

A Closer Look at Patent Settlements with Consideration

Issue:

Congress has raised questions about “patent settlements with consideration,” legal agreements that occur when generic manufacturers that challenge brand pharmaceutical patents choose to forgo expensive, drawn-out legal proceedings and settle out of court.

Question:

What is the impact of eliminating the option of a pharmaceutical patent settlement with consideration?

A new study, *The Benefits of Patent Settlements: New Survey Evidence on Factors Affecting Generic Drug Investment*, shows the first-ever empirical evidence highlighting the importance of an option to settle in a manufacturer’s decision to bring a drug to market.

Methodology

Survey and analysis were conducted by Bret Dickey, Executive Vice President, Compass Lexecon and Jonathan Orszag, Senior Managing Director, Compass Lexecon, on behalf of the Generic Pharmaceutical Association (GPhA). Fourteen manufacturer members of GPhA, representing 85 percent of the U.S. generics market, responded to the survey. Findings were compiled in April 2013 and included questions on factors influencing investment decisions, the strength of brand patents, and the frequency of settlements.

Key Findings:

- Respondents reported that settlements substantially increase the number of positive outcomes for generic manufacturers as compared to pursuing litigation to the end. In fact, generic medicines lose many more cases than they win if litigation is carried through in full.
 - On average, generic manufacturers report resolving 64 percent (165 of 256 resolved patent suits) by settlement.
 - When pursuing litigation to its full extent (through to judgment), survey respondents report losing two out of every three times.
- Generic manufacturer respondents report that many factors influence their decision to pursue drug development. A key factor is the uncertainty surrounding the introduction of a new medicine, which includes the ability to settle patent litigation, which reduces the risk of failure for the generic manufacturer.
 - The ability to settle patent litigation is ranked as important by generic manufacturers as a factor in making investment decisions, according to the report.
 - Among other factors that cause uncertainty, generic manufacturers also identified first filer opportunity and fewer blockbuster branded drugs facing patent challenges, as factors likely to make the opportunity to reliably settle patent litigation in the near future more important.

Conclusion:

The long-term impact of limiting the option to settle, including limiting the option for settlements with consideration, must be considered. Increasing uncertainty around a generic drug's market introduction from filing status, market size and the ability to settle patent litigation all negatively impact the likelihood that generic pharmaceutical manufacturers will challenge brand monopoly patents.

Preventing an option to settle, such as limiting the option to settle with consideration, reduces the manufacturer's incentive to bring medicines to market to the detriment of patients, payers and providers. Policies that restrict patent settlements hinder competition and innovation and must be avoided. Rather, a path must exist to hold down health costs by ensuring access to safe and effective, affordable generic medicines.

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About the Generic Pharmaceutical Association (GPhA)

GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 80 percent of the prescriptions dispensed in the U.S. but consume just 27 percent of the total drug spending. For more information visit www.gphaonline.org.