



US005508042A

# United States Patent [19]

[11] Patent Number: **5,508,042**

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

[75] Inventors: Benjamin Oshlack, New York, N.Y.; Mark Chasin, Manalpan, N.J.; John J. Minogue, Mount Vernon, N.Y.; Robert F. Kaiko, Weston, Conn.

Primary Examiner—Edward J. Webman  
Attorney, Agent, or Firm—Steinberg, Raskin & Davidson

[73] Assignee: Euro-Celtigue, S.A., Luxembourg, Luxembourg

### [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

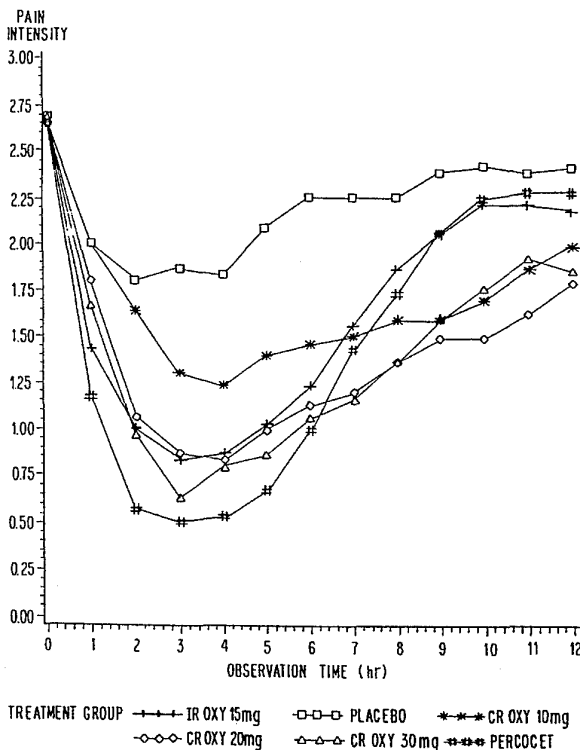
[58] Field of Search ..... 424/486, 464, 424/465, 468-469, 470, 487-488, 49-98, 494

