

Pharmaceuticals in the USA

What impact will the new administration have on antitrust enforcement?

by **Robert F Leibenluft and Eric J Stock***

Counsellors for pharmaceutical companies will be forgiven for thinking that their industry has received more than its fair share of antitrust attention over the past several years. During the Bush administration, the Federal Trade Commission (FTC) made challenges to conduct in the pharmaceutical industry one of its highest priorities, especially with respect to what are known as “reverse payment” patent settlements between brand name and generic pharmaceutical companies. Further, across the Atlantic, the European Commission began a broad sector inquiry into various practices in the pharmaceutical industry. But just when one may have thought that the antitrust scrutiny could not be any greater, the US election and its aftermath indicate that the enforcement attention faced by the pharmaceutical industry is only likely to escalate.

There are several reasons that the level of antitrust enforcement attention paid to the pharmaceutical industry is likely to continue – or even increase – over the next several years. These include: (1) the elevation to FTC chairman of the commissioner most focused on competition in the pharmaceutical industry; (2) the appointment of new, more aggressive, leadership at the Department of Justice (DoJ); (3) priorities and enforcement philosophies at the antitrust agencies that are likely to lead to new cases being brought against allegedly dominant firms; and (4) an economic environment that leaves the healthcare industry with the appearance, at least, of being one of the most profitable and least fragile areas of the economy. While we can hope that this congruence of events does not result in a “perfect storm,” there certainly are grounds for at least a tropical storm warning regarding future pharmaceutical antitrust enforcement.

New leadership

The most vocal proponent of aggressive antitrust enforcement in the pharmaceutical industry has been Commissioner Jon Leibowitz. Now that he has been appointed FTC chairman, Leibowitz’s views will only gain more prominence. In pursuit of an active healthcare agenda, he has appointed as director of the FTC Bureau of Competition Rich Feinstein, a former head of the health and pharmaceutical division who spearheaded the initial FTC reverse payment challenges in the late 1990s. Given President Obama’s public pronouncements supporting aggressive antitrust enforcement, his next two appointments to the FTC, which are expected imminently, can be expected to support Leibowitz’s enforcement outlook.

The changes at the DoJ are even more dramatic, although the effects on the pharmaceutical industry will be less direct due to the DoJ’s customary deference to the FTC in policing the industry. With the appointment of Christine Varney as assistant attorney general (AAG) in charge of the DoJ’s antitrust division, the FTC has a partner whose views are likely to be similar to those of the FTC. In fact, the DoJ under Varney recently filed

an amicus brief that moves the DoJ’s position on patent settlements closer to the FTC’s, and withdrew a report issued by the DoJ in the prior administration that would have led to decreased enforcement against single-firm conduct. Because of the DoJ’s role in advocating before the Supreme Court, submitting amicus briefs to lower courts and investigating criminal wrongdoing, the new DoJ enforcement philosophy is likely to contribute to increased antitrust enforcement in the pharmaceutical industry.

Patent settlements

One area that is sure to receive continued attention is the issue of reverse payment patent settlements. These settlements arise where a branded pharmaceutical company has sued a generic manufacturer for patent infringement, and the parties agree to settle the matter with terms providing, among other things, that: (1) the generic manufacturer will not enter the market for a period (for example, a few months or years prior to expiration of the key patents); and (2) the branded manufacturer will provide consideration to the generic manufacturer, perhaps as part of a side deal involving a separate co-promotion or licensing transaction. The FTC argues that such transactions harm competition because, in its view, one can presume that without the consideration provided to the generic manufacturer (sometimes called a “reverse payment” because ordinarily a settlement involves payment from the defendant to the plaintiff), the parties would have agreed to an earlier compromise date for generic entry.

Branded manufacturers typically contend that it is improper for the FTC to presume that a reverse payment settlement harms competition because such a settlement merely excludes a generic product that may be infringing and thus unlawful. Following this reasoning, it is typically argued that in the absence of proof that the branded manufacturer’s patent case was weak or frivolous, there is no harm to competition. In a series of district court and appellate rulings over the past few years, the courts have largely accepted these arguments and dismissed antitrust challenges to patent settlements.

These judicial setbacks have made it more difficult for the FTC to pursue its agenda against reverse payment patent settlements but, nonetheless, the agency is continuing – indeed, accelerating – those efforts. The FTC recently brought two new cases challenging patent settlements, and has been vocal in attempting to create more favourable judicial precedent, potentially leading to Supreme Court review. In its new cases, the FTC has continued to press its position that the reverse payment should be presumed unlawful irrespective of the likely outcome of the underlying patent litigation, but has also expressed a willingness to present evidence on this issue if necessary. The FTC has also come out in support of a bill pending in Congress that would make the settlements in

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question per se illegal. The recent DoJ amicus brief endorsing the FTC's position on reverse payment settlements can only further embolden the FTC's enforcement efforts in this area.

