UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION



In the Matter of

HOECHST MARION ROUSSEL, INC., a corporation, CARDERM CAPITAL L.P., a limited partnership,

and

ANDRX CORPORATION, a corporation.

Docket No. 9293

ANDRX CORPORATION'S OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO COMPEL ANDRX TO PRODUCE ADDITIONAL DOCUMENTS

Respondent Andrx Corporation ("Andrx") respectfully submits this memorandum in opposition to Complaint Counsel's untimely motion to compel Andrx to produce additional documents.

Preliminary Statement

For over two-and-one-half years before the commencement of this proceeding, the FTC staff aggressively obtained a massive amount of information from Andrx, the other respondents in this matter and third parties. Andrx fully cooperated with the FTC staff and was advised that it had wholly satisfied the various extensive requests for information made on it. As late as January 2000, Andrx supplied supplemental information in response to the FTC staff's investigation. At no time did the FTC staff complain about any insufficiency in Andrx's responses.

Based on the extensive information collected by the FTC staff, Complaint Counsel filed a pleading challenging the HMR/Andrx Stipulation. Complaint Counsel thereafter took no position as to the scheduling of a trial date, since it essentially had

compiled the information underlying its case and did not claim to require any substantial additional discovery.

To divert attention from its own discovery misconduct so far in this proceeding, Complaint Counsel now raises a host of wholly specious disputes regarding Andrx's document production -- and it does so belatedly. Andrx served its responses to Complaint Counsel's document requests on June 1, 2000. Under the Scheduling Order, any motion to compel must be brought no later than twenty days after the responses are served. Standing alone, the untimeliness of Complaint Counsel's motion is a sufficient basis to reject it. Indeed, Complaint Counsel waited so long because, in fact, it does not genuinely require the irrelevant documents being sought, but rather wants to muddy the waters and obscure its own discovery failures.

Even apart from the untimeliness of Complaint Counsel's motion to compel, it fails on the merits. In its motion, Corporate Counsel grossly distorts the record by claiming "Andrx has not provided a single document in response to our document requests". (Complaint Counsel Mem. at 2.) Andrx already provided extensive material responsive to the requests, and has gone even further and agreed to make an appropriate supplemental production. What, however, Complaint Counsel now seeks from Andrx is virtually every scrap of paper in the company pertaining to one of its most significant products -- potentially encompassing millions of pages of irrelevant records, taking hundreds of hours to collect. In seeking to impose that monumental burden on Andrx, Complaint Counsel has refused to act in good faith and place reasonable limitations on the scope of its requests. It has taken that approach because, after two plus years of the FTC staff obtaining all the documents it wanted, Complaint

Counsel does not require much, if any, additional discovery -- it only wants to keep

Andrx busy with discovery squabbles and thereby force it to squander valuable time

when instead the respondents should be obtaining affirmative discovery for themselves.

As further discussed below, anything in Andrx's files reasonably relevant to this action has been produced or Andrx has agreed to produce it. To the extent any disputes exist, it is because Complaint Counsel is either seeking wholly extraneous documents or pressing extraordinarily broad and burdensome requests, without clarifying or limiting the scope, as a distraction and means to obscure its own tactics in stalling the discovery crucial to Andrx.

BACKGROUND

A. Andrx's Good Faith and Responsive Production of All Relevant Documents

On November 24, 1997, the Commission issued a Subpoena Duces

Tecum and Civil Investigative Demand ("CID") to Andrx. Andrx reviewed those requests in detail with the FTC's staff and, together with the staff, reached agreement on the types and categories of documents that the staff wanted. Andrx fully satisfied the staff's requests, and the Commission so indicated. The Commission issued yet another Subpoena and CID on October 23, 1998, the breadth of which necessitated that Andrx move for a protective order. Subsequent to making that motion, Andrx again conferred with the staff and, with the staff, agreed to additional types and categories of documents to be produced. Andrx then fully complied with the second Subpoena and CID, as limited by its agreement with the staff. In addition to the 1997 and 1998 Subpoenas and CIDs, the staff also made numerous informal requests of Andrx during the course of the investigation. In fact, the staff continued to make informal requests of Andrx even after

it had recommended the commencement of the present enforcement proceeding.

