Testimony of

Mr. Robert Armitage

August 1, 2003

TESTIMONY ON BEHALF OF ELI LILLY AND COMPANY
ON THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"
AUGUST 1, 2003
SUMMARY
? Title VII of S. 1, the Greater Access to Affordable Pharmaceuticals Act, would substantially modify the Hatch-Waxman Act. The stated intent of the modifications is "to make generic drugs more available to consumers on a faster timeframe." The sponsors assert that they seek to "continue to encourage innovation ... in our brand name companies." They also disclaim any intention to "set up a massive atmosphere of litigation." S. 1, however, will produce just the opposite effect on each of these three counts.
? The sole intent of the Hatch-Waxman "generic exclusivity" provisions was and is to accelerate generic drug entry by providing exclusivity to one generic company as a reward for removing a patent barrier that also faces other generic companies. Under S. 1, the reverse will happen. "Generic exclusivity" as provided under S. 1 would rarely accelerate generic drug entry but will instead operate in a systematic fashion to create a separate, additional market-entry hurdle for competing generic companies. The result will be that consumers will commonly be forced to wait for months to years longer for true generic competition to start. For many blockbuster drugs, S. 1 would add an additional $1 billion price tag that consumers will be forced to pay at the time of generic drug entry.
? Innovation will also suffer if S. 1 becomes law. S.1 creates a new incentive for generic companies to bring early and entirely speculative patent challenges against the basic patents for a new medicine. These patents provide the entire economic basis for investing in the development of most new medicines. To earn the 180-day exclusivity under S. 1, a generic company must challenge every single innovator patent, preferably on the first day the law permits the challenge to go forward. This reverses provisions put into the law in 1984 that were designed to affirmatively discourage such early patent challenges.
? Innovators will incur substantial costs to defend these patent challenges, no matter how speculative or thin. A new hurdle will stand in the way of developing even the most promising medicines. Unless a potential new medicine has the most defensible patents, it might be impossible to justify the investment needed to develop it. Innovators will be forced to look beyond developing the best new medicines and focus on medicines that appear to have the best patents.
? The defects in S. 1 should be remedied. Congress should align the 180-day exclusivity with its 1984 intent. Congress should allow consumers to have the benefit of immediate competition among generic companies once the innovator's basic patents have expired and one or more competing generic companies have

demonstrated that they do not infringe any patents that then remain.
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TESTIMONY ON BEHALF OF ELI LILLY AND COMPANY
BEFORE THE COMMITTEE ON THE JUDICIARY - UNITED STATES SENATE
AUGUST 1, 2003
ON THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"
Offered by
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company
Chairman Hatch and Members of the Committee:
Eli Lilly and Company appreciates the opportunity to offer this testimony on the proposed changes to the Hatch-Waxman Act ("Drug Price Competition and Patent Term Restoration Act of 1984") that appear in the "Greater Access to Affordable Pharmaceuticals Act" (Title VII, S. 1). Lilly's testimony today will focus on only one facet of S. 1, the provisions that relate to so-called "generic exclusivity." However, the industry does have additional concerns with S.1 that will be addressed in a separate written submission by the Pharmaceutical Research and Manufacturers of America.
The Hatch-Waxman Act forms the foundation for Lilly's ability to invest in pharmaceutical innovation. It enables innovator companies, such as Lilly, to make the decade-long, nearly billion-dollar investments that are needed to develop the new medicines we discover.
The Hatch-Waxman Act was specifically designed to allow generic companies to get to market after the innovator's basic patents--the patents on the active ingredient and approved uses for a new medicine--have expired. Under the Hatch-Waxman Act, a generic company is entitled to do so if it can demonstrate that it does not infringe any of the innovator's unexpired patents that might then remain. Once generic drug entry takes place, consumers can derive substantial benefits from the resulting price competition among generic companies.
S. 1 manages to simultaneously undermine both of these pro-innovation and proconsumer underpinnings of the Hatch-Waxman Act. Congress would be unwise to endorse a new incentive contained in S. 1 to attack the basic patents that form the foundation of Lilly's ability to innovate. It would be unconscionable for Congress to do so in a manner that then forces the consumer to finance this new incentive by delaying access to generic drugs.
Lilly's Stake - Thirteen Decades of Answering the Need for Medicines
Lilly was founded nearly 130 years ago. Its mission centers on enriching and extending the lives of people across the globe through its innovative medicines. Today, it
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is no exaggeration to state that virtually every family in America has been touched by Lilly innovations.
Our contributions over thirteen decades have included the first medicine to enable juvenile diabetics to live full and productive lives, revolutionary antibiotics that pioneered the conquest of deadly infections, and drugs that have literally revolutionized the treatment of serious mental illnesses, including depression and schizophrenia.
Today, Lilly is busy producing the first medical miracles of the twenty-first

century. Just in the past several years, Lilly has offered American families the first medicine ever approved for treating severe sepsis and its often-fatal consequences and the first medicine to actually reverse osteoporosis and its debilitating consequences.

We want to preserve the ability to continue this work tomorrow, next year, and throughout the remaining decades of this century. Within our grasp are even better medicines that will be no less profound in their implications for the health of all Americans.

