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**Re: Rochester Drug Cooperative, et al v. Braintree Laboratories, Inc.
 C.A. 07-142-SLR**

Gentlemen:

Ruling¹

Relative to the documents sought, the controlling issue is whether, when balancing the probative value of the information requested against the cost and burden imposed upon the Plaintiffs, the Defendant's discovery should be allowed. Having considered the papers submitted by the parties as well as the arguments made before the Special Master, it is my decision that:

(1) Discovery concerning the Plaintiffs' purchase, chargeback and sales data is DENIED. (Requests 1-5, 9-10);

(2) Discovery concerning price setting decisions, price negotiations, product comparisons and promotional material relating to oral laxative products is GRANTED. (Requests 8, 11-13²).

Opinion

Plaintiffs' lawsuit seeks treble damages under Section 2 of the Sherman Act. It is based on allegations that Braintree Laboratories, Inc. ("Braintree") acquired an unlawful monopoly in the polyethylene glycol 3350 ("PEG3350") laxative market through an invalid patent which was improperly listed in the FDA "Orange Book" and then used to support a sham patent

¹ This letter was originally sent to the parties as a draft opinion, with the parties having the right to except to the Special Master. Following receipt, the parties advised that they were accepting the Ruling and did not believe that it was necessary to file their submissions to the Special Master.

² Requests 6 and 7 have been withdrawn. Also, at Argument, Defendant affirmed that he was not seeking price sheets, launch materials and communications of manufacturers regarding the delivery of generic MiraLAX. Transcript of May 27, 2011 at 19.

infringement case. According to the Plaintiffs, this conduct allowed Braintree to make illegal profits by delaying the entry of generic versions of PEG3350 laxatives into the national market. Consolidated Amended Class Action Complaint (“Compl.”) ¶¶ 71-86 (D.I. 21).

On October 14, 2010, Braintree served its Requests for Production. These included Requests 1 through 4, 9 and 10, pertaining to the Plaintiffs’ purchase and sales data of prescription, over-the-counter and generic MiraLAX, as well as other laxatives; and Requests 6, 7 and 11, pertaining to price setting decisions, price negotiations, promotional materials and product comparisons. (*See Defendant’s Opening Brief, Exhibits A-C*).

Plaintiffs generally objected to the Requests on burdensome and relevancy grounds. Following their general objections, they did state that they would produce “transaction-level electronic purchase and chargeback data in Excel format showing Plaintiffs’ direct purchases of MiraLAX from Braintree” and “purchases of generic versions of MiraLAX from December 23, 2003 through present.” (*See Defendant’s Opening Brief, Exhibit F, and Responses to Paragraphs 1-7*). In response to Request No. 8, they also stated, that subject to its objections, they would “produce responsive communications to the extent they exist and are not already in the possession of Defendants” (*Defendant’s Opening Brief, Exhibit F, Response to Paragraph 8*).

In the motion before me, Braintree argues that the unanswered discovery will lend support to its defense in that it will help to demonstrate that Braintree did not have monopoly power. Stated otherwise, Braintree maintains that Plaintiffs’ own documents will provide proof that the involved products do not represent a dominant share of the relevant market, (*United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005)), most notably because of the cross-elasticity of demand in the oral laxative industry. *See, Tunis Bros v. Ford Motor Co.*, 952 F.2d, 715, 722 (3d Cir. 1991).

Accordingly, Braintree requests documentation relating to the volume and price of the Plaintiffs’ purchases and sales of MiraLAX (both prescription and over-the-counter), generic MiraLAX and forty-four other laxatives to bolster its “market definition” arguments. In addition, it seeks various documents relating to Plaintiffs’ promotional and pricing strategies. (Requests 8, 12-13), citing *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962); and *In Re: Wellbutrin XL Antitrust Lit.*, No. 2:08-CV-02431, D.I. 175 (E.D. Pa. Mar. 12, 2010). Braintree relies, in large part, on the affidavit of its economic expert, Professor Ian Cockburn, to substantiate its need for the requested documents. (*See, Defendant’s Opening Brief at 8*).

While Braintree asserts that the Requests at issue are necessary and will not require excessive document collection when taking into consideration the damages alleged and the issues involved, the Plaintiffs object to the production, arguing that the data sought is cumulative and burdensome. More particularly, they assert that the documents which Defendant seeks (1) would not assist in any “relevant market” analysis in light of the fact that the products involved (or addressed by the discovery) “account for less than one-half of 1% of the historical purchases of MiraLAX;” (2) the sales data for prescription MiraLAX, its generic equivalents and “a host of

other products” have already been produced; and (3) the purchase, charge-back and sales data on the 40 or so drugs subject to the discovery would require 200 separate searches for purchase data, charge-back data, and sales data by each of the three representative Plaintiffs.

