

IN THE MATTER OF
ZENECA GROUP PLC

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT

Docket C-3880. Complaint, June 7, 1999--Decision, June 7, 1999

This consent order, among other things, requires Zeneca, a corporation engaged in the research and development of long-acting local anesthetics, to transfer and surrender certain assets in accordance with the Chiroscience/Zeneca Agreement, and to divest the Chiroscience shares.

Participants

For the Commission: *Steven K. Bernstein, David Inglefield, Ann Malester, Joseph Eckhaus, Elizabeth Piotrowski, William Baer, J. Elizabeth Callison, and Christopher Garmon.*

For the respondent: *Ronan Harty, Davis, Polk & Wardwell, New York, N.Y.*

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that respondent Zeneca Group PLC ("Zeneca"), a corporation subject to the jurisdiction of the Commission, has proposed to merge with Astra AB ("Astra"), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. DEFINITIONS

1. "*Long-Acting Local Anesthetics*" means pharmaceutical products used to relieve pain during the course of surgical or other medical procedures by blocking pain impulses from reaching the central nervous system. Long-Acting Local Anesthetics have an effective duration of up to six to seven hours, and allow patients to remain awake and conscious throughout the medical procedure.

2. "*Zeneca/Chiroscience License Agreement*" means the "Patent and Know-How Licence relating to Levobupivacaine and Trademark Assignment relating to Chirocaine," dated March 30, 1998, between

Chiroscience Group plc and Darwin Discovery Limited and Zeneca Limited; the "Share Subscription Agreement," dated March 30, 1998, between Chiroscience Group plc and Zeneca Limited; and the "Supply Agreement," dated March 30, 1998, between Chiroscience R&D Limited and Zeneca Limited.

3. "*Chiroscience*" means Chiroscience Group plc, Darwin Discovery Limited and Chiroscience R&D Limited.

II. RESPONDENT

4. Respondent Zeneca is a corporation organized, existing and doing business under and by virtue of the laws of England, with its office and principal place of business located at 15 Stanhope Gate, London W1Y 6LN, England.

5. Respondent Zeneca, through the Zeneca/Chiroscience License Agreement, is engaged in the research and development of Long-Acting Local Anesthetics.

6. Respondent is, and at all times relevant herein has been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and is a corporation whose business is in or affects commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. 44.

III. THE ACQUIRED COMPANY

7. Astra is a corporation organized, existing and doing business under and by virtue of the laws of Sweden, with its office and principal place of business located at S-151 85 Södertälje, Sweden.

8. Astra is engaged in, among other things, the research, development, manufacture and sale of Long-Acting Local Anesthetics.

9. Astra is, and at all times relevant herein has been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. 12, and is a corporation whose business is in or affects commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. 44.

IV. THE MERGER

10. On or about December 9, 1998, Zeneca and Astra entered into a Merger Agreement and Plan of Merger, whereby Zeneca agreed to acquire 100 percent of all issued shares of Astra stock for

approximately \$30.5 billion ("Merger"). Upon completion of the Merger, Zeneca will be renamed AstraZeneca.

V. THE RELEVANT MARKET

11. For purposes of this complaint, the relevant line of commerce in which to analyze the effects of the Merger is the manufacture and sale of Long-Acting Local Anesthetics.

12. For purposes of this complaint, the United States is the relevant geographic area in which to analyze the effects of the Merger in the relevant line of commerce.

VI. STRUCTURE OF THE MARKET

13. The market for the manufacture and sale of Long-Acting Local Anesthetics is highly concentrated as measured by the Herfindahl-Hirschman Index ("HHI"). The pre-merger HHI is 6,682 points. Astra is the leading supplier of Long-Acting Local Anesthetics in the United States and worldwide, and is one of only two companies with Food and Drug Administration ("FDA") approval for the manufacture and sale of Long-Acting Local Anesthetics in the United States. Abbott Laboratories is the only other company with FDA approval for the manufacture and sale of Long-Acting Local Anesthetics in the United States.

14. Zeneca does not currently compete in the relevant market for the manufacture and sale of Long-Acting Local Anesthetics. However, through the Zeneca/Chiroscience License Agreement, Zeneca is engaged in the research and development of a new Long-Acting Local Anesthetic, which it plans to begin marketing and selling in the United States in 1999.