What Lilly Is Seeking To Have Changed in S. 1 and Why

Against the background of our heritage, it should surprise no one that Lilly would be concerned about any change to the Hatch-Waxman Act. As a result, we have made a thorough study of the provisions of S. 1 through twin lenses. How will it affect incentives to innovate? What will it cost consumers?

Sponsors of S. 1 claim the intent of the complex changes contained in S. 1 will be to make generic drugs available to consumers on a faster timeframe while continuing to encourage innovation by brand name companies but without setting up a massive atmosphere of litigation. A careful analysis indicates that the bill would do the opposite on all three counts--

? Consumers will wait longer for the value that comes from competition among generic drug companies. In the most common situation in which generic drug entry occurs, consumers will wait up to eight months longer for this value-generating competition. In other common situations, the wait will be years longer.

? Innovators will see their basic patents on the active ingredients and approved uses for new medicines--the patents that provide the foundation for the ability to invest in innovation--made the subject of a new incentive to attack and destroy them. Generic companies will be driven by new incentives in S. 1 to make early and entirely speculative patent challenges. Generic companies that do so will reap huge rewards for attacking innovator patents--even when generic drug entry is not accelerated by even one day. These anti-innovation, and unearned, rewards will come at the expense of consumers.

? The creation of a massive atmosphere of litigation is something S. 1 will foster, not restrain. Indeed, its design explicitly drives early, speculative litigation. The costs and risks created by this litigation will ultimately be paid for by the consumer.

Lilly acknowledges that many provisions in S. 1 were motivated by a desire of some in Congress to address conduct by innovator companies that might unfairly delay generic competition once the basic patents on a new medicine had expired. For this reason, Lilly is not seeking changes that would reverse any provision of S. 1 that is calculated to reign in this conduct, would delay by even one day generic drug market entry, or would add to the burdens generic drug companies face in gaining approval to market.

What we cannot accept, and implore the Congress to change, are the S. 1 provisions that are flatly inconsistent with the 1984 guarantees Congress enacted to protect innovators and benefit consumers. Indeed, if S. 1 is to be made true to the stated

intentions of its sponsors--protecting consumers, protecting innovation, and avoiding wasteful litigation--then what we are asking for is nothing more than a fix for an unanticipated loophole that S. 1 would otherwise create.

Congress can close the S. 1 loophole by stripping out of the law the opportunity for a 180-day exclusivity period where it needlessly delays generic competition. What we seek can be boiled down to a single sentence. Lilly would ask that Congress add a provision to S. 1 stating that once all the innovator's basic patents have expired and a competing generic company has demonstrated that it does not infringe any of the remaining innovator patents, the 180-day exclusivity period will be forfeited.

Why should Congress do this? First and foremost, it obliterates any anticonsumer effects of S. 1. Generic competition starts when the Hatch-Waxman Act intended that it would begin--and common sense dictates is must begin--not later than when the innovator's basic patents on the drug's active ingredient and the approved uses have expired and competing generic companies have demonstrated that they do not infringe any patents that then remain.

Second, it keeps in place the policy-driven disincentive to making early and entirely speculative challenges to basic patents of innovators that has been a part of the Hatch-Waxman Act since 1984.

Third, it reverses the impact of S. 1 that would otherwise provide an incentive to attack all innovator patents at the earliest date the law permits.

The remainder of this testimony will review the operation of Hatch-Waxman today, the changes to Hatch-Waxman under S.1, the negative impact of these changes on consumers and innovation, and what Congress should do to remedy the defects in S.1.

Operation of the Hatch-Waxman Act and Impact of S.1

To understand the impact of S. 1 on the Hatch-Waxman Act requires an examination of how patents work to protect new medicines from generic competition and how the "patent challenges" provided under the Hatch-Waxman Act were designed to facilitate generic drug entry once the basic patents on a new medicine have expired.

Innovator patents operate to provide the incentive that drives the ability to invest in new and better medicines.

The decision to develop the vast majority of new medicines is undertaken because one or more patents have been sought that an innovator believes can defer generic drug entry until these patents expire. Such patents must afford the prospect of extended periods of innovator exclusivity after the new medicine is first approved for marketing. Absent the prospect of adequate patents and an adequate postapproval patent term, the development of many potential new drugs would not go forward.

The patents that can provide this type of ensured innovator exclusivity are the socalled "basic patents." They claim the active ingredient or the approved uses for the new drug. Basic patents are, thus, those that every generic competitor must infringe to get a generic drug approved since generic drugs cannot be approved unless they copy identically the active ingredient and at least one approved use.

The underlying design of Hatch-Waxman is, therefore, premised on the ability of one or more of these basic patents to reliably fuel the ability to invest in innovation. Impairing the expectation that basic patents can provide exclusivity until they expire impairs or removes altogether the ability to invest in a new medicine's development.

Hatch-Waxman's "patent challenge" provisions permit generic drug entry once the basic patents on new medicines expire.

A second fundamental design premise of Hatch-Waxman is that generic drug entry should be possible immediately after these basic patents have expired. Once the basic patents expire, the innovator's remaining patents may claim specific formulations, physical forms of the active ingredient, or like aspects of the innovator's drug. Generic companies, however, can use unpatented formulations and unpatented physical forms in making generic drugs. Generic companies that succeed in designing around these secondary patents can readily establish that they do not infringe them and proceed with marketing under the Hatch-Waxman mechanisms.