In support of their position, the Plaintiffs have each submitted an affidavit detailing the time its key personnel would have to expend to retrieve the requested documents (See Exhibits 3, 4 and 5 to Plaintiffs’ Answering Brief). Plaintiffs also submit that the purchase and chargeback data for Plaintiffs’ purchases of MiraLAX and its generic equivalents has already been produced.

It is my initial finding that Braintree can validly argue the relevance of its Requests in that they could provide information that bears on the involved market. (*See, U.S. v. Dentsply Intern, Inc.*, 2000 WL 654286 (D. Del.).

In order to avoid production otherwise permissible under Rule 26(b)(1), the Plaintiffs must then show that the burden or expense of production is disproportionate to its likely benefit to the Defendant. In analyzing the arguments, the Court must consider the needs of the case, the amount in controversy, the parties’ resources, the importance of the issues, and the importance of the requested discovery in resolving the issues. *Fed. R. Civ. P. 26(b)(2)(C)(iii)*.

While the data sought from the Plaintiffs is probative of the involved product sales, it is my conclusion that those materials are cumulative and, further, that it is unlikely that the materials concerning these sales, etc., would, in any meaningful way, assist the Defendant in proving that the involved product has a dominant share in the “relevant market”³ or, in fact, provide much other than anecdotal evidence.⁴

Braintree already has a great deal of data. As Professor Cockburn notes in his affidavit, for the *Schwartz* litigation he made a thorough review of both the IMS wholesale data for prescription drugs, and the ACNielsen retail data for OTC drugs.⁵ According to paragraphs 5 and 6 of the affidavit, this permitted him to “confirm” his economic analysis. In Dr. Cockburn’s report in *Schwartz*, he lists not only these two support references, but numerous others. (*See, Appendix B, Rebuttal Expert Report of Dr. Ian Cockburn*). In reviewing his trial testimony, I note that Dr. Cockburn did not need the requested data in order to reach the conclusion that Braintree does not enjoy monopoly power. (See excerpts of trial testimony of Ian Cockburn in *Braintree v. Schwarz*, February 1, 2007, attached as Exhibit “A”).

In my opinion, Professor Cockburn does not set out a sufficient need for these materials. While he says that he wants to supplement his analysis, he never says that he requires these

³ Defendant argues that “all oral laxative products” make up the relevant product market. The geographical market is the United States.

⁴ See also transcript of May 27, 2011 at p.10 where Defendant maintains the discovery “could provide examples of how specific price changes on laxatives effect the sales of other competing products in itself.”

⁵ This is industry-wide data accumulated and sold for the purpose of permitting recipients to analyze sales and prices. The material included the Plaintiffs’ sales and price information. Transcript of May 27, 2011 at pp.36-38.

materials to construct (or reconstruct) his analysis. Rather, his affidavit notes that his previously authored report provides the necessary evidence of “strong price competition,” suggesting only that this requested discovery “may provide useful information...or provide confirmation of the results of my previous econometric analysis.”⁶

It is noteworthy that paragraph 5 of Dr. Cockburn’s affidavit concludes: “In particular, such data would allow me to respond to certain critiques of my analysis...” (Cockburn Affidavit ¶5). Stated otherwise, Dr. Cockburn believes that the new discovery will allow him to “supplement” his earlier opinions (based on the IMS Health and ACNielsen data), where he was criticized for mixing the IMS data with the ACNielsen data. In their answering brief, Plaintiffs state that this is an area they do not intend to contest.

Finally, while there is certainly an argument that the Defendant should be entitled to put together any sales data which shows price elasticity, its suggestion that it could profitably use this particular data, which accounts for less than one-half of 1% of the overall sales in the MiraLAX market, requires some scrutiny.⁷ That data, without more, is of doubtful value.⁸ The report of Dr. Cockburn details why the changes in price, while effected by competing products, are dependent on a host of outside influences, including: (1) marketing; (2) diffusion of information; (3) economic incentives; (4) demographic changes (Cockburn report ¶7.2); (5) production costs (Cockburn report ¶61); as well as the sales arrangements with Managed Care Organizations (“MCOs”) (Cockburn report ¶29), Pharmaceutical Benefit Management Companies (“PBMs”) (Cockburn report ¶30) and Medicaid payments (Cockburn report ¶32). Stated otherwise, based on the testimony of its own expert, the information which Braintree seeks to gather is not likely to have any significant value without a detailed study regarding the above items over time. (Cockburn report ¶14). According to Dr. Cockburn, simple price comparisons have limited value, especially if one takes into consideration the variations in packaging. (Cockburn report ¶¶15, 16 and 62). While a detailed analysis could be done by Braintree, it would be impractical and the results, because of sample size, are of doubtful admissibility.