15. Astra is an actual competitor in the relevant market for the manufacture and sale of Long-Acting Local Anesthetics. Zeneca, through the Zeneca/Chiroscience License Agreement, is an actual potential competitor in the relevant market for the manufacture and sale of Long-Acting Local Anesthetics.

VII. BARRIERS TO ENTRY

16. Entry into the relevant market, other than the expected introduction of a new Long-Acting Local Anesthetic product by Zeneca and Chiroscience, would not be timely, likely, or sufficient to deter or counteract the adverse competitive effects described in paragraph 17 because of, among other things, the difficulty of

researching and developing a new product, obtaining FDA approval and gaining customer acceptance.

VIII. EFFECTS OF THE MERGER

17. The effects of the Merger, if consummated, may be substantially to lessen competition and to tend to create a monopoly in the relevant market in violation of 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, in the following ways, among others:

(a) By eliminating actual potential competition between Zeneca and Astra in the relevant market for the manufacture and sale of Long-Acting Local Anesthetics;

(b) By increasing the likelihood that customers of Long-Acting Local Anesthetics would be forced to pay higher prices, or by reducing the likelihood that customers of Long-Acting Local Anesthetics would benefit from price reductions; and

(c) By reducing innovation in the relevant market for the manufacture and sale of Long-Acting Local Anesthetics.

IX. VIOLATIONS CHARGED

18. The Merger agreement described in paragraph 10 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. 45.

19. The Merger described in paragraph 10, if consummated, would constitute a violation of 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.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of the proposed merger of Zeneca Group PLC ("Zeneca") and Astra AB ("Astra"), and Zeneca, hereinafter sometimes referred to as "respondent," having been furnished thereafter with a copy of a draft of complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing consent order, an admission by respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Acts, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed agreement containing consent order and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure described in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Zeneca is a corporation organized, existing, and doing business under and by virtue of the laws of England, with its office and principal place of business located at 15 Stanhope Gate, London W1Y 6LN, England.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I.

It is ordered, That, as used in this order, the following definitions shall apply:

A. "*Zeneca*" means Zeneca Group PLC, its directors, officers, employees, agents, representatives, successors (including but not limited to AstraZeneca) and assigns; its subsidiaries, divisions, groups and affiliates controlled by Zeneca Group PLC (including but not limited to Zeneca Limited) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Following the Merger, Zeneca includes Astra AB, its directors, officers, employees, agents, representatives, successors, and assigns;

its subsidiaries, divisions, groups and affiliates controlled by Astra AB, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "*Astra*" means Astra AB, a corporation organized, existing and doing business under and by virtue of the laws of Sweden, with its office and principal place of business located at S151 85 Södertälje, Sweden.

C. "*Respondent*" means Zeneca.

D. "*Commission*" means the Federal Trade Commission.

E. "*Chiroscience*" means Chiroscience Group plc, a corporation organized, existing and doing business under and by virtue of the laws of England with its office and principal place of business located at 283 Cambridge Science Park, Milton Road, Cambridge CB4 4WE, England; Darwin Discovery Limited, a corporation organized, existing and doing business under and by virtue of the laws of England with its office and principal place of business located at 283 Cambridge Science Park, Milton Road, Cambridge CB4 4WE, England; and Chiroscience R&D Limited, a corporation organized, existing and doing business under and by virtue of the laws of England with its office and principal place of business located at 283 Cambridge Science Park, Milton Road, Cambridge CB4 4WE, England.

F. "*Chirocaine™ License*" means the "Patent and Know-How Licence Relating to Levobupivacaine and Trade Mark Assignment Relating to 'Chirocaine,'" dated March 30, 1998, between Chiroscience Group plc and Darwin Discovery Limited and Zeneca Limited.

G. "*Chiroscience/Zeneca Agreement*" means the "Surrender and Termination of Patent and Know-How Licence Relating to Levobupivacaine and Trade Mark Assignment Relating to 'Chirocaine,'" dated March 12, 1999, between Chiroscience Group plc, Darwin Discovery Limited, Zeneca Group PLC, and Zeneca Limited; the Agreement Amending Share Subscription Agreement; and the "Agreement Terminating Supply Agreement of 30 March 1998," dated March 12, 1999, between Chiroscience R&D Limited and Zeneca Limited.

