Billy Tauzin
PRESIDENT AND CHIEF EXECUTIVE OFFICER

PhRMA

February 12, 2007

The Honorable Patrick Leahy
Chairman
Committee on the Judiciary
United States Senate
224 Dirksen Senate Office Building
Washington, DC 20510

ATTENTION: Nikole Burroughs, Hearing Clerk

Dear Mr. Chairman:

Thank you for the opportunity to testify before your Committee at the hearing on "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it be Prohibited?"

Enclosed are responses to the written questions submitted by Committee members.

Sincerely,

Billy Tauzin

Enclosures

Answers to Questions Posed to Billy Tauzin after Senate Judiciary Committee Hearing: "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?" (held January 17, 2007)

Senator Kohl's Questions for Billy Tauzin

Q. "At the hearing, you testified that 'I ask you not to shoot the good, while you are trying to kill the bad and ugly.' With respect to pharmaceutical patent settlements, please describe which settlements, in your view, fall in the 'bad' and 'ugly' categories, and which fall within the 'good' category?"

A. My reference to "good", "bad" or "ugly" settlements was not directed at a particular set of facts. Instead, it was meant to convey that each patent settlement should be evaluated individually to determine whether it is likely to harm competition and consumers.

On one hand, a "bad" settlement is one that, taking all relevant facts and circumstances into account, unreasonably restrains competition. Patent settlements in the pharmaceutical industry and other industries have the potential to harm consumers by restricting competition beyond the patent's scope in terms of duration or product range.

On the other hand, a "good" settlement does not restrict competition beyond the scope of the relevant patents. These settlements do not harm consumers, but instead typically benefit them by allowing the accused infringer to enter the market before the patent expires. They also allow innovator and generic companies to avoid the high cost of protracted patent litigation.[1] These settlements advance the federal public policy favoring resolution of disputes by settlements.[2] They also advance the policy encouraging innovation through the reward of patents that can be enforced.

Antitrust law already provides a methodology for federal courts and antitrust agencies to distinguish between "good" and "bad" patent settlements. This kind of analysis can and should be done under existing antitrust standards, and certainly the Federal Trade Commission and the Antitrust Division of the Department of Justice have the opportunity to perform this analysis in the first instance when a pharmaceutical patent settlement agreement (or description of the agreement) is filed with the agencies pursuant to provisions of the Medicare Modernization Act ("MMA").[3] The key is that the analysis should include a case-by-case evaluation of the particular settlement in relation to the situations of the parties and the scope of the patent at issue.

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[1] *Blonder-Tongue Labs, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 334 (1971) ("[P]atent litigation is a very costly process.").

[2] *See, e.g., McDermott, Inc. v. AmClyde & River Don Castings Ltd.*, 511 U.S. 202, 215 (1994) ("[P]ublic policy wisely encourages settlements.").

[3] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, § 1112, 117 Stat. 2461-64 (2003).

Senator Feinstein's Questions for Billy Tauzin

Q. You argue that it is important for the makers of name-brand pharmaceuticals to retain the ability to enter into pro-competitive settlements.

- ***In what way do you believe that Senator Kohl's proposed legislation would prohibit pro-competitive settlements?***

A. S.316 appears to prohibit any patent settlement in which the innovator company transfers "anything of value" to the generic and the innovator and generic agree on a date when the generic will enter the market (even if that date is before the patent's expiration date). This broad prohibition would chill all settlements – in fact, it appears to cover almost any settlement agreement because a generic challenger logically would only settle in exchange for something of value and all settlements transfer, at a minimum, the value inherent in the release of the claims and defenses.[4] For example, it would even cover settlements involving certain transactions that the FTC has opined should not be banned, such as the waiver of patent infringement damages against a generic for entry that has already occurred.[5]

This chill on settlements would have significant adverse consequences for brand and generic companies and ultimately for consumers. Fewer options for settlement would raise the cost of patent enforcement (and patent challenges) by forcing both sides to incur additional litigation costs. It also could reduce generic manufacturers' incentives to challenge patents in the first place by reducing their options in litigation against patent holders.

