

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: CLOZAPINE) MDL Docket No. 874
ANTITRUST LITIGATION)
) No. 90 C 6412
)
) Consolidated for Pretrial
) Proceedings with the
) Following Actions That
) Have Been Transferred
) from the Southern
) District of New York:
)
) 90 Civ. 7724, 8055, 8060,
) 8062-8065, 8067, 8069,
) 8071, 8073-8077, 8079-
) 8082, 8084, 8086-8087,
) 8089, 8092; 91 Civ. 0244,
) 0921, 1043, 1165, 1219-1220,
) 1392, 1673, 1813-1814
)
)
) Hon. Harry D. Leinenweber
)

_____)
This Document Relates To)
Document No. 90 CV 7724)

FIRST AMENDED COMPLAINT

NOW COMES plaintiff Richard Newell, on behalf of himself and all others similarly situated, by his attorneys, and for his complaint against defendants alleges:

COUNT I
JURISDICTION

1. Jurisdiction of this Court is based upon its jurisdiction to hear "any civil action or proceeding arising under any Act of Congress regulating commerce or protecting trade and commerce against restraints and monopolies" (Title 28, U.S.C. §1337). This action is brought under Sections 4 and 16 of the Clayton Act (Title 15, U.S.C. §§15 and 26) by plaintiff individually, and as representative of a class of all persons similarly situated,

against defendants to obtain injunctive relief and to recover damages and plaintiff's costs of suit, including reasonable attorneys' fees, by reason of defendants' violation of Sections 1 and 2 of the Sherman Act (Title 15, U.S.C. §§1 and 2).

VENUE

2. Venue as to each of the defendants is laid in this judicial district pursuant to the provisions of Title 15, U.S.C. §22 and Title 28, U.S.C. §§1391(b) and (c), in that defendants reside in this judicial district, or are licensed to do business, or are found or transact business in this judicial district, and/or the claims arose in this district.

PLAINTIFF

3. Plaintiff, Richard Newell, is a resident of Colorado. Plaintiff purchased and is currently purchasing Clozapine and associated blood testing services directly from defendant Sandoz Pharmaceuticals Corporation (hereinafter "Sandoz") and defendant Caremark, Inc. (hereinafter "Caremark") (hereinafter collectively "defendants"), as part of defendants' "Clozaril Patient Management System."

DEFENDANTS

4. Sandoz is a Delaware corporation with its principal place of business in Hanover, New Jersey. Sandoz is in the business of, among other things, manufacturing, marketing and selling ethical drugs. At all times pertinent hereto, Sandoz was registered to do

business in the state of Colorado and conducted and transacted business in the state of Colorado.

5. Caremark is a California corporation which has its principal place of business in the State of Illinois, and transacts business in the state of Colorado. Caremark is in the business of selling home health care services, including inter alia, dispensing of pharmaceutical therapies and administering clinical laboratory testing services.

CLASS ACTION

6. Plaintiff brings this action pursuant to Rule 23 F.R.Civ.P. on his own behalf and as representative of a class consisting of all persons, firms or other entities in the United States who have purchased Clozapine and blood testing monitoring services directly from defendant Sandoz and/or defendant Caremark, or any of their respective subsidiaries or affiliates, under the "Clozaril Patient Management System" at any time up to and including the date of class certification.

7. The members of the class are so numerous that joinder of all class members in this action is impracticable. While the exact number of class members is not known at this time and will require discovery, it is estimated that the class is presently comprised of approximately 5500 to 7000 persons, firms or other entities.

8. The rights of the plaintiff and the other class members involve common questions of law and fact which predominate over any questions affecting only individual members of the class.

9. This class action is superior to other methods for the fair and efficient adjudication of the controversy herein described.

10. The claims of the plaintiff are typical of the claims of the other members of the class and said plaintiff will fairly and adequately protect the interests of the members of the class.

**DEFENDANTS' MONOPOLY AND
MARKET POWER IN CLOZAPINE**

11. Clozapine is an antipsychotic drug used in the treatment of chronic schizophrenics who are refractory to treatment with standard antipsychotic drugs either because such standard drug treatment is ineffective or because of an inability to achieve an effective dose level due to intolerable adverse side effects. Clozapine was most recently approved by the Food and Drug Administration for commercial sale in October, 1989.

