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Antitrust and Trade Regulation Bulletin

2003-04-17

FTC and Bristol-Myers Squibb Settle Generic Blocking Dispute

The FTC has sought to increase competition by generic equivalents to branded drugs by challenging the practices of certain branded drug manufacturers. The FTC's claims arise out of alleged manipulation of the Hatch-Waxman Act, which was designed to aid generic entry, but which the FTC believes also has been manipulated to prevent it. Under the Hatch-Waxman Act, branded drug makers must submit certain information about the patents covering FDA-approved drugs for publication in the "Orange Book." Once a drug and its patents are listed in that book, any company seeking to manufacture a generic version must represent to the FDA that the listed patents are either invalid or not infringed by the proposed generic, and must provide notice to the branded manufacturer. The branded manufacturer then makes a determination whether to file a patent infringement suit to block generic entry. If the branded manufacturer sues the generic, the law grants an automatic stay that prevents the generic drug from being sold for 30 months, unless the infringement suit is resolved in favor of the generic prior to that time. Adding patents to the Orange Book and suing generic manufacturers, therefore, has the potential to result in lengthy delays to generic sales.

The FTC complaint against Bristol-Myers Squibb (BMS), manufacturer of the cancer drugs Taxol and Platinol and the anti-anxiety drug BuSpar, accused BMS of abusing the Hatch-Waxman process and illegally preventing generic competition to all three drugs. The FTC alleged that BMS listed patents in the Orange Book that did not qualify for listing and then brought baseless patent infringement suits for the purpose of obtaining the 30-month stay against generic entry. With respect to BuSpar, the FTC further alleged that BMS reached agreement with a generic manufacturer and paid that company to keep its product off the market.

BMS settled the FTC suit in March, agreeing that after a generic firm applies to the FDA for generic approval, BMS will not add any additional patents to its listed patents in the Orange Book pertaining to that drug. Based on its investigation, the FTC concluded that these so-called later-filed patents generally had the least merit and were most likely to be illegal blocks to generic entry. BMS may still sue a generic firm and obtain an injunction to block entry when it can meet the standards for a federal injunction. Separately, BMS settled with various states' attorneys general for a cash payment.

Agencies Challenge Three Mergers

In October 2002, the Department of Justice opposed the proposed merger between Hughes and Echostar, a transaction between two satellite television vendors that had been awaiting HSR clearance for nearly a year. In December, Hughes and Echostar abandoned the transaction. Also in October, the Federal Trade Commission decided to block the owner of the Vlasic pickle company from acquiring the Claussen pickle company. In March, 2003, the Federal Trade Commission authorized an injunction to prevent Häagen-Dazs (owned by Nestle) from acquiring Dryer's Grand Ice

Cream. The parties have proposed a divestiture settlement to the FTC. The FTC is evaluating the proposal as this bulletin goes to press.

Hughes and Echostar operate DirecTV and the Dish Network, respectively. The companies argued that together they would be better able to compete with incumbent cable systems in much of the United States. DOJ disagreed, concluding that in rural areas without cable television, DirecTV and the Dish Network were the only two providers of multi-channel video programming distribution and that in those geographic markets the merger would create a monopoly. Even in urban areas, the combination, DOJ asserted, would reduce the relevant players from three to two and further concentrate an already highly concentrated market. The competition between DirecTV and the Dish Network allegedly was intense, resulting in a variety of consumer benefits that would be lost in the event of a merger.

Claussen and Vlasic are the two largest firms selling refrigerated pickles. In addition, Vlasic sells shelf-stable pickles. The FTC concluded that there was a unique rivalry between the two companies in the refrigerated pickle arena and that Vlasic's shelf-stable pickles constrained the price of Claussen's refrigerated pickles. Finding that the two firms together would have a monopoly share of the refrigerated pickle market, the FTC unanimously agreed that it should sue to enjoin the transaction.

In the Häagen-Dazs–Dryers Grand Ice Cream matter, the FTC asserted that there was a separate market for "super premium" ice cream, which included only three companies—Häagen-Dazs, Ben & Jerry's and Dryer's (specifically their Dreamery, Godiva and Starbucks brands). The FTC concluded that the move from three competitors to two would harm competition and further concentrate an already concentrated super premium ice cream market.

