Testimony of
Bruce Downey
Chairman and CEO
Barr Pharmaceuticals Inc

January 17, 2007

TESTIMONY OF
BRUCE L. DOWNEY
CHAIRMAN AND CEO, BARR PHARMACEUTICALS, INC.
"Paying off Generics to Prevent Competition
with Brand Name Drugs: Should it Be Prohibited?"
BEFORE THE
JUDICIARY COMMITTEE
U.S. SENATE, CONGRESS OF THE UNITED STATES
JANUARY 17, 2007

Chairman Leahy, Ranking Member Specter, and members of the Committee, my name is Bruce Downey and I am the Chairman and Chief Executive Officer of Barr Pharmaceuticals, a leading generic pharmaceutical company.

I want to thank you for convening this hearing and for allowing me to express my Company's views on issues so vital to the continued success of the generic pharmaceutical industry - an industry that saves consumers and taxpayers literally billions of dollars each year in prescription drugs costs. Indeed, no other industry has made, or continues to make, a greater contribution to affordable health care than the generic pharmaceutical industry.

INTRODUCTION

Barr has always been deeply committed to providing the public with affordable generic drug products and to do so as expeditiously as possible under the circumstances. Barr has long championed legislative measures that would expedite generic market entry. Similarly, Barr has steadfastly fought against measures that would impede the progress made by the 1984 Hatch-Waxman Amendments and the 2003 Medicare Modernization Act (“MMA”).

The proposed legislation, which would stifle a generic company's ability to resolve patent disputes is one such measure. The simple fact is that, in some instances, litigation settlements turn out to be the means by which consumers gain access to generic drugs before patent expiration. Indeed, patent litigation settlements are the sole means by which the public can be guaranteed generic access prior to patent expiration.

The courts have recognized that parties to a legitimate dispute concerning the scope or validity of a patent can reach a settlement that involves consideration other than (or in addition to) a grant of early market entry to the patent challenger, and that such settlements do not implicate the antitrust laws, unless the settlement itself extends the scope or duration of the patent. Hence, patent holders in all industries can and often do enter into patent litigation settlements that involve an explicit or implicit flow of consideration from the patent holder to the patent challenger without subjecting themselves to antitrust risk.

The proposed legislation would not change this rule for most industries. It would allow patent holders and challengers in the automotive or computer fields to continue to settle their cases without requiring the patent holder and challenger to litigate rather than accept consideration in settlement. However, it would adopt a special rule that patent holders and challengers in the pharmaceutical industry alone would be restricted, in that the only settlements they could lawfully entertain would be those in which the patent holder grants early entry as the only consideration for the settlement.

Because the proposed legislation would effectively undermine the rights of inventors in the pharmaceutical arena, it will discourage innovation at a time when it is most needed. It will also discourage vigorous challenges of patents, because generic companies will lack the flexibility to settle some cases once they are filed. In sum, I am concerned that the legislation would discourage pro-competitive patent settlements, discourage patent challenges, and ultimately reduce, not increase, consumer benefits.

On the other hand, there is a potential issue with regard to pharmaceutical patent settlements that could be addressed by legislation. One protection that consumers typically have when patent disputes are settled is that other competitors may still litigate the validity of the disputed patent. When Congress enacted the MMA, it included a provision that was intended to permit ANDA applicants to bring a declaratory judgment action against the patent holder when the patent holder failed to sue the ANDA applicant. This provision would have ensured that all ANDA applicants would have the opportunity to litigate the merits of the patent with respect to their products. Unfortunately, the Federal Circuit has adopted a narrow interpretation of the provision that prevents ANDA applicants from bringing a declaratory judgment action in many circumstances. This may mean that an innovator can settle a patent suit with the first ANDA applicant, decline to initiate litigation against other generics that have filed ANDAs, and effectively prevent future patent challenges. Barr is ready to work with Congress to draft legislation that would address this problem related to innovator-generic settlement, without undercutting the important incentives to challenge innovator patents.

DISCUSSION

A. Generic Companies Have Been Able To Achieve Combination Settlements That Significantly Advance Competitive Entry.

Litigation settlements that guarantee generic market entry prior to patent expiration are inherently pro-consumer. The settlements with which I am most familiar have, in fact, guaranteed that a lower-priced drug product could enter the
market a total of nearly 28 years prior to patent expiration. My company, Barr, was able to settle our litigation over the Cipro patent and secure early generic entry when four subsequent challengers all lost their cases) Thus, with the benefit of hindsight, if Barr had not settled, it is pretty clear there would have been no benefit to consumers -- we would have lost. Allowing us to settle on terms to which Barr and the patent holder could agree thus secured a pro-competitive result. Similarly, we settled our patent litigation regarding tamoxifen to introduce a competing product years before patent expiration, despite the fact that the patent was later upheld in subsequent litigation. In short, these settlements all provided value to the consumer that would not have been achieved if the generics had proceeded to litigate and lose.

