

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

\_\_\_\_\_  
In re: )  
 )  
Clozapine Antitrust Litigation )  
 )  
THIS RELATES TO CASE NO. ) Honorable Harry D. Leinenweber  
90-C-6412 )  
 )  
 ) DEFENDANT SANDOZ  
 ) PHARMACEUTICALS CORPORATION'S  
 ) SUPPLEMENTAL RESPONSE TO  
 ) PLAINTIFF'S FIRST SET OF  
 ) INTERROGATORIES  
 )  
\_\_\_\_\_ )

Defendant Sandoz Pharmaceuticals Corporation ("Sandoz"),  
for its supplemental answers and objections to Plaintiff Victor  
Dauer's First Set of Interrogatories to Defendants, states as  
follows:

GENERAL OBJECTIONS

1. Sandoz objects to plaintiffs' requests to the extent  
they request information protected by the attorney-client  
privilege and/or the work product doctrine.

2. Sandoz objects to plaintiffs' requests to the extent  
they are overly broad, burdensome, and exceed the scope of  
discovery allowed under Fed. R. Civ. P. 26(b)(1).

3. Sandoz objects to plaintiff ' requests to the extent  
they seek information that is irrelevant and not reasonably  
calculated to lead to the discovery of admissible evidence.

4. Sandoz objects to plaintiffs' requests to the extent that the material sought was relevant, if at all, to matters that have been mooted by subsequent events.

5. Sandoz objects to plaintiffs' requests to the extent that they call for responses that would duplicate documents or information previously produced by Sandoz to plaintiffs or obtained by or available to plaintiffs from other sources.

INTERROGATORY NO. 1:

- A. Identify each department, divisional office, subsidiary or affiliate which had, or now has responsibility for, the manufacture or distribution, marketing or sale of Clozapine and/or associated blood testing/monitoring services and for each such unit or organization, identify each present or former director, officer or employee who has had or currently has supervisory, managerial, or executive responsibilities with respect to manufacture or distribution, marketing or sale of Clozapine and/or associated blood testing/monitoring services, and set forth:
- (i) His or her current business address,
  - (ii) His or her current home address,
  - (iii) His or her social security number,
  - (iv) His or her positions and dates of service in each position with your company, division, subsidiary or affiliate thereof,
  - (v) His or her termination date, if any,
  - (vi) Reasons for his or her termination, if any (e.g., retirement, resignation, severance by the company, death or other cause),
  - (vii) Identity of each such person's immediate assistant and, if different, immediate subordinate,

(viii) The identity of each such person's immediate superior(s).

- B. Identify all present and former officers, directors and employees of your company, its divisions and subsidiaries whose responsibilities or duties include or included the formulation, computation, supervision over, or the approval of the price charged or to be charged for Clozapine and/or associated blood testing/monitoring services sold through the "Clozaril Patient Management System", and further set forth with respect to each such person so identified the information requested in (i)-(viii) inclusive set forth in subparagraph 1(A) above.

RESPONSE: Pursuant to agreement of counsel, Sandoz has previously provided information responsive to this Interrogatory and incorporates herein by reference its answers to interrogatories propounded by the Federal Trade Commission and the State of Minnesota.

Sandoz will object to any attempt by plaintiffs to interview or otherwise communicate with its former management employees regarding matters within the scope of their authority at Sandoz. However, Sandoz will assist the plaintiffs in coordinating formal discovery directed to such persons identified as former employees of Sandoz, some of whom are represented by counsel in relation to these matters. Last known addresses of those persons are as follows:

Robert Essner  
1101 Red Rose Lane  
Villanova, PA 19085

Timothy Rothwell  
2 Deer Cross Lane  
North Brunswick, NJ 08902

Carrie Smith Cox  
35 Summer Hill Lane  
Phoenixville, PA 19460

Gary Harmon  
2076 Brentwood Circle  
Apt. 1-A  
Columbus, GA 43235

Joseph Zuccarini  
259 Marcella Rd  
Parsipanny, NJ 07054

INTERROGATORY NO. 2: Describe each method by which you determined the price for Clozapine and/or associated blood testing/monitoring services sold through the "Clozaril Patient Management System" during the relevant period and state:

- (a) The time period that each method was in effect;
- (b) The particular method of sale, if any, to which each method of pricing applied;
- (c) The identity of each of your employees or agents who established, was consulted or approved any prices established under each method of pricing; and
- (d) The identity of each document which reflects, refers or relates, in any way, to each method.

RESPONSE: Sandoz herein incorporates by reference its previous answers, as referenced in response to Interrogatory No. 1.