Mergers and acquisitions

The FTC also can be expected to review carefully mergers and acquisitions in the pharmaceutical industry. Indeed, recent enforcement activity suggests that the FTC will investigate and consider challenges to M&A transactions in a variety of circumstances, and under a wide range of legal theories.

For example, the FTC pursued a co-ordinated effects theory in challenging the proposed merger of CSL Ltd and Talecris Biotherapeutics. The FTC did not allege that the proposed transaction would create a firm with monopoly power, but rather that prior transactions in the market had created an oligopoly that the proposed transaction threatened to entrench further. Faced with a court challenge brought by the FTC, the parties abandoned the merger in June of this year.

A concurring statement by Commissioner Leibowitz in a case brought against Ovation Pharmaceuticals illustrates his willingness to pursue novel theories of anticompetitive harm. In that case, the FTC challenged the acquisition by Ovation of the rights to a drug named NeoProfen in a non-reportable transaction. The FTC alleged that Ovation's acquisition of NeoProfen, which treated the same condition as its product Indocin, allowed Ovation to insulate Indocin from future competition and raise prices. In Commissioner Leibowitz's concurring statement, he endorsed the challenge to the NeoProfen acquisition, but also stated that he would have challenged Ovation's original acquisition of Indocin from Merck. The theory – which was put forward by Commissioner Rosch – was that the transfer of Indocin to Ovation harmed competition not because of any overlap between the parties' products, but rather because Ovation was less sensitive to reputational concerns than Merck and thus was more likely to raise prices post-acquisition.

In addition to these transactions, the FTC has also extensively reviewed larger transactions such as Pfizer / Wyeth and Merck / Schering-Plough. Clearly, in the new administration, the FTC will be prepared to investigate and consider challenges to pharmaceutical M&A transactions of all types, whether large or small, consummated or unconsummated, reportable or unreportable. Additionally, as evidenced by his statement in the Ovation matter, Commissioner Leibowitz can be expected to lead the Federal Trade Commission towards pursuing novel theories of competitive harm that prior FTC leadership may have treated with more scepticism.

Unilateral conduct

All signs also point to increased interest by the antitrust agencies in challenging unilateral conduct by allegedly dominant firms. Under the prior administration, "monopolisation" enforcement activity by the DoJ was virtually non-existent, but AAG Varney has repeatedly emphasised her intention to bring cases in this area. Chairman Leibowitz has also expressed his interest in pursuing single-firm conduct, including the use of challenges under section 5 of the FTC Act (which prohibits unfair or deceptive practices) to encompass conduct that might otherwise be outside the scope of a conventional antitrust case. Ironically,

the fact that the healthcare industry is one of the few bright spots in the economy may make pharmaceutical companies a more tempting target for antitrust enforcers sensitive to the fragility of other industries.

One possible area to watch is for a potential challenge based on the product switching theory. "Product switching" takes place when a branded manufacturer develops a follow-on drug for a drug nearing patent expiration, and seeks to convert patients to the new drug. One effect of this strategy is that the market opportunity available to those seeking to sell generic substitutes of the drug going off-patent is significantly reduced. Some plaintiffs have attempted to base antitrust claims on such conduct where the follow-on product is allegedly no better than the original product (and thus the only purpose of the new product is allegedly to "interfere" with generic competition).

While the FTC has not brought a case directly based on the product switching theory, private plaintiffs have in at least two instances, one of which survived a motion to dismiss. In the case that was dismissed at the pleading stage – a challenge to AstraZeneca's introduction of Nexium, replacing its blockbuster Prilosec – the court dismissed the case because AstraZeneca had continued to sell Prilosec. The court found that there could be no antitrust liability merely for introducing a new product to the market, and deferred to the marketplace to determine if Nexium were superior to Prilosec. In the case that survived a motion to dismiss, the defendant was alleged to have withdrawn its prior product from the market. This suggests that while there is obviously no obligation to continue selling outdated products, continuing to do so might be persuasive in obtaining an early dismissal of claims brought based on this theory.

Protecting generic competition is one of the FTC's highest priorities, and the FTC has recognised the desire of pharmaceutical companies to product switch in other cases – even if it has not alleged that the switch itself constituted an antitrust violation. Enforcement activity in this area, therefore, is a real possibility.

Other issues

The antitrust agencies are also studying a variety of other issues that may impact on the way that pharmaceutical companies do business. The FTC recently released an interim report on authorised generics, and also addressed the feasibility of a regulatory pathway for follow-on biologics. Additional work on these and others issues is sure to follow.

Conclusion

In sum, like death and taxes, increased antitrust scrutiny into the pharmaceutical industry during the Obama administration is inevitable. This attention will certainly involve aggressive action against reverse payment patent settlements, but will also be felt in other areas, such as investigations of M&A transactions. Antitrust counsellors for pharmaceutical manufacturers will want to scrutinise carefully, in particular, any transactions entered into by their companies that have potential to impact on generic competition. Moreover, counsellors should expect even unilateral business practices – especially those with the potential to delay or reduce the threat of generic competition – to be under increased scrutiny by the agencies as well.