Concurring Statement of Commissioner Jon Leibowitz

As I understand the facts, Ovation is the sole-source seller of drugs critical to saving the lives of premature infants (many of whom are uninsured), who have a life-threatening heart condition, patent ductus arteriosus. To achieve its dominant position, Ovation monopolized the market and bought its most imminent threat. Doing so allowed it to raise prices by a disturbing amount – nearly 1300 percent. Put differently, the course of treatment rose from about $108 in 2005, before the transaction at issue, to about $1500 today.

Ovation’s profiteering on the backs of critically ill premature babies is not only immoral, it is illegal. Moreover, the company’s behavior is a stark reminder of why America desperately needs health care reform and why vigorous antitrust enforcement is as relevant today as it was when the agency was created almost one hundred years ago in 1914. Ensuring that consumers receive the benefits of health care competition will continue to be a priority of this Agency in the next administration.

For many years, Indocin IV was the only FDA-approved product to treat this serious heart condition. Merck, which owned Indocin, had kept prices low – perhaps because it was worried that a significant price increase would have harmed its reputation. (For that reason, I would have supported the approach proposed by Commissioner Rosch.) In any event, at that time, Indocin cost about $26 a vial for a treatment that generally requires three doses.

In August of 2005, Ovation purchased the rights to Indocin from Merck. A second product, NeoProfen, developed by another pharmaceutical company, was close to receiving FDA approval for the treatment of this condition. Rather than allow the entry of a competitive product, Ovation purchased the rights to the unapproved NeoProfen in January 2006. This transaction fell below the Hart-Scott-Rodino Act’s reporting thresholds for mergers and acquisitions, and so was not reported to the government competition agencies.

It should be obvious that under antitrust law a monopolist cannot buy a likely entrant product even if that product is not an exact substitute for the existing one. Here, the two drugs – Indocin and NeoProfen – both treat PDA, and the FDA-approved indications are almost identical. Many doctors and clinics view the two as interchangeable for most premature infants. Absent Ovation’s acquisition of NeoProfen, the two products would have competed fiercely against each other. That competition would have lowered prices and benefitted consumers, which is precisely what the antitrust laws protect, and why we are bringing this action today.

The victims of this conduct – newborns with a life-threatening condition – remind us of antitrust law’s continued relevance.
On these facts, it is also appropriate for the Commission to seek disgorgement of profits from Ovation; after all, malefactors should not keep the ill-gotten gains of their illegal acts. Recent literature on the subject makes a persuasive case for seeking disgorgement more frequently.\(^1\) I strongly agree: the Commission should use disgorgement in antitrust cases more often.

\(^1\)See generally Einer Elhauge, “Disgorgement as an Antitrust Remedy,” 76 Antitrust L.J. (publication forthcoming 2009).