A blanket prohibition on the exchange of "anything of value" also would foreclose the ability of innovators and generics to exchange assets that may or may not be involved in the litigation. This would put a straight jacket on the settlement negotiations because parties that have very different views of the merits of the patent case and different risk exposure in a given case will lose the ability to license unrelated technology or look for other ancillary business arrangements that could facilitate the parties' efforts to reach and structure a mutually acceptable – and pro-competitive – settlement.[6] Not only would the bill make settlements less likely, but it also would make them less efficient. It also would harm consumers because "Hatch-Waxman settlements . . . which result in the patentee's purchase of a license for some of the

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[4] *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

[5] *See* Prepared Statement of the Federal Trade Commission before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution, January 17, 2007, at 22-23.

[6] The per se ban on payment of "anything of value" to the accused infringer contemplated in S. 316 also would appear to foreclose a settlement in which the patentee pays an amount equal to or less than expected future attorneys' fees and litigation costs. For example, assume that enforcement of a patent through trial and appeal will cost the innovator at least $5 million. In this situation, the innovator should be able to pay $3 million to settle (and thereby avoid additional litigation costs). Indeed, the Federal Trade Commission has issued consent orders allowing patent holders to settle in this manner. *See In re Schering-Plough Corp.*, No. 9297, Opinion of the Commission at 37, www.ftc.gov (Dec. 18, 2003) (citing FTC consent orders expressly allowing settlement payment for litigation costs).

alleged infringer's other products may benefit the public by introducing a new rival into the market, facilitating competitive production and encouraging further innovation."[7]

- ***Is a settlement that prohibits or postpones a competitor's developing or marketing a competing product ever pro-competitive?***

A. Yes, if that settlement is within the patent's scope, and particularly if it allows the generic product to enter the market before the expiration of the patent. Critics of recent brand-generic patent settlements have characterized those settlements as agreements to postpone generic entry and have portrayed business transactions between the brand and the generic that accompany the settlements as "payments for delay." But it is important to remember that, as Bruce Downey of Barr Laboratories explained in his testimony before the Committee, the innovator's patent – not the consideration exchanged as part of a settlement – has the greatest influence over the date of the generic's entry.

Consistent with the antitrust laws, a patent holder may exclude others from producing a patented article or may grant limited licenses.[8] Innovators across industries rely on patents to ensure that their inventions are protected and that they will be given an opportunity to recover their research investments. Patents are a crucial factor in pharmaceutical innovation. Patents provide the minimum degree of assurance for investors to risk the capital investment necessary to fund the pharmaceutical discovery and development processes despite the uncertain chances of producing a commercially viable product.

Congress has determined that patents are legally entitled to a presumption of validity.[9] Absent a final judgment that its patent is invalid or not infringed, an innovative pharmaceutical company that has filed a patent infringement action against a generic challenger is not obligated to allow the generic company to enter the market prior to expiration of the patent. Nevertheless, federal court opinions and Federal Trade Commission reports demonstrate that many patent settlements between innovative and generic companies allow the generics to bring their allegedly infringing products to market well before patent expiration.[10] The settlements also may include additional terms or ancillary agreements that facilitate compromise of the dispute over the patented product and often promote competition on other products.[11]

These types of settlements, allowing for enforcement of patents within their scope, do not harm competition. To the contrary, the settlements allow the parties to avoid the costs and uncertainty of litigation and bring generic products to market sooner

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[7] *Schering-Plough*, 402 F.3d at 1075.
[8] *See, e.g., Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940).
[9] 35 U.S.C. § 282.
[10] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193-96 (2d Cir. 2006); Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2006* (Jan. 2007), at 6, www.ftc.gov.
[11] *See, e.g., Schering-Plough*, 402 F.3d at 1059-61 (discussing settlements in which assets were exchanged).

than if the innovator had succeeded in enforcing its patent through a trial and final judgment. Consumers benefit from this result.

Q. ***In your prepared statement and your testimony, you seemed to oppose Senator Kohl's legislation on the grounds that it would prohibit all settlements in which a brand-name company gives a thing of value to a generic drug manufacturer. Senator Kohl's bill, however, is not that broad: it would only bar settlements that involve both a payment of something of value to the generic and an agreement by the generic to delay the development or marketing of the generic product.***

- ***How would you propose modifying the bill to make it more narrowly targeted at only the settlements that are anticompetitive?***

Antitrust law disfavors per se rules. They are applied only in limited circumstances where conduct is so obviously pernicious that it automatically works against consumers' interests whenever it occurs, even without a case-specific analysis of its competitive impact.[12] The majority of courts that have examined patent settlements involving some transfer of value from the innovative to the generic pharmaceutical company have determined that it would be inappropriate to apply a per se rule to ban all of these settlements.[13] Even the Federal Trade Commission, in its opinion in the *Schering-Plough* case, declined to apply a per se rule.[14] First and foremost, any legislation addressing brand-generic patent settlements should likewise reject a per se ban on a whole category of settlements. As demonstrated in my testimony and in that of Mr. Downey of Barr Laboratories, a per se ban would chill all settlements and likely would have the unintended consequence of decreasing the number of Paragraph IV filings by generic companies (because generics would know that settlement options would be strictly limited and litigating the case through trial may be the only alternative).

