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Hearing on HR 1902, The Protecting Consumer Access to Generic Drugs Act of 2007
Subcommittee on Commerce, Trade, and Consumer Protection
Energy and Commerce Committee
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Introduction

Chairman Rush, Ranking Member Stearns, Members of the Subcommittee, thank you very much for the opportunity to testify before you on anti-competitive patent settlements between brand and generic pharmaceutical companies. My name is Bernard Sherman. I am the CEO and Chairman of Apotex Inc. Apotex is the largest Canadian pharmaceutical manufacturer. We are also one of the largest generic drug manufacturers in the world. In the United States, we are the 7th largest generic drug manufacturer measured by sales. Our U.S headquarters is located in Weston, Florida. We also have a distribution center in Indianapolis, Indiana.

Apotex is pleased to testify today in support of HR 1902. Apotex shares your view that settlements in which brand and generic pharmaceutical manufacturers thwart consumer access to generic drugs through collusive agreements should be unlawful. Such settlements are the antithesis of what was intended by Congress in the Hatch-Waxman provisions. Apotex applauds you for your introduction of this legislation and your leadership on this important consumer issue. We hope you find the recommendations we will put forward today, which we recognize fall under the jurisdiction of the Energy and Commerce Committee's Health Subcommittee, helpful as you and your colleagues in both subcommittees continue your work to ensure consumers have timely access to quality, affordable generic medicines.

At Apotex, we believe generic companies should endeavor to bring generics to market at the earliest possible time, and that the legislative and regulatory framework should facilitate, not obstruct, early generic entry. Our record in advocating for such a public policy framework, from our support for a district court trigger for exclusivity rather than an appellate trigger, our pursuit of declaratory judgment actions, our efforts in the courts to vacate anti-competitive settlements, our pursuit of infringement verdicts even where there is no guaranteed benefit to us, and our opposition to patent settlements, is unique and unmatched among generic manufacturers.

As one example, about 5 weeks ago, Apotex succeeded in invalidating Pfizer's patent for amlodipine besylate, sold by Pfizer as Norvasc[®]. Apotex undertook this battle despite the fact Mylan, and not Apotex, was the first to file with a paragraph iv certification. The result of our investment, our work and our victory was that Mylan, and not Apotex was



then immediately able to launch a generic amlodipine product. As a consequence, consumers are now saving hundreds of millions of dollars, Mylan is garnering hundreds of millions of dollars of profits that rightfully should have gone to Apotex, while Apotex receives no benefit whatsoever, and is left only with a large loss on the investment in the litigation. This is a perverse outcome of a system that rewards only the first to file, even if the first to file does not litigate and win, and ignores the needs of a subsequent filer who is prepared to fight to win. It is this flaw in the system that is the root of the settlement problem.

As another example, Apotex has sued to invalidate the settlement agreements between Cephalon and four generic first-filers. Under the settlement agreements, the generics have agreed to abandon the patent challenge and defer launch until shortly before patent expiry. Apotex is prepared to carry on the patent challenge, just as it did for amlodipine, but again will get nothing in return, because of two anticompetitive aspects of settlements. The first is that the first filers will continue to hold the 180 Hatch-Waxman exclusivity, despite the fact that they have settled. Thus, even if Apotex wins, it will still be unable to sell. The second is that the settlements invariably contain a “poison pill” provision, whereby market entry of the first filers will be accelerated if a subsequent filer, such as Apotex, continues to litigate and wins. This means that, if Apotex continues to litigate and wins, the result will again be that Apotex will continue to be held off the market, while the first filers, who agreed not to launch for years, will be able to launch and thus take all of the benefit properly earned by Apotex, again leaving Apotex with nothing but costs.

Apotex very much wants to continue to fight for the interests of consumers, as intended by the Hatch-Waxman provisions. However, it should be clear that we will be unable to continue to do what is right, unless Congress addresses the essential problems. Two things are sorely needed:

1. An amendment that gives shared (if not sole) exclusivity to a generic challenger who, although not first to file with a paragraph iv certification, is first to succeed in addressing the listed patents.
2. Amendments to stop settlement agreements from denying any benefit to a subsequent filer who continues to fight. Specifically:
 - i) a generic first filer who enters into any settlement agreement should immediately forfeit its exclusivity; and
 - ii) a generic first filer who agrees to defer launch should not be permitted to then accelerate launch as a result of a win by a subsequent filer who continues to litigate.

Having first filer settlements result in the forfeiture of exclusivity is crucial to ensuring that the system functions the way Congress originally intended. Allowing first filers to preserve exclusivity when they settle for market entry only months before patent expiry will result in a system in which every early generic entry will forever be capped at only months before patent expiry. There is no doubt, Mr. Chairman, that, if permitted to get



away with it, the first-filer and brand company will ALWAYS settle for generic entry only slightly before patent expiry, maintaining almost all of the life of every monopoly, even when the patents are clearly invalid and or not infringed. Consumers are much better off with a system that allows for the possibility of generic entry years rather than just months earlier. Indeed, Congress' intent in passing the Hatch-Waxman regime was to create a framework under which generics were incentivized – for the benefit of consumers – to break, not preserve, patents that are invalid or not infringed.

I would also emphasize, Mr. Chairman, that we are not proposing that settlements be barred. We do not think they should be. If a first filer thinks slightly earlier generic entry is a good deal, it should take that deal. But it should not be permitted to stand in the way of another generic who thinks it can get to market even earlier, and is willing to take up the patent fight. Otherwise, benefits that might have been won for consumers will never be realized.

Mr. Chairman, Apotex commends you for including in HR 1902 a provision that would correct the declaratory judgment problem -- a key loophole that contributes to the "bottleneck" problem. These bottlenecks arise when first to file generic companies conspire with their brand counterparts to block the market and delay generic competition.

