I apologize to the people of New Jersey for having placed the seat of the Senate that they have allowed me to occupy in this position. The day I was elected to the Senate remains among the most cherished of my life.

During recent weeks, I have spent long nights tormented by the question of how I could have allowed such lapses of judgment to compromise all that I have fought to build. It might take a lifetime to answer that question to my own satisfaction.

The question I want every person in New Jersey to have answered today is that all during this ordeal I never stopped fighting for the things in which I believe. I never compromised in the struggle to make the lives of the people I love better.

I am grateful that this matter has come to a close, regretful as they might be, sorrowful as I remain. I thank my colleagues for their time and their attention.

Mr. President, I yield the floor.

GREATER ACCESS TO PHARMACEUTICALS ACT

Mr. HATCH. Mr. President, I rise to speak again on the pending legislation—S. 812—the Greater Access to Pharmaceuticals Act.

First, let me say that I am hopeful the on-going talks among interested Senators and affected parties will succeed in reaching an acceptable compromise on a Medicare Prescription Drug Benefit. That is a promise to seniors we need to honor. I remain committed to achieving that goal.

I think that Senator SNOWE made a good point when she said earlier today that there is no reason to pull the bill down and halt the negotiations over the Medicare drug benefit at his point. Why not encourage these talks to continue over the August recess?

Although we got off to a rocky start when the Majority Leader decided to by-pass the Finance Committee to avoid the Tripartisan bill being reported by the Committee, I remain hopeful that we can come together if we stick to it.

Whether those talks succeed or fail, the Senate will have to dispose of the underlying legislation, S. 812. This is the legislation first introduced by Senators MCCAIN and SCHUMER that was almost completely rewritten by the HELP Committee via the Edwards-Collins substitute amendment.

In many respects, the Committee substitute is an improvement over the McCain-Schumer language. Let me hasten to say, though, there are still major problems with the language.

I have laid out in some detail the shortcomings in the provisions of the bill that purport to fix the problems associated with the statutory 30-month stay. We designed this stay to permit a reasonable period of time to litigate the status of pioneer drug patents, but has been used in several cases by brand name drug manufacturers to forestall improperly generic competition.

As this barely three-weeks old language is scrutinized by experts, many are concluding that it comes up short. For example, there is an interesting and growing correspondence between the architect of the pending legislation, my friend from Massachusetts, Senator KENNEDY, and the organization that represents the Nation's biotechnology companies—BIO, the Biotechnology Industry Organization.

In its letter of July 22, 2002 to Senator KENNEDY, BIO complains about the:

> carte blanche authority of FDA to determine testing methods applicable to full NDAs, [New Drug Applications] loss of the ability to protect our intellectual property because of failure to meet new filing deadlines under food and drug law, and an unwarranted private right of action afforded generic companies to sue members in efforts to ''delist'' patents or ''correct'' patent information. Whatever the purposes of these provisions, we fundamentally disagree with their consequences perhaps the result of producing totally new provisions only 36 hours before mark-up.

Actually, I think this completely new language was not available until 24-hours before the markup.

It is also my information that a meeting last Friday between Senator KENNEDY's staff and BIO staff did little to clear up these objections.

I have no doubt that Senator KENNEDY is aware this bill is opposed by the Massachusetts-based biotech firm, Millennium Pharmaceuticals, as well as the Massachusetts Biotechnology Industry Organization.

As I have laid out previously, in addition to the policy question of the extent to which these new provisions upset the balance of Hatch-Waxman, a broad spectrum of legal analysts who range from Susan Estrich to Judge Bork have raised a number of concerns about the pending legislation on a wide variety of issues, including concerns that the bill runs afoul of the Takings Clause as well as violates the GATT Treaty's intellectual property provisions.

Last week, I included in the RECORD a letter from the American Intellectual Property Law Association opposing the patent forfeiture and private right of action provisions of the bill.

This week I want to highlight a letter to Chairman KENNEDY from the Intellectual Property Owners Association expressing severe reservations about the bill.

The IPO represents U.S.-based owners of patents, trademarks, copyrights, and trade secrets. The organization includes some 100 American firms that are among the largest patent filers in the United States. The membership of the Intellectual Property Owners Association submit about 30 percent of all patents filed with the Patent and Trademark Office.

The IPO letter raises concerns about how the Substitute to S. 812 might conflict with the international Agreement on Trade Related Aspects of Intellectual Property Rights—the TRIPS provisions. Specifically, the IPO complains about the file-it-or-lose-it and sue-on-it-or-lose-it provisions of the bill. The letter states, in part:

> We believe these rigid barriers to enforcement of patent rights may conflict with ''normal exploitation of patent rights'' as that term is used in Article 30 of the TRIPS agreement, or could set a very damaging precedent for interpretation of Article 30 that would be used against the U.S. by its trading partners in other areas of intellectual property enforcement.

The new, untested, Edwards-Collins language has not been embraced by the intellectual property bar nor by the mainstream organizations that represent the interests of America's inventors.

The Administration has already issued a statement in opposition to S. 812.

Before we take any action to adopt the language that has agitated nearly everyone in the IP community, don't you think it would be prudent to factor in what the Patent and Trademark Office has to say about this new language that completely re-wrote the McCain-Schumer bill?

Commissioner James Rogan wrote to me today to give us PTO's initial reactions to re-write of S.812. Here is part of what the Commissioner of Patents and Trademarks says in his letter to me:

> USPTO does recognize that some changes to current law may be necessary to encourage appropriate access to generic substitutes and prevent abuses of the patent laws. But S. 812 clearly is not the answer. In fact, this bill would likely do the opposite of what its title suggests by limiting access to cutting-edge drugs, decreasing innovation, and ultimately harming the quality of treatments available to patients.

