PATENT FILE

Is antitrust law best way to deal with pharma costs?


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Erica J Pascal and **Steven Levitsky** question whether settlements reached with the FTC are the best way of resolving antitrust charges against Cephalon

Pay-for-delay has been in the consciousness of the pharmaceutical industry and government agencies for some time. It hit the headlines in 2013, when the Supreme Court of the US ruled in *Federal Trade Commission (FTC) v Actavis*,[1] that a rule of reason analysis should apply to antitrust claims involving the terms reached between branded and generic firms on entry of the generic drug into the marketplace.

Since the 2013 ruling, courts have continued to evolve the law in what constitutes antitrust behavior in the pay-for-delay arena – examining cash payments, settlement of additional lawsuits, promises to refrain from launching an authorised generic and negotiated dates for generic drug entry, among others. One of the most recent events is the 48-state settlement of the Cephalon Provigil case, announced in August 2016, which centered around so-called "pay-for-delay" or "reverse payments" involved in the agreements concerning generic entry of the drug.

The background

As you will see, the story is quite convoluted and goes back 15 years. The case involves the drug Provigil, used to treat sleep disorders including narcolepsy, obstructive sleep apnea and shift work disorder. Cephalon's original Provigil patent expired in 2001. Cephalon obtained a second patent, expiring in 2015, but this one covered only a smaller particle size of the drug, not the chemical structure or its formulation. The smaller particle size allegedly produced better therapeutic results, but Cephalon knew that potential generic entrants could design around the particle-size protection.

In 2002, four generic companies (Ranbaxy Pharmaceuticals, Mylan Pharmaceuticals, Barr Laboratories, and Teva Pharmaceutical Industries,) filed abbreviated new drug applications with the FDA on the first possible day. (According to the FTC, three of them camped out in the FDA's parking lot overnight.) The generic firms challenged the patent covering Cephalon's drug, and it appeared that these four companies could have their generics on the market by 2006.

In 2003, Cephalon sued all four potential entrants, claiming patent infringement. In response, the generics then challenged the patent's validity. The lawsuit triggered an automatic stay of the FDA's approval of the generics until June 2006. By 2005, the generics had received tentative FDA approval for their generic entries, leading to an expected 2006 entry. At that point, Cephalon entered into settlement agreements with the four generic drug makers.

The settlement agreements resolved the patent litigations and set 2012 for launch of the generic versions (unless another generic entered sooner). Additionally, separate agreements provided for payments from Cephalon to the generic drug makers, totaling $200m, structured as supply contracts, co-development, and licences for intellectual property. According to the FTC, this settlement, which preserved Provigil's patent protection for six more years, yielded about $4bn in sales that would have been diluted by generic entry.

Meanwhile, on a separate front in 2006, Apotex filed against Cephalon claiming antitrust violations as well as allegations that the patent was invalid and unenforceable. Consumer groups also sued that year.

The FTC then began an investigation of its own, and started litigation against Cephalon in 2008. At that time, the FTC sought only injunctive relief to speed generic entry. It disavowed any claim of monetary damages.[2]

In 2011, the court granted Apotex' claim that the Cephalon's particle-size patent was invalid. It also found that Cephalon's inequitable conduct in procuring the patent barred its attempts to enforce the patent.

While these developments were taking place in Apotex, the FTC's own case was placed on hold because of the *Activis* case, which was then working its way up to the Supreme Court. That case was decided in 2013 and, generally, held that (1) antitrust law's Rule of Reason applied to pay-for-delay cases; and (2) that a defendant's "scope-of-the-patent" claims were not a defence to pay for delay, because a patent "may or may not be valid".

By the time of the *Activis* ruling, generic entry in Cephalon's market had already occurred, so the FTC's claims for injunctive relief seemed irrelevant. At that point, five years after it filed its complaint, the FTC changed its sought-after relief, now retroactively seeking "disgorgement" for 2007 to 2012. Cephalon tried to strike the FTC's disgorgement claim, but the court denied that motion on 15 April 2015. The FTC submitted expert testimony that Cephalon's "ill-gotten gains" amounted to between $3.5bn to $5.6bn and sought "disgorgement". The parties settled two and a half months later.

Given the reverse-payments embedded in the settlement terms, Cephalon did not have much on which to distinguish its circumstances from *Activis*. Moreover, at the time it was settling with the FTC, its patent had been held invalid and unenforceable. However, this is a view with the benefit of hindsight. In 2005-2006, when the settlement agreements occurred, at least two Federal Courts of Appeal had rejected pay-for-delay claims. In *Schering-Plough Corp v FTC*,[3] the Eleventh Circuit reversed the district court and concluded that a "prohibition on reverse-

payment settlements would 'reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.'" That same year, in *In re Tamoxifen Citrate Antitrust Litigation*,[4] the Second Circuit reached a similar conclusion, citing *Schering-Plough*. Also, in the timeframe of the settlement between Cephalon and the generics, the patent was still valid and enforceable. The retroactive application of the law – here, resulting in a $1.2bn settlement – creates a dangerous lack of predictability.

