

**Analysis of the Agreement Containing Consent Order to Aid Public Comment**  
***In the Matter of King Pharmaceuticals, Inc. and Alharma Inc.***  
***File No. 081-0240***

**I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from King Pharmaceuticals, Inc. (“King”) and Alharma Inc. (“Alharma”), which is designed to remedy the anticompetitive effects of King’s acquisition of Alharma. Under the terms of the Consent Agreement, the companies would be required to divest to Actavis all rights to Kadian, Alharma’s branded long-acting morphine sulfate opioid analgesic product. Kadian’s patent runs until April of 2010. The divestiture gives Actavis all rights to Kadian, restoring the competition between Kadian and King’s Avinza that would be lost with the acquisition.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to a merger agreement executed on November 23, 2008, King intends to acquire all the outstanding shares of Alharma for approximately \$1.6 billion. Both parties sell branded pharmaceuticals in the United States. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45. The proposed Consent Agreement remedies the alleged violations by maintaining existing competition between branded Kadian and Avinza, and permitting an authorized generic version of branded Kadian to be launched prior to when the patent expires.

**II. The Competitive Effects of the Proposed Acquisition**

The proposed acquisition would cause significant anticompetitive harm by eliminating actual, direct and substantial competition between King and Alharma in the market for oral long acting opioid analgesics (“oral LAOs”). The merging firms today offer the only two competitively significant branded morphine sulfate oral LAOs, and the evidence shows that they are particularly close competitors within the larger oral LAO market. The loss of head-to-head competition between King’s Avinza and Alharma’s Kadian would result in higher prices for branded ER morphine sulfate.

While King and Alharma oral LAO products compete most directly with each other, they also compete, to a lesser extent, with other oral LAOs. Oral LAOs have become the standard of care for the management of moderate-to-severe chronic pain because of their effectiveness, ease

of titration and favorable risk-to-benefit ratio. Other oral LAOs are based on distinct chemical compounds, but all of these products have the same mechanisms of action, similar indications, similar dosage forms and similar dosage frequency. The most significant of the other oral LAOs is Purdue Pharma L.P.'s OxyContin, which is four times larger than Avinza and Kadian, combined. A fourth product, Endo Pharmaceutical's Opana ER, also competes in the market.

As with most pharmaceutical products, entry into the manufacture and sale of oral LAOs, is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration ("FDA") approval for the manufacture and sale of oral LAOs takes at least two years due to substantial regulatory, technological and intellectual property barriers. As a result, new entry is unlikely to ameliorate the anticompetitive effects of the acquisition.

### **III. The Consent Agreement**

The order would remedy the competitive concerns raised by the proposed acquisition by requiring King to divest Kadian to Actavis no later than ten days after its acquisition of Alpharma is consummated. Headquartered in Iceland, Actavis is one of the world's largest generic pharmaceutical companies. Currently, Actavis manufactures Kadian for Alpharma at its plant located in Elizabeth, New Jersey. With the divestiture, Actavis will continue to sell Kadian in competition with Avinza and other oral LAOs, and be able to introduce an "authorized" generic version of Kadian earlier than would have been otherwise possible, as Kadian's patent expires in April of 2010. An "authorized" generic is a pharmaceutical product that was originally marketed and sold by a brand company but is relabeled and marketed under a generic product name. As the current manufacturer of Kadian for Alpharma, Actavis has the incentive and ability to launch the first generic Kadian product prior to patent expiry.

The assets to be divested include all intellectual property and regulatory approvals, inventory, books and records, marketing materials, and assumed contracts necessary for Actavis to sell Kadian as either a branded or generic product. Because Actavis already manufactures Kadian, no divestiture of fixed assets, interim supply agreement, provision of technical assistance is required, or asset maintenance order are required.<sup>1</sup> The proposed order also contains provisions designed to restrict King's use of confidential business information relating to Kadian.

The FTC's prior orders involving the divestiture of branded pharmaceutical products have required that any buyer of branded products have the requisite brand marketing experience to replace the competition that would have been eliminated through the transactions. However, the Commission has determined that the divestiture of Kadian to the generic drug manufacturer Actavis is an appropriate remedy in this case because (1) with only a little over a year left to Kadian's patent life, further innovation of the Kadian product is unlikely, and (2) the proposed remedy not only prevents the loss of price competition between Avinza and Kadian which was the

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<sup>1</sup>The proposed order requires the respondents to maintain the assets pending divestiture.

competitive concern identified in our investigation, but also makes possible early introduction of a generic product – with lower pricing for consumers – before the patent expires.

In the event that the Commission determines that Actavis is not an acceptable acquirer, the proposed order requires the parties to unwind the sale and then divest Kadian within six months of the date the order becomes final to another Commission-approved acquirer. The proposed order also provides that, in the event that the Commission determines that the manner of the divestiture is not acceptable, that the Commission may appoint a divestiture trustee to effectuate such modifications as are necessary to satisfy the requirements of the order. Additionally, the proposed order allows the Commission to appoint an Interim Monitor to ensure the respondents' compliance with the terms of the order.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.