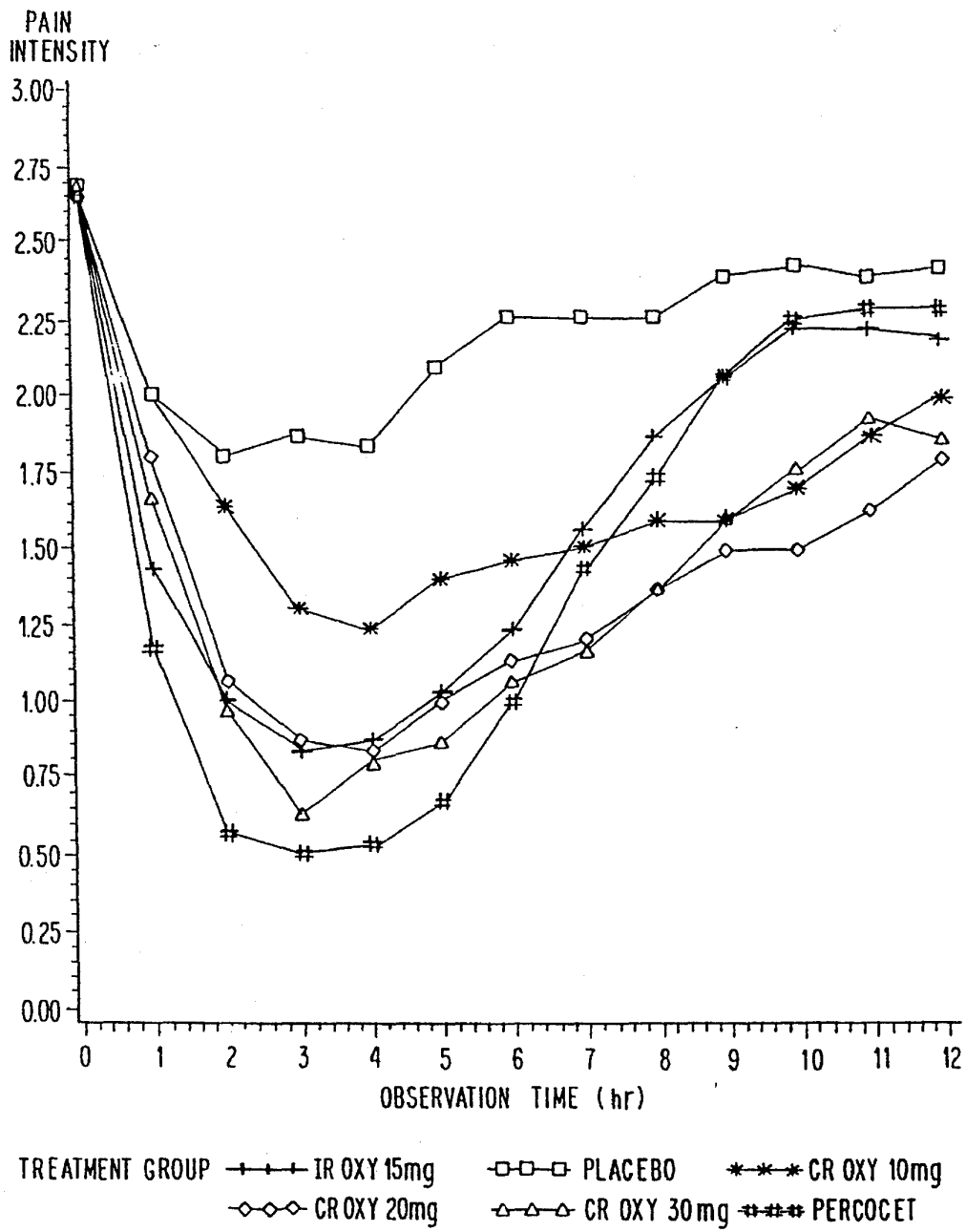
### [56] References Cited

#### U.S. PATENT DOCUMENTS

4,862,598 8/1989 Oshlack ..... 424/470  
4,990,341 2/1991 Goldie et al. .... 424/484

