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Overview

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Antitrust developments stemming from the agencies and private litigants have continued without abate in the United States. We provide a brief review of developments in several areas: the Federal Trade Commission's (FTC) first published statement of principles regarding its use of Section 5 related to unfair competition; important activity in the health-care industry; and the ever-evolving status of reverse payment settlements in the pharmaceutical industry.

FTC Section 5 Statement

Section 5 of the Federal Trade Commission Act declares unlawful unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. On 13 August 2015, the FTC issued a Statement of Enforcement Principles related to the unfair methods of competition part of Section 5. This is the FTC's first policy guidance on this subject since its establishment over 100 years ago. The Statement explains that Section 5's prohibition of unfair methods of competition encompasses conduct that does not violate these Acts but instead contravenes their spirit and could, if allowed to continue, grow into violations of these Acts. The Statement provides a framework for the FTC's exercise of its 'stand-alone' Section 5 authority related to anti-competitive practices.

The Statement is less than a page long and details three enforcement principles for the FTC:

- decisions will be 'guided by the public policy underlying the antitrust laws, namely, the promotion of consumer welfare';
- the analytical framework will be 'similar to the rule of reason', that is, an act or practice challenged by the Commission must cause, or be likely to cause, harm to competition or the competition process, taking into account cognisable efficiencies and business justifications; and
- Section 5 is less likely to be used on a stand-alone basis if the conduct can be addressed via the Sherman or Clayton Acts.

The statement leaves many questions unanswered, such as how the framework similar to 'the rule of reason' will be structured, how efficiencies will be evaluated given the focus on consumer welfare, and under what conditions the FTC would opt to use Section 5 on a stand-alone basis when conduct could be challenged under the Sherman or Clayton Acts. The FTC has brought several stand-alone Section 5 cases alleging unfair business practices in recent years. For example, it has brought cases related to trade association by-laws or ethics rules that restrict association members from competing with each other. It has also brought stand-alone Section 5 cases related to conduct that could be challenged under the Sherman or Clayton Acts. An example is the FTC's 2012 complaint against McWane and Star Pipe Products that alleged conspiratorial conduct and monopolisation via exclusionary conduct. This case was brought solely under Section 5 even though conspiracy and monopolisation are typically challenged using the Sherman Act. How the Statement of Enforcement Principles will change the standard used by the FTC to evaluate cases and the statutory authority it uses to challenge conduct will only become clear over time due to the limited guidance provided by the Statement itself.

Health care and antitrust

A continuing area of interest for the Department of Justice and FTC has been enforcement in the health-care industry. The industry has been undergoing substantial change in the US, with growth in Accountable Care Organizations, the purchase of physician practices by hospitals and industry mergers. Health care represents about 18 per cent of the US economy, and maintaining competition as the industry undergoes change is a priority. The agencies held workshops in February to study issues in the industry and have been active with investigations in the areas of pharmaceutical, health insurer and hospital mergers. Other examples of agency actions in the industry are the FTC's recent litigation regarding a merger in the sterilisation industry and the Department of Justice's case related to territorial allocation by hospitals in Michigan.

In February, the Supreme Court decided *North Carolina State Board of Dental Examiners v Federal Trade Commission*. The FTC had challenged under Section 5 of the FTC Act actions taken by the Board of

Dental Examiners to stop non-dentists from offering teeth-whitening services in North Carolina. The Board was established to license practising dentists, and after dentists complained that non-dentists were offering teeth-whitening services at lower prices, it issued orders to these providers that they stop offering these services. The Supreme Court ruled that the Board was not actively supervised by the State of North Carolina and so was not granted immunity from federal antitrust law, and therefore its actions to inhibit competition could be challenged by the FTC. Restrictions on competition from professional licensing boards sponsored by states are now an area of increasing antitrust review.

Reverse payment settlements

The US Supreme Court's *Actavis* decision in 2013 found that settlements of patent infringement litigations in the pharmaceutical industry that include a payment from a brand to a potential generic entrant may be anti-competitive. In particular, the Court rejected a 'scope of the patent test' developed and applied in some courts that essentially said so long as a settlement did not expand the scope of a patent, it was not anti-competitive. Instead, *Actavis* found that reverse payment settlements are to be evaluated under a rule-of-reason analysis and that courts should consider factors such as whether the payment was large and unjustified. However, the Supreme Court largely left it to the lower courts to work out the details of this analysis.