In addition to these significant concerns raised by the PTO, I would think that the report that was issued earlier today by the Federal Trade Commission, after a unanimous vote of the Commissioners, would compel my colleagues in the Senate to question the wisdom of adopting the HELP substitute to S. 812. While I am still studying the details of the report, it seems abundantly clear that the major recommendations of the Federal Trade Commission in no way mirror the legislation pending on the floor.

With respect to the 30-month stay, the FTC suggests a policy of one stay per generic drug application for all patents listed in the official FDA Orange Book prior to the date on which the generic drug application is filed.

This is precisely the position I advocated before the HELP Committee back in May.

This is the position that the Ranking Republican Member of the HELP Committee, Senator GREGG, attempted to get adopted by the HELP Committee during the mark-up.

The narrowly-tailored FTC recommendation in this area should be contrasted with the overly-broad Edwards-Collins language that contains the offensive file-it-or-lose-it and sue-

on-it-or-lose-it provisions, the new and unprecedented—and unnecessary—private right of action in the Federal Food, Drug, and Cosmetic Act, as well as the rule that allows the 30-month stay only for those patents issued within 30-days of the approval of the pioneer drug.

I know which policy I prefer—and it came from the FTC after its comprehensive year-and-a-half study of these issues, not from any secret backroom drafting sessions of various lawyers and lobbyists.

Let me now focus my comments on another major area addressed by the HELP Committee substitute to S. 812: the problem of collusion between brand name and generic drug manufacturers with respect to the rules in current law that grant 180-days of marketing exclusivity when a generic drug firm successfully challenges or navigates around a pioneer firm's drug patents.

The 180-day marketing exclusivity rule has been highly controversial in recent years.

The reason for this attention is simple. In a few number of documented cases, generic drug manufacturers entered into agreements with brand name manufacturers not to sell generic drugs.

As I will explain, due to the way the existing law—the Drug Price Competition and Patent Term Restoration Act of 1984—is written and has been interpreted by the courts, some of these arrangements had the effect of delaying multi-source generic competition well beyond the contemplated 180-days.

I should first note that the existing statute—the Waxman-Hatch Act—included this 180-day marketing exclusivity as an incentive to encourage patent challenges. If patents were found to be invalid, or if non-infringing ways to produce generic drugs were developed, consumers could benefit from the earlier-than-anticipated introduction of generic drugs into the marketplace.

In enacting these provisions, it was the intent of Congress to award this exclusivity only to a generic drug applicant that was successful in defeating a pioneer firm's patents.

FDA's 1994 regulations implementing the Hatch-Waxman Act required the generic drug challenger to defend successfully the lawsuit that a pioneer firm must initiate within 45-days after being notified that the generic firm was challenging the patent.

It must be emphasized that the reason the generic drug firm is the plaintiff in the suit, rather than the defendant, is that the statute contains a special protection allowing generic firms to conduct what would normally be infringing activities in order to secure FDA regulatory approval. This is the so-called Bolar Amendment, a provision of law that, in my opinion, has not been adequately recognized by the proponents of S. 812.

Essentially, the Bolar language trumps the general rule against patent infringement codified in section 271(a) of the patent code. The Bolar Amendment, codified in section 271(e) of the patent code, allows generic drug firm to infringe patents in order to win FDA approval and gear up production and creates an artificial act of patent infringement at the moment that the generic firm files an abbreviated new drug application with the FDA.

Once the application is filed, the pioneer firm has 45-days to file a lawsuit in order to take advantage of the statutory 30-month stay designed to allow the patent litigation to be completed before generic may be permitted to enter the marketplace.

For over a decade after Hatch-Waxman was enacted in 1984, it was thought that only a generic firm that was successful in the litigation, that is, a firm that had successfully defended the suit brought by the pioneer firm, could qualify for the 180-days of marketing exclusivity.

In 1997, FDA's successful defense requirement was struck down by the D.C. Circuit Court of Appeals in the case of Mova Pharma v. Shalala.

The following year, in 1998, the D.C. Circuit decided the case of Purepac Pharm v. Shalala. This decision upheld FDA's new system of granting the 180-day exclusivity to the first filer of a generic drug application even if the pioneer firm did not sue for patent infringement.

That same year, the Fourth Circuit Court of Appeals issued its opinion in Granutec v. Shalala. This case held that the exclusivity of the first filer could be triggered by a court decision with respect to a second, third, or subsequent filer.

Essentially, these decisions added up to one thing: mischief.

Once the exclusivity was awarded to the first filer of a generic drug application divorced from any requirement for a successful patent challenge, it became apparent to some that the first filer—with a financial inducement from the patent holder—could effectively forestall multi-firm generic competition by simply not going to market. If the 180-day clock never started, multi-source generic competition could be forestalled until the patents expired.

This could last for years.

As a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these type of reverse payment collusive arrangements appalling.

I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition.

To date, there are known to have been relatively few such agreements. The FTC has obtained consent decrees in two cases: with Hoescht and Andrx over the drug, Cardizem, and with Abbott and Geneva over the drug, Hytrin.

The agency suffered a set-back recently in the third case it brought in this area which involved an agreement between Schering-Plough, Upsher-Smith, and American Home Products with respect to the compound K-Dur 20, a widely prescribed potassium chloride supplement. While the FTC settled with American Home products, an Administrative Law Judge recently rejected the agency's argument in the case against Schering and Upsher-Smith. The ALJ's opinion looked at the facts of competition in the potassium chloride market and concluded that FTC had not proven its case given the highly-competitive nature of this particular market.

However the K-Dur case ultimately is decided, I commend FTC Chairman Tim Muris for indicating he will continue the agency's policy of zealously reviewing these type of reverse payments cases to determine whether such agreements run afoul of the antitrust laws.

In my earlier statements, I commended both the enforcement actions of the FTC and the development of the Drug Competition Act, S.754, by Senator LEAHY for creating a climate unfriendly to the execution of any additional collusive deals not to compete between generic and brand name companies.