The proposed legislation exacerbates the overbreadth of this per se ban by applying it to any patent settlement in which the innovator company transfers "anything of value" to the generic. As noted in my testimony and in response to another of Senator Feinstein's questions, the phrase "anything of value" encompasses nearly all settlement agreements. The following are just a few examples of circumstances where pro-competitive agreements that allow generic entry prior to patent expiration would be swept up in the per se ban against the transfer of "anything of value": (1) when the value that a patentee pays to the accused infringer is consideration for other goods or services unrelated to the allegedly infringing product; (2) when the payment enables the accused infringer to remain a viable competitor; (3) when the payment represents expected future attorney fees and litigation costs that would have been incurred had the parties litigated their dispute through trial and appeal; (4) when the value represents the

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[12] *Texaco Inc. v. Dagher*, 126 S. Ct. 1276, 1285 (2006); Antitrust Modernization Committee, Tentative Recommendations at 1.

[13] *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 202-03, 206-07 (2nd Cir. 2005); *Schering-Plough*, 402 F.3d at 1063-65.

[14] *In re Schering-Plough Corp.*, No. 9297, Opinion of the Commission at 14, 86 (Dec. 18, 2003), www.ftc.gov.

waiver of patent infringement damages against a generic for entry that has already occurred.

PhRMA believes that existing antitrust law, combined with the federal antitrust agencies' ability to review all innovator-generic patent settlement agreements under the MMA, safeguards consumers' interests. If Congress is concerned that these safeguards do not sufficiently deter anticompetitive settlements, it could change the filing requirements specified in MMA or potentially create other requirements that will enhance opportunities for judicial and/or agency review of individual settlements. But a case-by-case examination of each settlement compared to the scope of the patent should be the central component of any statutory requirements.

Senator Schumer's Questions for Billy Tauzin

Q. Congressman Tauzin and Mr. Downey, you have each stated that you oppose the legislation before us today. Do you believe that there are any anti-competitive patent settlements?

A. It is possible that a patentee and an accused infringer could structure a patent settlement in such a way as to restrict competition beyond what the innovator's patent lawfully could exclude. An example might be a settlement in which the parties to the patent litigation agree to restrict competition in products that are not alleged to be infringing. The innovator and accused infringer might benefit from that type of settlement, but such profit would come at the expense of competition and consumers. Antitrust agencies and courts have the authority to evaluate and condemn such settlements under existing antitrust laws. The MMA's filing requirements provide additional tools for evaluating patent settlements in the pharmaceutical industry.

Q. [Question for Mr. Tauzin and Mr. Downey] The brand company Cephalon negotiated agreements with four generic companies, including Mr. Downey's company, regarding the sleep medication Provigil. The generic companies agreed to stay off the market until October 2011 in exchange for a total of $136 million in payments. Cephalon paid $136 million in order to save six years worth of revenues for a drug that makes $500 million a year. Can you tell me how the consumer benefited from this settlement?

A. As President and CEO of PhRMA, I did not testify on behalf on any particular company, but rather offered a broad perspective on the importance of innovation and patents in the life sciences industry and on the need for public policies that foster innovation. In addition, it would be inappropriate for me to offer any opinion on specific settlements involving PhRMA's member companies. Having said that, it seems to me that the assumptions underlying this question may not be consistent with public reports about the settlements. Specifically, Cephalon has disclosed in its SEC filings that its various agreements with generic drug companies provide for the license to Cephalon of important intellectual property. Cephalon also has stated publicly that the referenced amounts are in exchange for these license grants. Cephalon's public statements

also disclose that the patent covering their product modafinil actually runs until 2014, and that the terms of these settlements allow for generic competition to begin a full three years before patent expiration. Generally, settlements that allow early generic entry may result in substantial savings for consumers because without these settlements competition might well not have occurred until the patent expired.