After designing around the patents remaining after the basic patents expire, generic companies can use the so-called "patent challenge" features in Hatch-Waxman. By providing a certification statement to the patent owner that demonstrates that the generic drug does not infringe any of the secondary patents, the Hatch-Waxman Act sets in motion a procedure that allows the FDA to approve the generic drug before expiration

of the challenged patents--in some cases without the need for the generic company to ever defend itself in court.

The design of Hatch-Waxman, therefore, puts all generic companies in a position to get FDA approval and secure generic drug entry on the day the basic patents expire if they bring patent challenges to the remaining patents in a timely fashion before the expiration of the basic patents.1 Today, the only possible confounding factor in the timing of generic drug entry after the basic patents expire is whether the operation of the 180-day exclusivity will get in the way of getting to market immediately.

Whether the 180-day exclusivity confounds generic drug entry after the expiration of the basic patents depends upon whether (1) the 180-day period has been triggered and (2) once triggered, runs out before or after the expiration date of the basic patents. Thus, the trigger that starts the 180-day period--and its relationship to the expiration date of the basic patents--is the crucial factor under the Hatch-Waxman Act that determines the start of--or delays in the start of--free-for-all generic competition.

"Generic exclusivity" can operate to delay, not accelerate, generic drug entry.

The Hatch-Waxman Act provides a generic company that is the "first applicant" the opportunity for a 180-day generic exclusivity period. During the 180-day period, the Hatch-Waxman Act bars the FDA from approving all generic drug applications, except the first applicant's generic application.

The "first applicant" is the generic company that is the first to file a generic drug application with the FDA containing a certification that at least one of the innovator's patents is invalid or that the first applicant's generic drug does not infringe the patent. The patents that can be certified as invalid or not infringed are the so-called "Orange Book patents." These are the basic patents related to a new medicine and certain secondary patents that the innovator is required by law to list with the FDA.

Once the first applicant files its patent challenge, the FDA is then barred from approving a subsequently filed generic drug application until the first applicant's "generic exclusivity" claim can be resolved.2 The resolution of the 180-day exclusivity issue

1 The Hatch-Waxman Act "patent challenge" mechanism operates to encourage generic companies to bring

these challenges approximately 30 months before the basic patents expire. In that way, if the patent owner
believes that a court should decide the patent infringement issue raised in the patent challenge statement,
this 30-month period allows a court the time to review the patent challenge and render a decision before the
expiration of the basic patents. The Hatch-Waxman Act also encourages the patent owner to bring a patent
infringement lawsuit immediately after receiving the certification statement if the patent owner believes
that a challenged patent has been infringed. If a patent infringement lawsuit is brought within 45 days after
receipt of the patent challenge statement, the FDA is required to stay the approval of the generic drug for a
30-month period (unless the patent expires first).
2 The FDA issued final regulations governing the granting of the 180-day exclusivity period in 1994.
These original regulations required that a generic company "successfully defend" against a patent claim
brought by the innovator company in order to gain the 180-day exclusivity. The FDA looked to the
congressional intent--that the 180-day monopoly was intended to reimburse for litigation costs--and
decided that only those companies that devoted the time and resources to litigate and won were entitled to

requires a three-pronged waiting period during which the FDA approval bar for
competing generic companies remains in force:
? waiting to see if the first applicant will trigger the 180-day exclusivity or not,
? waiting for the trigger event to actually occur, and
? waiting for the 180-day period to run its course.
Waiting out the resolution of the first applicant's 180-day exclusivity issues can
consume years.
When the waiting period to resolve the 180-day exclusivity continues at or after
the date that the basic patents for the new medicine have expired, the 180-day
exclusivity will typically delay generic drug entry.
On the day that the basic patents have expired, one or more of the competing
generic companies may already have established that they do not infringe any of the
innovator's unexpired patents that remain in the Orange Book. As noted previously, the
Hatch-Waxman Act provides a complete mechanism for each competing generic
company to do so by bringing a timely patent challenge to the remaining patents. For
each generic company that has successfully done so, the FDA can give final marketing
approval to each of the noninfringing generic companies but for the need to wait for the
180-day period to be triggered or not and, if triggered, to run its course.
However, the parallel efforts of the first applicant to establish that these same
Orange Book patents have not been infringed may or may not be complete when the

basic patents expire. Indeed, the first applicant may ultimately succeed or fail altogether in establishing it does not infringe the remaining patents. Until the first applicant does one or the other, the FDA's hands remain tied.

The FDA must delay final approval for each of the competing generic companies until the uncertainty of the first applicant's "generic exclusivity" is resolved.3 It must do so even if years tick away for the competing generic companies that had long ago demonstrated that they are not patent infringers.

the exclusivity period. In essence, the 180 days were awarded when generic companies cleared the way for

themselves and others. However, in 1997 the District Court for the District of Columbia Circuit in Mova v.

Shalala rejected the FDA's successful defense requirement - a ruling that was upheld by the Court of

Appeals for the District of Columbia Circuit in 1998. Therefore today, a generic company need not prevail

in litigation, nor even partake in any litigation to be awarded the 180 days.

