Statement of

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Before the
Subcommittee on Antitrust, Competition Policy and Consumer Rights
Committee on the Judiciary
United States Senate

Hearing Entitled
"Pay-for-Delay Deals: Limiting Competition and Costing Consumers"

Presented on

July 23, 2013

Chairman Klobuchar, Ranking Member Lee, and distinguished members of the Subcommittee, thank you for inviting me to appear before you today to testify regarding so-called Pay-for-Delay deals in general and, more particularly, in the context of proposed legislation S214.

I have been researching, writing about, lecturing about and testifying about such settlements for over 12 years, starting with my work on behalf of Schering Plough in the FTC action against Schering and others in 2001 and extending through articles recently published and pending publication. Based on my work, I would like to draw your attention to a few important points that seem to have been overlooked in the public debate and, indeed, in the draft legislation S214 as it stands. I will make these points in very summary form, but I urge that you consider, too, the more complete discussion of these points in some of my articles on the subject, which I have attached to my written testimony.

Settlement of patent litigation, including Hatch-Waxman cases between brand and generic manufacturers, can provide significant benefits to consumers. Any settlement that allows for entry prior to patent expiration has at least the potential to benefit consumers who might otherwise have had to wait until patent expiration to see such competition.

Unfortunately, a pure "term-split" settlement, i.e., one where the only terms of the settlement are that the alleged infringer will enter at some point before patent expiration, is

often simply not feasible, for a number of reasons which have been discussed in the literature. Diverging views about the strength of the patent, about the likely future of the market, asymmetric information, and other factors, can make such a pure settlement impossible.

What this in turn means is that any evaluation of the likely competitive effects of a settlement agreement needs to be carried out in comparison not to a hypothetical agreement that might never have been possible at all; rather, it has to be carried out in comparison to the likely or expected outcome of litigation. If the parties had not settled, but had litigated instead, would consumers have been better off or worse off than they are under the settlement before us?

That, of course, depends on the strength of the underlying patent. If the patent is very strong and was likely to have been adjudicated to be valid and infringed by the would-be entrant—the generic in the Hatch-Waxman case—a settlement that provides for entry before patent expiration may well be beneficial to consumers. On the other hand, if the underlying patent is weak—likely to be judged invalid or not infringed or both—a settlement that does not permit immediate or near-immediate entry may well be bad for consumers relative to the alternative of litigation.

I should stress that the fact of a so-called reverse payment does not convey much information about whether a given settlement is actually better for consumers than the alternative of litigating the patent. For reasons thoroughly discussed in the economic literature, a patentee may well make a "reverse payment" and still agree to an entry date that is better for consumers because it is earlier than the expected outcome under the litigation alternative: risk aversion, divergent views about the strength of the patent or future market developments or the time value of money are some of the factors that can engender this outcome.

The implication is obvious: rather than focusing on bright-line questions like "does the settlement contain a reverse payment," we need to consider the settlement in its entirety—including whatever payment terms it might contain—and then evaluate its effect on consumers relative to the likely outcome of patent litigation. Necessarily, this involves at least some consideration of the merits of the underlying patent case and of the likely strength of the patent.

Such analysis is not as onerous as some, including the Federal Trade Commission, have suggested. For every patent settlement that we actually have to deal with, there is a federal judge who has acquired considerable knowledge of the merits of the underlying patent case and, more often than not, has construed the claims of the patent in a *Markman* ruling. It seems entirely likely that a judge in that position has more than enough information about the underlying patent suit to have an informed judgment of the strength of the patent,

certainly enough to be able to judge—aided by expert analysis if necessary—whether a given settlement of that suit is likely to benefit consumers.

To be sure, the analysis that I describe is neither easy nor swift. And that brings me to my final point, one that seems curiously to have been lost in the debate. When analyzing settlements like this under the rule of reason—which is what the Supreme Court has said we must do—the very first step can be called a "gating" step. Does the patentee possess monopoly power? If not, *the inquiry ends*. There is *no need* to undertake the potentially difficult and time consuming tasks of ascertaining whether or not a reverse payment even exists (by no means self-evident in a complex agreement) and, should it exist, of evaluating the settlement's outcome against the outcome of litigation. And, as we should all know by now, a patent may confer exclusivity, but it by no means necessarily confers monopoly power. If there is no monopoly power present, there is no basis on which to condemn these settlements or, indeed, to analyze them in detail.

In light of the foregoing points, I respectfully suggest that S214 in its current form needs to be modified in three respects if it is to lead to the right economic outcomes. First, a reverse payment does not necessarily imply any anticompetitive effect, so the presumption of anticompetitive effects should be dropped. Second, the relevance of the underlying patent suit to any competitive analysis of a given settlement of that suit needs to be recognized explicitly and given due weight in the analysis prescribed by the bill. Finally, and perhaps most important, the bill needs to acknowledge the importance of the monopoly power screen and give due weight to that screen in the analysis of any settlement.

Thank you for your consideration. I have attached two articles that discuss these issues further and may be of use to you.

References (attached)

Sumanth Addanki and Alan J. Daskin, "Patent Settlement Agreements," Chapter 85, Volume 3, in *Issues in Competition Law and Policy*, published by American Bar Association, Section of Antitrust Law, August, 2008.

Sumanth Addanki, "*Schering-Plough* and the Antitrust Analysis of Patent Settlement Agreements in Pharmaceutical Markets," *Antitrust Insights*, National Economic Research Associates, Inc., 2005.