The inability of subsequent generic filers to get a declaratory judgment ("DJ") helps to sustain the monopoly. Current law requires subsequent filers to successfully litigate the same universe of patents to which the first filer has certified. To ensure that market entry remains indefinitely blocked, brand companies simply do not sue subsequent generic filers. The only avenue left for a subsequent filer is to pursue a DJ action. Unfortunately, the courts have routinely dismissed efforts to get a DJ, on the basis that the generic lacks standing to sue. It appeared that the decision of the Supreme Court in the MedImmune case might resolve this problem. However, patentees have come up with a new gimmick. In addition to not suing, they now give covenants not to sue.

As an example, Apotex has been seeking a DJ to trigger the exclusivity on alendronate, sold by Merck under the tradename Fosamax[®]. Merck responded with a covenant not to sue, and despite the Supreme Court's decision in MedImmune, the District Court has again held that Apotex' motion for a DJ is not justiciable because of the covenant not to sue. The situation is preposterous. A covenant not to sue has no meaning, because Apotex' market access will remain blocked by the exclusivity that Apotex cannot trigger.

HR 1902 corrects the DJ problem by making both the dismissal of a DJ action for lack of subject matter jurisdiction and the execution of a covenant not to sue triggering events for the first filer's exclusivity.

Apotex strongly supports the enactment of this provision. However, we must caution that even this provision will be ineffective, unless the problem of anti-competitive settlements is adequately addressed. If and when your proposed provision to fix the DJ problem is enacted, the result will be that the patentee will invariably sue the subsequent filer,



thereby subjecting the subsequent filer to the enormous cost of litigation. No subsequent filer will be able to justify the cost, whenever there has been a settlement wherein the first filer has agreed to delay launch, while maintaining exclusivity, as any subsequent filer who continues to litigate can get no reward. Anti-consumer patent settlements will continue unabated.

HR 1902 includes a provision that would ban so called “reverse payments” -- from a brand to a generic company settling a patent infringement case. The intuitive reaction shared by almost all is that reverse payments are unethical and wrong. However, Apotex believes that this issue is a “red herring” and that outlawing reverse payments, if not coupled with other amendments, will have no significant impact on the number of settlements or their anticompetitive impact, but will simply reduce the cost of such agreements for patentees. This can be understood from the following analysis.

A settlement typically includes a provision that the first generic applicant will be licensed to enter the market during the last year or less prior to patent expiration. The significant value for the first generic applicant is the 180 day exclusivity. Litigation is almost always uncertain as to outcome. If the generic litigates, there is a risk of losing and ending up with nothing. Hence, it is inevitable that it will *always* make more sense for a generic to settle for exclusivity during the last months of patent life rather than to litigate in the hope of winning and getting earlier entry. The reason that generics have been able to negotiate for "reverse payments" in addition to market entry during the last months is that the agreement is enormously valuable to the patentee. The patentee keeps the monopoly for all but the last months, so the benefit to the patentee is generally enormously greater than to the generic. The generic thus takes the position that it is not willing to settle for only a generic monopoly during the last months, and the patentee is always willing to provide a further benefit to the generic through a "reverse payment". It may appear that, if such reverse payments are made illegal, the generic company will simply demand that the patentee allow it to enter the market even earlier than the last months of patent life as a substitute for the banned payment. However, that fails to take into account that earlier entry for the generic has very little additional value, because the exclusivity will terminate and other generics will enter the market 180 days after first sale by the first generic. It follows that making reverse payments illegal is unlikely to have any substantive effect on settlements, that generics will still settle for guaranteed market entry during the last months of patent life, and the only effect, if any, will be that the cost of settling will be reduced for the patentee, with no benefit for consumers.

As mentioned earlier, in Apotex’s view, it is critical to recognize that the primary anticompetitive aspects of settlements are those that eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry.

We thus urge the Subcommittee to work for legislation that includes all of the following features:



1. A provision that makes both dismissal of a DJ action for lack of jurisdiction and execution of a covenant not to sue triggering events for the first filer's exclusivity, as now proposed in HR 1902.
2. An amendment that gives shared (if not sole) exclusivity to a generic challenger who, although not first to file with a paragraph iv certification, is first to succeed in addressing the listed patents.
3. Amendments to stop settlement agreements from denying any benefit to a subsequent filer who continues to fight. Specifically:
 - a. a generic first filer who enters into any settlement agreement should immediately forfeit its exclusivity; and
 - b. a generic first filer who agrees to defer launch should not be permitted to then accelerate launch as a result of a win by a subsequent filer who continues to litigate.

As aforesaid, we believe that there is a fundamental flaw in a system that rewards only the first to file, regardless of whether or not the first to file continues to litigate for the earliest possible market entry, and that, conversely, denies any reward for the generic that does litigate and wins. To ensure timely consumer access to generic competition, this fundamental flaw must be fixed.

Year after year, Apotex has tirelessly litigated to bring products to market, as we believe was intended by Congress. We want to continue down that path, and urge Congress to make it possible by addressing all of these issues.

Adopting this approach will bring a swift and just end to the bottleneck problem. This approach would preserve the right of all companies to settle litigation – a right that should be preserved. What it would not allow is the continued perversion of the 180 day exclusivity period -- an award Congress intended to incentivize generic companies to open markets early, not block them.

Conclusion

Thank you very much for inviting Apotex to share our views with you and the Members of this Subcommittee on this issue. Please know that Apotex stands ready to assist you and your colleagues in this Subcommittee and the Health Subcommittee in any capacity in which you may call on us. We hope that our insight has helped and will help in arriving at legislation that will work as intended by Congress for the benefit of consumers.