3 If the basic patents in the Orange Book have not expired, this bizarre outcome does not arise. The Hatch-

Waxman Act prohibits the FDA from approving any generic drug where it would infringe a valid patent.

Thus, so long as the basic patents remain in force and are infringed, the FDA cannot approve either the first

applicant or any competing generic companies. Thus, generic drug entry cannot be delayed by waiting for

the 180-day period to be triggered unless the trigger point can be delayed by the first applicant until the

date the basic patents expire.

Under Hatch-Waxman, Congress prohibited delaying or "parking" of the 180-day period after a "court decision"

Congress made certain in 1984 that the first applicant's opportunity for "generic exclusivity" could not unduly delay or "park" generic drug entry. It did so by imposing a "trigger" event that forced the 180-day period to start to run. Even if the first applicant had not begun commercial marketing of its generic drug, this trigger would ensure that the 180-day clock would begin ticking and the 180 days would come to an end. This trigger, therefore, ensured that those generic competitors that did not infringe any remaining patents could get FDA approval to market sooner rather than later.

What was the "trigger" that Congress enacted in 1984 to prevent delaying or "parking" the 180-day exclusivity period? Congress provided that, once a court determines that a challenged patent had not been infringed or was invalid, that court decision itself triggers the start of the 180-day period for the patent in question. This use of a "court decision" as the triggering mechanism was, thus, the key design feature of the 180-day exclusivity provisions because it alone prevented any further delays in the start of the 180-day period that could otherwise delay generic drug entry by competing generic drug companies.

Indeed, without such a trigger that could be pulled before the start of the first

applicant's commercial marketing of the generic drug, the 180-day exclusivity could systematically operate to delay the start of competition among generic drug companies - and frustrate its raison d'être. With the trigger, the Hatch-Waxman Act prevented the "parking" of the 180-day exclusivity period, which operates to delay the start of the 180-day period for months or years after other generic companies have demonstrated that they infringed no unexpired patents.

The "court decision" trigger also serves a second purpose, beyond protecting consumers from delays in generic drug entry. This second purpose was to provide a clear-cut, policy-driven disincentive to making early and speculative patent challenges against all the innovator's patents appearing in the Orange Book.

Without the "court decision" trigger to start the 180-day period, generic companies could routinely bring patent challenges at four years from the original FDA approval for the new medicine - the earliest possible date permitted in the Hatch-Waxman Act. These challenges could attack every patent in the Orange Book--both the basic patents and those that would remain after the basic patents expire.

If the attack on the basic patents failed (i.e., the basic patents were found valid and infringed), the first applicant could not then "park" the opportunity for the 180-day exclusivity until the basic patents expired and only secondary patents that the court found had not been infringed still remained in force.

Because Congress provided that the "court decision" of noninfringement for the remaining patents always triggers the start of the 180-day period, the 180 days will nearly

always run their course before the basic patents have expired. No incentive exists, therefore, for bringing such an early challenge that, in some cases, would be made a decade before the expiration of the basic patents. In fact, there exists a strong disincentive for doing so.

Permitting "parking" would be bad policy because it delays generic market entry and creates an incentive to bring early and entirely speculative patent challenges--both of which are bad for consumers and innovation.

Permitting "parking" of the generic exclusivity after an early patent challenge would not only encourage speculative attacks on the innovator's basic patents, but it also would virtually always operate to delay generic drug entry by competing generic companies at just the moment that the Hatch-Waxman Act was designed to ensure that all generic companies could get FDA approval. Competing generic companies that had also used the patent challenge mechanism to demonstrate that they too had designed around all the patents remaining after the basic patents expire would be irrationally penalized.

For a blockbuster drug, even a six-month delay in the start of competition resulting from "parking" of a first applicant's 180-day period until the expiration date of the basic patents could mean an extra $1 billion price tag for the consumers. Thus, no part of the Hatch-Waxman Act has been more essential over the past 20 years to help avoid irrational delays in generic drug entry and competition among generic drug companies than the "court decision" trigger for the 180-day exclusivity period.

S.1 does away with the "court decision" as a "trigger," which has negative consequences for innovation and consumers.

Without noting its significance or consequences, S. 1 simply erases the "court decision" trigger for the start of the 180-day period. In doing so, S. 1 permits the 180-day

exclusivity period to be "parked"--in some cases for years. It permits the parking to continue until the first applicant actually begins commercial marketing--even if this occurs years after the "court decision" that today would trigger the 180-day period. Where the first applicant has brought an early, speculative challenge to all the innovator's Orange Book patents, the "parking permit" can remain in effect until the innovator's basic patents have expired. The first applicant can exit the parking lot just as competing generic companies would today get final FDA approval and begin marketing competing generic drugs.

The significance of erasing the "court decision" trigger can hardly be understated. In some situations, this will mean competing generic companies will get to market months to years later than they do today. Many of these generic companies will have demonstrated conclusively that they do not infringe any of the innovator's patents that remain after the basic patent expires. Like the first applicant, they will be forced to use the patent challenge mechanism--and perhaps go to court to establish that they do not

infringe the remaining patents. For all this effort and expense, they will find themselves barred from the market for months to years longer than could be the case today.