Today's release of the report: Generic Drug Entry Prior to Patent Expiration: An FTC Study underscores the importance of Senator LEAHY's work in developing the Drug Competition Act. This bill was reported by the Judiciary Committee last year.

I was pleased to work with him to refine the bill before the Committee adopted this measure. I am particularly pleased that he became convinced it was wise to abandon a patent forfeiture feature very similar to the provisions contained in the Edwards-Collins substitute to S. 812 that so many biotech and pharmaceutical firms and intellectual property experts find so objectionable.

I did have a few additional suggestions for improving S. 754, but in the interest of moving the legislation forward in a bipartisan fashion, I supported the bill in Committee.

Frankly, one of my suggestions is very simple and amounts to recognition of the importance of the bill. This simple suggestion would be to codify the bill as part of the Clayton Act, rather than let the language float as a statute-at-large.

Here are the other concerns that I have with S. 754.

The Leahy bill exempts three types of agreements: first, purchase orders for raw material supplies; second, equipment and facility contracts; and third, employment or consulting contracts.

These three categories were also exempted by the FTC in its recently completed study of the pharmaceutical industry. To these three, I would suggest adding two other classes of non-germane agreements: first, packaging and labeling agreements and, second, confidentiality agreements. It seems to me

that the thrust of the legislation is to get a quick review of actual executed agreements relating to settlements of patent non-infringement or patent invalidity cases arising out of Hatch-Waxman Paragraph IV certifications.

Garden variety packaging and licensing agreements or mere agreements to talk about possible settlements in a confidential manner are not what we are after with this legislation.

I think we should start with the presumption that the law will be followed. Given this perspective, I favor the total deletion of proposed Section 8, subsection (b) which creates a special rule for contract unenforceability. My understanding is that this is a relative recent addition to the Leahy bill and that only current sections 8(a) and 8(c) were in the original Leahy bill and, in fact, precisely mirror the long-standing Hart-Scott-Rodino enforcement language. In short, what does this new section 8(b) accomplish that is not included in the more general provision of section 8(c) that grants a broad authority for equitable relief?

And what is the real chance that one or both parties will not comply with the statute in the first place? And if one party reports, what could possibly be gained by the other party not reporting the agreement? For that matter, it might be preferable to change the bill to require a joint submission of a certified copy of the agreement because one can hardly imagine some poor FTC staff attorney doing a side-by-side, word-by-word reading of documents to make sure both parties sent the same agreement.

In addition, I think that language should be added to make explicit that nothing in this Act should be construed to discourage or prohibit legitimate settlements between brand name and generic drug companies. The Joint DOJ/FTC guidelines smile upon such settlements so long as they do not run afoul of other laws such as the antitrust statutes. The FTC Administrative Law Judge's decision in the K-Dur 20 case reminds us of this fact, no matter how the case is finally decided.

The essence of S. 754 is to see that every agreement between pioneer and generic firms that raises antitrust questions are promptly reported to the FTC and DOJ for appropriate scrutiny.

I think the emergence of the Leahy bill—and I must give credit as well to the McCain-Schumer bill, coupled with the strict FTC enforcement in this area and the agency's extensive industry-wide survey helps explain why these so-called reverse payment cases appear to be dwindling, and perhaps have completely halted for the time being.

Senator LEAHY should be pleased that the chief recommendation that the FTC is making today with respect to the collusive 180-day marketing exclusivity agreements amounts to an endorsement of S. 754.

The FTC report recommends that Congress:

> Pass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to the Federal Trade Commission.

This straight-forward recommendation is a far cry from the complex, barely comprehensible, 180-day marketing exclusivity fix that emerged from the HELP Committee.

As a Wall Street Journal article yesterday described the discussion of the Edwards-Collins substitute: ''In a remarkable session, it became clear that many lawmakers didn't understand the complex bill.''

Why should that be surprising given the fact that this completely new, incredibly- intricate, highly-technical language was made available the day before the mark-up? A review of proceedings of the two-day HELP Committee mark-up is very revealing and I would urge that the press and the public make the effort to review this discussion. I can see why Senators GREGG and FRIST are so frustrated about some changes in language that appear to have been agreed to one moment, only to vanish the next. One can only wonder who, how, where, when, and why such language was drafted—although yesterday's Wall Street Journal article may shed some light on some of the actors behind the scenes.

In many ways, the Edwards-Collins substitute misses the mark, and is too complicated to boot.

Nevertheless, I do think we need to re-examine the statute in this area in light of the potential for these type—or perhaps new types of—anticompetitive agreements to crop up in the future given how the current statutory language and court decisions work together to help create a climate for mischief.

The McCain-Schumer bill addressed the 180-day collusive reverse payments situation by a so-called rolling exclusivity policy. This rolling exclusivity means that if the eligible generic drug filer does not go to market within a specified time period, the 180-day exclusivity rolls to the next filer.

I do not favor rolling exclusivity.

I agree with what Gary Buehler, then Acting Director of FDA's Office of Generic Drugs, told the Judiciary Committee last year:

> We believe that rolling exclusivity would actually be an impediment to generic competition in that the exclusivity would continue to bounce from the first to the second to the third if, somehow or other, the first was disqualified.

I believe a better course of action was advanced by FDA in its 1999 proposed rule which suggested a use it or lose it policy. This simple rule is that if the first eligible generic drug applicant did not promptly go to market, all other approved applicants could commence sales.

Molly Boast, Director of the FTC Bureau of Competition, testified last May that, at the staff level, FTC supported FDA's use it or lose it proposal.

My first reading of the summary of the new FTC Report leads me to conclude that the agency favors a very aggressive use it or lose it policy. In this regard I must point out that the FTC Report contains three minor recommendations that center on the 180-day provision:

First, the agency would run the 180-day clock if a generic firm marketed the pioneer's product under a license, not an ANDA.

Second, FTC would codify current case law and run the 180-day clock from the time of any court decision, not an appellate decision as allowed under the HELP Committee language.