INTERROGATORY NO. 3: State whether you have ever been a party plaintiff or defendant in any lawsuit or have been requested to provide information in connection with any governmental investigation in the United States alleging or concerning any violation or potential violation of any state or federal antitrust law relating to the production, pricing, marketing, sale or distribution of Clozapine and/or associated blood testing/monitoring services and/or the "Clozaril Patient Management System" and if so:

- (a) State with respect to each such lawsuit the names of all parties, the docket or case number, the court or courts in which the lawsuit is or was pending, the

date of the complaint, and the disposition, if any, whether by settlement or judgment;

- (b) If you were a respondent to any governmental investigation, as to each governmental investigation state the governmental investigation unit (Department of Justice, FTC, etc.), the nature of investigation (e.g., grand jury, civil investigation), the identity and location of the government office conducting the investigation and the attorney in charge, the disposition, if any, of such investigation and the identity of all persons who you know or who you believe:
- (1) Responded to a subpoena or other process and the dates each such process was served or received;
  - (2) Testified or produced information to government lawyers and the dates of such testimony or the production of such information; or
  - (3) Received immunity.
- (c) Identify all documents which were produced for, or which refer or relate to, any such lawsuit or governmental investigation.

RESPONSE: Responsive information has been provided.

INTERROGATORY NO. 4: Identify any meeting at which any of your officers, directors, agents or employees was present and at which any officer, director, agent or employee of your co-defendant was present, at which meeting there was any discussion or communication which reflected, referred or related, in any way, to any of the following with respect to Clozapine and/or associated blood testing/monitoring services and/or the "Clozaril Patient Management System":

- (a) Any actual, proposed or prospective or suggested prices;
- (b) Pricing, pricing practices, or pricing policies to be followed by the "Clozaril Patient Management System";
- (c) Actual, proposed or prospective prices to be quoted to purchasers of Clozapine and associated blood testing services through the "Clozaril Patient Management System";

(d) Terms and conditions of sale or changes therein.

RESPONSE: Sandoz objects to this Interrogatory as overly broad and unduly burdensome. Such information is available through other means of discovery, including reference to documents produced and interrogatory answers previously provided by Sandoz.

INTERROGATORY NO. 5: Identify any communication between any of your officers, directors, agents or employees and any officer, director, agent or employee of your co-defendant or any of its predecessors, divisions, subsidiaries or affiliates relating to the subjects listed in Interrogatory 4(a)-(d), inclusive.

RESPONSE: See response to Interrogatory No. 4.

INTERROGATORY NO. 6: Describe your company policy with respect to the retention or destruction of documents including but not limited to data stored in computed readable form, including time periods, and, if such policy is different with respect to any certain category of documents or at any different times, identify each such category or time period and state your retention policy with respect to each such category or time period and identify each document reflecting or relating to same.

RESPONSE: See responses to Interrogatory Nos. 2 and 3.

INTERROGATORY NO. 7: Identify each document in your possession, custody or control discussing, reflecting or referring to the "Clozaril Patient Management System", including but not limited to all contracts and other documents reflecting any agreements or arrangements between and/or among Sandoz Pharmaceuticals, Inc., Caremark, Inc., Roche Biomedical Laboratories and/or any other person relating to any aspect of the "Clozaril Patient Management System".

RESPONSE: See general objections 2, 3, and 4. See also responses to Interrogatory Nos. 2 and 3.

INTERROGATORY NO. 8: As to each of the foregoing interrogatories, identify each person who has knowledge of information contained in each of your answers thereto.

RESPONSE: See responses to Interrogatory Nos. 2 and 3.

Dated: June 10, 1991.

GRAY, PLANT, MOOTY,  
MOOTY & BENNETT, P.A.

By Quentin R. Wittrock  
Daniel R. Shulman  
Quentin R. Wittrock  
Attorneys for Defendant Sandoz  
Pharmaceutical Corporation  
3400 City Center  
33 South Sixth Street  
Minneapolis, Minnesota 55402  
Telephone: (612) 343-2800

BAKER & MCKENZIE  
Michael K. Murtaugh  
Thomas R. Nelson  
Donald J. Hayden  
2600 Prudential Plaza  
Chicago, Illinois 60601  
Telephone: 312-861-8000

Attorneys for Defendant Sandoz  
Pharmaceuticals Corporation

1757v



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

\_\_\_\_\_)  
In re: )  
)  
Clozapine Antitrust Litigation )  
)  
THIS RELATES TO CASE NOS. )  
90-CIV-8060, 8063, )  
8055, 8079, 8062, 8064, )  
8065, 8067, 8069, 8071, ) MDL-874  
8073, 8074, 8092, 8075, )  
8076, 8077, 8080, 8081, )  
8082, 8084, 8086,, 8087, )  
8089, and 91-CIV-0244, )  
0921, 1219, 1392, 1220, )  
1165, 1043, 1673, 1814, )  
and 1813 )  
)  
\_\_\_\_\_)

Sandoz Pharmaceuticals Corporation ("Sandoz"), for its responses to the States' Joint First Discovery Requests, answers, objects, and otherwise responds as follows:

GENERAL OBJECTIONS

1. Sandoz objects to plaintiffs' requests to the extent they request information protected by the attorney-client privilege and/or the work product doctrine.