An early, speculative patent challenge that would today have failed to yield a generic marketing monopoly, because the 180-day period would have expired years before the valid, basic patents of the innovator expired, would be virtually guaranteed of success. With the ability to exit the "parking lot" at the time the basic patents have expired, the first applicant could always use the 180-day period as long as it could demonstrate that it did not infringe any remaining patents.

This virtual guarantee of success brews a powerful incentive to be the first to challenge and grab hold of the virtually certain reward. Even if a generic company challenging on the fourth anniversary of innovator marketing approval must wait for a basic patent expiration 10 years later to retrieve a $100 million or $1 billion prize from the six-month generic monopoly, the opportunity to invest in speculative patent challenges and the resulting litigation can be a compelling one.

In short, removal of the "court decision" trigger in S. 1 is profoundly anticonsumer and anti-innovation. By encouraging speculative challenges, it fosters the very type of litigation its sponsors say it was intended to avoid.

S. 1 adds new "forfeiture" provisions that further compound the anticonsumer and anti-innovation consequences of the repeal of the "court decision" trigger.

S. 1 creates new "forfeiture" provisions under which the first applicant can forfeit the right to the 180-day exclusivity. These new forfeiture provisions do not serve to replace the "court decision" trigger. Instead, they operate to further negatively affect the consumers of generic drugs.

The key forfeiture provision in S. 1 is a new "failure-to-market" forfeiture. This provision provides that, in certain situations where the first applicant fails to market after a "court decision" on the patent challenge, the 180-day exclusivity is forfeited. However, this "court decision" forfeiture is no substitute for the existing "court decision" trigger. In fact, it operates backwards--S. 1 provides that the forfeiture of the 180-day exclusivity can be avoided whenever a court holds a challenged patent both valid and infringed Indeed, compared with current law, this new "court decision" forfeiture is triply defective:

? First, the "court decision" forfeiture produces no immediate forfeiture. The "court decision" forfeiture takes effect only after 75 days from the first applicant's commercial marketing. In terms of delaying the onset of competition among generic companies, these 75 days to get to a forfeiture event must be tacked onto the 180-day period itself. Viewed through this calculus, the 75 days can be added to the 180 days to produce a possible 255 days--eight and one-half months--when the FDA is barred from approving competing generic drugs after the "court

decision." This, again, is 255 days during which competition among generic drug companies could be taking place under current Hatch-Waxman law.

? Second, S. 1 redefines the "court decision" not as the district court, but the appellate court decision.4 This change in the law potentially tacks another one to two years of possible delay before the FDA is allowed to approve competing generic drug applications--even if a host of competing generic companies have already demonstrated in their certification statements made during a patent challenge that they do not infringe a single remaining patent of the innovator!

? Third is the most problematic defect in the new forfeiture provision. The forfeiture is rendered inoperative--that is, the "court decision" is simply ignored as creating the possibility for a forfeiture - for any challenged patent where the challenge is a complete failure and the challenged patent is found both valid and infringed.

Under this third aspect of the new forfeiture, S. 1 throws out the court decision--even the appellate court decision--as a trigger for the 180-day period. Instead, S. 1 extends any possible forfeiture until 75 days after the expiration of each valid, infringed patent.

As discussed previously, this last feature creates the incentive in S. 1 for generic companies to bring early and entirely speculative patent challenges on every single innovator patent-- including the basic patents. It is what allows the incentive to operate flawlessly for the first applicant, even if the challenge to a basic patent is launched a decade prior to its expiration.

The anti-innovation implications could hardly be more clear-cut: innovators will incur greater costs to defend these patent challenges, no matter how speculative or thin. It means a new hurdle will stand in the way of developing even the most promising medicines. Unless a potential new medicine has the most defensible patents, it might be impossible to justify the investment needed to develop it.

And, however slight, the incentive creates a new risk that a basic patent might even be lost in litigation before the medicine could ever return its investment. For those medicines, it would mean cutting short the life of a drug for which its most promising uses and greatest contribution to mankind might come from the postmarketing research into new uses that no one will have the incentive to pursue.

What Congress Should Do To Fix the Loophole in S. 1

Congress should act in conference to fix the defect in S. 1. The defect will be costly to the Medicare Drug Benefit--the federal government will foot part of the bill for

4 Under the FDA's original approach, a "court decision" was defined as: "the court that enters final judgment from which no appeal can be or has been taken." However, in 2000, the District Court