Third, the Commission would trigger the 180-days if a court dismissed a declaratory judgment for lack of case or controversy.

While I am just beginning my review of the FTC report, it appears that the FTC is advocating a very aggressive form of a use-it-or-lose-it policy.

As I have argued on a number of occasions, my view is that rolling exclusivity delays the day when multi-generic competition can commence. It appears to me that the FTC shares this view.

If our goal is to maximize consumer savings after a patent has been defeated, I find it difficult to see how rolling exclusivity achieves this goal. I certainly prefer a use it or lose it approach over the McCain-Schumer brand of rolling exclusivity.

I commend the sponsors of the Edwards-Collins substitute for rejecting the McCain-Schumer rolling exclusivity policy in favor of what Senator EDWARDS calls modified use-it-or-lose-it. Having said that, I am disturbed to learn that during the HELP Committee mark-up Senator EDWARDS and HELP Committee staff stated that, in fact, the exclusivity could roll indefinitely.

I understand the intent is to transfer the exclusivity once and only once, but having reviewed the language of the bill and the discussion at the mark-up, I am not convinced that the exclusivity will roll over only once.

In any event, even if the exclusivity only rolled over once, I question the rationale behind a policy that only delays the day when multi-source generic competition can commence.

It is only after the time when many generics enter the market that consumers receive the full benefits of price competition.

During the first 180-days when only one generic is on the market, the change in price may be marginal. This is so because when there is only one generic competitor during this 180-day time frame, neither the pioneer firm nor the generic firm is under any tremendous pressure to cut the price. The report, Drug Trend: 2001, published by Express Scripts, notes this dynamic:

> The A.P. [average wholesale price] for the first generic is usually about 10 percent below the brand. After the six month exclusivity granted to the first generic manufacturer, the price paid . . . for the generic quickly falls, often by 40 percent or more, as multiple manufacturers of the same generic product compete for market share. Moreover, it appears that the value of the 180-day

marketing exclusivity incentive may be worth much more today that it was back in 1984.

I understand that, in 1984, the number-one selling drug in the United States was Tagamet, with U.S. sales of about $500 million.

Today, it is estimated that Lipitor, the anti-cholesterol medicine, has a domestic market of over $5 billion annually. In nominal dollars, Lipitor sales today are 10-times higher than Tagamet sales were in 1984. In real dollars, I am told that this amounts to about a six-fold increase.

If we are going to open up the 180-day provisions of the 1984 law—and I think we should so long as we do it carefully and thoughtfully—I think we should reexamine other aspects of the 180-day rule such as whether we should retain the 180-days or some other number of days given the substantial six-fold growth in potential value of this incentive.

Why should we be locked into 180-days? The dirty little secret of the 180-day provision is that both the pioneer firms and generic firms like this provision because it delays the full price competition that only occurs when many generic enter the market.

I think that the mutual economic interest of the generic and the pioneer firms is not in perfect alignment with the interests of consumers with respect to the 180-day incentive.

Moreover, even if we could perfect the modified use it or lose it language of the Edwards-Collins substitute and the first qualified generic manufacturer could not, or would not, commence marketing and the exclusivity moved to the next qualified applicant, why should the second manufacturer get the full 180-days? Why not 90 days? Why not 60 days?

Frankly, I am disturbed that, in some circumstances, the Edwards-Collins language appears to grant exclusivity not to the successful generic litigant—but to a firm which was merely first to file papers with the FDA that triggered a legal proceeding.

I understand the rationale for this is that it will supposedly ensure multiple patent challenges. But, when we start rewarding the first to trigger lawsuits in place of actually winning the challenge, it strikes me as out of sync with the traditional American value of rewarding the actual winner.

I am all for assuring that there are sufficient incentives to ensure patent challenges. But, isn't there a limit beyond which we should direct these potentially enormous profits back to consumers?

While I have not seen any formal estimates, one would think that 180-days of marketing exclusivity for a $5 billion seller like Lipitor must mean hundreds of millions of dollars, and perhaps even $1 billion, in lost consumer savings.

Would we rather see 25 percent to 40 percent of that money in the hands of the trial attorneys who brought the case? Or, would we rather see that at least some of those funds earmarked for attorneys' fees be channeled to help citizens lacking access to prescription drugs?

Shouldn't we get more facts concerning the change in value of the 180-day marketing exclusivity today compared to 1984 and make any appropriate adjustment to this incentive? We don't want to set the incentive so low as to discourage challenges to non-blockbuster patents, but we don't want to set the incentives too high either.

As a matter of fact, some have questioned the need for retaining the 180-day marketing exclusivity at all.

For example, Liz Dickinson, FDA's senior, career attorney in this area, has asked:

> I suggest we look at whether 180-day exclusivity is even necessary, and I know that there is this idea that it is an incentive to take the risk. I say the facts speak otherwise. If you have a second, third, fourth, fifth generic in line for the same blockbuster drug . . . undertaking the risk of litigation without the hope of exclusivity, is that exclusivity even necessary?

Ms. Dickinson, a fine lawyer with no political axe to grind, went on to make the following observation with respect to the 180-day rule,

> We have got a provision that is supposed to encourage competition by delaying competition. It has got a built in contradiction, and that contradiction . . . is bringing down part of the statute.

Similarly, Gary Buehler, FDA's top official in the Office of Generic Drugs agreed with his colleague's assessment when he testified before the Senate Judiciary Committee last year:

> . . . we often have the second, third, fourth, fifth challengers to the same patent, oftentimes when the challengers actually realize that they are not the first and there is no hope for them to get the 180-day exclusivity. So with that in mind, I would agree with Liz's statement that generic firms will continue to challenge patents. Whether the 180-day exclusivity is a necessary reward for that challenge is unknown, but it does not appear that it is.
>
> I personally favor retaining some incentive to ensure vigorous patent challenges. But in light of this testimony and other factors, I do not believe there is a need to be locked into the current incentive—the 180-day exclusivity benefit.