This narrow ice cream market definition—super premium ice cream—most clearly demonstrates how market definition can be outcome determinative. Presumably, if the FTC had accepted a market that included all ice cream, the proposed merger would not have meaningfully reduced competition in that market. Even a "premium" ice cream market definition presumably would not have resulted in a conclusion that the proposed merger was anticompetitive. To be sure, the parties argued for a broader market definition, but that proposed market definition will be tested only if the parties decide to proceed to trial.

DOJ Settles Gun-Jumping Allegations with Substantial Fine

Parties to merger agreements cannot integrate their business functions prior to the expiration of the Hart-Scott-Rodino waiting period and the closing of the transaction. This means that the companies that have been competing must remain competitors while a government review proceeds. Back in October1999, Gemstar and TV Guide agreed to merge and filed their HSR forms promptly. The DOJ investigated the merger but ultimately closed the review without action in July 2000. The two firms subsequently merged with no restrictions whatsoever.

In February 2003, the DOJ filed a complaint against Gemstar and TV Guide, alleging that they had begun integrating their operations and ceased competing with each other (commonly called "gun-jumping"), even before they entered into a formal merger agreement. Allegedly, the two companies allocated customers and markets and agreed on prices from some time prior to the formal agreement, up until the consummation of the merger. To settle this complaint, Gemstar agreed to pay the maximum allowable fine of $11,000 per day for each day each company was alleged to be in violation, a sum totaling $5.67 million. In addition, Gemstar is required to allow customers who entered into contracts with either company during the period of the alleged violation to rescind their contracts if they choose.

While large fines in gun-jumping cases are not unique, this is the first such case brought against firms that were allowed to merge with no restrictions. The DOJ approved the Gemstar/TV Guide merger exactly as structured by the parties, ultimately agreeing that it was acceptable for them to combine as one entity. Nevertheless, because they had allegedly acted in that manner prior to the conclusion of the HSR waiting period, the Department alleged that the companies violated the HSR Act as well as Section 1 of the Sherman Act. The decision by the Department to sue Gemstar long after the transaction closed suggests the DOJ is making a statement and wants to be heard. Parties preparing to merge should carefully monitor their integration activities to ensure they continue to compete until the merger review ends and the transaction finally closes.

R. Hewitt Pate, Acting Assistant Attorney General for Antitrust, Speaks Out

After Charles James resigned last fall as the Assistant Attorney General for the Antitrust Division of the Department of Justice, the President appointed R. Hewitt Pate to serve as the Acting Assistant Attorney General for Antitrust on an interim basis. In March 2003, the President nominated Pate to fill that role permanently. Recently, Pate was interviewed and spoke at a conference; his remarks provide some insight into the current climate at the DOJ.

Companies that integrate their operations prior to approval of a formal merger are commonly said to have “jumped the gun.” Prior to his departure, James had told the antitrust bar that the DOJ intended to issue some "guidance" on the subject of gun-jumping. On his watch, the Division brought and settled a gun-jumping case against Computer Associates. (An article on that decision can be found in the July 2002 edition of the Antitrust and Trade Regulation Bulletin. Pate indicated that such "guidance" would continue, and suggested it would take the form of speeches and appearances rather than formal written guidance. In addition, Pate suggested that companies and practitioners watch the enforcement actions the DOJ takes. (Shortly after publication of the interview, the DOJ announced a new gun-jumping settlement reported above).

Another continuation of a James initiative is called the Merger Review Process Initiative—an attempt to speed-up and streamline the merger review process at the DOJ by making the best possible use of the first thirty-day waiting period. Pate deemed the initiative a great success and said he is aware of several circumstances in which the parties and the DOJ effectively worked together to focus early on the most significant issues and reduce the burdens associated with the merger review process. Pate cautioned, however, that in order to obtain the benefits the initiative offers, merging parties must recognize that the DOJ will help the parties only when the parties are also willing to assist the DOJ in the conduct of the review. In other words, there must be some give-and-take.

In January, Pate spoke at an intellectual property law conference in Florida. While he acknowledged a tension between antitrust and intellectual property rights, he expressed his view that the conflict is often exaggerated and that the two areas of law are aligned in promoting innovation and consumer welfare. Pate spoke of the recent DOJ/FTC hearings on the intersection of intellectual property law and antitrust law, acknowledging that there remained considerable disputes in a number of areas. Pate suggested the hard issues would be best solved by reforms initiated by the intellectual property community rather than by increased antitrust enforcement that limits intellectual property rights.