In the exercise of the discretion allowed to the Court, I am persuaded that compelling the production of the volume and price data related to the Plaintiffs’ purchase and sales in response to the Defendant’s requests would impose a burden on the Plaintiffs which is cumulative and outweighed by any benefit Defendant might obtain. *Fed. R. Civ. Pro* 26(b)(2)(C); *See also, Mannington Mills v. Armstrong World Indus., Inc.* 206 F.R.D. 525, 529 (D.Del.2010). As previously indicated, in addition to the fact that Dr. Cockburn already has much of this information, the data which would be obtained from the plaintiffs constitutes so small a sample

⁶ Cockburn Affidavit ¶5.

⁷ See transcript of the 4/11/11 Status Conference at p.24, as well as Braintree’s Answering Brief in Opposition to Plaintiffs’ Motion for Injunction at 4-5 wherein Defendant states that gross Braintree sales to Plaintiffs were one-half of one percent, i.e., “minimal revenues.”

⁸ Compare plaintiffs’ market with that of *McKesson, Cardinal Health & AmeriSourceBerger*, three wholesalers (whose records have been subpoenaed) that control 90-95% of the market. Transcript of May 27, 2011 at 28.

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that it has questionable utility and thus, questionable admissibility.⁹

However, the promotional materials, pricing strategies, negotiations and the like relate to the parties' decisions and admissions relative to the relevant market, and I will compel that production (Requests 8, 11-13) as it relates to MiraLAX, generic MiraLAX and other laxatives, to the extent that they reference MiraLAX and generic MiraLAX.¹⁰ See, *Brown Shoe*, 370 U.S. at 325; *In re. Wellbutrin XL Antitrust Litig.*, No. 2-08-Lu02431, DJ 175 (E.D. Pa. Mar. 12, 2010). With the discovery now limited to three requests, it is not so burdensome as to overcome the Defendant's right to review materials that are calculated to lead to the discovery of admissible evidence. *Paluch v. Dawson*, 2008 WL 2785638 (M.D. Pa. July 17, 2008).¹¹


B. WILSON REDFEARN
Special Master

BWR:ma

Encl.

⁹ I acknowledge that in reaching this conclusion, I have been unable to find (and the parties have not provided) a definition for "irrelevant market share size." Such issues must be resolved on a case-by-case basis. *Maple Flooring Manufacturing Assn. v. United States*, 268 U.S. 563, 579 (1925).

¹⁰ Reference transcript of May 27, 2011 at 6-7, 14-15, 24-25, for Braintree's expanded arguments, etc.

¹¹ The third area of discovery discussed by the Defendant in its briefs, which relates to the propriety of purchases of the generic prescription version of MiraLAX, after the over-the-counter version was approved, is not covered by the Requests at issue. See also, Transcript, May 27, 2011 at 4-5.

ROCHESTER V. BRAINTREE – Exhibit “A” to Letter Opinion dated June 2, 2011

Excerpts from the transcript in the matter of *Braintree Laboratories, Inc. v. Schwarz Pharma, Inc.*, C.A. No. 08-00477, United States District Court for the District of Delaware; February 1, 2007.

P.1208, line 3 through p. 1209, line 17:

P.1208:

3 Q. What economic measures do you use in determining a
4 relevant market?

5 A. We will typically look at cross price elasticity.

6 Q. And what does cross price elasticity mean?

7 A. Cross price elasticity is a quantitative measure of
8 a degree to which sales for one product are sensitive to
9 changes in the rises of another product.

10 Q. What were the methods by which an economist
11 determines cross price elasticity of demand?

12 A. Occasionally, I think it can be clear from market
13 outcomes, you know, whether or not cross price elasticity
14 exists.

15 More frequently, economists will rely on
16 methods such as surveys of consumers or experiments
17 designed to reveal the degree to which products are
18 substitutes. And very frequently, economists will rely
19 upon econometric estimates of a demand model to obtain a
20 direct quantitative measure of cross price elasticity

21 parameter.

22 Q. Can you describe what an econometric demand model

23 is?

24 A. Yes. An econometric demand model is a tool used by

25 economists to address this type of question, usually you

P.1209:

1 can think of it as consisting of two parts: The first

2 will be a characterization of the – sometimes we call it

3 the consumption choice problem. That is to say, rely

4 upon economic theory to – to develop some hypotheses or

5 relationships between demand for products and factors

6 which you could think of as affects go that demand.

7 Typically, these will be pricing, promotion behavior,

8 product attributes, behavior of competitors and so forth.

9 Having characterized that model in a

10 theoretical sense, often that can be distilled down to some

11 mathematical equations.

