Would Have, Could Have, Should Have: **An Antitrust Tragedy in Three Parts**

Michael McFalls and Frances Murphy at Jones Day examine the outcomes of the final report of the Pharmaceutical Sector Inquiry, comparing it to antitrust challenges in the US, and predict what this could mean for the future

In July 2009, the European Commission issued its final report on the Pharmaceutical Sector Inquiry, describing a variety of routine commercial practices by innovative pharmaceutical and biotechnology companies which have allegedly prevented generic products from entering member state markets as soon as the Commission staff believed they should have. Although the Commission gave an obligatory nod to intellectual property rights, there is no doubt that the report betrayed an overwhelming preference by the Commission and its staff for enforcement actions that aimed to maximise the degree of generic entry and minimise the amount of time that branded pharmaceutical companies have to prevent generic companies from appropriating their inventions and investments.

For US readers, the report was not surprising in any respect, but this was not due to the conventional expectation that European competition law would be more restrictive than US antitrust law. Rather, the predictability of the report was due to the experience of the pharmaceutical and biotechnology industry with the broad-based and unprecedented assault on almost every aspect of these businesses by the Federal Trade Commission (FTC), state attorneys general and the private plaintiffs bar. The only arguable surprise was that the European Commission took so long to become active in an area that has witnessed – and in some ways precipitated – a revolution in how the US agencies, particularly the FTC, have approached the enforcement of antitrust law.

WOULD HAVE: THE ANTITRUST REVOLUTIONARY CONSENSUS OF THE 1980s AND 1990s

Perhaps this current attack on the pharmaceutical industry should be deemed a counter-revolution, not a revolution. After all, it represents an attempt to pull antitrust law back from a fundamental recognition in the 1980s – a revolution of its own at the time – that antitrust analysis must begin with a competitive benchmark for determining whether a transaction or practice has harmed, or is likely to harm, competition. That benchmark is the level of competition in the 'but-for' world – the world that would have existed in the absence of the transaction or practice. This is by no means a static definition – the Supreme Court had made clear in the 1970s that the but-for world is the reasonably predictable future that would exist in the absence of the practice under review. Though this mode of analysis is dynamic and predictive, the focus is on the probable, not the possible.

Nowhere did this revolution have a greater impact than in the analysis of intellectual property licensing agreements. After years of defeats in the federal courts, the agencies finally recognised that a number of their operating presumptions about intellectual property and licensing were not only wrong, but were genuinely harmful to the high-technology economy that was beginning to emerge with full force in the US. Traditionally, the agencies had assumed that a patent conferred market power; the courts began to point out that such presumptions were unfounded. Traditionally, the agencies viewed limits on licensees as anti-competitive; the courts explained that even monopolists could refuse to license, so licensing itself is pro-competitive, and essentially a vertical transaction even when occurring between competitors. Traditionally, agencies and even some courts had viewed patenting and patent litigation with some suspicion; in 1993, the Supreme Court made it clear that litigation and other forms

of government petitioning enjoyed significant latitude under the antitrust law, even if undertaken with the intent to obtain or maintain monopoly power.

The agencies officially recognised these principles in the widely applauded Antitrust Guidelines for the Licensing of Intellectual Property in 1995. They also articulated standards for challenging mergers involving the technology and innovation markets. Although these cases were based on novel theories of competitive harm and expansive notions of potential competition, they remained tethered to the new analytical rigour required by courts in determining whether transactions would reduce competition below levels that would exist in their absence. Instead of shying away from the necessity of establishing likely anti-competitive effects, the agencies used a mix of traditional evidence (such as documents) and new methods (principally economic tools) to challenge transactions and conduct. The courts rewarded the discipline of the agencies in a series of merger and non-merger cases, including the Antitrust Division's challenge to Microsoft.

COULD HAVE: A CRUSADE AGAINST THE PHARMACEUTICAL INDUSTRY?

In the late 1990s, however, the FTC became alarmed by litigation settlement agreements that began to arise under the Hatch-Waxman pharmaceutical litigation framework. The Hatch-Waxman system encourages challenges by potential generic entrants to patents covering pharmaceutical products by providing 180 days of exclusivity to the first generic firms that file certifications, asserting that the branded company's patent is invalid or would not be infringed by the generic drug. If the branded firm responds to this assertion with a lawsuit, it can obtain an automatic 30-month injunction against generic entry while the parties litigate. Over time, settlement agreements inevitably emerged. Although there were significant differences among some of these agreements, they generally shared two common terms: the branded firm conveyed to the generic challenger compensation in some form; the generic challengers agreed to defer entry for a period of time, or, in some cases, until patent expiration.