2. Sandoz objects to plaintiffs' requests to the extent they are overly broad, burdensome, and exceed the scope of discovery allowed under Fed. R. Civ. P. 26(b)(1).

3. Sandoz objects to plaintiffs' requests to the extent they seek information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

4. Sandoz objects to plaintiffs' requests to the extent that the material sought was relevant, if at all, to matters that have been mooted by subsequent events.

5. Sandoz objects to plaintiffs' requests to the extent that call for responses that would duplicate documents or information previously produced by Sandoz to plaintiffs or obtained by or available to plaintiffs from other sources.

SANDOZ' RESPONSES TO INTERROGATORIES

1. For each of the following interrogatories, document requests and requests for admissions identify: (a) each person who provided any information for or who was otherwise involved in the preparation of the response of that interrogatory, other than persons whose participation was solely of a clerical nature; (b) each document referred to, reviewed, utilized or relied upon by each person identified in your answer to subpart (a) in providing information for or being involved in the preparation of the response to that interrogatory; and (c) each person who is responsible for the completeness and accuracy of the response. If more than one person furnished information for or was otherwise involved in the preparation of the response to that interrogatory, indicate which information was supplied by or which portion of the response involved each person.

RESPONSE: See general objections 1, 2 and 3.

2. Identify each person you expect to call as an expert witness at any hearing or trial in this matter, the subject matter on which the expert is expected to testify, and state the substance of the facts and opinions to which the expert is expected to testify and a summary of the grounds for each opinion.

RESPONSE: Expert witnesses will be identified and information will be provided in advance of trial.

3. State all facts in support of your contention that the Court lacks subject matter jurisdiction over the Complaints of the Plaintiff States and each of the counts thereof and identify each person who has knowledge of such facts and may be called as a witness at the hearing on such contention.

RESPONSE: The stated defense or denial is based on legal grounds, including the doctrine of primary jurisdiction, in addition to substantive and pleading defects in the Complaints filed by the plaintiff States; see also general objection 1.

4. State all facts upon which you base your fourth affirmative defense to each of the Complaints of the Plaintiff States, that "the plaintiff lacks standing and/or has not

sustained sufficient antitrust injury to maintain the claims set forth in the complaint and each count thereof" and identify each person who has knowledge of such facts and may be called as a witness at any hearing on such contention.

RESPONSE: The stated defense or denial is based on legal grounds, in addition to substantive and pleading defects in the Complaints filed by the plaintiff states; see also general objection 1.

5. State all facts upon which you rely to support your denial of Paragraph 9 of each of the Complaints of the Plaintiff States, which alleges, "The activities of defendants and the co-conspirators that are the subject of this complaint are within the flow of and substantially affect interstate commerce. A not insubstantial volume of trade and commerce is involved and affected by the violations alleged in this complaint" and identify each person who has knowledge of such facts and may be called as a witness at any hearing on such defense.

RESPONSE: See response to Interrogatory No. 4.

6. State all facts in support of your contention that the tying arrangement alleged in the Complaints of the Plaintiff States does not involve at least two products, but only one product and identify each person who has knowledge of such facts and may be called as a witness at hearing on such contention.

RESPONSE: See general objection 4. Notwithstanding and without waiving said objection, Sandoz states that the CPMS was a unified system that included both Clozaril and associated monitoring.

7. State all facts in support of your contention that Sandoz has no financial interest in the alleged tied product and identify each person who has knowledge of such facts and may be called as a witness at any hearing on such contention.

RESPONSE: See general objection 4; see also response to Interrogatory No. 4.

8. State all facts in support of your contention that whatever restraints are imposed in the distribution of clozapine are justified by considerations of health and safety and

identify each person who has knowledge of such facts and may be called as a witness at any hearing on such contention.

RESPONSE: See general objection 4. Notwithstanding and without waiving said objections, Sandoz states generally that the incidence of agranulocytosis and the benefits of required monitoring justified the CPMS.

9. State the number of patients enrolled in the CPMS, who have, respectively, contracted either agranulocytosis or leukopenia since the Commercialization Date.

RESPONSE: See general objection 4. Notwithstanding and without waiving said objection, such cases through February of 1991 included 55 agranulocytosis cases and 192 leukopenia cases.

10. State whether you contend that Clozaril/clozapine cannot be safely distributed in the U.S. without the requirement of a national database or patient registry, and if so, state all facts in support of this contention.

RESPONSE: Yes. The mobility of Clozaril patients and the risk of rechallenge after development of agranulocytosis require comprehensive, unified patient tracking.

11. State whether you contend that the CPMS is justified in order to protect you from possible tort liability, and if so, state all facts in support of this contention.

RESPONSE: See general objections 1 and 4. Notwithstanding and without waiving said objections, Sandoz states that potential product liability was one factor considered in the development of CPMS.