Barr's settlements and those of most other generic companies of which I am aware have included a significant advance in the date of launch of the generic product, as compared to the expiration of the patent. Generic companies are strongly motivated to achieve early entry into a patent protected market, because it enables them to sell a product with much higher margins than most generic products. Generic companies also want to obtain that entry sooner rather than later, because the value of early entry diminishes over time due to uncertainty over future market conditions.

Brand companies are obviously reluctant to grant immediate early entry, as it is the most expensive form of settlement consideration they can offer. A grant of early entry is tantamount to the branded company losing the litigation on the date of early entry, or the generic company winning the case on the date of early entry. Even if the branded company receives a royalty from the generic company, it still incurs a significant loss, as the royalty on lower-priced generic products will be substantially lower than the branded company's profits on the branded drug. However, branded companies are usually willing to allow early entry at a later point in time, as it allows them the opportunity to replace the lost profits with sales of other products in development.

Consideration in addition to early entry can be useful in bridging the gap between the generic company's

proposed entry date and the branded company's proposed entry date. A branded company that is dead set against an earlier entry date may nevertheless be willing to provide economic value other than early entry in order to persuade the generic company to accept a later entry date. When this occurs, consumers win, because they obtain the market advantage of guaranteed early entry that may well not occur if the case were litigated to its final conclusion. The public, without question, benefits from the pre-patent expiration marketing of more affordable drug products.

B. The Proposed Legislation Will Discourage Pro-Consumer Settlements And Discourage Hatch-Waxman Patent Challenges.

Restricting the allowable settlement consideration will discourage pro-competitive settlements. The proposal seems to assume that the settlement of Hatch-Waxman litigation for money or other consideration "harms" consumers, because in the absence of such consideration, the brand-name company would settle by permitting the generic drug company to introduce its competing product even earlier. That conclusion is wrong. The proposed legislation would in fact harm the public by chilling patent challenges animated by the Hatch-Waxman Act.

Contrary to the proposal's easy assumption that a monetary settlement could always be converted into a time period of early entry, other consideration will often be essential to allowing the parties to a patent dispute to reach agreement. First, the parties will often be unable to agree upon an acceptable entry date because the brand-name drug company and the generic challenger have substantially different perspectives on the relative risks of the litigation. In order to agree to settle on an entry date alone, the parties would need to have similar views on the outcome of the litigation. If both parties believe they are likely to prevail - as can often be the case - then the generic company will insist on an early entry date to which the branded company simply will not agree. Again, early entry is tantamount to a victory for the patent challenger and a defeat for the patent holder. In contrast, parties may be able to settle litigation that they both believe they are likely to win if their settlements can include consideration other than the entry date alone.

Second, the parties may have different perspectives on future market conditions. The branded company may believe that its product will continue to grow, such that it will be providing significant future value with its proposed entry date. The generic company may believe that the product's future is less certain. These differences in perception about the value of entry on a certain date could well prevent the parties from being able to settle a case when the date of entry is the only permissible consideration. The ability to include other consideration as part of an overall settlement provides the ability to bridge that gap. Once again, consumers unambiguously benefit when the parties settle on a date-certain entry that is earlier than the expiration of the patent. That it may take additional consideration to get the case resolved is not a reason to discourage such settlements. In short, while the parties may be able to agree upon some form of license in most cases, a rule requiring that all settlements take the form of a "time only" license would make settlements less likely.

C. Because This Bill Would Make Settlements Less Likely, It Would Decrease The Number Of Challenges.

In rendering settlement less likely, this proposal would inevitably raise the costs and risks of bringing patent challenges, thereby reducing the number of patent challenges a generic company can effectively mount. Generic companies may have many ANDA challenges at anyone time. In deciding whether to challenge a patent, the generic challenger must consider the potential gains from the challenge - including the possible settlement alternatives - against the risk of recovering nothing. The generic challenger will lack the necessary resources to litigate every patent challenge to final judgment upon appeal, particularly when there is the risk that the challenger might ultimately win nothing.

To be sure, the generic company cannot know what kind of settlement it would obtain in deciding whether to file an ANDA statement, but like any other litigant, it does count on the possibility of settlement in budgeting its litigation costs. A generic challenger's ability to bring a Hatch-Waxman challenge depends in significant measure upon its having the flexibility to decide when, and on what terms, to compromise the

litigation.

The ability to settle a patent challenge on flexible terms has a procompetitive effect because it increases the number of patent challenges by decreasing barriers to entry, i.e., the costs of bringing a patent challenge. In contrast, the proposed rule prohibiting a settlement for other consideration could be anticompetitive because it would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement.

In sum, parties in Hatch- Waxman cases would not always "get to yes" if forced to negotiate over a "time only" tenn of entry, rather than over both flexible license terms and other consideration. The proposed bill therefore would undennine the incentives Congress has carefully created to promote generic competition.

CONCLUSION

Thank you, Mr. Chainnan, Ranking Member Specter, and Members of the Committee, for giving me the opportunity to explain our views and concerns about these important topics. We look forward to continuing to assist Congress in this area.