12. A potential side effect of Clozapine which affects approximately 1-2% of the patients treated with it is bone marrow failure causing agranulocytosis, a severe and sudden drop in the patient's white blood cell count. Agranulocytosis lowers a patient's immunities and ability to fight off infection and, if not detected early, can be fatal. Because of this potentially life threatening side effect, Clozapine is a last resort treatment, indicated solely for chronic schizophrenics who, based on prior experience, cannot be effectively treated with other standard antipsychotic drugs.

13. Clozapine is the first major innovation in the treatment of schizophrenia since the introduction of phenothiazines almost forty years ago. From a therapeutic point of view, Clozapine is superior to standard therapies and uniquely effective in schizophrenic populations well-proven to be treatment-resistant. Clozapine provides treatment of otherwise untreatable patients. There are no adequate substitutes for Clozapine. If Clozapine treatment is stopped or interrupted, prior therapeutic effects of the drug dissipate and cease.

14. Sandoz holds United States patents on Clozapine. Sandoz, acting in conjunction with Caremark, is the exclusive United States distributor and seller of Clozapine, which is sold under the trade name "Clozaril". There is no source in the United States from which Clozapine can be purchased other than Sandoz and Caremark.

15. Sandoz and Caremark have market power and monopoly power over Clozapine in the United States by reason of (a) Sandoz's patents on Clozapine and its exclusive relationship with Caremark; (b) the absence of adequate substitutes for Clozapine; (c) the last-resort circumstances under which Clozapine treatment is indicated; (d) the uniqueness of the drug; and (e) the fact that Sandoz, in conjunction with Caremark, is the sole source of Clozapine in the United States.

16. Due to the risk of contracting agranulocytosis, the Food and Drug Administration has restricted sales of Clozapine to patients who also submit to blood testing to determine their white

blood cell count prior to the dispensing of the drug. The Food and Drug Administration has not required use of, or endorsed any particular or specific firm or system to perform blood testing associated with the dispensing of Clozapine. In fact, the Food and Drug Administration has publicly stated that it does not require or endorse any particular firm or system for such associated blood testing.

17. The blood testing which the Food and Drug Administration requires in conjunction with the dispensing of Clozapine is a routine "white count" blood test which can be competently and accurately performed by virtually any medical/clinical laboratory. Clozapine and white count blood testing services are separate and distinct products and/or services.

OFFENSE CHARGED

18. Beginning at least as early as 1989, the exact date being unknown to plaintiff, and continuing through the present, Sandoz and Caremark entered into and have participated in a continuing contract, combination and conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, Title 15 U.S.C. §1. The substantial terms of defendants' continuing contract, combination and conspiracy were and are as follows:

- a. Sandoz and Caremark agreed that they would jointly exploit Sandoz's market and monopoly power over Clozapine by requiring all Clozapine purchasers in the United States to purchase associated blood testing services solely from Sandoz and/or Caremark at a supra-competitive price;

- b. Sandoz and Caremark agreed that Caremark would be the exclusive distributor and administrator of Clozapine in the United States through its nationwide network of outlets, that Caremark would administer associated blood tests to Clozapine patients in the United States, and, upon information and belief, that Sandoz and Caremark would share in the profits obtained from blood testing services rendered to Clozapine patients. Further, upon information and belief, Sandoz has an economic interest in the price charged by Caremark for associated blood tests to Clozapine patients in the United States through the "Clozaril Patient Management System";
- c. Sandoz and Caremark further agreed that they would offer to sell and sell Clozapine and associated blood testing services in the United States only as a package for a single, inflated supra-competitive price and that they would sell Clozapine only to those who also purchased associated blood testing services from them;
- d. Caremark and Sandoz further agreed upon the supra-competitive price to be charged purchasers of Clozapine in the United States for associated blood testing services rendered by Caremark and/or Sandoz.

19. Defendants, through establishment and operation of their "Clozaril Patient Management System," jointly did those things which they agreed, contracted, combined and conspired to do, as described hereinabove. Plaintiff and the other members of the class have been and are participants in defendants' "Clozaril Patient Management System" and, as a condition of purchasing Clozapine, have been required to purchase associated blood testing services from defendants.

20. Various other individuals and entities, including affiliates of defendants, not named as defendants in this

Complaint, have participated as co-conspirators in the violations alleged herein and have performed acts and made statements in furtherance thereof.

