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Implications of the Recent Cipro Decision

Robert D. Stoner

Robert D. Stoner has expertise related to intellectual property, particularly as it relates to pharmaceuticals. He has worked on a number of cases that involve generic entry.

Recently the US Court of Appeals for the Federal Circuit upheld a 2005 District Court ruling rejecting a challenge to the lawfulness of a patent litigation settlement related to the antibiotic Cipro. The settlement involved so-called reverse cash payments from the patent holder (Bayer) to the generic manufacturer (Barr Laboratories) as part of an agreement whereby Barr postponed entry until after the patent-at-issue expired. The major question analyzed by the Court of Appeals is whether the District Court erred in holding that patent law immunizes a settlement agreement from antitrust scrutiny if any exclusionary terms are within the scope of the patent. Both antitrust agencies, the Federal Trade Commission (FTC) and the Department of Justice (DOJ), submitted amicus briefs asking for a reversal. This case is important to the balance between the antitrust and intellectual property laws.

The Appeals Court found that the settlement could only violate the antitrust laws if it affected entry beyond the patent's scope. The decision finds no evidence that happened. It notes that the patent was subsequently challenged by four other generic manufacturers, and was eventually upheld as valid.

The Appeals Court decision rejects the fundamental position of the antitrust agencies that the scope of the patent should be defined not by its nominal scope, but by the exclusionary power of the patent at the time of the settlement. The antitrust agencies view a patent as a probabilistic property right whose power to exclude is fundamentally tempered by uncertainty as to whether the patentee, if challenged, will win or lose a court judgment. By contrast, the Court of Appeals views the scope of a patent right as identical to its nominal scope unless the patent is gained by fraud or the patent infringement suit is objectively baseless. This broader definition of patent scope makes it more difficult to attack patent settlements under the federal antitrust laws.

The Appeals Court decision also addresses burden of proof. The Appeals Court, unlike the antitrust agencies, presumes a patent is valid unless the generic entrant rebuts that presumption in court. Given that presumption, if the settlement is consistent with the presumed scope of the patent, even in a reverse payments transaction, the Appeals Court finds there is nothing the antitrust laws can do.

Also In This Issue

The GAO Report on the FTC's Policy Towards Petroleum Mergers

Philip B. Nelson reviews the implications of a report by the Government Accountability Office (GAO) on the FTC's policy towards petroleum mergers. The GAO report does not recommend that the FTC adopt a stricter policy towards these mergers. That is not surprising, as the FTC historically has been particularly strict with these mergers, regardless of the party in power. Moreover, the GAO presents data that indicate that concentration in this industry is not very high and has not been increasing. The GAO's major recommendation is that the FTC conduct more regular analyses of past petroleum industry mergers. For that and several other reasons, the FTC likely will start a retrospective study of one or more oil mergers in the next year or two, even though it has already completed three such retrospective reviews.

Sampling Methodology in Merger Analysis: the Whole Foods Survey

Carol K. Miu explains that while a survey may be a valuable tool in merger analysis, any survey must be designed and executed with care to minimize sources of inaccuracies and statistical bias. She uses the recent Whole Foods case, where the Court rejected a survey, to illustrate how to avoid problems potentially involved with the use of surveys in litigation. Sampling methodology involves four steps: 1) defining the population of interest, 2) selecting a sampling frame, 3) developing a sampling method, and 4) deciding on a sample size. Errors were made during each of these steps in preparing the survey submitted in the Whole Foods case. An alternative methodology could have produced a survey that would have been of significant value to the Court.

The GAO Report on the FTC's Policy Towards Petroleum Mergers

Philip B. Nelson

This fall, the Government Accountability Office (GAO) released a 63-page report that summarizes the findings of its 19-month study of the FTC's policy towards petroleum mergers. ("Analysis of More Past Mergers Could Enhance Federal Trade Commission's Efforts to Maintain Competition in the Petroleum Industry") The study was done because members of Congress asked the GAO to examine mergers in the U.S. petroleum industry and the FTC's review of these mergers. The GAO report finds little at the FTC that deserves changing, but a few points merit some attention.

First, the GAO's major recommendation is that the FTC conduct more regular analyses of past petroleum industry mergers. As part of this recommendation, GAO recommends that the FTC employ "risk-based guidelines" that "provide criteria for taking action based on the likelihood that agency goals were not met," since this "would allow FTC to selectively use resources to evaluate past merger decisions in circumstances where it deems there is greater likelihood, and hence risk, that the goal of maintaining competition was not met." However, the GAO's guidance as to how these risk-based guidelines would work is not clear, since no mechanism for assessing risk is provided and no risk thresholds for selecting cases are identified. (The cross-reference to a similar GAO recommendation related to FERC's review of utility cross-subsidization adds little relevant detail.)