12. State whether you contend that any system, other than the CPMS, which requires blood monitoring in the distribution or dispensing of Clozaril/clozapine is justified in order to protect you from possible tort liability.

RESPONSE: Sandoz objects to this Interrogatory as vague.

13. Identify all former and current employees who are responsible for or familiar with the discovery, development and future of Clozaril/clozapine (including, but not limited to, any patent and FDA applications, other potential uses for the drug, how long the drug will be marketable and plans for when the period of exclusivity ends).

RESPONSE: See general objections 2 and 5. Such persons have been previously identified by Sandoz, including in its June 29, 1990 responses to Interrogatories that were part of the State of Minnesota's Civil Investigative Demand. Sandoz incorporates by reference its responses to those Interrogatories.

14. What date was the Commercialization Date, as the term is used in Article 1.5 of the Commercial Agreement between Caremark and Sandoz dated October 2, 1989?

RESPONSE: February 5, 1990.

15. Has Clozaril/clozapine been available for purchase without the purchase of CPMS? If so, identify each and every instance in which you have sold or distributed Clozaril/clozapine in the United States separately from the package of services sold in conjunction with the drug and known as CPMS.

RESPONSE: Yes; see general objection 2 as to the second sentence of this interrogatory.

16. Identify any person employed or retained by you whose responsibilities included the formation, development, design, pricing, marketing or implementation of the CPMS.

RESPONSE: See response to Interrogatory No. 13.

17. State whether the Commercial Agreement between you and Caremark, Inc. dated October 2, 1989 constitutes the entire agreement between you and Caremark relating to the sale and distribution of Clozaril/clozapine. If not, describe all modifications to said Commercial Agreement and state when such modifications were made, the reasons therefor, and identify the person(s) who made such modifications.

RESPONSE: No; see general objections 1 and 4 as to the second sentence of this interrogatory.

18. State whether the Commercial Agreement between you and Roche Biomedical Laboratories, Inc. dated April 2, 1990 constitutes the entire agreement between you and Roche relating to the services to be performed in conjunction with the sale and distribution of Clozaril/clozapine. If not, describe all modifications to said Commercial Agreement and state when such modifications were made, the reasons therefor, and identify the person(s) who made such modifications.

RESPONSE: See general objections 1 and 4.

19. Identify any person employed or retained by you whose responsibilities include the development, design, pricing or analysis of any alternative to the CPMS.

RESPONSE: See response to Interrogatory No. 13.

20. Identify all former and current employees who are familiar with any plans, whether under consideration, adopted or rejected to distribute and to price clozapine separately from CPMS.

RESPONSE: See general objections 1 and 4.

21. State whether prior to the Commercialization Date, you considered alternatives to the CPMS for the sale, pricing and distribution of Clozaril/clozapine, and if so, describe the alternatives considered and the reasons why they were rejected.

RESPONSE: Yes; see general objections 1, 2, 4, and 5.

22. State whether subsequent to the Commercialization Date, you have considered alternatives to the CPMS for the sale, pricing and distribution of Clozaril/clozapine, and if so,

describe the CPMS alternatives so considered and the status or results of your consideration.

RESPONSE: Yes; see general objections 1, 2, 4, and 5.

23. For each of the CPMS alternatives listed in response to the preceding interrogatory, provide a brief summary of the substance of your considerations of said CPMS alternative and state the current status of it.

RESPONSE: See general objections 1, 2, 4, and 5.

24. State whether you have received from any governmental entity any proposal regarding the purchase and dispensing of Clozaril/clozapine outside of CPMS, and if so, identify the governmental entity, the date you received the proposal, your response to the proposal and the reason for your response.

RESPONSE: See general objections 1, 2, 3, 4, and 5.

25. State whether you have received from any private entity, including but not limited to insurance companies, health maintenance organizations, medical and pharmaceutical professional organizations, and health care providers such as psychiatric hospitals, clinics or individual psychiatrists, any proposal regarding the purchase and dispensing of Clozaril/clozapine outside the CPMS, and if so, identify the entity, the date you received the proposal, your response to the proposal and the reason for your response.

RESPONSE: Yes; see general objections 1, 2, 3, 4, and 5.

26. Identify any person employed or retained by you who is familiar with the fees paid to Caremark under the Commercial Agreement dated October 2, 1989, or any subsequent modification of said Agreement.

RESPONSE: Sandoz objects to this Interrogatory as vague as to the phrase "familiar with." See also general objection 2. Notwithstanding and without waiving said objections, Sandoz states that the following persons may have some such information:

Barbara Rosengren  
Group Business Director  
Sandoz Pharmaceuticals Corporation

Dr. Gilbert Honigfeld  
Business Unit Director  
Sandoz Pharmaceuticals Corporation

Wayne Smith  
Vice President/Controller  
Sandoz Pharmaceuticals Corporation

27. Identify any person employed or retained by you who is familiar with the fees paid to Roche Biomedical Laboratories pursuant to the Commercial Agreement dated April 2, 1990 or any subsequent modification of said Agreement.

