Top 10 Antitrust Developments and Trends to Watch in 2016

Attention in the US during 2016 will be on the presidential campaign, and the election in November will bring a change in the "antitrust guard" at the top of the DOJ and FTC – even if a Democrat wins – that will drive the direction of antitrust enforcement in years to come.

With that change on the horizon, we offer insights on what to expect on the antitrust enforcement agenda during 2016.

Election year politics and antitrust

In 2008, then-presidential candidate Barack Obama pledged to "reinvigorate antitrust enforcement" and "step up review of merger activity." While there is some debate about whether President Obama fulfilled this promise, since he took office both the DOJ and FTC have challenged a number of transactions, and have garnered high-profile courtroom victories like FTC v. Sysco Corporation and US v. Bazaarvoice.

Antitrust has again attracted the spotlight in 2016. Democrats often promise more interventionist antitrust agendas, as President Obama did, and this year is no exception. Hillary Clinton has targeted what she deems lax antitrust enforcement, promising that, if elected, she will "beef up the enforcement arms" of the DOJ and FTC, including hiring "aggressive regulators who will conduct in-depth industry research to better understand the link between market consolidation and stagnating incomes."

Likewise, Bernie Sanders has encouraged antitrust investigations and introduced legislation to curb increasing generic drug prices.

Focus on pharmaceutical pricing

Pharmaceutical pricing will be under heavy fire in 2016, as investigations by both the DOJ and FTC in this space have exploded. The attack on the industry is bipartisan as

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Presidential candidate Donald Trump has called price increases in the industry "disgusting" and Marco Rubio has attacked what he has said is "pure profiteering." While unilateral pricing behavior is not subject to antitrust attack, the agencies are likely to push the envelope.

DOJ continues to expand its ongoing probes of generic drug pricing, with Mylan joining the list of companies that have disclosed receipt of a subpoena, which includes Allergan, Eli Lilly, Impax, Lannett, Par, and Valeant.

Both the House and Senate are focused on drug pricing, with the Senate Select Committee on Aging holding a hearing and sending inquiries to Retrophin, Rodelis, Turing, and Valeant. In November, the Democrats on the House Oversight and Government Reform Committee launched an Affordable Drug Pricing Task Force and also seek hearings on Turing and Valeant. The Connecticut and New York Attorneys General and the Department of Health and Human Services are conducting investigations as well.

Close scrutiny of conduct at the expiration of pharmaceutical patent life

The FTC, state attorneys general, and private plaintiffs continue to aggressively litigate conduct by pharmaceutical
companies at the expiration of patent life.

"Reverse payment" challenges have proliferated in the wake of the Supreme Court's FTC v. Actavis decision. The Third Circuit in King Drug v. Smithkline Beecham held that antitrust challenges can reach more than cash payments, including other forms of consideration, likely encouraging even more government and private suits.

The FTC settled its long-standing suit challenging alleged reverse payments against Cephalon for $1.2 billion, highlighting the agency's increasing proclivity to seek significant monetary relief.

The so-called "product hopping" arena witnessed its first appellate decision in New York v. Actavis. The Second Circuit upheld an injunction requiring Actavis to continue to make available an older drug until generic entry, after introducing a new version of the drug, to facilitate generic competition. In Mylan v. Warner-Chilcott, on appeal before the Third Circuit, the lower court took a dimmer view of antitrust challenges to product hopping. A decision is likely in 2016, and if the lower court decision is upheld the circuit split could be ripe for Supreme Court review.

Claims of abuse of REMS (Risk Evaluation and Mitigation Strategies) to exclude generics by withholding drug samples continue as well. In Mylan v. Celgene the N.J. District Court appeared amenable to the claim, denying a motion to dismiss, while in Natco v. Gilead the court dismissed the action because the plaintiff failed to follow the protocols to obtain a sample.

Mergers fly high on the antitrust radar in 2016

Bolstered by big wins in 2015, expect the DOJ and FTC to continue to focus on mergers – with particular focus on high tech and pharma deals – and to bring enforcement actions based on narrow market definitions.

DOJ investigations resulted in parties abandoning major acquisitions, including Comcast/Time Warner Cable, Applied Materials/Tokyo Electron, GE/Electrolux, and Bumble Bee/Chicken of the Sea, after incurring huge expenses and paying large break-up fees.

In a notable court victory, the FTC successfully enjoined the proposed Sysco/US Foods combination after an eight-day hearing. The DC District Court agreed with the FTC's "broadline foodservice distribution" market, defeating the parties’ argument that the FTC's market was based on an unrepresentative sample of subjective customer preferences. This decision and other enforcement actions portend a continued focus on narrow market segments impacting select customers.

SEPs and FRAND commitments: the battle continues

Litigation over royalties for standard essential patents (SEPs) runs rampant as courts wrangle with the meaning of fair, reasonable, and non-discriminatory (FRAND) terms and whether SEP holders with FRAND commitments are entitled to seek injunctive relief. Further litigation is likely in 2016 in the wake of the Ninth Circuit’s Microsoft v. Motorola decision.

That dispute involved cross-claims by Microsoft for breach of FRAND obligations and by Motorola to enjoin Microsoft from infringement. To establish the FRAND rate, the lower court employed a modified Georgia-Pacific methodology – the traditional framework for calculating royalty rates – by removing factors it deemed contrary to non-discriminatory licensure, leading to a royalty rate far smaller than that sought by Motorola.

