

Mr. BENNETT. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. DURBIN. Madam President, unless the Senator from Utah has any further amendments or modifications, I do not believe there are any additional actions on the bill.

Mr. BENNETT. Madam President, one of the pleasures of handling this bill is that there are almost always no additional amendments or complications.

Mr. DURBIN. I thank the Senator from Utah and yield back all my time.

The PRESIDING OFFICER. Does the Senator from Utah yield back his time as well?

Mr. BENNETT. The Senator from Utah yields back all his time.

The PRESIDING OFFICER. All time is yielded back.

The question is on agreeing to the committee amendment.

The committee amendment was agreed to.

The PRESIDING OFFICER. Under the previous order, the question is on the engrossment of the amendments and third reading of the bill.

The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time.

The PRESIDING OFFICER. The Senator from Nevada.

Mr. REID. Madam President, I ask unanimous consent that the vote on passage of H.R. 5121, the legislative branch appropriations bill, occur at 1:50 p.m. today, with rule XII, paragraph 4 being waived.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### MORNING BUSINESS

Mr. REID. Madam President, I ask unanimous consent that there be a period of morning business with Senators allowed to speak therein for a period not to exceed 10 minutes each up until 1:50 today, the time set for the vote, and the time to be equally divided and controlled in the usual form between the two leaders or their designees.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. REID. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. HATCH. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### GREATER ACCESS TO PHARMACEUTICALS ACT

Mr. HATCH. Mr. President, I rise to speak on the pending legislation, S. 812, the Greater Access to Pharmaceuticals Act. Even if I had major dif-

ferences of opinion on the substance of this legislation, I commend Senators MCCAIN and SCHUMER, KENNEDY and EDWARDS for their efforts in this area.

I especially wish to recognize the efforts of Senators KENNEDY, EDWARDS, and COLLINS for their work, which was almost a complete rewriting of the McCain-Schumer bill. Let me also hasten to commend Senators GREGG and FRIST for working to improve the bill that emerged from the HELP Committee and for their leadership during the debate.

Mr. President, last week, I provided a brief summary of the existing statute that S. 812 seeks to amend, the Drug Competition and Patent Term Restoration Act of 1984. I happen to know something about this law, which is commonly referred to as the Waxman-Hatch Act, or alternatively, the Hatch-Waxman Act.

Last week, I gave an overview of my concerns with the HELP Committee legislation. With those comments in mind, today, I want to delve further into the details of the HELP Committee re-write of S. 812 the bill originally introduced by Senators MCCAIN and SCHUMER.

The central components of S.812 are aimed at rectifying concerns raised in recent years over two features of the 1984 law: first, the statutory 30-month stay granted to a pioneer firm's facing legal challenges to its patents by generic competitors; and, second the 180-day period of marketing exclusivity awarded to generic drug firms that successfully challenge a pioneer firm's patents.

During debate on S. 812, there have been a number of comments indicating that there is a substantial problem with these two provisions. That may or may not be the case. One great disadvantage of holding the floor debate at this time is that we do not have the benefit of an extensive Federal Trade Commission survey of the pharmaceutical industry that focuses on precisely these two issues that go to the heart of S. 812 and the substitute adopted by the HELP Committee. The results of this long-awaited, extensive, industry-wide FTC survey are expected in a few weeks.

I have stated on numerous occasions that before this body undertakes a substantial rewrite of provisions central to the Hatch-Waxman Act, we should have the benefit of the FTC study and its implications.

The Senate could have taken a more prudent course. The Senate could have waited for the FTC report. We—and by we I specifically include the Senate Judiciary Committee—could have held hearings on the FTC study, evaluated the data, and then discussed, debated, and refined the actual, now barely two-week old, legislative language that is pending on the floor today.

But this was not possible due to the tactical decision of the Majority to dispense with the regular order so as to minimize the politically-inconvenient

fact that the Senate Finance Committee would have most likely have rejected any Democratic Medicare drug proposal in favor of the Tripartisan approach.

To my great disappointment, although not anyone's great surprise, we failed to arrive at the 60-vote consensus required to enact a Medicare drug bill in the Senate. Make no mistake about it. This is a great failure for the American people because for two years now we have set aside \$300 billion in the federal budget to be spent over 10 years to provide prescription drug coverage for Medicare beneficiaries.

We have all heard from elderly constituents many of whom live on limited, fixed-incomes—who have had substantial difficulties in paying for prescription drugs. Rather than rise to the occasion and make good on our promise to rectify that situation, and we are letting this abundant opportunity slip between our fingers.

I am very disappointed with the outcome of the votes Tuesday. It is my hope that we can find a way to come together on the important issue of a Medicare drug benefit for our seniors.

At a minimum, we should use the \$300 billion already in the budget to expand drug coverage for those seniors who need the most help. What we should not do is enact an expensive, government-run scheme that could bankrupt our country and plunge our economy further into the abyss when the government usurps what should legitimately be a private-sector-run benefit.

The collapse of any 60-vote consensus on the Medicare drug benefit does not show the public the type of bipartisan spirit that voters across the country say they prefer, in poll after poll after poll.

And so, we move back to the important, if more mundane, matters in S. 812.

One of the real marvels of this debate is that we have finally found out who the bad guys are in this debate.

It is not the government that has failed to make good on the promise to provide needy seniors with pharmaceutical coverage.

No, it's the pharmaceutical industry, an industry that is working day and night to bring us the medicines, the miracle cures that seniors seek.