12 You'll, then estimate the parameters in those

13 equations using statistical techniques and actual data or

14 market outcomes.

15 Q. Did you estimate econometric demand model in this

16 case?

17 A. Yes, I did.

P. 1214, lines 16 through 24:

16 Q. Did the market analysis of other than Braintree and

17 Schwarz –

18 A. We focus on pricing in antitrust cases. I think

19 more generally economists recognize competition can take

20 the form of promoting along promotion or innovation. I

21 thought it noteworthy that in terms of marketing,

22 producers of competing laxatives apparently recognize

23 MiraLax as a competitor and responded to them by taking

24 actions in this marketed go dimension.

P. 1217, line 12 through P. 1218, line 5:

P. 1217:

12 Q. As a general matter, Professor Cockburn, is it

13 possible to draw definitive conclusions about either

14 relevant markets or monopoly power based solely on

15 similarities or differences in prices?

16 A. No.

17 Q. Why not?

18 A. Prices per se can be informative to some degree

19 about these questions but, in and of themselves, I think

20 their value is very limited.

21 On the one hand, you have to understand what
22 its determining price is in differentiating product
23 markets, it's important to recognize that prices are
24 determined by a number of factors, one of which might
25 simply be differences in the way consumers value different

P.1218:

1 characteristics of products.
2. Beyond that, I think it's a very fundamental
3 point, is that antitrust analysis recognizes that prices
4 only have meaning for antitrust purposes when considered
5 relative to the true economic marginal cost of production.

P. 1222, lines 1 through 25:

1 BY MS. MILLER:

2 Q. Would you now take a look at Exhibit 6 to your
3 report, which I believe is PTX-614? And we have a graphic
4 enhancement of it on the screen.

5 A. Yes. This displays the results of computing all
6 these prices on a daily dose basis for most of the major
7 laxative products. What you can see, if you take a look
8 on the left, for example, there are four triangles above
9 Benefiber. That indicates I considered four different
10 prices of Benefiber. I believe one of them is the orange

EXHIBIT 'A'

11 cream flavor, one is the sugar free, grit-free flavor.
12 One is, if you like the plain vanilla fiber. Buried
13 within each of those data points, I've averaged across
14 there the daily dose price, averaged across bottle size.
15 You can see, just considering Benefiber,
16 there's a considerable range of prices in which these
17 different versions of the product are sold.
18 I've done this, but for all of those, 24
19 OTC products, and two or three prescription products.
20 I've circled the results of doing this calculation for
21 MiraLax. There are two data points there, one of which
22 reflects the retail price, which is directly comparable
23 to those of the OTC products. The other is the
24 wholesale rise price, which I've included in case that's
25 helpful.

P. 1225, lines 23 through P. 1226, line 1:

P. 1225:

23 Q. Professor Cockburn, did you perform your own analysis
24 of the changes and the prices of laxative products during
25 the relevant period?

P. 1226:

1 A. Yes, I did.

P. 1227, line 14 through P. 1228, line 25:

P. 1227:

14 Q. Turning now to your regression model, are you able
15 to draw any definitive conclusions about the relevant
16 market in this case from the medical market and pricing
17 evidence you've just described?

18 A. Yes. The evidence that I talked about so far strongly
19 suggests to me as someone who studied the pharmaceutical
20 business for many years that MiraLax is one product in a
21 highly competitive market consisting of all oral laxatives
22 sold in the United States.

23 Q. And what is the basis for that?

24 A. Well, I think, you know, to summarize that the medical
25 evidence indicates that there are many products which are

P.1228:

1 therapeutic substitutes, physicians can and do prescribe a
2 range of both OTC and prescription products. All of those,
3 at the very least, should be considered candidates of the
4 substitutes. The business documents we've discussed clearly
5 indicate to me market participants viewed themselves as a big
6 part of this larger market definition.

7 And then, finally, the pricing evidence, you

8 know, which, as I said, I think it's typical to draw any
9 conclusions from per se, is nonetheless, in my view not
10 consistent with exercise of monopoly power by MiraLax.

11 Q. Please explain why you went on to do an econometric
12 demand model to determine the cross price elasticity of
13 demand.

14 A. The market for differentiated products are quite
15 complex. There are many products, many things are going
16 on at once. There are changes in prices, changes in
17 promotion, entry and exit of products with different
18 characteristics. It's very difficult to make sense of
19 what has gone on and to understand and determine the
20 prices relying solely on a simplistic descriptive analysis.

21 Circumstances such as these, economists
22 typically turn to econometric methods and a regression
23 model to attempt to isolate the impact of each of these
24 factors considered one by one, holding all the other ones
25 constant.