Applying the new analytical approach to these agreements proved difficult. What was the proper competitive benchmark that could be used to determine whether such agreements harmed competition? What was the but-for world? There are plenty of possibilities: the settling generic firm could prevail in the litigation; the generic firm could launch at risk even before prevailing; even if these firms settle, other firms might prevail in their Hatch-Waxman challenges; the branded firm could win. But what was the most likely outcome?

Instead of wrestling with these critical factual and legal questions, the FTC decided that it did not need to deal with them at all. In Schering-Plough, the FTC held that settlements of Hatch-Waxman litigation that provided the generic firm any compensation in excess of its legal costs would be unlawful. This is tantamount to holding that the only possibility in the but-for world would be a litigation victory by the generic firm, transforming a patent from a presumptive right to exclude into a meaningless hurdle to generic entry. Thus, even if a generic firm had only a 10 per cent likelihood of winning the patent litigation, the FTC would find unlawful any settlement whereby the generic firm received compensation in excess of litigation costs. This falls far short of any reasonable legal standard that would require an agency to show evidence that an agreement would reduce competition levels. If accepted by the courts, this position would permit the FTC (and any other plaintiff) to prevail, merely by showing that, in the absence of the agreement, a more competitive outcome could have resulted.

The Eleventh Circuit agreed that the FTC had gone too far in Schering-Plough, holding that settlements that did not result in exclusion beyond the potential scope of the patents at issue would have legal effect unless the underlying patent claim was so weak as to be 'objectively baseless'. Because that standard is extremely hard to satisfy, such settlements would, for all practical purposes, be lawful. Other courts – including the circuit that reviews almost all patent cases – followed suit, essentially holding that settlements that do not exclude entry beyond the scope of patents are *per se* legal, as long as the patent claim is not a sham.

SHOULD HAVE: BEYOND SETTLEMENTS TO OTHER PRACTICES

Despite repeated attempts to interest the Supreme Court in the settlement cases, the FTC has failed to make any headway on these issues in the appellate courts. Now that the new Antitrust Division has agreed with the FTC's approach to these cases, the appellate courts may become more interested, but neither the FTC nor private plaintiffs will wait for them to reverse the tide.

In addition to its attempts to obtain legislation prohibiting settlements, the FTC has continued to challenge a variety of settlements in federal courts. This is seen as a transparent attempt to deprive pharmaceutical companies of their ability to choose their federal appellate court after administrative litigation and to create a split among the federal appellate courts that would prompt the Supreme Court to act. The variety of settlements and broader legal doctrines at issue have also taken the FTC into realms where only private plaintiffs would previously go. Among the areas of interest to the FTC, states and private plaintiffs are:

'Restrictions' on Licensees

The FTC has taken the position that even settlements authorising entry prior to patent expiration are unlawful when the generic company receives significant compensation. The

flawed premise of this theory is that the parties could have settled with an earlier entry date in the absence of compensation, and indeed, that they should have. True in many cases, perhaps, but legally irrelevant since courts have long held that licensors are not required to maximise competition when licensing their intellectual property.

Exclusive Authorised Generics Agreements

The FTC has noted its objection to provisions in settlement agreements in which the branded firm promises the generic firm that it will not authorise another generic company to enter. Again, the premise of the objection must be that the parties could have settled without the restriction. But the courts have stated that patent holders can exercise their intellectual property rights by choosing to license only a single firm, just as a consumer products firm can appoint an exclusive distributor.

Citizen's Petitions

Plaintiffs have complained that petitions from branded pharmaceutical companies to the FDA have excluded or impaired generic entry. Even if this is true, the right to petition is constitutionally protected and can only be challenged and enjoined under extreme circumstances. Moreover, the FDA, the recipient of petitions, can modify its procedures to make petitioning more efficient and has recently done so.

Refusals to Deal

Some have challenged the core right of patentholders to refuse to license their intellectual property or sell patented products. In the US, there is no question that firms, even monopolists, have no obligation to begin dealing with firms which would like to use that relationship to compete. Forcing firms to deal with potential generic competitors would contravene fundamental principles of patent and antitrust law.