RESPONSE: See response to Interrogatory No. 26.

28. Identify any person employed or retained by you who is familiar with revenues, expenses, costs, gross and net profits generated for Sandoz by CPMS.

RESPONSE: See response to Interrogatory No. 26.

29. State the number of patients currently enrolled in the CPMS in (a) the U.S. and (b) in each state.

RESPONSE: See general objections 2, 3, 4, and 5.

Notwithstanding and without waiving said objections, there have been no such patients since May 31, 1991.

30. For each state in which no patients are enrolled in CPMS, please state whether CPMS is available in that state.

RESPONSE: No; see response to Interrogatory No. 29.

31. State the number of Caremark Qualified Patients, as defined in the Commercial Agreement between Caremark and Sandoz dated October 2, 1989, who were enrolled in CPMS for each week since the Commercialization Date.

RESPONSE: See general objections 2, 3, and 4.

Notwithstanding and without waiving such objections, Sandoz states that some such information may be derived from documents that may be produced.

32. State the number of Continuing Patients, as the term is used in Article 4.3.4 of the Commercial Agreement dated October 2, 1989 between Caremark and Sandoz, who were enrolled in CPMS for each week since the Commercialization Date.

RESPONSE: See response to Interrogatory No. 31.

33. State whether the number of Continuing Patients in a single draw setting ever exceeded 5% of the total number of Continuing Patients to whom Clozaril/clozapine is dispensed in all treatment settings combined.

RESPONSE: Sandoz objects to this Interrogatory as vague. Notwithstanding and without waiving such objection, see response to Interrogatory No. 31.

34. If the number of Continuing Patients in a single draw setting ever exceeded 5% of the total number of Continuing Patients, please state: (1) the week(s) for which it exceeded 5%; (2) the percentage of single nurse draws for that week; and (3) the percentage of single phlebotomist draws for that week.

RESPONSE: See response to Interrogatory No. 34.

35. State, for each dosage of Clozaril, the number of patients who are currently administered said dosage.

RESPONSE: See general objections 2 and 3. Notwithstanding and without waiving such objections, Sandoz states that some such information may be derived from documents to be produced.

36. State the number of persons suffering from schizophrenia who you believe would be eligible to initiate treatment with Clozaril under FDA guidelines. Please include in your response what percentages would be expected to be maintained at what dosage levels.

RESPONSE: See general objections 2, 3, and 5. Notwithstanding and without waiving such objections, Sandoz states that the estimated highest number of patients likely to receive Clozaril at any one time will be 60,000 to 80,000.

37. For each state in which Caremark provides services under the Commercial Agreement dated October 2, 1989, state whether the blood draw and drug delivery are performed by a nurse or a phlebotomist. If the services in any state are performed by both nurses and phlebotomists, please state what percentage of blood draws and drug deliveries are performed by each.

RESPONSE: See general objections 2, 3, and 4.

38. If, in any state in which Caremark provides services under the Commercial Agreement dated October 2, 1989, blood draws and drug deliveries are performed by both nurses and phlebotomists, please describe under what circumstances nurses would perform such services and under what circumstance phlebotomists would perform such services.

RESPONSE: See general objections 2, 3, and 4.

39. State the total dollar amount of sales of Clozaril (a) in the U.S. and (b) in each state since the Commercialization Date.

RESPONSE: As to part (a) of this Interrogatory, Sandoz states that such information may be derived from documents to be produced. As to part (b) of this Interrogatory, Sandoz does not have the requested information.

40. State total profits earned by Sandoz under the Commercial Agreement dated October 2, 1989 since the Commercialization Date.

RESPONSE: None.

41. State the total weekly gross revenues received from Caremark under the Commercial Agreement dated October 2, 1989 for each week since the Commercialization Date.

RESPONSE: See response to Interrogatory No. 39.

42. State the total amount of fees paid to (or billed by) Caremark under the Commercial Agreement dated October 2, 1989 or any subsequent modification of said agreement, for each week since the Commercialization Date.

RESPONSE: See response to Interrogatory Nos. 31 and 39.

43. For each week described in the preceding Interrogatory, please state: (1) what percentage of the total fees for the week were based on the Fee Schedule in Article 4.3.3(a) of the Commercial Agreement dated October 2, 1989; (2) what percentage of the total fees for the week were based on each of the seven treatment settings enumerated in Article 4.3.3(a) of the Commercial Agreement dated October 2, 1989; (3) what percentage of the total fees for the week were based on the Fee Schedule in Article 4.3.3(b) of the Commercial Agreement dated October 2, 1989; and (4) what percentage of the total fees for the week were based on each of the seven treatment settings enumerated in Article 4.3.3(b) of the Commercial Agreement dated October 2, 1989.

