

IN THE MATTER OF

SANDOZ PHARMACEUTICALS CORPORATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3385. Complaint, July 28, 1992--Decision, July 28, 1992*

This consent order prohibits, among other things, a New Jersey-based company from requiring any purchaser of clozapine, a schizophrenia drug, or a patient taking clozapine sold by Sandoz, to buy other goods or services from the respondent or anyone designated by the respondent. In addition, the consent order requires that, if any company needs information about patients who have had adverse reactions to clozapine, the respondent must provide that information on reasonable terms.

Appearances

For the Commission: *Karen E. Berg* and *Jonathan Banks*.

For the respondent: *Daniel R. Shulman* and *Quentin Wittrock*,
Gray, Plant, Mooty, Mooty & Bennett, Minneapolis, MN.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Sandoz Pharmaceuticals Corporation has violated and is violating Section 5 of the Federal Trade Commission Act, and that a proceeding by it in respect thereof would be in the public interest, hereby issues this complaint, stating its charges as follows:

RESPONDENT

PARAGRAPH 1. Sandoz Pharmaceuticals Corporation ("Sandoz") is a Delaware corporation with its mailing address and principal office located at 59 Route 10, East Hanover, New Jersey. Sandoz

derives substantial revenues from the manufacture and sale of pharmaceutical products in the United States.

PAR. 2. Sandoz developed, obtained regulatory approval for, and sells clozapine in the United States.

JURISDICTION

PAR. 3. Sandoz is, and has been at all times relevant to this complaint, a corporation within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. 44.

PAR. 4. The business and activities of Sandoz, and the acts and practices described below, are in or affect commerce as "commerce" is defined in the Federal Trade Commission Act.

RELEVANT PRODUCTS AND SERVICES

PAR. 5. Schizophrenia is a psychiatric disorder that causes a wide variety of symptoms including paranoia, delusions, hallucinations, thinking disturbances, apathy, lack of motivation, and withdrawal. There are approximately 2.5 million patients who suffer from schizophrenia in the United States, about 1 percent of the total population. Patients suffering from schizophrenia occupy a significant percentage of the nation's hospital beds.

PAR. 6. About 200,000 of the schizophrenic patients in the United States are refractory, *i.e.*, they fail to respond adequately to standard antipsychotic drug treatment, either because of insufficient effectiveness or intolerable adverse effects of the drugs.

PAR. 7. Clozapine is the first new drug for the treatment of schizophrenia in more than 20 years. It has been approved by the Food and Drug Administration for use in the treatment of schizophrenia in refractory patients.

PAR. 8. Clozapine is the only antipsychotic drug approved by the Food and Drug Administration for the treatment of refractory schizophrenic patients. For these patients, there is no substitute for clozapine. Approximately 95 percent of these patients are eligible for state or federal financial assistance to purchase clozapine.

PAR. 9. Clozapine causes agranulocytosis, a blood disorder characterized by a decrease in the number of white blood cells, in a

small percentage of patients. If undetected, patients with agranulocytosis may become seriously, and in some cases fatally, ill from infections.

PAR. 10. Under the Food Drug and Cosmetic Act, Sandoz has the exclusive right to market clozapine in the United States until September 26, 1994. Because of this exclusive right, Sandoz is the only source of clozapine in the United States. Sandoz markets clozapine in the United States under the trade name Clozaril.

PAR. 11. The sale of clozapine in the United States is a relevant market. Sandoz has market power in the market for clozapine.

PAR. 12. Pharmacy services are those services involved in the dispensing of prescription drugs and are generally provided by a licensed pharmacist in a licensed pharmacy.

PAR. 13. Distribution and delivery services are those services involved in the delivery of prescription drugs to the patient or patient's custodian.

PAR. 14. Blood drawing or phlebotomy services are those services involved in taking a blood sample from a patient under controlled conditions for subsequent analysis. Blood drawing services are generally provided by a phlebotomist or nurse.

PAR. 15. Patient tracking services are those services involved in the generation, maintenance, and review of health care records in general or in regard to specific events. These services are usually provided by physicians, nurses, pharmacists, and other health care personnel in connection with medical treatment.

PAR. 16. Clinical laboratory services are those services involved in analyzing the composition of blood specimens and reporting the results of such analysis. These services are generally provided by commercial laboratories, hospitals, health maintenance organizations, and physicians' offices.

PAR. 17. Pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services are available, individually or in combination, from many providers in competitive markets. These markets are separate and distinct from the market for clozapine in the United States.

THE CLOZARIL PATIENT MANAGEMENT SYSTEM

PAR. 18. The Clozaril Patient Management System ("CPMS") was Sandoz's program for the sale of clozapine. It consisted of a package that included the sale of clozapine together with pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services. Sandoz required all purchasers of clozapine to purchase its product as part of the CPMS.