H. "*Agreement Amending Share Subscription Agreement*" means the "Agreement Amending Share Subscription Agreement of 30 March 1998," dated March 12, 1999 between Chiroscience Group plc and Zeneca Limited.

I. "*Chiroscience/Zeneca Agreement End Date*" means the "End Date" as defined in clause 11.3 of the Chiroscience/Zeneca Agreement.

J. "*FDA*" means the United States Food and Drug Administration.

K. "*Chirocaine*TM" means the chemical compound (S)-1-butyl-(N)-(2,6-dimethylphenyl)-2-piperidinecarboxamide known as levobupivacaine and having CAS registration number 27262-47-1 in all its forms including base and hydrochloride salt.

L. "*Chirocaine*TM Product" means ChirocaineTM and any "Licensed Products" as defined in the Chiroscience/Zeneca Agreement.

M. "*Chirocaine*TM Improvements" means any "Improvement" as defined in the Chiroscience/Zeneca Agreement.

N. "*Chirocaine*TM Information" means all "Chirocaine Know-how" as defined in the Chiroscience/Zeneca Agreement.

O. "*Chirocaine*TM Intellectual Property Rights" means the "Intellectual Property Rights" as defined in the Chiroscience/Zeneca Agreement.

P. "*Chirocaine*TM Assets" means:

1. The ChirocaineTM Product;
2. The ChirocaineTM Improvements;
3. The ChirocaineTM Information;
4. The ChirocaineTM Intellectual Property Rights; and
5. The ChirocaineTM License.

Q. "*Chiroscience Shares*" means all of the stock, share capital, equity or other interest of Chiroscience owned by respondent.

R. "*Merger*" means the acquisition by Zeneca of all or substantially all of the share capital of Astra.

II.

It is further ordered, That:

A. Within ten (10) business days after the date the Commission accepts this agreement containing consent order for public comment, respondent shall transfer and surrender, absolutely and in good faith, all the ChirocaineTM Assets, in accordance with the Chiroscience/Zeneca Agreement.

B. Within four (4) months after the expiration of the Agreement Amending Share Subscription Agreement, respondent shall divest, absolutely and in good faith, the Chiroscience Shares. Pending such divestiture, respondent shall not, directly or indirectly: (i) exercise

dominion or control over, or otherwise seek to influence, the management, direction or supervision of the business of Chiroscience; (ii) seek or obtain representation on the Board of Directors of Chiroscience; (iii) exercise any voting rights attached to the Chiroscience Shares; (iv) seek or obtain access to any confidential or proprietary information of Chiroscience; or (v) take any action or omit to take any action in a manner that would be incompatible with the status of respondent as a passive investor in Chiroscience.

C. Pending the transfer and surrender of the Chirocaine™ Assets, respondent shall take such actions as are necessary to maintain the viability and marketability of the Chirocaine™ Assets, and to prevent the destruction, deterioration, or impairment of any of the Chirocaine™ Assets. Respondent shall also take such actions as are necessary to maintain the viability and marketability of the Chirocaine™ Assets, and to prevent the destruction, deterioration, or impairment of any of the Chirocaine™ Assets, in accordance with the Chiroscience/Zeneca Agreement.

D. Respondent shall comply with all terms of the Chiroscience/Zeneca Agreement, and such agreement is incorporated by reference into this order and made part hereof as Confidential Appendix I. Any failure by respondent to comply with the requirements of such agreement may constitute a failure to comply with this order.

E. The purpose of this order is to ensure the continued use of the Chirocaine™ Assets in the same business in which the Chirocaine™ Assets are engaged at the time of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

III.

It is further ordered, That:

A. At any time after respondent signs the agreement containing consent order in this matter, the Commission may appoint an Interim Trustee to assure that respondent expeditiously performs its responsibilities as required by this order and the Chiroscience/Zeneca Agreement.

B. If an Interim Trustee is appointed pursuant to paragraph III.A. of this order, respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Trustee:

1. The Commission shall select the Interim Trustee, subject to the consent of respondent, which consent shall not be unreasonably withheld. If respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after notice by the staff of the Commission to respondent of the identity of any proposed trustee, respondent shall be deemed to have consented to the selection of the proposed trustee.

2. The Interim Trustee shall have the power and authority to monitor respondent's compliance with the terms of this order and with the terms of the Chiroscience/Zeneca Agreement, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Trustee in a manner consistent with the purposes of this order and in consultation with the Commission.