for the
District of Columbia ruled in Mylan Pharmaceuticals, Inc. v. Shalala, that "court" means district court.
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the new generic monopolies that will be unleashed under S. 1 at just the moment competition among generic drug companies should be affording consumers the full value of a generic drug.
It will be costly for innovation, forcing innovators to look beyond developing the best new medicines and focus on medicines that appear to have the best patents.
Lilly would propose that Congress simply add to S. 1 one more forfeiture to close the loophole. After the basic patents have expired and one or more competing generic companies have demonstrated that they infringe no remaining Orange Book patents, the 180-day period should no longer apply--it should be forfeited by the first applicant.
After the basic patents have expired and competing generic companies have already demonstrated that the remaining patents have not been infringed, the only function that the 180-day period can serve is to delay, not accelerate, generic competition. In this situation, there is nothing the patent challenge could do to clear a patent barrier standing in the way of generic drug entry--because it is clear that no such barriers can possibly remain.
With this new forfeiture, the 180-day exclusivity could accelerate, but never delay generic drug entry. Adding this additional forfeiture would return the 180-day exclusivity to its original policy underpinnings, only rewarding those generic companies that clear way for themselves and other generic competitors.
Conclusion
Title VII of S. 1 contains provisions that would substantially modify the Hatch-Waxman Act. These changes, while intended to close loopholes, actually create a new loophole that is anticonsumer, anti-innovation, and prolitigation.
Innovation will suffer because of a new incentive to make early, speculative patent challenges to all the Orange Book patents of the innovator. Consumers will suffer because of the systematic manner in which generic drug approvals will be delayed.
As a result, the loophole created in S. 1 must be closed prior to passage. Congress should mandate forfeiture of the 180-day exclusivity once the basic patents have expired and competing generic companies have demonstrated that they do not infringe any patents that then remain. No reasoned justification for continuing the opportunity for "generic exclusivity" could possible apply once its only possible effect would be to delay generic drug competition.
Appendix A1
TESTIMONY ON BEHALF OF ELI LILLY AND COMPANY
BEFORE THE COMMITTEE ON THE JUDICIARY - UNITED STATES SENATE
AUGUST 1, 2003
ON THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"
Offered by
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company
Appendix A

Illustrative Examples of the Impact of S. 1

The "generic exclusivity" provisions in S. 1 are complex and can be difficult to translate from statutory language into their practical effects. This appendix offers some illustrative examples of the practical impact of S. 1. It uses as a factual predicate for several of these examples past patent challenges. However, these historical examples are updated to apply the Hatch-Waxman law as it would exist if the loophole in S. 1 is not closed, i.e., Congress does not enact a new forfeiture provision that applies once the basic patents of the innovator have expired and competing generic companies have demonstrated that they do not infringe any patents that then remain.

Glynase Patent Challenge: Illustrative Example of the Impact of Moving to the Appellate Court Decision in the Failure to Market Forfeiture

The Glynase patent challenge represents an example of the impact of the new S. 1 provision allowing a first applicant to wait for the appellate court decision before any possible forfeiture of the 180-day exclusivity can occur.

In this case, Mova was the first applicant and thus entitled to the 180-day exclusivity. The subsequent filer, Mylan, was not sued during the 45-day period after the patent owner received the patent certification statement. As a result, Mylan was given tentative FDA approval in December 1996. It was not subject to the 30-month stay in FDA approval that would have applied had a patent infringement suit been brought within the 45-day period.

The FDA was precluded from approving the Mylan generic drug application for a further 18 months after it had tentative approval solely because the first applicant Mova was still in the middle of a court challenge related to the sole Orange Book patent. Mylan received no conceivable benefit from the patent challenge of the first applicant Mova. Both Mylan and Mova devised different means for designing around the sole Orange Book patent. Both generic companies were required to separately and independently establish that the sole Orange Book patent was not infringed.

Appendix A2

The courts ultimately found the patent to be both valid and enforceable but not infringed by either generic company. All the basic patents had expired by the time this patent challenge was brought.

Mylan was nonetheless burdened irrationally by the imposition of generic exclusivity grounded on a patent that was ultimately held valid but that neither generic drug company infringed.

Jury Verdict; Dec. 2, 1997

1995 1997 1998 1996

Mylan

ANDA:

Mova ANDA Filed 12/9/94; Approved 12/27/97 180 Days

180-Days End; May 31, 1998

Filed 11/21/95;

Approved 12/19/96 18 Months

"First-Filer" Mova Actually Delayed Noninfringer Mylan's Final Approval by 18 Months from Mylan's Tentative Approval Date

1999 2000

Fed. Cir. Decision;

Sept. 11, 2000
S. 1 Adds
Another 33-Month Delay
Sole Orange Book Patent Limited to
Specific Formulation - Never
Infringed by Any Generic Company
Mylan was not sued in "45-day
window" and not subject to "30-
month" FDA approval delay
S. 1 would have pushed back
Mova's 180-day trigger for an
additional 33 months - until the
appellate court ruled on the Mova
noninfringement issue.
But for 180-day
exclusivity obstacle,
Mylan would have
commenced generic drug
marketing in 1996!

S. 1 would make Mylan's situation worse. Under S. 1, Mylan might have been forced to wait an additional 33 months in order to gain marketing approval, the date of the appellate court decision. Even more perversely, had Mova lost its appeal and been found to infringe the patent, Mylan might have been forced to wait until September 2000 to get final approval - even though it would have been the only generic drug company not infringing the Orange Book patent.

If a simple forfeiture provision were added to S. 1 that would operate to allow Mylan to certify to the FDA that its patent certification statement demonstrated to the patent owner that it did not infringe the patent and that it had not been sued for patent infringement during the 45-day period after receipt of the notice by the patent owner, Mylan would have come to market in 1996, not 2000. "First applicant" Mova could have come to market a year later.

Appendix A3

Prilosec Patent Challenge: What if the "First Applicant" Infringes But a Subsequent Applicant Demonstrates It Does Not Infringe?

The most significant patent challenge in the 20 years since Hatch-Waxman became law in 1984 is the Prilosec patent challenge. U.S. sales of Prilosec in 2002 were in excess of $3 billion. Prilosec provides an example in which a 180-day generic monopoly could be worth $1 billion or more in profits for the first applicant.