I find it curious that neither the McCain-Schumer bill, nor the Kennedy mark, nor the Edwards-Collins amendment, proposed any changes in the current 180-day regime in light of the views of the FDA officials, the dramatic increase of the potential value of 180-days of exclusivity, and other factors.

This may have been partly due to the fact that neither the FDA nor FTC nor any representatives from the Administration testified at the HELP Committee hearing on May 8th. In fact, no committee of Congress has ever held a hearing of the language that was marked-up and reported by the HELP Committee.

On any number of occasions, I have heard Senator SCHUMER and others argue that the simple goal of this legislation is to close loopholes in order to return to the original balance in the 1984 law.

But what if conditions have changed and the original policies of the 1984 need to be reassessed?

Or what if there were an area that we didn't get right the first time?

For example, consider how Paragraph IV litigation treats patent invalidity and patent non-infringement challenges. These are lumped together, and both, if proven, can result in identical 180-day marketing exclusivity awards. In truth, invalidity and non-infringement are two very different types of claims.

I want to remind my colleagues of, and challenge them to question the implications of, lumping these two concepts together. We need to re-think this policy. As Al Engelberg, a smart and tough-as-nails attorney who specialized in attacking drug patents on behalf of generic drug firm clients, has said about this difference:

> In cases involving an assertion of non-infringement, an adjudication in favor of one challenger is of no immediate benefit to any other challenger and does not lead to multi-source competition. Each case involving non-infringement is decided on the specific facts related to that challenger's product and provides no direct benefit to any other challenger. In contrast, a judgment of patent invalidity or enforceability creates an estoppel against any subsequent attempt to enforce the patent against any party. The drafters of the 180-day exclusivity provision failed to consider this important distinction.

Once again, as one of the drafters of this law, I accept my share of responsibility for failing to fully appreciate the implications of this distinction.

The 180-day rule acts as only a floor in non-infringement cases. A particular non-infringer's marketing exclusivity can extend beyond the statutory 180-days. This period of marketing exclusivity can last until such time as another non-infringer might enter the picture or until the underlying patents are invalidated or expire.

Conversely, it can be argued that the 180-day floor actually works to the detriment of consumers whenever the 180-days of exclusivity acts to block entry of a second non-infringing generic product during the 180-day period. Why shouldn't a second or third non-infringer be granted immediate access to the market as would occur in any other industry? Consumers could enjoy the savings that accrue from immediate price competition.

I would hope that my colleagues working on the bill, and others interested in this debate carefully consider the distinctions between invalidity and non-infringement challenges. This is an area where we might have gone off-base in 1984.

While I am of the mind to retain a strong financial incentive to encourage vigorous patent challenges by generic drug firms, I am unconvinced at this point that we should retain the old language that grants identical rewards for

successful invalidity and non-infringement claims. I welcome debate and discussion on this matter.

Before we change the law, let us have a serious re-examination of whether to retain the 180-day marketing exclusivity in its current form both in terms of the length of the exclusivity period and whether the rewards for successful invalidity and non-infringement challenges should be treated identically.

My purpose in raising these points is to get an indication from the sponsors of this legislation and other interested parties, such as patient advocacy organizations, state Medicaid agencies, and insurers, whether there is interest in discussing the advisability of passing on more of the value associated with the current 180-day marketing exclusivity to consumers if it appears it is fair and appropriate to do so?

If there is interest, I would be willing to help fashion an appropriate amendment. It seems to me that we need to provide enough of an incentive to assure vigorous patent challenges, but we should give away no more exclusivity than is necessary. Every day of marketing exclusivity awarded to a generic firm comes at the expense of consumers. While we want to ensure vigorous patent challenges, we don't want to set the benefit too high at the expense of consumers.

I think we can and should explore this area further.

Frankly, I am not certain that I completely understand how the forfeiture language in Section 5 of the bill works. I do not think I am alone in this confusion. I understand that this language was the source of much confusion during the mark-up in the HELP Committee.

At some point, I would like to engage in a colloquy with the bill managers to ask some questions designed to clarify precisely how this provision works.

Let me say that if the bill reinstates the successful defense requirement and gives awards to the successful challenger so long as the firm goes to market in a timely fashion, I may be supportive of the general concept. I do wonder if the language in the HELP substitute overturns the effect of the *MOVA*, *Purepac*, and *Granutec* cases that I described earlier?

I must say that I think that there are some real advantages to Senator GREGG's simple and straight-forward policy of more closely following FDA's old-fashioned, easy to understand use-it-or-lose-it proposal.

I will continue to study the particulars of the three minor recommendations that the FTC has made in connection to the 180-day issue.

I must also indicate that part of the confusion concerning the effect of this new Edwards-Collins language stems from the discussion of the provision at the mark-up. I understand that when Senator EDWARDS first explained this section of the bill he said that the exclusivity could roll over one time if the first qualified applicant did not use it. I am told that Senator EDWARDS indicated his language would eliminate the possibility that this could just continue to roll over and over and over during which time the exclusivity in the marketplace continues.

However, upon questioning from Senators GREGG, FRIST, and SESSIONS, the Committee staff then explained that if the second generic firm qualified does not use the exclusivity then the process would start all over again. The HELP Committee staff went on to explain, apparently in direct contradiction to Senator EDWARD's first explanation, that the exclusivity could roll indefinitely if there is no generic ready to go to market.

On the second day of the mark-up, Senator EDWARDS seemed to indicate that the Committee staff had it right and he had it wrong when he at first said that the provisions of Section 5 of the bill eliminated the policy of rolling exclusivity. In fact, I am told that Senator EDWARDS then acknowledged that if there were nobody to compete, then the exclusivity could keep rolling over and over.

I am afraid that the Edwards-Collins brand of modified-use-it-or-lose-it is, at least, very confusing. At worst, it is just another version of rolling exclusivity.

I want to learn what the FTC thinks about the Edwards-Collins language.

