GPhA’s Amicus Brief in \textit{FTC v. Actavis, Inc.}: 
\textbf{Settlements of Hatch-Waxman Litigation Benefit Consumers} 
\textbf{By Guaranteeing Access To Lower-Cost Generic Drugs Before Patents Expire}

The Generic Pharmaceutical Association (GPhA) has filed an amicus curiae brief with the Supreme Court of the United States in \textit{FTC v. Actavis, Inc.}, supporting several pharmaceutical companies against an antitrust lawsuit by the Federal Trade Commission (FTC).

The FTC has asked the Supreme Court to rule that whenever generic and brand-name pharmaceutical manufacturers settle a patent lawsuit with an agreement including a so-called “reverse payment,” the settlement violates the antitrust laws unless the companies can show a good reason for holding otherwise. GPhA has joined many other amici, including businesses, economists, mediators, and public-interest groups, in filing briefs rebutting the FTC’s argument.

Here are the key points of GPhA’s brief:

- \textit{Settlements remove patents as an obstacle to generic competition}. Patents often prevent the Food and Drug Administration (FDA) from approving generic drugs to compete with brand-name drugs. A successful patent lawsuit can prevent the FDA from approving the generic drug until the patent expires, which can take 20 years. In the \textit{Actavis} case, the parties settled the patent lawsuit and ensured that the generic drug could enter the market five years \textit{before} the patent expires.

- \textit{Litigation is a risky and expensive alternative}. The FTC argues that the law should encourage generic drug companies to litigate patent cases, because if they win, they might gain access to the market even sooner than the settlement allows. But patent litigation is risky. Generic companies have won some important victories, but have also suffered some significant defeats, and the outcome of litigation is not certain until after the case is both tried and appealed. The generic version of an important anticancer drug, tamoxifen, came to market \textit{only} because of settlement; the generic companies that chose to litigate all lost their cases. Settlement allows the parties to reach an agreement that avoids the risks and costs of drawn-out, high-stakes litigation. The FTC’s rule would make cases much harder to settle, because every settlement could potentially give plaintiffs’ lawyers grounds to threaten suit under the antitrust laws.

- \textit{Settlements do not threaten the robust competition among generic drug companies}. Often many generic drug companies will apply for approval of a generic equivalent to a brand-name drug, and will challenge the brand-name drug’s patents. Even if one of those generic drug company settles, the others can still litigate the patent challenge if they have good legal and business reasons. GPhA’s brief shows how the competition among generic drug companies ensures that patent settlements do not hurt consumers.

- \textit{The antitrust laws give breathing space to these complex legal and economic judgments}. The FTC is trying to rely on a rule of antitrust law that is reserved for cases where an anticompetitive effect is “obvious,” but here settlements actually \textit{benefit} consumers.

The Supreme Court will hear argument on March 25, 2013, and decide the case by late June.