Andrx has fully complied with <u>all</u> of these informal requests. Andrx, for example, voluntarily provided the staff with information, in response to their requests, as late as January 2000.

Indeed, Complaint Counsel's satisfaction with the information that the FTC obtained is not only demonstrated by the fact it was able to prepare its pleading.

Beyond that, Complaint Counsel, during the scheduling conference before Your Honor on April 24, 2000, refused to take a position on the scheduling of a trial date because it did not claim to have a need for any substantial additional discovery.

On May 3, 2000, Complaint Counsel served document requests on Andrx largely duplicative of the formal and informal requests Andrx previously satisfied.

Thereafter, Andrx served its timely responses on June 1, 2000.

B. Complaint Counsel's Obstruction And Delay of Discovery

Unlike Complaint Counsel, Andrx and the other respondents have not had the benefit of two plus years of gathering information to substantiate their positions. To take advantage of that disparity in information, Complaint Counsel has refused to provide respondents with a complete set of the meaningful documents in its possession. Since the proceeding began, Complaint Counsel has unilaterally determined that crucial areas of discovery are off limits and encouraged various third parties working in collaboration with Complaint Counsel to do the same.

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¹ Complaint Counsel now suggests that Andrx's responses were late because they were served on June 1 (in compliance with the FTC rules); in fact, Complaint Counsel itself had taken the same period of thirty days to provide its responses. Andrx had advised Complaint Counsel that it would furnish responses sooner if Complaint Counsel also did so. In response, Complaint Counsel balked. Thus, Complaint Counsel is taking, yet again, a self-serving approach to discovery and contending different rules ought to apply to it.

As a result of Complaint Counsel's obstructivist tactics, Andrx and the other respondents have been substantially prejudiced in their ability to marshall evidence important for their defenses -- and the clock is running out on our ability to accomplish the task. Complaint Counsel, for instance, has refused to provide basic discovery concerning various other transactions similar to the HMR/Andrx Stipulation. Not only will such discovery be important in demonstrating that these types of deals are pro-competitive when understood in the context of actual industry practices, but Complaint Counsel <u>itself</u> has sought <u>precisely the same</u> discovery from Andrx. Complaint Counsel also has resisted important discovery concerning Biovail, which is featured prominently in Complaint Counsel's pleading and witness list. Biovail and its agents, in turn, have taken their cue from Complaint Counsel, and they also have refused to provide any discovery.

ARGUMENT

Given its own obstructionist approach to discovery, Complaint Counsel now turns the world on its head by arguing that the "Commission's rules of practice adopt a liberal approach to discovery" and discovery should be "broad". (Complaint Counsel Mem. at 5.) In fact, during more than two years of investigation, the FTC staff has requested (either formally or informally) and received from Andrx all the documents it deemed relevant to the issues here -- and even documents going well beyond anything conceivably relevant.

Complaint Counsel now presses an untimely motion, which should be rejected on that basis alone. Beyond that, the motion lacks any substantive merit. In particular, Complaint Counsel takes issue with Andrx's responses to requests involving

six basic categories of documents. However, each of the requests at issue, due to its over-breadth, clearly seeks information that is irrelevant to the present proceeding and was propounded solely to derail Andrx's trial preparation and further to capitalize on Complaint Counsel's preparational advantage. Below, each of the categories subject to Complaint Counsel's motion will be addressed separately.

Complaint Counsel's Motion Should Be Denied Because It Is Untimely

Paragraph 2 of the Scheduling Order, Additional Provisions (dated April 26, 2000) provides:

Any motion to compel responses to discovery requests shall be filed within 5 days of impasse if the parties are not able to resolve their dispute, but no later than 20 days after service of the responses and/or objections to the discovery requests. Any response to a motion to compel discovery shall be filed within 5 days of service of the motion to compel. (Emphasis added.)