What the proponents of this language have failed to do is to explain why any third, fourth, fifth, or subsequent filer should be given 180-day of very valuable marketing exclusivity?

Moreover, why for example should a fifth filer be treated any differently than a sixth filer if neither has won a patent challenge and both are ready to go to market?

This dog just won't hunt.

Recall that some experts at FDA don't even think this incentive is necessary.

As I stated earlier, I am somewhat sympathetic to the concerns of generic drug firms that any exclusivity awarded should be measured from the time of an appellate court decision. But this principle may not hold up if any form of rolling exclusivity is adopted or if we have multiple patents and multiple challengers, some of whom are attacking on invalidity and some of whom are attacking on non-infringement.

Frankly, in light of the FTC report just issued this morning, I feel compelled to reconsider if my sympathies are consistent with my use-it-or-lose-it view even in the case, increasingly rare, I am told, of one patent and one challenger.

I am troubled by the provision of the bill that appears to grant each generic firm that qualifies for the benefit of the 180-day marketing exclusivity incentive a 30-month period to secure FDA approval. This is measured from the time of the filing of the generic drug application.

If the first firm eligible to take advantage of the 180-day benefit drops out for some reason, it seems to me that the best thing for consumers would be to approve all applications that are ready to go without singling out any of these applications for 180-days of exclusivity. If, for example, the second firm eligible under the terms of Section 5 is in a dispute with FDA over a good manufacturing practice inspection and can't go to market, it is consumers who will suffer. In a case where, say, there are 14-months remaining on the 30-month clock allowed under Edwards-Collins, it does not seem fair if the next firm eligible on the list already has satisfied all of the FDA requirements and is ready to go to market.

I would hope that the proponents of the substitute amendment will help us all understand just how Section 5 is intended to work.

It is difficult for me to see why we should adopt a policy whereby the balance of the 30-month period described in Section 5(a)(2)''(D)(i)(III)(dd)'' on page 44 of the bill could conceivably be greater than the 180-days of marketing exclusivity. Upon default of the first qualified applicant, why should we wait for a second eligible drug firm to obtain FDA approval when there may be a third, fourth, or fifth applicant in line with FDA approval ready to go?

I hope the sponsors of the legislation are not locked into their so-called modified-use-it-or-lose-it policy. The discussion at the HELP Committee mark-up suggests that the language is, in fact, just another elaborate version of the flawed rolling exclusivity policy. While I can readily see why rolling exclusivity is attractive to generic drugs firms—and their lawyers—who routinely challenge patents, I don't see where this policy is good for the American people.

Whatever happened to the American tradition that rewards success in litigation, not just filing papers with FDA and making a claim in court?

For all of the reasons I have just discussed, I think it would be wise for Congress to take time and reassess the wisdom of retaining the 180-day marketing exclusivity provision in essentially the same form as enacted in 1984.

As I argued last night, the Senate would be well-served if we had a more orderly discussion of the facts and recommendations contained in the new FTC study.

I see that my friend from Massachusetts is trying to spin the FTC study as supporting the changes in patent law contained in the HELP Committee substitute.

But the fact is, and it is a fact that will be better understood over time, that the FTC recommendations are at variance with the major provisions of the bill on the floor.

Let me just spell some of them out for you.

The FTC urges adoption of legislation that would allow one 30-month stay, measured from the time that each generic drug application is submitted while S. 812 limits the stay to

those patents issued within 30-days of the approval of the pioneer drug.

The HELP Committee Substitute contains several provisions that require innovator firms to list all, and sue on, their patents related to each particular pioneer drug or forfeit their customary patent rights; the FTC makes no such recommendations regarding patent forfeiture.

The HELP Committee Substitute creates a new private right of action to attack the listing of patents with FDA, while the FTC report makes no such recommendation.

The HELP Committee Substitute embraces a form of 180-day marketing exclusivity that allows the exclusivity to roll from one generic drug manufacturer to another in, I might add, a very complicated fashion that potentially has no clear endpoint. The FTC Report appears to support a very aggressive form of a use-it-or-lose-it policy which, for example, would trigger the 180-day period from the time of a district court decision. The pending legislation allows generic competition to be delayed until after an appellate court rules.

The FTC recommends that certain potentially anti-competitive arrangements between pioneer and generic firms be reported to the FTC in a fashion similar to Senator LEAHY's legislation, S. 754, the Drug Competition Act. The HELP Committee is silent in this respect.

So the differences are significant between the bill on the floor and what the FTC recommends.

No amount of spinning in the press will change these facts. In light of the FTC study and some of the arguments that I have made here today, I wonder if some of those who are backing S. 812 because they were told it is a good bill will now reconsider what the bill does and decide that they are being sold something of a bill of goods?

I would urge my colleagues, as well as consumer organizations and pharmaceutical purchasers such as insurers and self-insured businesses to reflect upon what I have said on this subject today.

This is an area in which I think we would be wise to reject Senator SCHUMER's argument that all we are doing with this legislation is restoring the balance of the old Hatch-Waxman Act.

On a number of occasions, I have commended Senator SCHUMER and Senator MCCAIN for moving their legislation forward. Even if the bill that came out of the HELP Committee does not resemble very closely their bill, and even if I still have major problems with this hastily considered floor vehicle, I commend them again today. I just hope that they, and Senators KENNEDY, FRIST, COLLINS, and EDWARDS will work to improve this legislation.

I think that over the last two weeks that I have made a case for taking the time to get this legislation right.

We all know that S. 812 was plucked from the calendar to be used as a vehicle to debate the Medicare Prescription Drug Benefit, not because it was some finely tuned consensus bill.

As I said last night, let us not rush to adopt legislation in this area before the ink is dry on the FTC report. We need to understand and debate the FTC report and its recommendations. My first reading of the Executive Summary of the FTC Study reveals a fundamental disconnect between the agency's recommendations and the legislation that emanated from the HELP Committee. The floor of the Senate is not the best place for the type of discussion the FTC Report warrants.