PAR. 19. In order to obtain certain services that were part of the CPMS, Sandoz entered into an exclusive fifteen-year contract with Caremark, Inc. Under this contract, Caremark provided various services for Sandoz, including pharmacy, distribution and delivery, blood drawing, and patient tracking for patients receiving clozapine. Under its contract with Sandoz, Caremark was also responsible for billing patients or third-party payers, for collecting payments on behalf of patients participating in the CPMS, and for submitting all payments received to Sandoz. The contract further provided that, for the term of the agreement, Caremark would not sell or distribute any product containing clozapine other than Clozaril, and that for 7 ½ years from the date of the agreement, Caremark would not perform services in connection with any antipsychotic drug that could compete with Clozaril.

PAR. 20. In order to obtain certain additional services that were part of the CPMS, Sandoz entered into an exclusive ten-year contract with Roche Biomedical Laboratories, Inc., ("Roche"). Under this contract, Roche provided various services for Sandoz, including clinical laboratory services for patients receiving clozapine. The contract further provided that during the contract's term Roche would not provide clinical laboratory services for manufacturers or patients utilizing any form of clozapine not sold by Sandoz.

PAR. 21. Sandoz received a direct economic benefit from its requirement that clozapine purchasers also purchase pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services through the CPMS.

PAR. 22. Sandoz set the retail price of CPMS. Sandoz's retail price for CPMS was \$172.00 per week per patient. Sandoz charged each patient the same price without regard to the actual dose of clozapine the patient required.

PAR. 23. Sandoz intended the requirement that clozapine purchasers also purchase pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services through the CPMS to increase its profits and to deter generic pharmaceutical manufacturers from entering the market after Sandoz's period of exclusivity expired.

ANTICOMPETITIVE CONDUCT

PAR. 24. Sandoz exercised its market power in the clozapine market by requiring purchasers of clozapine also to purchase pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services through the CPMS.

PAR. 25. Sandoz's actions described above have foreclosed competition in a substantial volume of commerce in the markets for pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services.

PAR. 26. The purpose, effect, tendency, or capacity of Sandoz's conduct described above, has been to restrain trade unreasonably, and injure purchasers of clozapine in the United States in the following ways, among others:

(a) By forcing purchasers of clozapine to purchase pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services only through the CPMS under terms and conditions set by Sandoz;

(b) By preventing federal, state, and local government agencies and private health care providers from providing their own pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services in connection with the use of clozapine;

(c) By restraining competition on the merits in the provision of pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services to purchasers and users of clozapine; and

(d) By raising the cost of clozapine treatment.

PAR. 27. The acts and practices alleged herein constitute an unfair method of competition in violation of Section 5 of the Federal

Trade Commission Act, as amended, 15 U.S.C. 45. These acts or practices, or the effects thereof, are continuing and will continue or recur in the absence of appropriate relief.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a 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, 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 respondent had violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, and having duly considered the comments filed thereafter by interested persons pursuant to Section 2.34 of its Rules, and having duly considered the recommendations of its staff to modify the consent agreement pursuant to the comments received and the supplemental letter agreement executed by the respondent's counsel, now in further conformity with the procedure prescribed 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 Sandoz Pharmaceuticals Corporation is a corporation organized, existing and doing business under and by virtue of

the laws of the State of Delaware, with its office and principal place of business located at 59 Route 10, in the City of East Hanover, State of New Jersey.

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 for the purposes of this order, the following definitions shall apply:

A. "*Respondent*" means Sandoz Pharmaceuticals Corporation ("Sandoz"), a Delaware corporation, its directors, officers, employees, agents, and representatives, its predecessors, subsidiaries, divisions, groups, and affiliates controlled by Sandoz, its successors and assigns, and their respective directors, officers, employees and representatives, and their respective successors and assigns.

B. "*Clozapine*" is an antipsychotic prescription drug manufactured or sold by Sandoz Pharmaceuticals Corporation under the trade name "Clozaril" for the treatment of schizophrenia.

C. "*Monitoring services*" means pharmacy, distribution and delivery, blood drawing, patient tracking, and clinical laboratory services, or other diagnostic techniques used to detect agranulocytosis, either individually or in any combination of such services.

D. "*Purchasers*" means persons who purchase or attempt to purchase clozapine from Sandoz or from a wholesaler approved by Sandoz, including, but not limited to, third-party payers or providers such as federal, state, and local government agencies, community mental health providers, managed health care providers, pharmacies, and physicians.

II.

It is further ordered, That respondent, in connection with the sale of clozapine in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, shall forthwith cease and desist from, directly or indirectly, or through any corporation or other device:

A. Requiring any purchaser of clozapine or patient taking clozapine sold by Sandoz to purchase or obtain other goods or services from Sandoz or from any person designated by Sandoz.