3. Within ten (10) days after appointment of the Interim Trustee, respondent shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Interim Trustee all the rights and powers necessary to permit the Interim Trustee to monitor respondent's compliance with the terms of this order and with the terms of the Chiroscience/Zeneca Agreement in a manner consistent with the purposes of this order.

4. The Interim Trustee shall serve until the Chiroscience/Zeneca Agreement End Date; provided, however, the Commission may extend this period as may be necessary or appropriate to accomplish the purposes of this order.

5. The Interim Trustee shall have full and complete access to respondent's personnel, books, records, documents, facilities and technical information relating to the research, development, manufacture, importation, distribution and sale of Chirocaine™ and any Chirocaine™ Product, or to any other relevant information, as the Interim Trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of Chirocaine™ or any Chirocaine™ Product and all materials and information relating to FDA and other government or regulatory approvals. Respondent shall cooperate with any reasonable request of the Interim Trustee. Respondent shall take no action to interfere with or impede the Interim Trustee's ability to monitor respondent's compliance with this order and the Chiroscience/Zeneca Agreement.

6. The Interim Trustee shall serve, without bond or other security, at the expense of respondent, on such reasonable and customary terms

and conditions as the Commission may set. The Commission may, among other things, require the Interim Trustee to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with performance of the Interim Trustee's duties. The Interim Trustee shall have authority to employ, at the expense of respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Trustee's duties and responsibilities. The Interim Trustee shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission.

7. Respondent shall indemnify the Interim Trustee and hold the Interim Trustee harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Interim Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparations for, or defense of, any claim whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Trustee.

8. If the Commission determines that the Interim Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Trustee in the same manner as provided in paragraph III.A.1. of this order.

9. The Commission may on its own initiative or at the request of the Interim Trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this order and the Chiroscience/Zeneca Agreement.

10. The Interim Trustee shall obtain and evaluate reports submitted to it by Chiroscience with respect to the performance of respondent's obligations under the Chiroscience/Zeneca Agreement. The Interim Trustee shall report in writing to the Commission every two (2) months from the date the Interim Trustee is appointed concerning compliance by respondent and Chiroscience with the provisions of this order and the Chiroscience/Zeneca Agreement until the Chiroscience/Zeneca Agreement End Date.

IV.

It is further ordered, That within thirty (30) days after the date this order becomes final and every ninety (90) days thereafter until

respondent has fully complied with the provisions of this order, respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this order. Respondent shall include in such compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the order.

V.

It is further ordered, That respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent that may affect compliance obligations arising out of the order, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation.

VI.

It is further ordered, That, for the purpose of determining or securing compliance with this order, upon written request, respondent shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of respondent relating to any matters contained in this order; and

B. Upon five days' notice to any respondent and without restraint or interference from it, to interview officers, directors, employees, agents or independent contractors of respondent, who may have counsel present, regarding such matters.

**[Confidential Appendix I Redacted from
Public Version of Decision & Order]**

IN THE MATTER OF
DESIGN ZONE, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
TEXTILE FIBER PRODUCTS IDENTIFICATION ACT
AND SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3881. Complaint, June 10, 1999--Decision, June 10, 1999

This consent order, among other things, prohibits Design Zone, Inc., a California-based manufacturer and distributor of t-shirts and other textile wearing apparel, from misrepresenting the extent to which any t-shirt or other textile wearing apparel is made in the United States or any other country.

Participants

For the Commission: *Robert E. Easton, Sr., Mary Engle, and Elaine Kolish.*

For the respondent: *Donald Stein, Manatt, Phelps & Phillips, Washington, D.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Design Zone, Inc., a corporation ("respondent"), has violated the provisions of the Textile Fiber Products Identification Act and of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Design Zone, Inc. is a California corporation with its principal office or place of business at 337 South Anderson Street, Los Angeles, California.

2. Respondent has manufactured, assembled, labeled, and offered for sale, sold, and distributed t-shirts and other textile wearing apparel that are sold through retailers to consumers. Such t-shirts and other textile wearing apparel are textile fiber products as the term "textile fiber product" is defined in the Textile Fiber Products Identification Act, 15 U.S.C. 70.

3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent has sold and distributed, or has caused to be sold and distributed, certain t-shirts manufactured in China. In at least one instance, respondent removed the foreign country-of-origin labels