We need to allow the Judiciary Committee to play a role in fashioning legislation that is fundamentally an antitrust bill with patent law and civil justice reform implications. Certainly, the FTC smiled upon what the Judiciary Committee was doing in this area. And just as certainly, the PTO did not smile upon how the substitute to S.812 treats longstanding patent rights.

The detailed criticism that I have made to the pending bill in no way minimizes the importance of the matters that are the subject of the pending legislation, because they deserve Congressional attention.

Let me be clear. We should make some changes in the Hatch-Waxman Act. No law so complex cannot be improved.

But let's do it the right way because the American public deserves both the newest medicines and the most affordable medicines.

I do not believe, moreover, that S. 812 even identifies the most important issues we should address in Hatch-Waxman reform.

I hope to return to the floor to discuss some ideas for a more comprehensive approach to reforming the Drug Price Competition and Patent Term Restoration Act. I suspect that many others, including my friend, Henry Waxman, will want to participate in such a discussion.

I am unconvinced that focusing on how best to bring the law back to the old days of 1984 is the right way to go about reforming the Hatch-Waxman Act.

I think we may be well served if we attempt to modify the law in order to help usher in a new era of drug discovery while, at the same time, increasing patient access to the latest medicines.

Let us not adopt this hastily-crafted bill in the last week before August recess. Please do not hold your nose and close your eyes and vote for this bill by telling yourself that we can fix it in conference. We can do better.

We would do better in the long run for the American people if we put S. 812 aside for the time being and devote our attention to passing the Omnibus Trade Promotion Authority, Trade Adjustment Assistance, and Andean Pact legislation before this week runs out. We need to get the economy going again and trade can help us achieve that goal.

Let's face it. S. 812 is not ready for adoption, but the trade legislation is long overdue.

I ask unanimous consent that the letters from the PTO and BIO, discussed earlier in my speech, be made part of the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

BIOTECHNOLOGY INDUSTRY ORGANIZATION,
Washington, DC, July 22, 2002.

Hon. EDWARD KENNEDY,
U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR SENATOR KENNEDY: Thank you for your prompt response to my letter of July 15 objecting to several new provisions of S. 812, the Schumer-McCain legislation. No one was more surprised than members of the biotechnology industry at these last-minute changes, which pose significant problems for our companies. At this stage in the debate, we must strongly object to these provisions and urge that they be deleted from the bill under consideration on the floor of the Senate.

The Biotechnology Industry Organization quite intentionally took no position on the particulars of the original version of the Schumer-McCain bill, leaving debate on the practices described in your letter to others. But the bill has been changed radically, without opportunity for members of our industry to provide legal and policy reaction to the new provisions on bioequivalence, loss of rights to sue for patent infringement, and a right of action for generics to sue our companies to ''correct'' patent information filed with the Food and Drug Administration.

In BIO's July 15 letter, I pointed out the potentially damaging consequences to our emerging industry that could result from these provisions—*carte blanche* authority of FDA to determine testing methods applicable to full NDAs, loss of the ability to protect our intellectual property because of failure to meet new filing deadlines under food and drug law, and an unwarranted private right of action afforded generic companies to sue members in efforts to ''delist'' patents or ''correct'' patent information. Whatever the *purposes* of these provisions, we fundamentally disagree with their *consequences*—perhaps the result of producing totally new provisions only 36 hours before markup.

We also point out that we were assured by committee staff that the bioequivalence provision was intended only to confirm FDA's authority to craft tests for bioequivalence for products not easily absorbed in the bloodstream. We were also assured that this provision (section 7) would be worked out before floor consideration. This has not occurred, despite the fact that BIO provided draft language that accomplishes precisely the stated purposes of the bioequivalence section.

BIO retains its admiration for you and your staff and appreciate very much your past efforts to respond to challenges that confront our industry in Massachusetts and across the nation. We have no doubt that you did not intend that the bill's new provisions pose threats to BIO companies, and look forward to an opportunity to work with you to remove from S. 812 the provisions on bioequivalence, loss of rights to sue for infringement and the private cause of action during its consideration on the Senate floor.

Sincerely yours,

CARL B. FELDBAUM,
President.

UNITED STATES PATENT
AND TRADE OFFICE,
Washington, DC, July 30, 2002.

Hon. ORRIN HATCH,
U.S. Senate,
Washington, DC.

DEAR SENATOR HATCH: In a few months, the United States Patent and Trademark Office (USPTO) will celebrate its 200th year in existence. During that time, we have been the only Federal agency charged with administering this Nation's patent laws and determining whether inventions are patentable. USPTO plays a critical role in promoting and protecting intellectual property and the work of our Agency helps to stimulate American innovation and investment.

At your request, USPTO is providing its views on the advisability of the changes in patent laws in S. 812, the Greater Access to Affordable Pharmaceuticals Act. This letter is intended to inform you of our objections to the current language in S. 812.

First, in some cases, S. 812 would forfeit unnecessarily the core right of patent holders—the right to exclude others from practicing the invention for the entire patent term. After years of research and development and significant investment, the patent right is extinguished for the mere failure to satisfy an administrative task or respond in a timely manner. For example, if a patent holder fails to list the patent with the Food and Drug Administration within a certain time period, the patent is invalidated. Furthermore, if a patent owner fails to bring an infringement action within 45 days of receiving notice (also known as 'Paragraph IV') from a drug manufacturer that the patent is invalid or not infringed by the generic drug, then the patent right is forfeited. In this circumstance, the patent owner is barred from ever bringing an infringement case in connection with the generic drug at issue.