Here, Complaint Counsel has failed to make its motion within the required time frame. Complaint Counsel does not (and cannot) even attempt to justify an exemption from the express 20-day limitations period in the Scheduling Order, which began to run when, on June 1, Andrx served its responses. The significance of Complaint Counsel's failure to make its motion promptly – and within the deadline of the Scheduling Order – is not only that it reflects that Complaint Counsel genuinely does not have an interest in much of the material being sought. The significance of the delay is also that it further reflects Complaint Counsel's efforts at protracting discovery and complicating the discovery-related motion practice pending before Your Honor.

By reason of its untimeliness, Complaint Counsel's motion to compel should be denied.

Board of Directors Meeting Minutes

Complaint Counsel's present motion seeks to expand the scope of requested materials set forth in Specification 3, as defined by the party's meet-and-confer sessions. Specifically, the meet-and-confer sessions focused solely on Board of Directors meeting minutes and <u>not</u> on minutes or notes from any other Andrx committee. Indeed, Complaint Counsel raised <u>no</u> issues at all with respect to the production of non-board of directors' materials. Consequently, Complaint Counsel has not complied with its meet-and-confer obligations concerning this class of documents.

With respect to Board of Directors meeting minutes, Andrx agreed to produce board minutes up to July of 1999 -- which is almost two years after the HMR/Andrx Stipulation was executed. Complaint Counsel takes the position that it is entitled to Board of Directors' meeting up until the present day, but such an argument is without any merit. This proceeding concerns Andrx's entry into a Stipulation pendente lite with HMR in 1997. Thus, at most, the mental state of Andrx's board in 1997, around the time the Stipulation was drafted and adopted, is arguably germane to this proceeding. (If Complaint Counsel believes the Stipulation is, on its face, a per se violation, then it should not view the issue of mental state as relevant at all.)

Nevertheless, and in the interests of facilitating discovery, Andrx has agreed to produce responsive documents through the termination of the HMR/Andrx patent litigation in July 1999 -- which resulted in the 1997 Stipulation no longer being effective.

Indeed, by agreeing to produce board minutes through July 1999, Andrx has agreed to produce documents not only for a period of almost two years after the HMR/Andrx Stipulation was executed, but also for a period of one year <u>after</u> the filing of the first of the now multi-districted class actions. With the commencement of that litigation, the board discussions likely will be privileged and/or, at the very least, not probative of the facts pertaining to the relevant time period of the HMR/Andrx Stipulation.²

Because Andrx, by agreeing to produce minutes through July 1999, has erred on the side of over-inclusivity with respect to its production, Complaint Counsel's request for even more should be denied.

3. Budgets for Research and Development

Specification 5 calls for the production of "documents sufficient to show Andrx's monthly research and development budgets for each product until June 1999 -the month the FDA approved Andrx's reformulated version of generic Cardizem CD":
(Complaint Counsel's Mem. 7). Complaint Counsel has refused to focus this over-broad request on the product line at issue. Nonetheless, in the interests of facilitating discovery (and without waiver of any of Andrx's objections), Andrx will produce responsive documents on a quarter-by-quarter basis -- the same frequency with which Andrx created these budgets.

4. Documents Relating to Andrx's Reformulated Product

Specification 7 is an extraordinarily broad and unfocused request, calling for all:

² The first class action, Lightner v. Hoechst et al., was filed in Alabama state court on August 26, 1998.

[d]ocuments relating to Andrx's Reformulated Product, including, but not limited to the likelihood that the product infringed (or infringes) a patent owned or controlled by HMRI; Andrx's ability to market the product; any actual, considered, or possible effect the product had or would have had on any HMRI obligation pursuant to the Stipulation and Agreement; and any actual, considered, possible or proposed effect the product had or would have had on Andrx's obligation pursuant to the Stipulation and Agreement."