B. *Provided, however,* that nothing in this order shall prevent Sandoz from requiring clozapine purchasers to provide monitoring services for patients in order to obtain clozapine. Pursuant to this proviso, Sandoz may refuse to allow purchasers to obtain clozapine for failure to agree to provide patient monitoring services, only if:

1. Sandoz determines (a) within thirty (30) days of Sandoz's receipt of the purchaser's request that Sandoz supply clozapine, that the purchaser has not undertaken to provide monitoring services that adequately identify patients who may develop agranulocytosis, or (b) that the purchaser has, after having been supplied with clozapine, failed to provide monitoring services that adequately identify patients who may develop agranulocytosis;

2. Within seven (7) days of making its determination that it will not supply or will stop supplying clozapine, Sandoz notifies the purchaser in writing of its determination, specifically identifies all bases for that determination, provides a description of acceptable methods for providing clozapine to patients, and provides a copy of this order and the accompanying complaint;

3. Sandoz's determination is based solely on standards that are (a) publicly available or available on request from Sandoz, (b) objective, and (c) under medical standards or regulatory requirements current at the time Sandoz makes its determination, reasonably necessary to protect patients against agranulocytosis; and

4. Sandoz notifies the Commission of its implementation of any standards under this proviso, and of any changes to any such standards, on or before the day those standards or changes take effect.

III.

It is further ordered, That:

A. If, in order for a person other than Sandoz to market clozapine in the United States, it is necessary to have access to information about patients who have suffered adverse reactions to clozapine, Sandoz shall provide that information upon request, to the extent it is maintained by Sandoz, on reasonable non-price terms and at a price not to exceed ten (10) dollars and that reflects only the cost of receiving, processing, and responding to each such request as such costs are stated under generally accepted accounting principles for public reporting purposes, and Sandoz shall not realize any profit on such transactions; and

B. For a period of eight (8) years after the date this order becomes final, Sandoz shall not unreasonably withhold information about clozapine patients from scientists and researchers who request such information in order to examine medical aspects of clozapine use, and Sandoz shall not charge for providing such information.

IV.

It is further ordered, That respondent shall:

A. Retain all records and documentation related to the review and approval of purchasers of clozapine for five (5) years from the date of approval;

B. Retain all records and documentation related to the consideration of its disapproval of any clozapine purchaser or discontinuance of sales of clozapine to any purchaser for five (5) years from the date of disapproval or discontinuance;

C. Distribute a copy of this order and the accompanying complaint, by first class mail within thirty (30) days after this order becomes final, to each person that has at any time been a purchaser of clozapine;

D. File a written report with the Commission within sixty (60) days after this order becomes final, and annually for ten (10) years on the anniversary of the date this order becomes final, and at any other

time the Commission, by written notice, may require, setting forth in detail the manner and form in which it has complied and is complying with this order, and including a list of the names, addresses and phone numbers of purchasers that were disapproved or discontinued during the period covered by the report; and

E. For a period of ten (10) years after the date this order becomes final, maintain and make available to Commission staff, for inspection and copying upon reasonable notice, records adequate to describe in detail any action taken in connection with the activities covered by Parts II and III of this order.

V.

It is further ordered, That respondent shall:

A. Require, as a condition precedent to closing the sale or entering into any agreement, contract, or license for the transfer or other disposition of any right, title, or interest in clozapine or New Drug Application (NDA) 19-758, that the acquiring party file with the Commission, prior to closing such sale, or entering into any such agreement, contract, or license, a written agreement to be bound by the provisions of this order; and

B. For a period of ten (10) years after the date this order becomes final, notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the order.

CONCURRING STATEMENT OF COMMISSIONER MARY L. AZCUENAGA

Because the consent order in this matter may remedy a real competitive problem, I have voted to accept it, but I find the revisions to order paragraph III troubling. Paragraph III, part A, is highly regulatory. It specifies not only that access to information about patients who have suffered adverse reactions to clozapine be provided by Sandoz to potential entrants at a price equal to cost, but

also places an absolute limit on what that price may be, regardless of cost. It is rare, if not unprecedented, that a Commission consent involves itself so directly, and rigidly, in pricing policies, and I view any movement in that direction as unnecessary and unwelcome. Paragraph III, part B, provides access to Sandoz's information about clozapine patients to researchers, again at cost, for a period of eight years. The relationship between this requirement and any anticompetitive theory articulated in the complaint is tenuous at best. I would have preferred to leave paragraph III as originally drafted and placed on the public record for comment.

IN THE MATTER OF

PYRAPONIC INDUSTRIES II, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 5
OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3386. Complaint, July 30, 1992--Decision, July 30, 1992*

This consent order prohibits, among other things, a San Diego-based company and its owner from making false or unsubstantiated representations that the Phototron indoor greenhouse, or any air cleaning device, removes or reduces indoor air contaminants.

Appearances

For the Commission: *Linda Badger, Matthew Gold, Jeffrey Klurfeld and Barry Cutler.*

For the respondents: *Richard Circuit, Circuit, McKellogg, Kinney & Ross, La Jolla, CA.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Pyraponic Industries II, Inc., a corporation, and Jeffery Julian DeMarco, individually and as an officer of said corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. (a) Pyraponic Industries II, Inc. is an Illinois corporation. It has its principal office and place of business at 15090 Avenue of Science, P.O. Box 27809, Carmel Mountain Ranch, San Diego, CA.

(b) Jeffery Julian DeMarco is an officer of the corporate respondent. He formulates, directs, and controls the acts and practices of the corporate respondent, including the acts and practices