21. As a proximate result of the contract, combination, conspiracy and unlawful conduct described hereinabove:

- a. Plaintiff and the other members of the class throughout the United States have been deprived of free and open competition in the sale of associated blood testing services;
- b. The price paid by plaintiff and the other members of the class in the United States for associated blood testing services has been fixed, maintained and stabilized at a supra-competitive level;
- c. Competition in the sale of blood testing services has been unreasonably and appreciably restrained in that potential competitors of Sandoz and/or Caremark in the sale of associated blood testing services in the United States have been prevented from competing with Sandoz and Caremark for such sales;
- d. The purchase price charged by Sandoz and/or Caremark for Clozapine and associated blood testing services in the United States (which currently approximates \$9,000 per year, per patient) has exceeded the total amount which plaintiff and the other members of the class would otherwise pay for Clozapine and associated blood testing services;
- e. Defendants have the power to control and inflate the price charged Clozapine purchasers for associated blood testing services at supra-competitive levels;
- f. A substantial amount/volume of commerce in blood testing services has been affected, restrained and foreclosed.

TRADE AND COMMERCE

22. During the time period covered by this complaint:

- a. Sandoz and/or Caremark have sold and shipped substantial quantities of Clozapine in a continuous and uninterrupted flow of interstate commerce to purchasers of Clozapine and Caremark outlets throughout the United States;
- b. Plaintiff and the other members of the class, numbering approximately 5,500 to 7,000 persons, have purchased and/or are presently purchasing Clozapine and the associated blood testing services from Sandoz and/or Caremark under their "Clozaril Patient Management System" at a weekly cost of approximately \$172, or an annual cost of almost \$9,000 per person. The dollar amount of Clozapine and associated blood testing services purchased by plaintiff and the other members of the class from defendants in the United States presently exceeds \$49 million per year;
- c. On information and belief, plaintiff alleges that substantial quantities of the raw materials used by Sandoz in manufacturing Clozapine have been and are presently being shipped in a continuous and uninterrupted flow of interstate commerce into the state or states where Clozapine is manufactured;
- d. Substantial quantities of the equipment and supplies used by Sandoz and/or Caremark for collecting and analyzing the blood samples collected in connection with the "Clozaril Patient Management System" have been shipped in interstate commerce;
- e. As part of their "Clozaril Patient Management System", Sandoz and/or Caremark have shipped, and presently are shipping blood test samples from thousands of purchasers of Clozapine nationwide in interstate commerce across state lines to Roche Biomedical Labs at various locations around the United States for analysis.

23. Sandoz's and Caremark's "Clozaril Patient Management System" imposes substantial restraints on interstate commerce by (a) preventing plaintiff and the other members of the class from

obtaining associated blood testing services, whether in Colorado or by crossing state lines into a neighboring state, from any source other than Sandoz and/or Caremark and requiring plaintiff and the other members of the class to pay supra-competitive prices for the associated blood testing services; and (b) preventing clinical laboratories in Colorado and elsewhere in the United States from competing in the sale of blood testing services to purchasers of Clozapine in Colorado and elsewhere in the United States.

**Injury to Plaintiff and the
Other Members of the Class**

24. By reason of defendants' continuing contract, combination, conspiracy and unlawful conduct alleged hereinabove, plaintiff and the other members of the class have been and will continue to be injured in their business and/or property and have suffered and will continue to suffer damages in an amount presently undetermined by:

- a. Paying more for associated blood testing services than they would have paid in the absence of defendants' unlawful conduct; and
- b. Paying more for the Clozapine/blood testing package sold by defendants than they would otherwise pay in the aggregate for Clozapine and associated blood testing services in the absence of defendants' unlawful conduct.

25. The specific amount of damages suffered by plaintiff and the other members of the class has not yet been determined because such determination will require discovery. When this amount has

been determined, plaintiff will seek leave of court to amend this First Amended Complaint to include such amount.

COUNT II

As paragraphs 1 through 20 and 22 through 23 of his Count II, plaintiff realleges paragraphs 1 through 22 as if fully set forth herein.

23. Beginning at least as early as 1989, the exact date being unknown to plaintiff, and continuing through the present, Sandoz and Caremark, acting pursuant to the contract, combination and conspiracy alleged hereinabove, have intentionally and unlawfully exploited and extended and continue to unlawfully exploit and extend the monopoly power Sandoz enjoys in the market for Clozapine in the United States into the market for white blood cell testing services in the United States, with the intent and purpose of obtaining an unlawful competitive advantage in that market, and thereby have foreclosed and eliminated a substantial amount of competition in the market for white blood cell testing services in the United States, in violation of Section 2 of the Sherman Act, Title 15 U.S.C. §2.

24. Defendants engaged in the foregoing conspiracy to monopolize with the purpose and intent of foreclosing and eliminating competition in the sale of blood testing services to plaintiff and class members and their conduct has had its intended effect.