On its face, Specification 7 calls for the production of essentially every scrap of paper in Andrx's possession that relates to Cartia XT -- one of Andrx's most significant products. It would, for example, call for the production of the following wholly irrelevant documents:

- A written request for ordinary service on a piece of machinery used by
 Andrx to produce the Reformulated Product;
- A Hallmark card wishing a senior executive congratulations on his company's success in developing the Reformulated Product; and
- A fax sent by Andrx to the supplier of an inactive ingredient concerning the scheduling of a particular day for that suppliers' shipment of the ingredient.

Given its sheer breath Andrx has repeatedly asked Complaint Counsel to focus its request. Because Complaint Counsel was wholly unwilling to provide the requisite focus, Andrx agreed to undertake to provide documents sufficient to reflect Andrx's marketing practices with respect to Cartia XT. Andrx takes seriously its discovery obligations and, once again, reiterates its willingness to consider a narrowly focused request that would not require Andrx to review and produce millions of pages of superfluous information.

5. Additional Research and Development Materials

In Specification 8, Complaint Counsel calls for the production of all:

[d]ocuments created prior to July 1, 1999 relating to Andrx's research, development, manufacture of a bio-equivalent or generic version of Cardizem CD, including, but not limited to, Andrx's Reformulated Product.

Although its seeks an order of compulsion with respect to Specification 8, the reason for Complaint Counsel's apparent dissatisfaction with Andrx's proposed production is far from clear. In its response, Andrx specifically stated that it would produce "non-privileged documents sufficient to describe Andrx's research, development or manufacture of a bio-equivalent or generic version of Cardizem® CD, including, but not limited to Andrx's Reformulated Product." However, "all" documents "relating to" research and development efforts potentially encompasses millions of pages of entirely irrelevant records that would take hundreds of hours to compile. Complaint Counsel does not and cannot set forth any justification for imposing such a burden on Andrx.

Andrx reiterated its position in a letter from Hal Shaftel to Brad Albert dated June 28, 2000, which confirmed its willingness to produce research and development material up to the marketing of the Reformulated Product. Moreover, the June 28 letter specifically stated that Andrx will produce documents such as "failed batch records, laboratory notebooks and dissolution profiles." Given Andrx's willingness to comply with Specification in a reasonable manner, Complaint Counsel's expressed desire for a compulsion order is frivolous.

6. Cartia XT Plans

Specification 12 is another classic example of over-breath on the part of Complaint Counsel. This specification calls for:

All documents relating to Andrx's or any other person's plans relating to Cartia XT, including, but not limited to, business plans; short term and long range strategies and objectives; collaboration plans; budgets and financial projections; research and development plans; manufacturing plans; regulatory plans; and presentation to management committees, executive committees, and board of directors.

First, read literally, Specification 12 potentially would call for the production of millions of pages of clearly irrelevant documents. For example, because the request calls for the production of "any other persons plans relating to Cartia XT", it could be read to require the production of health insurance information for an Andrx employee relating to that employee's decision to take Cartia XT to reduce his own hypertension. Second, to the extent that Specification 12 purports to provide examples of responsive classes of documents, the request is largely (if not entirely) duplicative of other specifications in the request. See e.g. Specification 3 (calling for the production of board of directors minutes); Specification 5 (calling for the production of research and development budgets, projections and expenditures); Specification 8 (calling for documents "relating to Andrx's research, development, or manufacture of a bioequivalent or generic version of Cardizem CD"); Specification 9 (calling for the production of sales and pricing information with respect to Cartia XT); Specification 14 (calling for the production of Cartia XT invoices).

Perhaps the most puzzling aspect of Complaint Counsel's claimed dissatisfaction with Andrx's proposed production is the suggestion that Andrx has refused to provide pricing information with respect to Cartia XT. (See Complaint Counsel Mem. at 11.) That is simply untrue. During the various meet-and-confer conversions, Andrx offered (and Complaint Counsel agreed to accept) Andrx's production of documents sufficient to identify the pricing of Cartia XT as well as the

production of invoices, in machine readable form, for one week in December of 1999 and one week in January 2000. (See June 28 letter.)

Because Complaint Counsel has already requested elsewhere documents that are responsive to Specification 12, Complaint Counsel's motion to compel with respect to this specification should be denied as moot.

