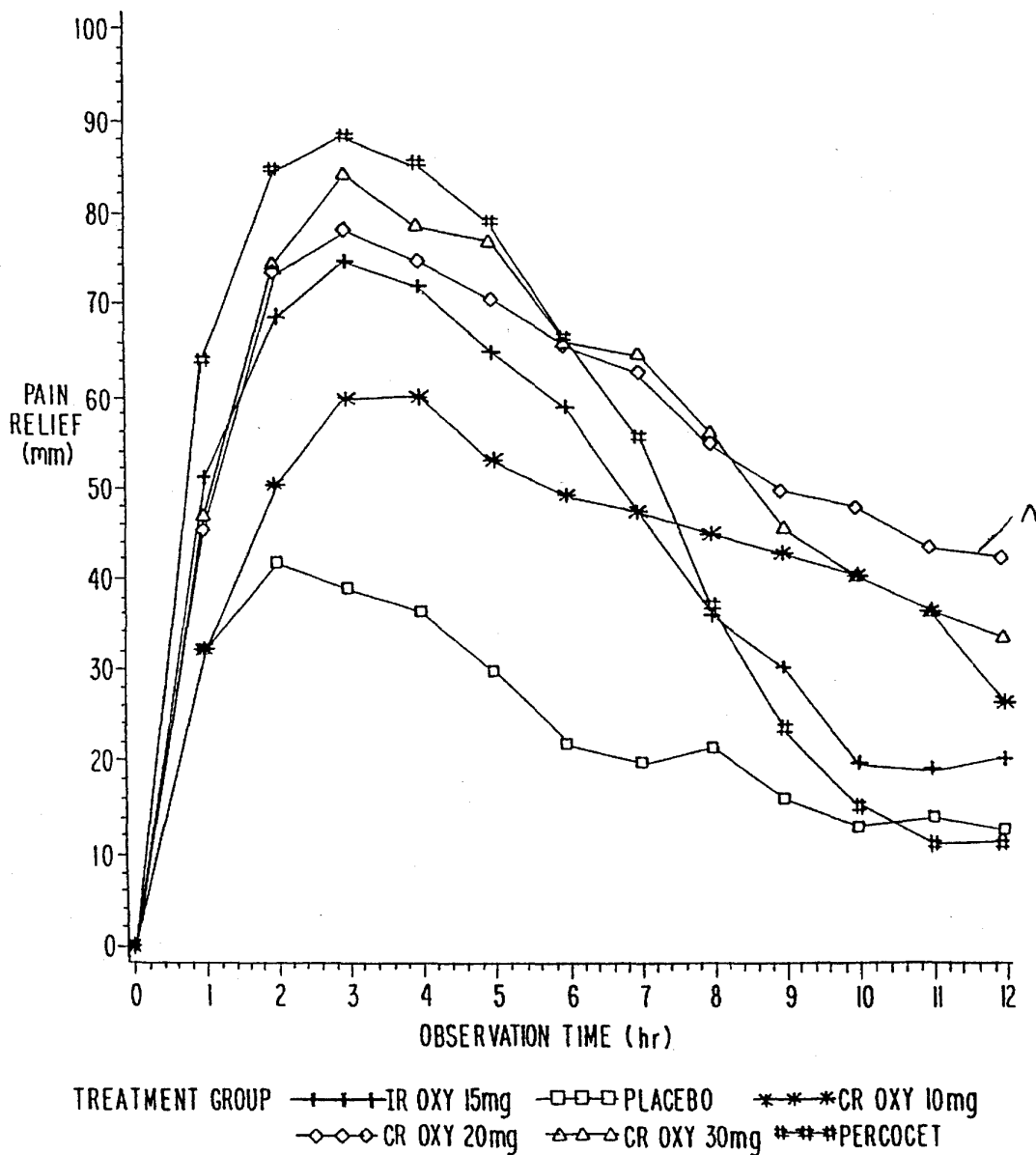


FIG. 4

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