25. As a proximate result of defendants' unlawful conduct

described hereinabove:

- a. plaintiff and the other members of the class throughout the United States have been deprived of free and open competition in the sale of associated blood testing services;
- b. the price paid by plaintiff and the other members of the class in the United States for associated blood testing services has been fixed, maintained and stabilized at a supra-competitive level;
- c. competition in the sale of blood testing services has been unreasonably and appreciably restrained in that potential competitors of Sandoz and/or Caremark in the sale of associated blood testing services in the United States have been prevented from competing with Sandoz and Caremark for such sales;
- d. the purchase price charged by Sandoz and/or Caremark for Clozapine and associated blood testing services in the United States (which currently approximates \$9,000 per year, per patient) has exceeded the total amount which plaintiff and the other members of the class would otherwise pay for Clozapine and associated blood testing services;
- e. defendants have the power to control and inflate the price charged Clozapine purchasers for associated blood testing services at supra-competitive levels;
- f. a substantial amount/volume of commerce in blood testing services has been affected, restrained and foreclosed.

26. By reason of defendants' continuing contract, combination, and unlawful conspiracy to monopolize alleged hereinabove, plaintiff and the other members of the class have been and will continue to be injured in their business and/or property and have suffered and will continue to suffer damages in an amount presently undetermined by:

- a. Paying more for associated blood testing services than they would have paid in the absence of defendants' unlawful conduct; and
- b. Paying more for the Clozapine/blood testing package sold by defendants than they would otherwise pay in the aggregate for Clozapine and associated blood testing services in the absence of defendants' unlawful conduct.

27. The specific amount of damages suffered by plaintiff and the other members of the class has not yet been determined because such determination will require discovery. When this amount has been determined, plaintiff will seek leave of court to amend this First Amended Complaint to include such amount.

COUNT III

As paragraphs 1 through 17 of his Count III, plaintiff realleges paragraphs 1 through 4, 6 through 14, 16-17 and 22 through 23 of Count I as if fully set forth herein.

18. Sandoz has monopoly power over Clozapine in the United States by reason of (a) its patents on Clozapine and its exclusive relationship with Caremark; (b) the absence of adequate substitutes for Clozapine; (c) the last-resort circumstances under which Clozapine treatment is indicated; (d) the uniqueness of the drug; and (e) the fact that Sandoz, through its agreements and exclusive distribution arrangements with defendant Caremark, is the sole source of Clozapine in the United States.

19. Beginning at least as early as 1989, the exact date being unknown to plaintiff, and continuing through the present, Sandoz, acting individually has unlawfully monopolized, exploited and

extended and continues to unlawfully monopolize, exploit and extend the monopoly power it enjoys in the market for Clozapine in the United States into the market for white blood testing services in the United States with the intent of obtaining an unlawful competitive advantage in that market, and thereby has foreclosed a substantial amount of competition in the market for white blood testing services in the United States, in violation of Section 2 of the Sherman Act, Title 15 U.S.C. §2.

20. As a proximate result of defendant Sandoz' unlawful conduct described hereinabove:

- a. Plaintiff and the other members of the class throughout the United States have been deprived of free and open competition in the sale of associated blood testing services;
- b. The price paid by plaintiff and the other members of the class in the United States for associated blood testing services has been fixed, maintained and stabilized at a supra-competitive level;
- c. Competition in the sale of blood testing services has been unreasonably and appreciably restrained in that potential competitors of Sandoz and/or Caremark in the sale of associated blood testing services in the United States have been prevented from competing with Sandoz and Caremark for such sales;
- d. The purchase price charged by Sandoz and/or Caremark for Clozapine and associated blood testing services in the United States (which currently approximates \$9,000 per year, per patient) has exceeded the total amount which plaintiff and the other members of the class would otherwise pay for Clozapine and associated blood testing services;
- e. Sandoz has the power to control and inflate the price charged Clozapine purchasers for associated blood testing services at supra-

competitive levels;

- f. A substantial amount/volume of commerce in blood testing services has been affected, restrained and foreclosed.

21. By reason of Sandoz's unlawful conduct alleged hereinabove, plaintiff and the other members of the class have been and continue to be injured in their business and/or property and have suffered and will continue to suffer damages in an amount presently undetermined by:

- a. paying more for associated blood testing services than they would have paid in the absence of Sandoz' unlawful conduct; and
- b. paying more for the Clozapine/blood testing package sold by defendants than they would otherwise pay in the aggregate for Clozapine and associated blood testing services in the absence of defendants' unlawful conduct.