Second, we are concerned with the bill's disparate treatment of patents depending on issue date. The Hatch-Waxman Act gives a patent holder an automatic 30-month stay to defend a challenge to the patent by a generic drug company. S. 812 would apply this 30-month stay only to patents that issue within 30 days of the new drug application approval. This limitation is arbitrary and unrealistic. The timing of issuance bears no relation to the importance of innovation. Moreover, the patent applicant often has no control over when a patent issues. Therefore, affording certain benefits to patents that issue only within a certain time frame would be unworkable and unjust.

Finally, USPTO believes it is vital to consider each patent rigorously and uniformly to determine whether the application satisfies the standards of patentability. All patent applications are examined with equal scrutiny and all patents must satisfy the same criteria of utility, novelty, and nonobviousness before they are issued. Each pharmaceutical patent, like all other patents, is entitled to a presumption of validity and should be judged accordingly.

USPTO does recognize that some changes to current law may be necessary to encourage appropriate access to generic substitutes and prevent abuses of the patent laws. But S. 812 clearly is not the answer. In fact, this bill would likely do the opposite of what its title suggests—by limiting access to cutting-edge drugs, decreasing innovation, and ultimately harming the quality of treatments available to patients.

Before considering any future legislative efforts, we should applaud the success of the time-tested Hatch-Waxman Act and respect the delicate industry balance it forged. In all cases, any changes should incorporate the expertise of the Committees on the Judiciary of Congress, in addition to the appropriate Government agencies. Only through a carefully conducted analysis can a result be reached that benefits consumers while promoting the progress of science and innovation.

I hope this information is helpful and I would welcome the opportunity for consultation on future endeavors.

Sincerely,

JAMES E. ROGAN,
Under Secretary and Director.

AMERICA MEMORIALIZES TWO MORE VIETNAM WAR HEROES

Mr. LOTT. Mr. President, I rise today in remembrance of a fellow Mississippian, Fred C. Cutrer Jr. and his navigator Leonard L. Kaster, who died serving their country during the Vietnam War. Captain Fred C. Cutrer Jr. was a pilot on a B57 Canberra Bomber, and during his service for his country, he became instantly known around his base as a loving husband and an immensely proud father of two sons. He would often be found showing pictures of his family to his friends and squadron. Fred was also courteous and friendly, exemplifying the character of a true southern gentleman. Jimmy Speed, a child-hood buddy described his charming character by stating,

I use to call him good-humor man. He was a very smart man, and people liked him immediately. I always felt that if he had gotten to the ground alive, those people wouldn't have hurt him because he was so likeable and friendly that he would have fit into any crowd.

On August 6, 1964 Cutrer and 1Lt. Leonard L. Kaster, unknowingly flew the skies for their last time. They were flying over South Vietnam, North East of Tan Son Nhut, and according to Defense Intelligence data, their airplane came under heavy fire from Viet Cong forces, causing them to crash and explode near the Sang Dong Nai River in Long Khan Province. Both men were classified ''Killed in Action, Body Not Recovered,'' and Cutrer was promoted to the rank of Major.

In the spring of 1997, the Department of Defense, with the help of a Vietnamese native, helped bring closure to Cutrer's family by finding Cutrer's dog tag and aircraft identification plate that had been buried one meter beneath the surface of a jungle bog. This discovery led to the declaration of these men's ceremonial burial for June 6, 2002, with full military honors. I am thankful to say that both of these men, nearly forty years following their patriotic death for their country, now lay buried in Arlington National Cemetery.

Both the Cutrer and Kaster families flew from Mississippi to attend the ceremony, and Air Force General Frank Faykes presented flags to the families of both men. Buried alongside Cutrer is his wife, Shirley, who was killed in an automobile accident four years ago. The children were pleased to see their father properly honored as a hero and their mother rightfully buried beside him.

American troops have a slogan stating, ''We leave no man behind.'' I believe this manifests the pride and patriotism of our troops. Cutrer's sister, Lillie Cutrer Gould, promised her younger brother that if anything were to happen to him in Vietnam, then she would bring him back home. Not too many days ago, Mrs. Gould successfully achieved her promise to her brother, and America again exercised its duty and commitment to its soldiers.

I salute John C. Cutrer Jr. and Leonard L. Kaster for serving their country and helping make America a better and safer place to live. I am thankful that I reside in a country where we take pride in our soldiers, and we carry a strong commitment never to forget their courageous acts nor to leave anyone behind. I want to thank God for allowing John and Shirley Cutrer to eternally lay side-by-side in Arlington's National Cemetery, and I want to thank America for again making me proud of our citizens. I know my colleagues will join me in memorializing and commending the lives of John C. Cutrer Jr. and Leonard L. Kaster, two American heroes.

REMEMBERING MR. JOHN M. McGEE

Mr. LOTT. Mr. President, I rise today to pay proper tribute to Mr. John M. McGee, a devoted husband, father, and grandfather as well as a memorable American patriot. John was born in Brookhaven, MS on September 16, 1933, and in February 23, 2002, John passed away as a result of a sudden heart attack. In his high-school years, John was blessed with speed and athleticism that contributed to his becoming an extraordinary football player and an excellent athlete. John's athleticism led him to set the state record in the 100-yard dash. John attended my alma mater, the University of Mississippi, where he played football for the Ole Miss Rebels. John's patriotism towards his country convinced him to interrupt his education at Ole Miss and enlist with the U.S. Navy where he served on the destroyer tender *Shenandoah* and the destroyer *Willard Keith*. During his duty in active service, John took part in the decisive Inchon invasion commanded by General Douglas McArthur.

John went on to earn his bachelor's degree in engineering from the Armed Forces Institute. After an honorable discharge, he pursued his career in engineering until 1966 when he accepted a job with the Department of Defense where he conducted operations in Vietnam, Cambodia, Laos, and Thailand until 1969. During John's service in Vietnam, he discovered and exposed extensive corruption in American military operations. The Governmental Accounting Office confirmed these allegations, and John's discovery revealed the theft of 5.5 million gallons of fuel that had been originally intended for U.S. Military forces but had been penetrated and used by the enemy. John's inquiry helped save the lives of many