Lopping three years off a patent to settle litigation doesn’t seem like the kind of strategy investors would applaud. But in December 2005, when Cephalon Inc. announced that as part of an agreement with four generic drugmakers it would shorten the lifespan of its best-selling drug Provigil, the pharmaceutical company’s stock price soared more than 70 percent. The move meant that Cephalon would forgo potential sales of $1–$2 billion. In return, the company gained assurance that it could market Provigil, a sleep disorder drug, for six more years—without litigation.

Cephalon could not afford to lose its monopoly on Provigil. In 2002, when the generic companies first challenged the patent on the drug’s main ingredient, Provigil accounted for close to two-thirds of Cephalon’s sales. In 2005 the drug brought in nearly half of Cephalon’s $1.2 billion in revenue. Cephalon is teeing up a next-generation drug called Nuvigil as a replacement, but that drug hasn’t received FDA approval, and would hit the markets this summer, at the earliest. The settlement gives the Frazer, Pennsylvania–based company breathing room: Nuvigil should be on the market well before 2011, when Provigil’s patent protection expires. (Protection was originally set to end in 2014.)

Cephalon’s settlement signals a seismic shift in the way pharma companies handle patent suits. In
the past, some branded drug companies disposed of these cases with "reverse payments"—giving generic drugmakers cash to delay a product’s launch. But in 2002 the Federal Trade Commission declared these deals anticompetitive, and the percentage of settled lawsuits between branded and generic companies fell from 38 percent to 22 percent between 2002 and 2005, according to a study by Paragraph IV, a drug industry trade publication. But two recent rulings in federal appeals courts have thrown the FTC’s stance into uncertainty. 

And pharma companies, comforted by these cases, are getting back in the ring. Like Cephalon, they’re taking a kinder, gentler approach to settlements—agreeing to shorten the lifespan of disputed patents. In the past few months, Wyeth Pharmaceuticals, Forest Laboratories Inc., and Shire Pharmaceuticals have all gone this route. Gregory Glass, who edits Paragraph IV, says it’s a smart move, since the FTC is still keeping a close watch on these settlements. If a branded company agrees to early entry by its generic rivals, the FTC will find it harder to argue that the deal is anticompetitive, he says.

Settling these cases is particularly important for mid-cap companies like Cephalon. “A large company like Pfizer can afford to fight on one or two products until the end,” says Cephalon’s general counsel, John Osborn. “But with the litigation, we were carrying a significant amount of risk and uncertainty coming into 2006. That level of risk concerns investors.”

Still, it took nearly three years of litigation to remove that risk, including almost 100 days of depositions and hundreds of thousands of pages of document production, says David Bassett, one of three Wilmer Cutler Pickering Hale and Dorr partners who worked on the case for Cephalon. That was just discovery—they were nowhere near trial, he says.

The litigation might have been arduous, but Cephalon knew that it was coming. Contesting a lucrative drug is business as usual for generics, who, if successful, win a 180-day exclusivity period during which other generic companies are blocked from marketing it. The question was: How many generics would go after Provigil? As it happened, four—Teva Pharmaceuticals USA, Inc., Mylan Pharmaceuticals Inc., Ranbaxy Pharmaceuticals Inc., and Barr Laboratories, Inc.—sought federal approval to market a generic. In their filings with the FDA, Teva and Mylan, represented by Kenyon & Kenyon and Rothwell, Figg, Ernst & Manbeck, respectively, claimed that Cephalon’s patent was invalid; while Ranbaxy and Barr, represented by Knobbe, Martens, Olson & Bear and Winston & Strawn, claimed their product would not infringe Cephalon’s patent. None of the four generic companies or their lawyers would comment for this article.

Four generic drugmakers were gunning for Cephalon’s patent on Provigil. To fend off the threat, the company agreed to chop a few years off its patent—the drugmakers’ stock soared.

Osborn called on William Lee, whom Osborn knew from his days as an associate at Hale and Dorr in the 1980s. Lee brought in Bassett and his partner Peter Kolovos, and, along with Osborn, and Cephalon’s chief patent counsel, Robert Hrubiec, they sued all four drug companies in federal district court in Newark.

Cephalon announced the lawsuit on March 31, 2003. Almost immediately, the company’s stock—which had traded as high as $78 a share—sank to $37, where it languished over the next two years. As late as November 2005, industry analysts were issuing gloomy forecasts. Settlement prospects looked grim. The FTC’s stance on reverse payments made it “exponentially more difficult to settle,” Bassett says.

The turning point came on August 29, 2005, when the U.S. Court of Appeals for the Eleventh Circuit ruled, in Schering-Plough v. FTC, that reverse payments were not always anticompetitive. “The judge chided the FTC, saying you can’t just apply a blanket rule in anticompetitive analysis, but have to look at all the factors,” says Glass. The FTC took another hit in November, when the U.S. Court of Appeals for the Second Circuit upheld a dismissal of antitrust lawsuits against AstraZeneca PLC and Barr Pharmaceuticals, Inc., over a 1993 reverse payment agreement.

Shortly after the decisions, two generic companies approached Cephalon about settling, Osborn says. By then, the FDA had ruled that all four companies would share the six-month exclusivity period. That ruling, Osborn says, “was both a curse and a blessing. On the one hand, we had to structure settlements with all four firms. On the other hand, because they shared exclusivity, no single firm enjoyed a significant economic opportunity. That dynamic helped us in the negotiation process.”

Over the next two months, Osborn hammered out settlements with each of the generics. Each pact is essentially the same, giving the generic companies shared exclusivity in 2011. Cephalon also announced a collaboration with Mylan to develop drugs. Financial terms were not disclosed. As required, Cephalon submitted the settlements to the FTC, but has yet to find out what, if anything, the agency will do.

Lingering questions over FTC approval aren’t troubling investors. In November 2005 Lehman Brothers had a target stock price for Cephalon of $37. After the settlements were announced, it revised the number to $98.

Capitulation has an upside.