In this challenge, four generic drug companies attempted to design around the remaining patent held by the innovator after the basic patents had expired. All four challengers were joined together in a single lawsuit that addressed the issues of validity and patent infringement.

The challenge resulted in the "first applicant" Andrx being held by the district court to infringe the patent, but one of the subsequent applicants, Schwarz Pharma, being determined not to infringe the patent.

2000 2002 2003 2001 2004 2005

District Court
Decision
(October 2002)
Anticipated Appellate
Court Decision (Late
2004 or Early 2005).
Cheminor
Genpharm
Andrx
Prilosec--First-filer
infringes; tentatively
approved later-filer
does not!
S. 1 allows a generic company to wait for appellate decision to trigger
180-day exclusivity; had Andrx done so in the Prilosec challenge, noninfringer
Schwarz would have been kept off the market for 1-2 years.
District Court trigger
would force Andrx to
allow Schwarz Pharma to
gain final FDA approval
or its 180-day exclusivity
would run out.
Appellate
trigger
afforded
Andrx the
option to keep
exclusivity all
to itself - at no
risk.
Only adjudicated noninfringer!
Infringes!
Infringes!
First-filer; Owns 180 Days; Infringes!
180 Days
2-year delay for "appellate" trigger"? Schwarz Pharma
Under current law, the "court decision" of noninfringement by Schwarz Pharma
would have triggered the start of the 180-day period by Andrx. The Prilosec patent
challenge was governed, however, by a prior FDA interpretation under which the final
appellate court decision was the trigger for the 180-day period.
Appendix A4
Even though Andrx could have waited for the appellate court to rule on its
assertion of noninfringement, it elected not to do so. Instead, with the 180-day
exclusivity worth potentially a billion dollars or more, Andrx quickly passed its 180-day
exclusivity off to Schwarz Pharma so that generic competition would begin and the two
companies could share in the bounty.

Had S. 1 passed, it might have dramatically undone this result. Under S. 1, the decision of the district court would not have been a trigger. Andrx would have been able to "park" its exclusivity period and wait to see if an appellate court would reverse the infringement judgment and allow it to keep the well-over-$1-billion prize that the 180-day exclusivity might represent.

Such an outcome, however, would mean that the public would still be waiting today for generic Prilosec. The long delay in generic drug entry - and the billions of dollars it would cost consumers - just might have produced a political outcry that would have moved Congress to remove the anticonsumer provisions from S. 1 that are the subject of this testimony.

How much of Andrx's decision to allow generic drug entry after the district court decision was an economic one and how much was political is merely a matter of speculation. However, closing the loophole in S. 1 would have a less-speculative outcome - generic drug entry would have taken place after the basic patents had expired and one or more competing generic companies demonstrated that they did not infringe any remaining patents.

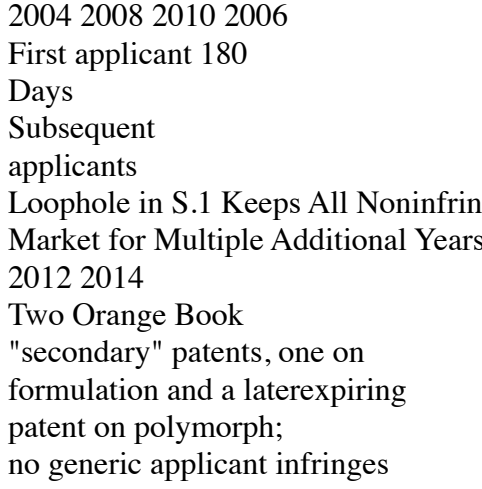
Hypothetical Example of the Loophole in Its Most Pernicious Incarnation

One final example illustrates the ultimate absurdity of S. 1 and the changes it will make in the 180-day exclusivity provisions. Again, it illustrates the perversity of the operation of the 180-exclusivity once the basic patents have expired and one or more competing generic drug companies have demonstrated that they infringe no remaining Orange Book patents.

Consider the situation where only two Orange Book patents exist, an earlierexpiring patent on the specific formulation for a new medicine and a later-expiring patent on a polymorph form of the drug. The first applicant challenges both patents, and under S. 1 qualifies for generic exclusivity. S. 1 will allow the first applicant to park the exclusivity after a court finds that the polymorph patent is valid, but not infringed, while the formulation patent is held both valid and infringed.

In this case the "court decision" will not result in any forfeiture until 75 days after the expiration of the formulation patent. In the example illustrated below, the expiration of the formulation patent is six years after "tentative approval" is given to the first applicant as well as three subsequent applicants.

Appendix A5



either patent - except for "first applicant" that infringes formulation patent.
All applicants get tentative approvals
Formulation Patent Expires
Polymorph Patent Expires
Subsequent applicants
Subsequent applicants
Approval Effective
Approval Effective
Approval Effective
Subsequent applicants get final approval after 180 days
First applicant gets final approval at formulation patent expiration - 180 days must start within 75 days thereafter
First applicant cannot get final FDA approval because of formulation patent infringement
Subsequent applicants not sued during 45-day period.