Alleged Abuse of Standard Setting Process Generates Controversy on Numerous Other Topics

In June 2002, the Federal Trade Commission sued Rambus, Inc. after a Virginia jury determined that Rambus defrauded Infineon Technologies by failing to disclose Rambus' patents to Infineon (and others) during a standard setting process. The FTC alleged that Rambus participated in the JEDEC Solid State Technology Association's standard setting process with the knowledge that the standard under consideration included technology Rambus believed was claimed by its patents. After adoption of the standard, Rambus brought infringement suits against Infineon and others that incorporated the standard. The FTC's case against Rambus already has included some unusual elements.

By way of background, when the U.S. District Court upheld the jury's fraud verdict, it also awarded Infineon attorneys' fees for what the court found to be serious litigation misconduct by Rambus. In particular, the court concluded that Rambus intentionally had destroyed presumably harmful documents (related to the standard setting process) after it had threatened suit and knew litigation was likely. While Rambus appealed the Virginia fraud finding to the Federal Circuit, it did not appeal the award of attorneys' fees nor challenge the finding of litigation misconduct and document destruction. After bringing its own complaint against Rambus, the FTC moved for a default judgment because the document destruction allegedly impaired the FTC's case. However, while the FTC's motion was pending, the Federal Circuit reversed much of the lower court's fraud ruling. The

Administrative Law Judge (ALJ) for the FTC proceeding thereafter denied the FTC's request for default judgment, finding the less drastic remedy of drawing adverse inferences (rebuttable presumptions) against Rambus sufficient. Unless Rambus rebuts these presumptions, the FTC is almost certain to prevail on the merits.

At the same time, the ALJ found that the crime-fraud exception to the attorney-client privilege barred Rambus from withholding documents exchanged with its attorneys after it withdrew from the standard setting organization. Rambus alleged that documents created after its exit from the standard setting process were not relevant, but the ALJ disagreed because, after the withdrawal, Rambus continued to hold and apply for additional disputed patents. Such an exception to the attorney-client privilege is quite unusual. It is not yet clear whether Rambus will produce the disputed documents or seek to overturn the ALJ decision.

As a further complication, the Department of Justice has convened a grand jury to investigate price fixing in the industry that adopted the standard. Rambus alleges such price fixing and claims that its competitors are conspiring to exclude it from the market. Accordingly, in the FTC litigation, Rambus has issued subpoenas to industry members, seeking documents each supplied to and received from the grand jury. The DOJ has intervened to block discovery of grand jury materials.

Yet another Rambus FTC subpoena has generated controversy. Rambus issued a subpoena to a United States subsidiary of Mitsubishi Electric, seeking documents from the parent company in Japan. The subsidiary objected, arguing that it had no legal right to the documents sought from its parent and, therefore, could not be forced by subpoena to supply them. The ALJ determined that because the parent and subsidiary had exchanged documents on the subject at issue in the ordinary course of business, the subsidiary had the ability to obtain the parent's documents and should produce them. Shortly thereafter, the parent refused to produce the documents, arguing that the subpoena (which sought sixty-three different categories of documents) was overly broad and unduly burdensome.

In a final twist, the original ALJ retired in January and has been replaced by an ALJ new to the FTC. The administrative trial had been scheduled for April 2003.

FTC Adopts Changes to Merger Review Process

Having heard the antitrust bar complain for years about the unnecessary burdens the standard instructions a Request for Additional Information (commonly called a second request) impose, the FTC convened a series of meetings to solicit suggestions for reducing these burdens. Near the close of 2002, the FTC published "guidelines for merger investigations," incorporating many of the changes urged by the private bar. These changes should reduce some of the burdens associated with second requests and merger review in general.

Longstanding FTC policy had prevented a deponent (in the course of a merger review) from obtaining his deposition transcript.Instead, the FTC would allow a transcript to be provided only if and when it filed suit to challenge the merger. Under the new policy, any deponent may purchase a deposition transcript directly from the court reporter.

Other changes include:

- eliminating the requirement that documents be sorted by subject matter (a time consuming and mechanically difficult task);

- minimizing the number of a person’s files that must be searched more than once;
- encouraging electronic production when possible in specified file formats;
- possibly limiting email searches, including shortened time periods for lower level employees (such as only one year); and
- possibly limiting production from archives and electronic back-up systems.

The efficacy of these measures will depend upon the FTC staff’s willingness to agree to modifications in particular instances. The guidelines should, however, give practitioners and their clients some added help in seeking particular types of modifications and burden reductions.

For more information, contact Hale and Dorr’s Antitrust and Trade Regulation Group.

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