RESPONSE: See response to Interrogatory No. 31.

44. State the total dollar amount paid by you to Roche Biomedical Laboratories, Inc. pursuant to the Commercial Agreement dated April 2, 1990 or any subsequent modification of said Agreement for CPMS services.

RESPONSE: See general objections 2, 3, and 4.

Notwithstanding and without waiving such objections, Sandoz states that some such information may be derived from documents to be produced.

45. For each month that Roche Biomedical Laboratories, Inc. performed services pursuant to its contract with you dated April 2, 1990, state the number of tests per week that were performed under that contract.

RESPONSE: See response to Interrogatory No. 44.

46. Identify all state mental health agencies who are payees for patients enrolled in CPMS and, for each state agency identified, please provide the number of patients so enrolled for each week since the Commercialization Date.

RESPONSE: See general objections 2, 3, 4, and 5.

47. Identify all local or county mental health agencies who are payees for patients enrolled in CPMS and, for each agency identified, please provide the number of patients so enrolled for each week since the Commercialization Date.

RESPONSE: See general objections 2, 3, 4, and 5.

48. Identify all state Medicaid agencies who are financially responsible for patients enrolled in CPMS and, for each agency so identified, please provide the number of Medicaid beneficiaries so enrolled for each week since the Commercialization Date.

RESPONSE: See general objections 2, 3, 4, and 5.

49. Describe whether you financially account for the research and development costs associated with Clozaril/clozapine, and if so, describe how such accounting is done.

RESPONSE: Sandoz objects to this Interrogatory as vague; see also general objections 2 and 5.

50. Describe all communications, prior to approval of the NDA for Clozaril, with the FDA concerning distribution systems for or safety concerns about Clozaril/clozapine.

RESPONSE: See general objections 2 and 5.

51. Describe all communications, subsequent to the Commercialization Date, with any official of the U.S. Food and Drug Administration relating to the sale and distribution of Clozaril.

RESPONSE: See general objections 2 and 5.

52. Describe all communications, subsequent to approval of the NDA for Clozaril, with the FDA concerning the language on the package insert or labeling for Clozaril.

RESPONSE: See general objections 2 and 5.

53. State to what extent you contend that the FDA requires blood monitoring in the marketing of Clozaril (including if appropriate the type of monitoring required) and set forth all facts upon which you rely to support that contention.

RESPONSE: See general objection 5.

54. For each country outside the U.S. in which you sell Clozaril/clozapine, state:

- (a) the name of the country;
- (b) the prices (in U.S. dollars) at which the drug is sold;
- (c) the incidence of clozapine-induced agranulocytosis;
- (d) the number of individuals treated with the drug;

- (e) the year in which the drug was first sold;
- (f) the number of deaths resulting from clozapine-induced agranulocytosis; and
- (g) any restrictions on the sale, distribution or dispensing of the drug relating to safety concerns about the incidence of clozapine-induced agranulocytosis.

RESPONSE: Not applicable.

55. Identify all current and former employees who are familiar with the sale, distribution or marketing of Clozaril/clozapine in countries outside of the United States.

RESPONSE: Sandoz objects to this Interrogatory as vague as to the phrase "familiar with"; see also general objections 3 and 5.

56. State whether you have for any product sold or distributed in the United States, other than Clozaril, required that blood monitoring and case management services be provided in conjunction with the sale or distribution of the drug, and if so, identify each such drug.

RESPONSE: No.

57. State whether you sell, manufacture or distribute drugs that require monitoring under the supervision of a physician for side effects or negative reactions, and if so, identify each drug and the possible side effect or negative reaction.

RESPONSE: See general objections 2 and 3. Notwithstanding and without waiving said objections, Sandoz states that each drug it sells is associated with certain possible side effects or adverse reactions, which are described in the package insert for the product.

SANDOZ' RESPONSES TO DOCUMENT REQUESTS

1. All documents concerning the discovery and development of Clozaril/clozapine, including documents concerning any patent applications and any U.S. Food and Drug Administration applications for approval.

RESPONSE: Sandoz has previously produced documents bearing numbers S000001-S017445, some of which may be responsive to this individual request. Except where specifically stated below, the documents produced as a whole include those documents requested herein, to the extent responsive documents are in Sandoz' possession; see also general objections 1, 2, 3, and 5.

2. All documents concerning projections for the further development and use of Clozaril/clozapine, including but not limited to its useful life, anticipated number of patients using the drug, anticipated developments in the uses for the drug.

RESPONSE: See response to Request No. 1; see also general objections 1 and 5.

3. All documents concerning the use of Clozaril for schizophrenic patients who are suffering severe side effects from other forms of treatment for schizophrenia.

RESPONSE: See response to Request No. 1; see also general objections 2, 3, and 5. Sandoz further objects to this Request as vague.