In 2015, the Ninth Circuit affirmed, emphasizing the risk of patent hold-up by SEP holders and suggesting that FRAND royalties based on end product calculations are inappropriate, absent proof that both the SEP and the standard itself relate to the functionality of the end product. With that decision arguably at odds with the Federal Circuit's decision in Ericsson v. D-Link, the debate will continue on how to properly calculate FRAND terms, whether a SEP patentee must substantiate accusations of patent hold up and royalty stacking before such concerns can be a factor in determining a FRAND rate, and whether a patent owner subject to FRAND commitments is precluded from enjoining a willing licensee.

Forthcoming FTC report on patent assertion entities

For the past two years, the FTC has been studying patent assertion entities (PAEs), defined by the FTC as "firms with a business model based primarily on buying patents and then attempting to generate revenue by asserting them against businesses that are already practicing the patented technologies."
The FTC issued requests for information from 25 PAEs across various industries, and 15 non-practicing entities and firms in the wireless chipset sector. Though the study covers multiple industries, the FTC is specifically targeting the wireless industry because of the intensity of patent assertion claims in that sector. The FTC’s report, expected in early 2016, may influence court decisions and legislation involving PAEs.

**Rise of disgorgement as antitrust remedy**

The upcoming year will likely see additional demands by the DOJ and FTC for disgorgement of allegedly "ill-gotten gains" from anticompetitive conduct.

*Disgorgement* is increasingly used as an enforcement tool by the antitrust agencies. In 2015 the FTC settled a pharmaceutical monopolization case against Cardinal Health, obtaining a $26.8 million disgorgement, and the "reverse payment" case discussed above against Cephalon for $1.2 billion in disgorgement. These settlements are the two largest disgorgement penalties in FTC history.

Meanwhile the DOJ reached a settlement with a "hop-on, hop-off" bus tour company in New York City, including a $7.5 million disgorgement. This is the first time – but likely not the last – the government obtained disgorgement in a consummated merger.

**New FTC chief technologist foreshadows continued scrutiny of technology industries**

Scrutiny of technology industries by both the competition and consumer protection bureaus of the FTC is likely in 2016, with a focus on privacy, big data, data security, geolocation, mobile, and the internet of things. FTC Chairwoman Edith Ramirez recently highlighted that "[t]echnology is playing an ever more important role in consumers’ lives, whether through mobile devices, personal fitness trackers, or the increasing array of internet-connected devices."

The appointment of Lorrie Cranor as the FTC’s new Chief Technologist, starting this month, highlights this persistent attention to the industry, especially in the areas of privacy and data security, as Cranor previously directed the CyLab Usable Privacy and Security Laboratory at Carnegie Mellon University and has authored over 150 research papers on online privacy and security.

**Trend towards stiffer criminal penalties against price fixing continues**

The DOJ continues to obtain outsized *criminal penalties* for antitrust violations. The FY 2014 record-breaking total of nearly $1.3 billion was surpassed only five months into 2015 when five banks pled guilty to conspiring to manipulate foreign exchange markets, paying more than $2.5 billion in criminal fines.

Also notable in 2015 was the DOJ’s focus on enforcing criminal antitrust laws in the tech industry, including electrolytic capacitors and an e-commerce executive for allegedly using algorithm-based software to fix prices.

The DOJ also continues to prosecute individual wrongdoers, charging 66 individuals in FY 2015, up from 44 in FY 2014, while the average prison sentence of 24 months in 2010-2015 has increased by a factor of three since the 1990s.

Individual prosecutions will continue in 2016, consistent with the so-called Yates Memo, the September memorandum from Deputy Attorney General Sally Yates which details DOJ policy to target individual wrongdoers involved in corporate misconduct, underscoring the importance of effective compliance programs.

**EU/China as centers of antitrust enforcement**

2016 is likely to bring a series of significant European Commission (EC) actions in the high tech sector as the EC is expected to issue decisions in long running cases in the online commerce and mobile communications sectors, with a focus on infrastructure and inputs (such as semiconductors and operating systems) and content delivery to consumers through the internet (such as search results, e-books and pay-TV content).

In 2015, the EC launched an expansive inquiry into the Digital Single Market, assessing use of the internet for the sale of goods and services. A significant aim is to break down barriers to cross-border trade within the EU, for example by firms imposing restrictions or creating technical barriers on resellers selling outside designated EU territories. Technical barriers through "geo-blocking" (practices that block access to certain websites based on the user’s location) are also the subject of a separate inquiry. Preliminary results of the inquiry are expected this year and could result in the EC taking enforcement action against
individual firms or recommending industry-wide legislative changes.

The impact of antitrust enforcement is also increasingly felt in Asia – in particular China. Last year, the Chinese Ministry of Commerce (MOFCOM) received more merger notifications than in any previous year. MOFCOM's eight years of experience enforcing the Anti-Monopoly Law will be reflected in updated rules on the notification and review of mergers. These changes should result in shorter merger review periods – a welcome development in a jurisdiction where reviews have often taken longer than elsewhere.

MOFCOM is also likely to step up its enforcement action against firms that do not notify mergers meeting the Chinese thresholds. In September 2015, MOFCOM announced four decisions fining companies for implementing transactions without receiving prior approval.

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