2 Claims, 5 Drawing Sheets





**FIG. 1**

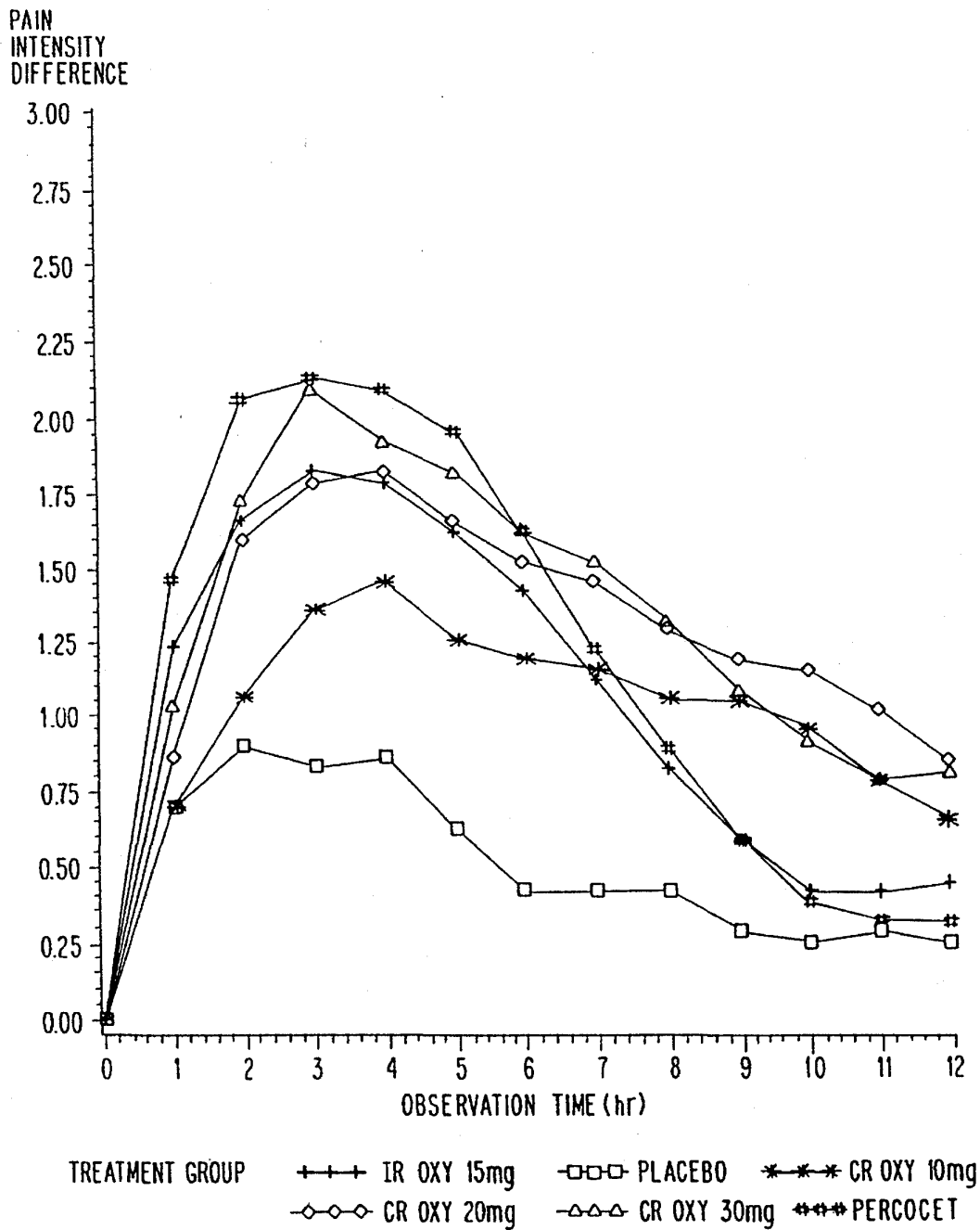


FIG.2

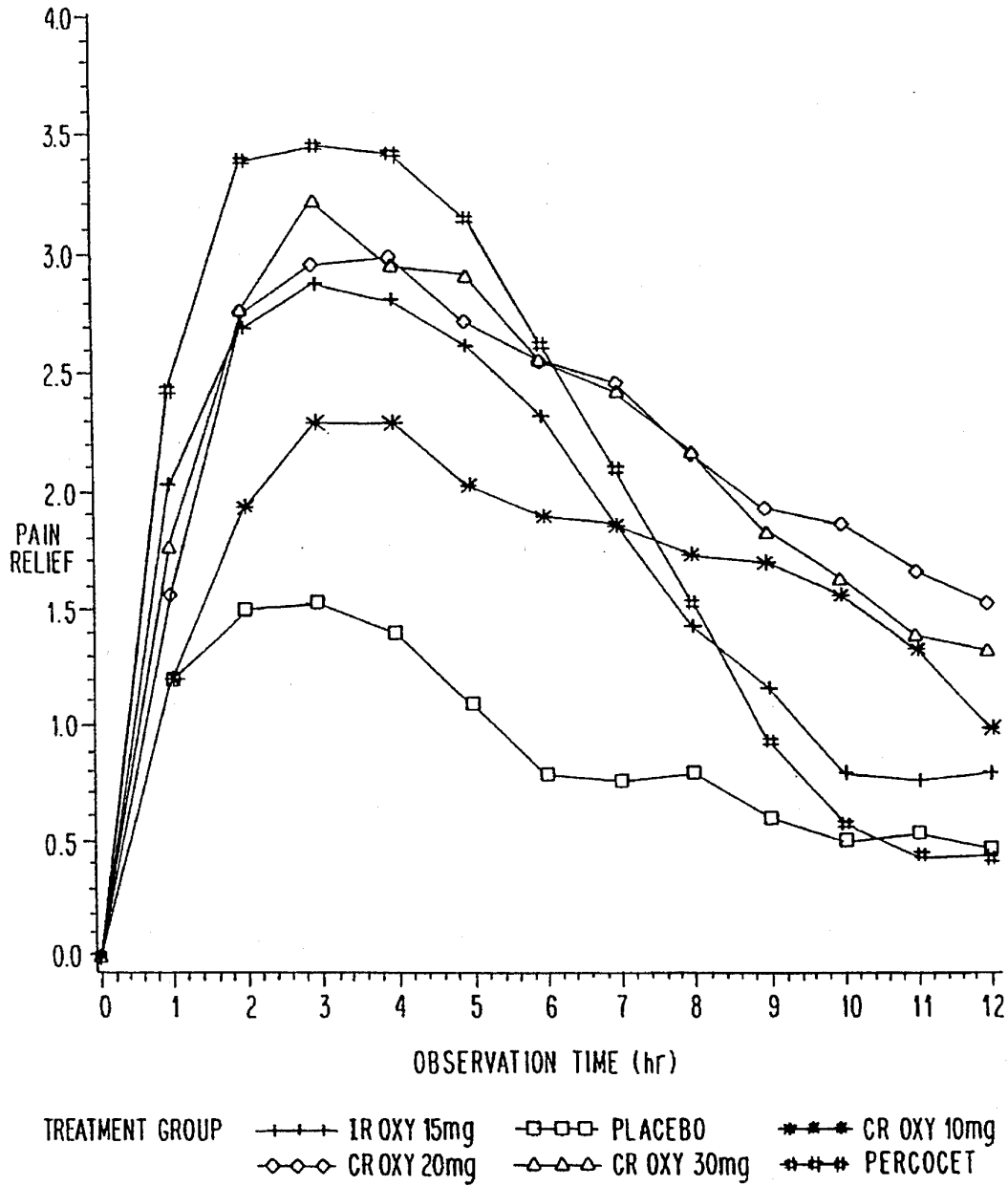