4. All documents concerning recovery of research and development costs of Clozaril/clozapine.

RESPONSE: See response to Request No. 1; see also general objections 2 and 5. Sandoz further objects to this Request as vague.

5. All documents concerning the possible sale and distribution of clozapine by manufacturers of generic drug products upon the expiration of your period of exclusivity.

RESPONSE: See response to Request No. 1; see also general objections 1 and 5.

6. All patent applications or patents held for Clozaril/clozapine or the patient monitoring system, known as CPMS.

RESPONSE: See response to Request No. 1; see also general objections 1 and 5.

7. All documents concerning the formation, development, design, pricing and implementation of CPMS.

RESPONSE: See response to Request No. 1; see also general objections 1, 2, 3, 4, and 5.

8. The Commercial Agreement dated October 2, 1989 between you and Caremark.

RESPONSE: See response to Request No. 1; see also general objection 5.

9. All documents concerning any modification of the Commercial Agreement dated October 2, 1989 between you and Caremark.

RESPONSE: See response to Request No. 1; see also general objections 1, 2, and 3.

10. The Commercial Agreement dated April 2, 1990 between you and Roche Biomedical Laboratories.

RESPONSE: See response to Request No. 1; see also general objection 5.

11. All documents concerning any modification of the Commercial Agreement dated April 2, 1990 between you and Roche Biomedical Laboratories.

RESPONSE: See response to Request No. 1; see also general objections 1, 2, and 3.

12. All documents concerning the incidence of clozapine-induced agranulocytosis.

RESPONSE: See response to Request No. 1; see also general objections 1, 2, and 5.

13. All documents concerning any contention that safe distribution and dispensing of Clozaril requires a national database or patient registry.

RESPONSE: See response to Request No. 1; see also general objection 5. Sandoz further objects to this Request as vague.

14. All documents concerning any contention that the CPMS or any other limitation on the distribution or dispensing of Clozaril is justified in order to protect you from possible tort liability.

RESPONSE: See response to Request No. 1; see also general objections 1, 2, 4, and 5.

15. All documents concerning payments by any governmental entity to you or to Caremark for purchases of Clozaril/clozapine, blood monitoring and CPMS services associated with dispensing of Clozaril/clozapine.

RESPONSE: See general objections 2, 3, 4, and 5.

16. All documents concerning systems for distribution, marketing, or dispensing systems of Clozaril (including the pricing of such systems) that were proposed, developed or considered as alternatives to CPMS, prior to the Commercialization Date and the pricing of such alternative systems.

RESPONSE: See response to Request No. 1; see also general objections 2, 4, and 5.

17. All documents concerning systems for distribution, marketing, or dispensing systems of Clozaril (including the pricing of such systems) that were proposed, developed or considered as alternatives to CPMS, subsequent to the Commercialization Date and the pricing of such alternative systems.

RESPONSE: See response to Request No. 1; see also general objections 1, 2, 4, and 5.

18. All documents concerning projected profits from the sale of Clozaril under any alternative to the CPMS.

RESPONSE: See response to Request No. 1; see also general objections 2 and 5.

19. All documents related to any current plans to provide Clozaril outside of the CPMS distribution system.

RESPONSE: See general objections 1, 2, and 5. Notwithstanding and without waiving its objections, Sandoz will produce responsive documents.

20. All documents concerning any proposed or adopted changes in the CPMS distribution system for Clozaril.

RESPONSE: See general objections 1, 2, and 5. Notwithstanding and without waiving its objections, Sandoz will produce responsive documents.

21. All documents concerning any proposed or adopted changes in pricing of Clozaril or CPMS.

RESPONSE: See general objections 1, 2, and 5. Notwithstanding and without waiving said objections, Sandoz will produce responsive documents.

22. All documents concerning any alternative monitoring programs presented by any governmental or private entity.

RESPONSE: See response to Request No. 1; see also general objections 3 and 5.

23. The package insert for Clozaril that have been approved by the FDA.

RESPONSE: See response to Request No. 1; see also general objection 5.

24. All documents concerning any informal or formal communications with the FDA, either before or during the

approval process, concerning distribution systems (including CPMS and alternatives to CPMS) and safety concerns.

RESPONSE: See response to Request No. 1; see also general objections 2, 3, and 5.

25. All documents concerning any formal or informal communications with the FDA concerning the package insert, after the Clozaril New Drug Application ("NDA") was approved.

RESPONSE: See general objections 2, 3, and 5.

Notwithstanding and without waiving its objections, Sandoz will produce responsive documents.

26. All NDAs made to the FDA for approval of Clozaril/clozapine.

RESPONSE: See response to Request No. 1; see also general objections 2, 3, and 5.

27. All documents concerning any requests to the FDA for approval of a blood monitoring system.

RESPONSE: See response to Request No. 1; see also general objection 5.