Questions persist, such as whether *Actavis* strictly applies to settlements with cash payments only, whether payments greater than avoided litigation costs are large and unjustified, and how promises by a branded manufacturer to not launch an authorised generic (no-AG clauses) should be treated. Furthermore, at least one court has dismissed antitrust claims because plaintiffs did not sufficiently value non-cash payments involved in the settlement, and thus failed to meet pleadings requirements in its view. At the start of 2015, 14 reverse payment litigations were underway, and developments in some of these matters shed at least some light on key outstanding questions.

In the *Nexium* matter brought by a private class, in the first trial following *Actavis*, a jury found that the reverse payment was large and unjustified, and that the settlement was anti-competitive. Importantly, the alleged payment included a no-AG clause. However, in a somewhat surprising decision, the jury did not find that in the absence of the anti-competitive settlement, the brand and the potential generic would have agreed an earlier launch for the generic (therefore benefiting consumers). Therefore, the jury did not find that this anti-competitive settlement caused overcharges alleged by the plaintiff. In August 2015, in an introspective decision, the judge denied plaintiffs' motions for a new trial.

The FTC settled the *Cephalon* matter in May 2015 in the FTC's first settlement of a reverse payment antitrust case following *Actavis*. In the settlement, the FTC secured US$1.2 billion for purchasers who allegedly overpaid for a blockbuster drug in what was effectively a disgorgement payment by the brand. Interestingly, in an ongoing restriction, the settlement also bars Teva (who now owns Cephalon) from entering into any business deal within 30 days of settling a patent litigation that limits generic entry. The FTC has also continued to argue in several venues that a reverse payment should not be limited strictly to cash payments.

Finally, in its *King Drug* decision, the 3rd Circuit became the first appellate court to address several issues post-*Actavis*. The court found that a no-AG clause can be subject to antitrust scrutiny. The court also set forth a potential path for conducting a rule of reason analysis. First, the plaintiff must demonstrate a payment (which can be non-cash) was made to prevent the risk of competition from the generic. Next, the defendants have the burden of demonstrating that the payments are justified. Finally, the plaintiff can rebut the justifications offered.

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Henry J Kahwaty is a managing director in Berkeley Research Group's Washington, DC office and head of BRG's antitrust and competition policy practice. His areas of expertise include microeconomics, industrial organisation, antitrust economics and econometrics. He has completed antitrust reviews of mergers and horizontal and vertical contractual arrangements, and studies of monopolisation and abuse of dominance in the context of government investigations and private litigation. His merger work includes studies in metals, solid and hazardous waste, industrial products, avionics and pharmaceuticals. He has analysed competition issues in industries including mining, luxury goods, banking, chemicals and diamonds. He has completed studies of vertical restraints and vertical integration, and the impact of such vertical relationships on competition. His work also includes analysis of merger efficiencies, price-fixing allegations, class certification, and competition damages.

Dr Kahwaty has presented analyses to the US Department of Justice, the Federal Trade Commission, the Directorate-General for Competition of the European Commission, the Canadian Competition Bureau, the Competition Tribunal of Canada and other agencies. He has prepared studies for the Competition Authority in Ireland. He started his career as an economist with the US Department of Justice, where he specialised in market power analysis for merger and monopolisation cases with a focus on the computer software, banking, manufacturing, and defence industries. He spent 15 years as an economist, principal and director with LECG in both Washington, DC and London. He received his PhD in economics from the University of Pennsylvania in 1991.

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Cleve B Tyler is a director in Berkeley Research Group's Washington, DC office. He has analysed competition, intellectual property and damages issues in matters before federal and state courts, administrative law judges and regulatory commissions, and in merger investigations. Dr Tyler has testified at deposition and trial in federal court regarding damages issues. He has developed or analysed damages models in a range of industries pertaining to various allegations including patent infringement, antitrust, breach of contract and fraud. His work includes evaluation of market definition and competitive effects using regression analysis and economic modelling. He has evaluated horizontal and vertical competition issues in many industries including waste collection and disposal, pharmaceuticals, insurance, avionics, video games, automobile components, home appliances, software, and food and beverages. Dr Tyler has evaluated the antitrust implications of reverse payment settlements between branded and generic pharmaceutical companies under Hatch-Waxman regulations. He also has analysed competition and regulation in the electric industry, including issues related to electric power sales, forward sales, derivative trading, entry conditions and capacity payments.

Dr Tyler holds a PhD in economics from Clemson University specialising in industrial organisation, finance and public sector economics. He is an adjunct professor of Economics at Johns Hopkins University, has published papers and made presentations on competition and damages issues, and is the editor of the *BRG Review*. Dr Tyler is a member of the American Economic Association (AEA) and American Bar Association (ABA).

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