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The Hon. Patrick Leahy
Chairman, Judiciary Committee
United States Senate
Attn: Nikole Burroughs
224 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Senate Judiciary Committee -- January 17, 2007 Hearing Questions

Dear Senator Leahy:

I am writing to answer the questions submitted to me after my January 17, 2007 testimony before the Judiciary Committee on behalf of Barr Pharmaceuticals. I have set forth the answers to the best of my ability to each of the questions, which are repeated below for ease of reference, preceded by the name of the senator who submitted the question.

Questions and Answers

By Senator Kohl: *In your view, are there any circumstances in which consumers are benefited by a patent settlement in which a generic firm agrees to keep its drug off the market in return for a cash payment from a brand name manufacturer? If you believe there are such circumstances, please explain. If you believe there are no such circumstances, why wouldn't you support a bill banning such settlements?*

Yes, I do believe there are circumstances in which consumers are benefited by patent settlements in which a generic firm settles its patent challenge, thus relinquishing its right to market a generic product immediately, yet often securing the right to market a competing product years before the brand name manufacturer's patent would otherwise expire.

For example, in the case of my company's Prozac challenge, we settled our case in the district court, which had dismissed all but our inequitable conduct claim, for a cash payment. That settlement allowed us to immediately appeal the court's decision. We ultimately prevailed, a result that saved consumers about a billion and a half dollars. Our cash settlement at the trial court level not only facilitated an appellate court decision, it benefited consumers by enabling us to bring a generic version to market at least a year earlier than would have been possible if we had been forced to litigate the inequitable conduct claim to its conclusion at the trial court level. Obviously, that year of savings would have been lost if the restrictions in the proposed legislation had been in place.

Another example is Tamoxifen. There, in addition to monetary consideration, we obtained a license that enabled us to enter the market with a competing product and saved consumers about $300 million, despite the fact that subsequent generic companies brought

similar patent challenges and lost. Again, those savings would have been lost if the restrictions in the proposed legislation had been in place.

By Senator Kohl: *The FTC reports that in the year after the two court decisions allowing these "reverse payment" patent settlements, half of all patent settlements contained terms in which the brand name company paid the generic money in return for the generic's agreement to keep its drug off the market. The year before the court decision, no patent settlements contained such terms. Doesn't this data show that such "reverse payment" settlements are likely to become increasingly common in the years ahead?*

We are at a disadvantage to analyze or discuss the conclusions reached by the FTC because we do not have access to the universe of settlement agreements the FTC has been able to analyze. Those settlements are typically confidential and it is my understanding that they were submitted to the FTC as confidential. The FTC's own reports in turn do not identify the specific settlements or terms, so it is very difficult to comment on settlements other than those involving my own company.

However, based on my knowledge of my own company's challenges, I believe the FTC's statement may not be completely accurate. My company did in fact enter into settlements involving monetary consideration *prior to* the *Schering* decision. Two of those settlements, involving Cipro and tamoxifen, were upheld by the courts. Another, involving Prozac, led to our eventual generic launch of Prozac which has been lauded as an example of the Hatch-Waxman process at its best. These three settlements led to consumer savings in excess of $2 billion.

In any event, I do not believe that looking at just one year (the year before the *Schering* decision, for example) provides an adequate sample. These cases take years to litigate, so a one-year window may not be the most informative method for identifying trends. I know that prior to the *Schering* decision my company in fact settled several cases in which monetary consideration was part of the settlement. Moreover, it would not surprise me for there to be more settlements, including more settlements including monetary consideration, in the past two years simply because there have been an increasing number of patent challenges during this time period.

By Senator Feinstein: *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. You also seemed to object that the bill would be an obstacle to settlements that included collateral agreements involving payments for unrelated products. Senator Kohl's bill, however, is not that broad: it would only bar settlements that involve both a payment of a 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?*

- *Would the bill as currently written prohibit a settlement with a bona fide collateral agreement involving a payment from the brand-name company to the generic, if that settlement did not include an agreement by the generic to delay bringing the generic product to market?*

The bill as currently written would in fact ban anything "of value" to a generic manufacturer *unless* the generic company also received the right to enter the market *immediately*. That would make settlement impossible, since the brand-name company would never agree to immediate entry in settling rather than litigating to the end. Ironically, the legislation may have the unintended consequence of discouraging brand manufacturers from ever settling patent challenges, a result, as demonstrated over the last decade, which would not be in the interest of consumers. Any patent settlement will inevitably involve the generic company accepting less than *immediate* entry, and therefore "agreeing to delay" marketing its product. Unfortunately, the bill as written would in effect ban the receipt of "anything of value" by the generic company, making it impossible to settle these kinds of cases. For example, if the brand-name company has a patent that does not expire for ten years, and the generic company obtains through a settlement the right to enter the market in five years the generic company has not delayed but *accelerated* entry. Under the bill as drafted, this accelerated entry would not be possible because other consideration (*i.e.*, anything of value) is also part of the settlement.

By Senator Schumer: *Mr. Downey, you stated in your testimony that the proposed legislation would "harm the public by chilling patent challenges." Yet from 2000 to 2004, the five years during which the anti-competitive settlements targeted by this legislation were not allowed, there were plenty of patent challenges filed. In fact, the number of patent challenges almost tripled during the period that anti-competitive settlements were prohibited. Can you please explain why we did not see a chilling effect during this period?*

I respectfully disagree that the settlements that would be targeted by this legislation were "not allowed" from 2000 to 2004. In fact, my company vigorously litigated the Cipro case during that time period, in which we ultimately prevailed, with the court upholding our settlement that involved both early entry and monetary consideration.

By Senator Schumer: *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?*

I believe that there can be anti-competitive patent settlements, and that is why it is proper for the government to challenge such settlements on a case-by-case basis when they see fit. A settlement that expanded the brand-name company's rights beyond the relevant patent or patents could be anti-competitive under the rule of reason. A settlement that was a sham could be anti-competitive. Each would have to be examined on its own terms. I do not have access to all the terms of *other* company's settlements, but I do not believe any of my company's settlements

were anti-competitive. But speaking of whether there can be theoretical patent settlements that would be anti-competitive, I would say "yes."

By Senator Schumer: *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?*

Cephalon's patent on Provigil will not expire until 2014. My company's settlement agreement thus benefited consumers by giving us the right to enter with a competing modafinil product as early as October 2011 -- *three years earlier* than if we had never challenged the patent or if we had lost in court. Moreover, given that the case was not filed until 2005,and would have taken several years to litigate, even if Barr had prevailed, it could not have entered the market before 2009. Thus, the settlement guaranteed a right to enter in 2011 rather than a possible date of 2009 if Barr had won, or 2014 if Barr had lost. My company did not agree to "stay off the market." Under current law, we cannot enter the market because of Cephalon's patent until 2014. As a result of our settlement, we will be able to enter the market *three years early, and we believe t*hose three years of *accelerated* entry will greatly benefit consumers.

Please do not hesitate if I can provide any further assistance.

Sincerely,

Bruce Downey
Chairman and CEO
Barr Pharmaceuticals, Inc.

cc: Nikole_Burroughs@judiciary-dem.senate.gov