28. All documents which reflect total sales of Clozaril and CPMS on a weekly and annual basis, in the United States and in each state in the United States, since the Commercialization Date.

RESPONSE: See general objections 2, 3, and 4.

Notwithstanding and without waiving said objections, Sandoz will produce responsive documents in its possession.

29. All documents which reflect the number of patients enrolled in CPMS in each state in the United States.

RESPONSE: See general objections 2 and 4. Notwithstanding and without waiving said objections, Sandoz states that it has no such documents.

30. All documents concerning actual or projected profits to you from Clozaril as marketed with CPMS.

RESPONSE: See response to Request No. 1; see also general objections 2, 4, and 5.

31. All documents concerning the pricing decisions (including, but not limited to, alternative pricing options) concerning the marketing of Clozaril in conjunction with CPMS.

RESPONSE: See response to Request No. 1; see also general objections 2, 3, 4, and 5.

32. All documents concerning the profits realized by or projected for Caremark through its participation in the CPMS or any alternative to CPMS.

RESPONSE: See response to Request No. 1; see also general objections 4 and 5.

33. All documents which reflect fees paid to Caremark pursuant to the Commercial Agreement dated October 2, 1989 between you and Caremark.

RESPONSE: See general objections 2, 3, and 5.

Notwithstanding and without waiving such objections, Sandoz will produce responsive documents.

34. All documents concerning profits realized by or projected for Roche Biomedical Laboratories through its participation in CPMS or any alternative to CPMS.

RESPONSE: See general objections 4 and 5.

35. All documents which reflect fees paid to Roche Biomedical Laboratories pursuant to its contract with you dated April 2, 1990.

RESPONSE: See general objections 2, 3, and 5.

Notwithstanding and without waiving such objections, Sandoz will produce responsive documents.

36. All documents concerning profits made by you on services provided by either Caremark or Roche for CPMS.

RESPONSE: No such documents exist.

37. All documents reflecting any breakdown in the price of CPMS which includes, but is not limited to, fees paid to Caremark and Roche, the cost of manufacturing the drug, development costs, promotional costs, overhead and profits on services and the sale of the drug.

RESPONSE: See response to Request No. 1; see also general objections 2, 4, and 5.

38. All promotional and sales material and documents used in presentations to or otherwise provided to state mental health agencies, state medicaid agencies, professional associations, or health care providers (including but not limited to, psychiatric hospitals and psychiatrists) concerning Clozaril and CPMS.

RESPONSE: See general objections 2, 3, 4, and 5.

39. All documents which reflect projections, estimates or actual figures on the number of schizophrenic patients in the United States who would be eligible, consistent with the FDA approved labeling, to use Clozaril.

RESPONSE: See response to Request No. 1; see also general objection 5.

40. All documents concerning any analysis of savings to any governmental or private entity to be realized from treating patients with Clozaril.

RESPONSE: Sandoz objects to this Request as vague. See also response to Request No. 1 and general objection 5.

41. All documents concerning the costs of treating schizophrenic patients with Clozaril and by other treatments.

RESPONSE: See response to Request No. 1; see also general objections 2 and 5; Sandoz further objects to this request as vague.

42. A complete and current resume or curriculum vitae for each person you expect to call as an expert witness at any hearing in this matter.

RESPONSE: See response to Interrogatory No. 2.

43. Any written report prepared for or submitted to you by each person you expect to call as an expert witness at any hearing in this matter.

RESPONSE: See response to Interrogatory No. 2

44. All documents which were identified in your answers to, or the identification of which was requested in, Plaintiffs' First Set of Interrogatories to you.

RESPONSE: See responses to said Interrogatories.

Responsive documents will be produced.

45. All documents used or reviewed in connection with the preparation of your responses to Plaintiffs' First Set of Interrogatories to you.

RESPONSE: See response to Request No. 1; see also general objections 1, 3, and 5.

46. All documents upon which you rely to support each defense asserted in your answer to the Plaintiffs' Complaints, segregated according to the defense to which they relate.

RESPONSE: See response to Request No. 1; see also general objections 1, 2, and 5.

47. All documents you intend to offer into evidence at any hearing in this matter.

RESPONSE: See response to Request No. 1; see also general objections 1, 2, and 5.

Dated: June 10, 1991

GRAY, PLANT, MOOTY,  
MOOTY & BENNETT, P.A.

By Quentin R. Wittrock  
Daniel R. Shulman  
Quentin R. Wittrock  
3400 City Center  
33 South Sixth Street  
Minneapolis, Minnesota 55402  
Telephone (612) 343-2800

BAKER & MCKENZIE  
Michael K. Murtaugh  
Thomas R. Nelson  
Donald J. Hayden  
2600 Prudential Plaza  
Chicago, Illinois 60601  
Telephone: 312-861-8000

Attorneys for Defendant Sandoz  
Pharmaceuticals Corporation

069079.46159.0559v