The funds were then made available to private plaintiffs in related cases, including a $512m settlement with direct purchasers. Trial on the FTC's case had been scheduled to start 1 June 2015, but the parties reached a settlement on 28 May 2015. August's settlement with the 48 states also comes from the $1.2bn FTC settlement fund. Under the settlement, Cephalon additionally agreed to restrict future settlement terms of Hatch-Waxman cases.

We express no opinion on the merits of this case. But we do ask whether the antitrust laws are the best way to deal with highly political, consumer-oriented issues like pharmaceutical costs, especially when antitrust and Hatch-Waxman may be philosophically contrary.

We also think the following elements are relevant:

- The only statute the FTC named in its complaint was Section 5 of the FTC Act, that allows the FTC to sue over "unfair methods of competition". The FTC's use of this vague provision has been widely criticised. In contrast, the Department of Justice must use either section 1 of the Sherman Act (that condemns unreasonable restraints of trade) or section 2 (that condemns monopolisation). It may be that the FTC could have prevailed on either of these traditional antitrust claims. But instead it chooses (controversially) not to invoke either section of the Sherman Act.
- The $1.2bn fund (from which the 48-state settlement will be paid) was the result of a settlement with the FTC. Some commentators have argued that the government could never have achieved the same result in court under existing law. Yet, this consent decree will undoubtedly be used as a model in future litigation. The important question is whether the antitrust agencies should be able to shape antitrust law by fiat (by coercing settlements), rather than earning changes in the law that are ruled on by the courts.
- Although the claims were structured as depriving consumers of entitled savings, the settlement provides for residual funds of the settlement to go, not to consumers, but to the Federal and state treasuries.
- In light of the highly-publicised, 48-state settlement dated 28 July 2016, with state attorneys general extolling their "consumer protection" efforts, you may wonder when those states actually filed their complaints. The answer is 4 August 2016. In other words, the states joined the case more than one full year *after* the FTC had obtained the $1.2bn in relief (which also funds these state settlements). The states essentially contributed nothing.

"A claim of this size virtually demands settlement – regardless of the merits of the case. This comes close to coercion."

Rule of law – or toss of the dice?

The irony in this area is that these agreements were made when, at least in some jurisdictions, courts did not hold those terms as anti-competitive. Yet, years have passed and penalties are being imposed retroactively.

Predictability (or the use of precedent) is supposed to be one of the goals of law, especially business law, so that it can guide future behaviour. That is why many international agreements prefer US and UK law, because of its reliance on precedent. Frederick Schauer, a well-known law professor, wrote (somewhat enigmatically, it is true):

> "An argument from precedent seems at first to look backward... But… an argument from precedent looks forward as well, asking us to view today's decision as a precedent for tomorrow's decision-makers. Today is not only yesterday's tomorrow; it is also tomorrow's yesterday."[5]

In less poetic and more concrete terms, the Supreme Court of the US wrote:

> "A penalty should be reasonably predictable in its severity, so that even Justice Holmes's 'bad man' can look ahead with some ability to know what the stakes are in choosing one course of action or another."[6]

Summary

Some might say that Cephalon suffered no injustice under its settlement with the FTC, based on the court's 2011 finding that the patent was invalid. But in 2008, when the FTC brought suit, the patent still carried its entitlement to a presumption of validity, and case law provided holdings that these types of settlements were legal.

Moreover, when the FTC could no longer obtain injunctive relief, because generic entry had already occurred, it succeeded in adding a retroactive "disgorgement" claim that its own expert estimated at between $3.5bn to $5.6bn. A claim of this size virtually demands settlement – regardless of the merits of the case. This comes close to coercion.[7]

When a federal agency obtains a settlement in this manner, and then uses this settlement model as a basis for future claims, the agency itself makes the law, not the courts. This precedent is not what antitrust law or American business needs or deserves. It defies predictability. Addressing decade-old agreements with ever-evolving mores is not a forward-looking means of answering present and future healthcare costs. For what may be "blessed" by the FTC now, may look very different to the agency 10 years down the road.

Footnotes

1. 133 S Ct 2223 (2013).
2. In 2010, the FTC stated, "The FTC, throughout this case, has been seeking to open up that market sooner. We're not seeking damages; we don't have the authority to do that. We're not seeking any kind of monetary relief. We're only seeking an injunction." (Tr of proceedings on 22 Apr 2010).
3. 402 F3d 1056 (11th Cir 2005).
4. 429 F3d 370 (2d Cir 2005).
5. Frederick Schauer, Precedent, 39 Stanford Law Review, 571, 572-73 (1987).
6. *Exxon Shipping Co v Baker,* 554 US 471, 502 (2008) (citing See The Path of the Law, 10 Harv. L.Rev. 457, 459 (1897).
7. The two US antitrust agencies are often able to get their desired result simply by threatening lawsuits that very few commercial enterprises are willing to consider. (This occurs especially in merger control cases.)

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