22. The specific amount of damages suffered by plaintiff and the other members of the class has not yet been determined because such determination will require discovery. When this amount has been determined, plaintiff will seek leave of court to amend this First Amended Complaint to include such amount.

COUNT IV

Plaintiff realleges paragraphs 1 through 17, 20, 22 through 23 of his Count I as paragraphs 1 through 20 of the Count IV as if fully set forth herein.

21. Beginning at least as early as 1989, the exact date being unknown to plaintiff, and continuing through the present, Sandoz and Caremark entered into and have participated in a continuing

contract, combination and conspiracy in unreasonable restraint of interstate trade and commerce in the United States, in violation of Section 1 of the Sherman Act, Title 15 U.S.C. §1.

22. The substantial terms of the aforesaid combination, agreement, understanding and concert of action between the defendants were to fix the price plaintiff and the other members of the class must pay for Clozapine therapy, (including Clozapine and associated blood testing services) in order to participate in the "Clozaril Patient Management System."

23. Defendants, through establishment and operation of their "Clozaril Patient Management System," jointly fixed the price at which Clozapine therapy sold by the "Clozaril Patient Management System" has been and is currently sold to plaintiff and the other members of the class at a supra-competitive level, as defendants agreed, contracted, combined and conspired to do.

24. As a proximate result of the contract, combination, conspiracy and unlawful conduct described hereinabove:

- a. Plaintiff and the other members of the class throughout the United States have been deprived of free and open competition in connection with the administration of Clozapine therapy by virtue of the "Clozaril Patient Management System";
- b. The price paid by plaintiff and the other members of the class in the United States for Clozapine and associated blood testing services through the "Clozaril Patient Management System" has been fixed, maintained and stabilized at a supra-competitive level;
- c. The purchase price charged by Sandoz and/or Caremark for participation in the "Clozaril Patient Management System" in the United States

(which currently approximates \$9,000 per year, per patient) has exceeded the total amount which plaintiff and the other members of the class would otherwise pay for the administration of Clozapine therapy;

- d. Defendants have the power to control and inflate the price charged participants in the "Clozapine Patient Management System" at supra-competitive levels;
- e. A substantial amount/volume of commerce in connection with the administration of Clozapine therapy has been affected, restrained and foreclosed.

25. By reason of defendants' continuing contract, combination, conspiracy and unlawful conduct alleged hereinabove, plaintiff and the other members of the class have been and will continue to be injured in their business and/or property and have suffered and will continue to suffer damages in an amount presently undetermined by:

- a. Paying more for Clozapine therapy than they would have paid in the absence of defendants' unlawful conduct; and
- b. Paying more for the "Clozaril Patient Management System" sold by defendants than they would otherwise pay in the aggregate for Clozapine therapy in the absence of defendants' unlawful conduct.

26. The specific amount of damages suffered by plaintiff and the other members of the class has not yet been determined because such determination will require discovery. When this amount has been determined, plaintiff will seek leave of court to amend this First Amended Complaint to include such amount.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays:

- a. That the Court determine that this action may be maintained as a class action under Rule 23(b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), Federal Rules of Civil Procedure, be given each and every member of the class;
- b. That the unlawful contract, combination and conspiracy, conspiracy to monopolize and monopolization alleged herein be adjudged and decreed to be in unreasonable restraint of trade or commerce in violation of Sections 1 and 2 of the Sherman Act (Title 15 U.S.C. §§1 and 2);
- c. That plaintiff and each and every member of the class recover threefold the damages determined to have been sustained by each of them, and that joint and several judgments in favor of plaintiff and each and every member of the class be entered against the defendants, and each of them;
- d. That defendants be enjoined from continuing the unlawful contract, combination and conspiracy alleged herein;
- e. That defendants be enjoined from conditioning sales of Clozapine on the purchase of associated blood testing services from themselves or their designees;
- f. That plaintiff and the other members of the class recover their cost of this suit, including reasonable attorneys' fees, as provided by law; and
- g. That plaintiff and the other members of the class be granted such other, further and different relief as the nature of the case may require or as may seem just, equitable and proper to this Court.

JURY DEMAND

Please take notice that plaintiff demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues triable of right by a jury.

Dated: May 31, 1991



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the Class**

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing First Amended Complaint has been served this date by telecopier upon the following:

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I further certify that on May 31, 1991, all counsel of record have been served by first class mail, postage prepaid with a copy of the foregoing.

Dated: May 31, 1991


HOWARD J. SEDRAN