7. Documents Concerning "Other Deals"

In Specifications 16 and 17, Complaint Counsel calls for the production of other patent settlements, as well as licensing and joint development agreements, in which Andrx has participated. Andrx has stated its willingness to provide responsive documents with respect to Specifications 16 and 17, but only if Complaint Counsel agrees to produce similar information from its own files.

To date, Complaint Counsel has steadfastly refused to treat discovery regarding "other deals" as a two-way street. Indeed, the resulting impasse is due entirely to Complaint Counsel's arrogant belief that Andrx is proceeding on the "legally incorrect assumption that [it] is entitled to discovery 'equal' to that of Complaint Counsel." (Complaint Counsel Mem. at 13.)

Complaint Counsel expressly claims the right to use documents it selected from other investigations. In particular, at page 4 of its purported reply memorandum in further support of its motion to strike, Complaint Counsel announced its intention to reply upon a document produced by HMR <u>not</u> in the context of Investigation no. 981-0368, but in the context of an investigation conducted by "one of the FTC's merger divisions." (5/26/00 Complaint Counsel Reply Mem. at 4 n.4). The very fact that Complaint Counsel has had access to these other investigations and has made tactical decisions abut what additional documents it intends to reply upon bespeaks the

unfairness of Complaint Counsel's refusal to search these files as part of its basic discovery obligations. Fundamental due process requires that Andrx be given the same opportunity to survey the entire universe of responsive documents so that it too can make tactical assessments about those documents it intends to rely upon.

In addition to the two investigations specifically concerning the subject of these proceedings, the FTC has conducted other investigations relating to transactions similar to the HMR/Andrx Stipulation. For example, the FTC concluded an investigation concerning a deal with certain similar provisions between Abbott Laboratories and Geneva Pharmaceutical, Inc. See Matter of Geneva Pharmaceuticals, Inc., File No. 981-0395. Moreover, Complaint Counsel itself has relied on the Abbott/Geneva investigation, as part of these proceedings, to argue before this Court that there is no basis for the defense that Complaint Counsel labels "selective enforcement" (see 4/28/00 Complaint Counsel Mem. at 5 n.5.)

Beyond that, there are numerous other deals, known to the FTC, as having similar provisions. As stated in Andrx's Answer, there is a March 31, 1998 agreement between Abbott Laboratories and Zenith Goldline Pharmaceuticals, with some of the same types of provisions as Complaint Counsel challenges in the HMR/Andrx Stipulation. The Commission has publicly compared the Abbott/Geneva agreement with the HMR/Andrx Stipulation and has indicated that it will take no action against the Zenith Goldline agreement.

As a matter of basic fairness, Complaint Counsel should not be allowed to "cherry pick" in that manner and select, for self-serving purposes, what information to use from other files concerning other deals. In fact, Complaint Counsel's approach is

clearly incorrect as a matter of law. See Exxon Corporation, 1980 FTC LEXIS 121, at * 5-6, * 8-9 (February 8, 1980) (rejecting Complaint Counsel's attempt to "den[y] [respondents] all discovery beyond those materials held in Complaint Counsel's files" on the basis of Complaint Counsel's blanket and non-specific privilege claims and ordering Complaint Counsel to review and produce or make specific claims of privilege with respect to "8 [other] apparently relevant petroleum-based matters in which the commission has been involved").

Andrx reiterates its position that it is fully prepared to respond to Specifications 16 and 17, but it is not fair or reasonable for it to do so unless Complaint Counsel is required to do likewise.

CONCLUSION

For the foregoing reasons, Complaint Counsel's motion to compel the production of yet additional documents from Andrx should be denied in all respects.

Dated: July 25, 2000

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CERTIFICATE OF SERVICE

I, Peter M. Todaro, hereby certify that on July 25, 2000, I caused to be served upon the following persons, by hand delivery, Respondent Andrx Corporation's Opposition to Complaint Counsel's Motion to Compel Andrx to Produce Additional Documents (dated July 25, 2000):

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