If the group of three subsequent applicants challenge the same patents but establish so convincingly in their patent certification statements that they do not infringe either patent, such that the innovator cannot bring a patent infringement action against any of them, the noninfringers will be kept off the market under the provisions of S. 1 for six full years.

In the example above, instead of getting to market in 2007, the generics wait for six years for the start of the 180-day period and then the additional 180 days (up to 8.5

months) before they are eligible for FDA approval. If S. 1's loophole is closed through a simple provision allowing any of the three subsequent applicants to certify that they were never sued for infringement of any of the remaining Orange Book patents, then marketing approval will begin in 2007, not 2013!

Conclusion

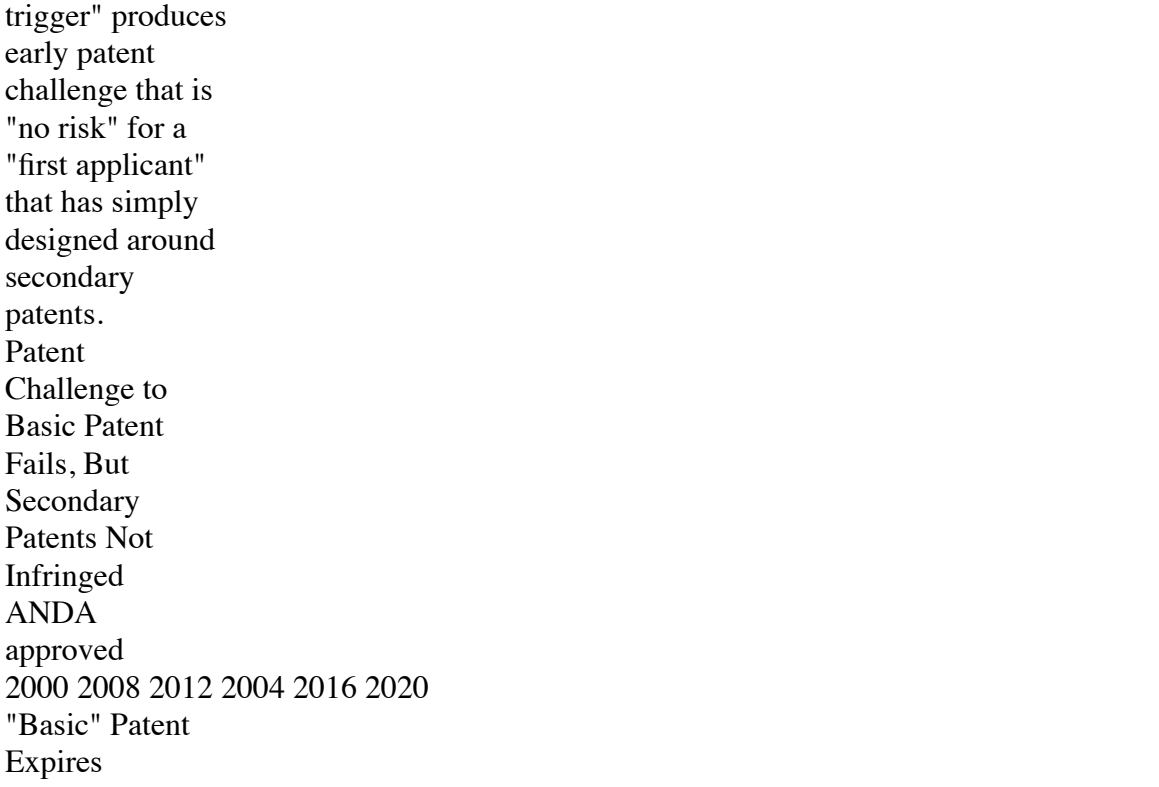
The imperative for a simple forfeiture to close the loophole could hardly be more apparent or imperative. In no case above is the 180-day exclusivity operating as an "incentive" to challenge patents that otherwise might not be challenged. In every case, the 180-day exclusivity is given to one applicant that undertook no different or greater burden than any of its generic competitors. S. 1 - without closing the loophole - would make utter nonsense of "generic exclusivity", at a huge cost to consumers.

Appendix B1

TESTIMONY ON BEHALF OF ELI LILLY AND COMPANY
BEFORE THE COMMITTEE ON THE JUDICIARY - UNITED STATES SENATE
AUGUST 1, 2003
ON THE "GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"
Offered by
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company

Appendix B

Illustrative Example of "Parking" Exclusivity Under
S. 1 and H.R. 1
Comparison With Existing Law



Secondary (Formulation-
Related, Polymorph,
Etc). Patents Expire
Subsequent Applicants
Approved
NDA for
NCE Drug
Approved.
Four-year Moratorium
Period Ends; ANDAs
Can Be Filed
Court
decision
ANDA
filed
180
days
ANDA
approved
Court
decision
ANDA
filed
Subsequent Applicants
Approved
Court decision trigger in current
law puts early challenges at risk
of loss of 180-day exclusivity
period--
S. 1 - H.R. 1:
Existing Law:
No trigger for
180 days until
"basic patent"
expires.
Consumers bear cost of higher generic drug prices at a point when all generics would otherwise have been free to market - competing generic companies have independently established noninfringement of all the unexpired Orange Book patents.
Exclusivity
cannot be
"parked" &
expires before
ANDA approval.
parking
permitted