Product Improvements

It is no secret that branded firms frequently introduce line extensions designed to extend the lifecycle of a basic compound. Because these improvements are often covered by patents, they can extend the life cycle of a basic branded product for additional time. The FTC, following the lead of private plaintiffs, has been investigating whether some of these product changes are sufficiently innovative for the product to enjoy extended protection. Again, this takes the FTC into areas that have been the exclusive province of the Patent & Trademark Office and FDA.

We should not forget, moreover, that every one of these challenges is premised on the assumptions that a single branded pharmaceutical product is a relevant product market, and the branded firm is a monopolist. All of these enforcement positions go well beyond even the aggressive enforcement policies of the Clinton administration. It is as if the FTC has taken all of the learning and wisdom that had accumulated from years of enforcement and analysis in the field and thrown them overboard, choosing presumptions over careful analysis.

At this juncture, it is no exaggeration to say that the agency is acting well outside the Sherman Act. Instead of reexamining its legal theories, however, the FTC has increasingly resorted to its nebulous authority to prevent 'unfair methods of competition' under Section 5 of the Federal Trade Commission Act. This section allows the agency to use its administrative expertise in evaluating and challenging novel or complex practices. But none of the practices identified above can be called novel in any meaningful sense, and neither the conduct nor the theories necessary to challenge it could be called complex. Although Section 5 permits the Commission to go beyond the Sherman Act, courts still exercise appellate review, and have not hesitated to impose serious limitations on the Commission's authority to use Section 5 where the Commission would otherwise fail to prevail in a challenge under the Sherman Act. In fact, the DC Circuit recently did just that in a case involving the alleged misuse of patent rights outside the pharmaceutical industry, reminding the FTC that it has an obligation to determine what would have happened in the absence of the conduct it challenged, not just what could have happened. Ironically, the FTC may end up back where it started before the antitrust revolution of the 1980s, when the agency was under attack from the courts and elsewhere as hopelessly doctrinaire and far behind the developments in economics and law that the Commission was intended to lead.

THE EUROPEAN TRANSLATION

From a European perspective, the final report of the European Commission on its Pharmaceutical Sector Inquiry makes clear that it is interested in investigating the same conduct that has attracted the interest of government enforcers and private litigants in the US. This comes as no surprise. The sector investigation was borne out of a case by the European Commission against AstraZeneca, in which the European Commission, while expressly maintaining that it was following the American model, uniquely found AstraZeneca to have been abusing an alleged monopoly by misusing the patent system. The European Commission, inherently suspicious of the pharmaceutical sector and the basis upon which intellectual property rights are secured and then used, embarked on its 'no holds barred' investigation of the pharmaceutical sector to convey a message – that its mission is to root out and sanction anything the Commission deems to be a misuse of an intellectual property right, be it the means by which a patent is obtained, licences granted, litigation commenced or litigation settled. Because of significant procedural differences between the EU and US legal systems, it is far more likely that the European Commission could pursue a successful enforcement agenda against the pharmaceutical and biotechnology industries. Compared to the US enforcement agencies, the European Commission faces significantly fewer judicial constraints. Moreover, the quality and quantity of evidence required to show anticompetitive effects have traditionally been lower in the EU than in the US, and the European Commission's approach in AstraZeneca shows just how low those thresholds are. Demonstrably, the European Commission considers that the US is leaps and bounds ahead of it on matters such as patent fraud and settlement arrangements, and is desperate to catch up. The AstraZeneca case shows that the European Commission is perfectly prepared to point to the

approach taken in the US in an endeavour to justify its actions and in this connection to put its own spin on what the legal position in the US actually is.

This is an extremely worrying development which, unless checked by the European Courts, will see European law sanctioning conduct that the US has expressly not gone as far as sanctioning. However, the EU courts, like the US courts, do take the rights of firms to litigate, petition and patent seriously, so there are likely to be some limits on the actions that the European Commission will ultimately succeed in taking. Because there are significant differences between the jurisdictions with respect to pharmaceutical patent litigation, it is possible that the Commission will not see many agreements similar to those that have arisen from the Hatch-Waxman framework. Finally, one can always remain optimistic that the Commission, unlike its US counterparts, will realise that requiring firms to maximise competition against themselves is inconsistent with long-standing patent policy and sound antitrust thinking. However, its approach towards AstraZeneca and its final report of its Pharmaceutical Sector Inquiry suggest that such optimism would be misplaced.

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