Nonetheless, there is a good chance that the FTC will start a retrospective study of one or more oil mergers in late 2009 or early 2010 (even though, as FTC Chairman Kovacic points out in his response to the GAO report, it has already completed three retrospective reviews). The recent political concerns with high oil prices, the GAO's recommendation, and recommendations from other sources, such as the American Antitrust Institute, for retrospective studies, all increase the likelihood the FTC will begin such a study after a new Chairman is appointed. In addition, the ongoing FTC self-assessment may trigger an increase in retrospective analyses. Finally, the incoming FTC Chairman probably will be grilled during the confirmation process on what will be done about the petroleum industry, likely leading to some sort of promise to undertake a study, with a review of historical petroleum mergers being a particularly likely type of study to promise.

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Second, the GAO Report contains some data that, if accurate, suggest that the FTC's policy on petroleum mergers has been more aggressive than some might think. In particular, the report contains a series of charts that report estimates of concentration levels (some of them over time) for different levels of the industry. While, as FTC Chairman Kovacic points out, "concentration is just a starting point" and the GAO's concentration statistics may be somewhat misleading because they are not based on well-defined antitrust markets, GAO's charts suggest some fundamental facts that should be recognized when considering the likely competitive effects of historical mergers in the petroleum industry:

(1) Worldwide crude production is very unconcentrated (HHI around 400) and there has not been any significant increase in concentration from 2000 to 2006.

(2) US regional refining markets vary in concentration levels, but only the San Francisco area has HHIs around 1800. (While New York is shown as also having an HHI level above 1800, the GAO Report correctly points out that this statistic is an overestimate because it ignores the significant flow of refined products into the area by pipeline, ship, and barge.) Moreover, concentration has not significantly increased in any region from 2000 to 2007.

(3) Based on state level data, wholesale gasoline concentration levels vary regionally, with only a handful of states (mostly upper Midwest and low population density states) having HHIs above 1800. Moreover, concentration has not changed much from 2000 to 2007.

Third, the report is largely silent on competition among pipelines (crude oil pipelines, natural gas pipelines, natural gas liquids pipelines, and petroleum product pipelines). The GAO indicates that this silence is largely due to the absence of

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Sampling Methodology in Merger Analysis: the Whole Foods Survey

Carol K. Miu

A survey may be a valuable tool in merger analysis, as it can shed light on consumers' likely reactions to price increases, the core issue in market definition. A survey used in litigation, however, must be designed and executed with care, to minimize sources of inaccuracies and statistical bias. In FTC v. Whole Foods, US District Court Judge Paul Friedman decided against giving "any weight or consideration" to the survey submitted by Whole Foods' expert. The judge relied on the FTC's expert, who argued that the methodological flaws of the survey rendered the data and results unreliable.

A better sampling plan would have eliminated many of the problems. Sampling methodology involves four steps: 1) defining the population of interest, 2) selecting a sampling frame, 3) developing a sampling method, and 4) deciding on a sample size.

The first step in sampling is to define the population of interest to which survey results will later be generalized. The correct population of interest would have been all current customers of the merging parties, Whole Foods and Wild Oats, because these are all of the identifiable individuals who will be affected by the merger. (While future customers would also be affected by the merger, it is difficult to reliably ascertain whether someone who is not a current customer will be a future customer.)

However, Whole Foods' expert mistakenly defined two populations: "Frequent" and "Cusp" shoppers at Whole Foods or Wild Oats. Frequent shoppers visited Whole Foods or Wild Oats at least once per month, while Cusp respondents ranged from shopping a few times a year to having shopped at least once or twice at Whole Foods or Wild Oats. Then in generalizing her results to all current Whole Foods and Wild Oats customers, she erroneously gave the two customer groups equal weight, even though that likely would not be representative of the population of interest.

The sampling frame is the list of individuals or households that corresponds to the population of interest. Examples include a public telephone directory, a list of Fortune 500 executives, or all individuals over the age of 18 who shopped at the Pentagon City Mall between the hours of 10 AM and 9:30 PM on Friday, July 25, 2008. The last type of sampling frame is known as the mall intercept or "convenience" sample.

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Academic and commercial marketing researchers seldom use convenience samples, for fear that the data collected from a small number of respondents at a particular location and time are biased and cannot be extrapolated to the population of interest, which is often the general population of all American consumers. However, when the population of interest is Whole Foods and Wild Oats customers, store-intercept data may be extrapolated to a universe of customers of those two particular grocery retailers, as long as steps are taken to minimize systematic bias. In particular, store locations should be selected randomly and days of the week and times of the day for data collection should be varied.

Whole Foods' expert selected a random-digit dialing (RDD) sampling frame. RDD call centers are equipped to randomly dial telephone numbers from a list generated according to certain selection specifications, such as ZIP code, telephone exchange code (the 3 digits that follow the area code in a telephone number), or telephone company. The problem with RDD in this case is that the population of interest (current Whole Foods and Wild Oats customers) is very small compared to the sampling frame (every household in the RDD database in the selected ZIP codes). Surveyors made 427,397 phone calls to find 25,011 Whole Foods or Wild Oats customers, only 1,607 of whom ultimately completed the interview. Using RDD for this type of study may be an inordinately expensive approach.