FIG. 3

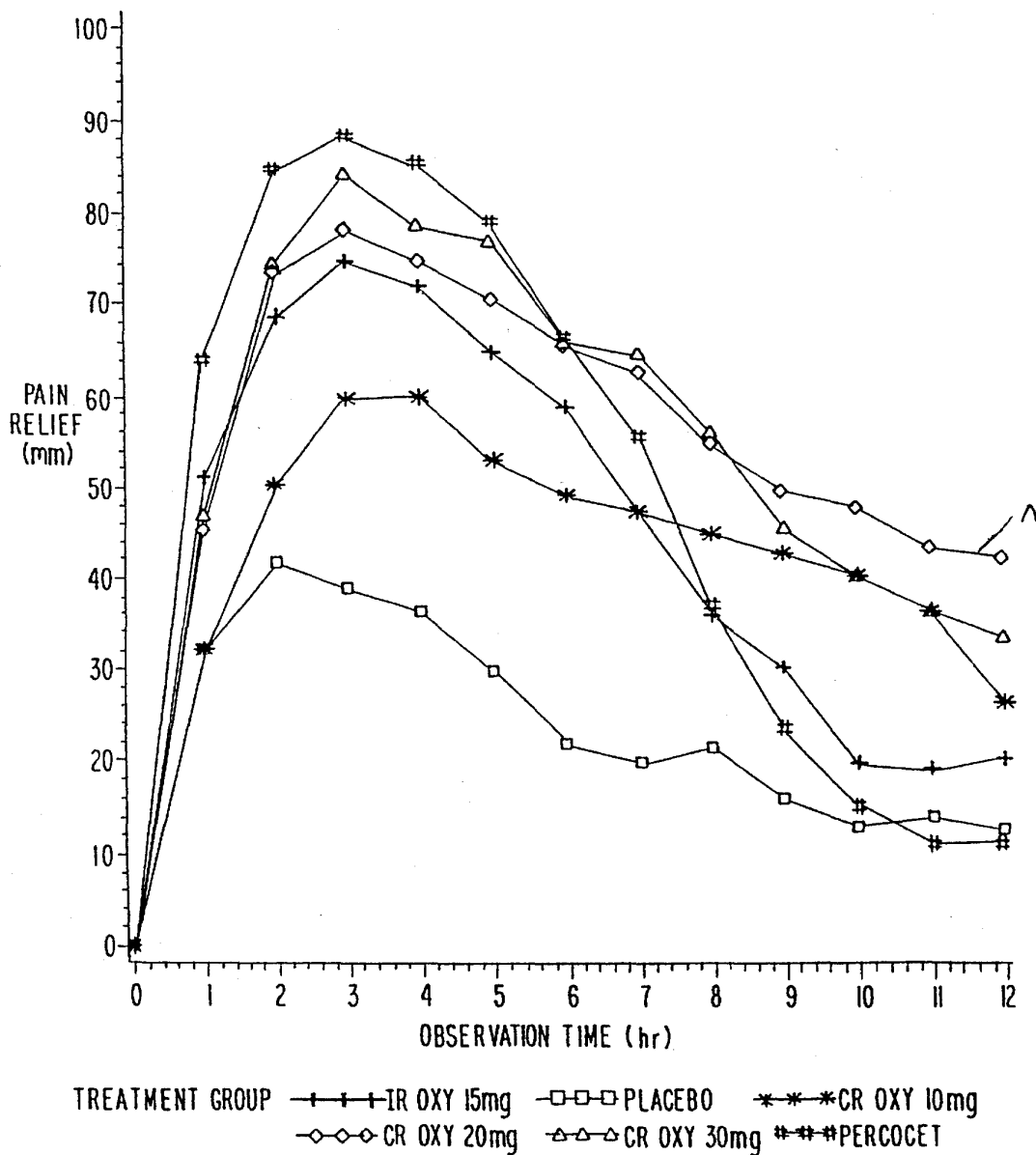


FIG. 4

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.