The Whole Foods survey was based on eight metropolitan areas. Because these areas were non-randomly selected, there is no statistical basis to generalize from these areas to

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EI News and Notes

FCC Hearing on Broadband Technology

Scott J. Wallsten participated on a panel titled "The Broadband of Tomorrow," during an FCC hearing on "Broadband and the Digital Future." Dr. Wallsten compared broadband investment in the United States to investment in other OECD countries. The U.S. data show rapid broadband adoption and improving performance. Dr. Wallsten argued that proposed regulations should be subject to cost-benefit tests. He also suggested that the Government should collect more data on broadband. Finally, he proposed evaluating the many current programs intended to promote broadband to learn what works and what does not before considering new programs.

FLSA Class Decertified After Trial

A federal judge in New Orleans granted national retailer Big Lots' motion to decertify a Fair Labor Standards Act (FLSA) collective action. Approximately 1,000 opt-in plaintiffs alleged that Big Lots misclassified them as exempt from the overtime provisions of the FLSA. At trial, plaintiffs relied on a mail survey. EI President Jonathan L. Walker testified on behalf of Big Lots that the survey was statistically biased in plaintiffs' favor yet still tended to refute the plaintiffs' contentions when tabulated properly and taken at face value.

Jury Finds For ATP Tour, Inc. In Antitrust Suit

ATP Tour, Inc. (ATP) operates the leading international men's professional tennis tour. The operators of a tournament in Hamburg, Germany that is part of the ATP Tour sued ATP to block ATP's restructuring. ATP intended to reclassify the Hamburg event within the Tour as part of a broader effort to respond to market demand. The plaintiffs alleged violations of the Sherman Act. EI President Jonathan L. Walker testified that the ATP and its member tournaments operated as a single entity and that the ATP had no market power.

GAO Report

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data. For this reason, the silence on pipeline competition should not be taken as a sign that the FTC will not be aggressively investigating mergers between petroleum companies that involve pipeline overlaps. To the contrary, there is every reason to believe that the FTC will continue to break out detailed pipeline maps to figure out what transportation options exist for moving petroleum products out of or into particular areas. In particular, with the potential expansion of exploration efforts in the deepwater portions of the Gulf where there are fewer pipeline options, the FTC likely will seriously review mergers that combine pipelines that overlap in these areas (or are particularly well-positioned to expand into these deepwater areas).

Finally, the GAO reports that the FTC "has said publicly that it scrutinizes mergers in the energy industry more closely than those in any other industry." This comment, which aligns with data-based studies of FTC merger investigations, should be taken seriously. The FTC has historically been subjected to tighter Congressional oversight with respect to the petroleum industry than any other industry. Moreover, the career FTC staff members who work on these mergers have historically been dedicated enforcers who have reviewed mergers in this industry quite carefully. Even under President Reagan, the FTC intervened in petroleum mergers (e.g., Mobil's attempt to acquire Marathon led the FTC to vote out a complaint). As a result, while a new administration may look somewhat harder at the industry, the fundamental standards are unlikely to change significantly, since these standards have historically been quite tough under both Republican and Democratic administrations. Only extreme political pressure from Congress would pose a serious risk that the FTC might abandon its long-standing analytical approach to petroleum industry investigations.

Sampling Methodology

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all Whole Foods and Wild Oats stores. The areas should have been selected from a random sample, or a stratified random sample based on criteria such as geographic region, consumer demographics, and presence of Whole Foods and Wild Oats.

Moreover, even within the eight areas, the survey sampled potential respondents non-randomly because it had quotas of Frequent and Cusp customers. Additionally, the survey violated the sampling methodology by collecting RDD data from respondents outside of the specified ZIP codes. While store-intercept studies can have potentially serious drawbacks and should be performed with extreme caution, a carefully-executed store-intercept study likely would have yielded better results than a poorly performed RDD study in the Whole Foods case.

Researchers should carefully choose a sample size, taking into account available resources and potential response rates. The final number of responses must be large enough to allow statistical inferences. If a pilot test indicates that response rate is likely to be unacceptably low, a different sampling frame or sampling method should be considered.

The survey collected 1,607 responses from a sample size of 25,011 eligible customers, for a comparatively low response rate of 6%; 94% refused the survey. That low response rate makes it probable that survey respondents were not representative of the entire population of Whole Foods and Wild Oats customers. Thus, the results are likely tainted by non-response bias.

Although Judge Friedman excluded the Whole Foods survey from consideration, surveys have the potential to provide valuable information in litigation, especially in antitrust and consumer protection. Unfortunately survey data are often discounted because of the numerous sources of potential bias. Before attempting to conduct a survey, researchers must understand how to design surveys that will be defensible and to identify issues such as biased sampling procedures, problems with questionnaire design and administration, omitted control variables, and improper interpretation of results.

The United States Court of Appeals has since overturned the District Court's decision to deny a preliminary injunction to block the merger. The Court of Appeals based its decision on the argument that Whole Foods and Wild Oats cater to a submarket of core customers who the Court believes would not switch to traditional supermarkets even in the event of a small but significant non-transitory increase in price. A properly performed survey could have shed light on many pertinent issues in this case, including the share of Whole Foods and Wild Oats who are core customers and the shopping and switching behaviors of those consumers.

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