I just had no idea that is who was going to be blamed.

This game plan comes right out of the Clintoncare play-book. As you hear attack after attack on the drug companies, I just want all of you listening to this debate to know that a similar tactic was employed by the Democrats when they tried to foist Clintoncare on a very unreceptive public back in 1993 and 1994.

Here is how David Broder and Haynes Johnson, two highly respected journalists, described the tactics of the Clinton White House in trying to pass its too grand health care reform plan:

This quote is from "The System," a book by Haynes Johnson and David

Broder, two leading political writers in this town, both of whom write for the Washington Post. Neither of them would be considered, by any stretch of the imagination, conservative. This is what they had to say in this book called "The System," talking about the American way of politics and how health care policy is formed:

In the campaign period, Clinton's political advisors focused mainly on the message that, for "the plain folks, it's greed—greedy hospitals, greedy doctors, greedy insurance companies. It was an us versus them issue, which Clinton was extremely good at exploiting.

This is the second quote:

Clinton's political consultants—Carville, Begala, Grunwald, Greenberg—all thought "there had to be villains." At that point, the insurance companies and the pharmaceutical companies became the enemy.

As you can see, here are two liberal political writers who summarized the Clinton health plan.

Villains . . . enemies all this sounds familiar in this debate. So, I will stipulate for the purpose of this debate that the pharmaceutical industry is the designated villain.

It strikes me as curious at least that the sector of the economy that plows back the highest portion of its revenues back into research—and research on life-threatening diseases no less—is treated with such disdain, at times even contempt, on the floor of the Senate.

Mr. President, from what has been said on the floor of the Senate you would think that this industry is trying to cause cancer, not trying to find cures.

I note that Senator KENNEDY has suggested our nation's biomedical research establishment has not really made much progress over the past few decades in terms of developing new drugs. I think the facts speak otherwise.

For example, consider the array of medicines that have been developed to treat HIV infection and the complications of AIDS. Through the unique public/private sector partnership that comprises the U.S. biomedical research enterprise, AIDS is being transformed from an invariably fatal disease into a chronic condition that we are so hopeful one day will have a cure.

These advances do not come easily or on the cheap. I would note the exciting reports from the recent International AIDS meeting in Barcelona concerning the new class of AIDS medications represented by the new drug, T-20. Unlike many of the current anti-retroviral medications like AZT that seek to inhibit the replication of the HIV virus, T-20 attempts to block entry of the virus into healthy cells.

Here is what one press account has said about this still unapproved, but highly promising drug:

But it takes 106 steps more than 10 times the usual number of chemical reactions to make the lengthy peptide, making production a serious factor in its price. Roche refurbished a plant in Boulder, Colorado, just to make T-20. Almost 100,000 pounds of spe-

cialized raw materials are needed to make a little more than 2,200 pounds of the drug. In all, Roche has invested \$490 million in T-20's development and manufacturing.

Let us not be too quick to characterize as villains and enemies those scientists and companies who are working every day to overcome dread diseases like AIDS. Think of the imagination and expertise required to design all 106 chemical reaction required to make T-20. How many times must they have failed to come up with the correct chemical pathway?

I might add, as Senator FRIST pointed out on the floor last week, that infectious disease experts like Dr. Tony Fauci at NIH have said that despite the substantial promise of T-20, there is still more work to be done on this drug. Specifically, it is imperative to develop a tablet form of this currently intravenous preparation if we will be able to effectively use the product in the Third World.

Some in this debate have minimized the importance of product formulation patents and have suggested that such patents should not be eligible for the 30-month stay. But public health experts such as Dr. Anthony Fauci one of the leading experts in the world, are telling us that the formulation of drugs like T-20 is critical. Who is to say that the steps in addition to the 106 steps already painstakingly identified to make the IV preparation necessary to make a tablet form of the drug are not worthy of the same protection afforded other pharmaceutical patents since 1984?

And if it turns out that such a formulation patent issues more than 30-days after FDA can one-day approve a new drug application for a tablet form of T-20, why should this patent be given less procedural protection than other related patents? But this differential treatment of patents is exactly what could occur if we adopt the pending legislation.

Mr. President, the Hatch-Waxman Act has been called one of the most important consumer bills in history. It has helped save consumers, by the Congressional Budget Office reckoning, \$8 billion to \$10 billion every year since 1984. It created the modern generic drug industry by creating this delicate balance between the pioneer research companies, and the generic companies that could readily copy drugs under Hatch-Waxman. The scientific work that had taken R & D firms up to 15 years, \$800 million and at least 5,000 to 6,000 failed drug companies for each successful new drug could be used by general firms under the 1984 law.

I might add, the Hatch-Waxman Act has brought the generic industry from little over 15 percent of the marketplace to 47 percent as we speak, and it is going up all the time. That is what we thought should happen.

We are at \$490 million and still counting for this still unapproved promising new AIDS drug, T-20.

Remarkable progress in the field of drug development has been made over

the past 18 years since Waxman-Hatch was adopted. We have seen enormous strides in the treatment of heart disease, diabetes, arthritis, Alzheimer's and many others, including the 200 new drugs that have been approved to treat lower prevalence, so-called orphan diseases another bill that I helped author. I am proud to have been an author of the Orphan Drug Act that has given hope to so many American families.

If our Nation is going to develop diagnostic tests, treatments, and vaccines to prevent and counter attacks of bioterrorism and potential chemical or even nuclear terrorism, just whom do you think is going to develop these products? I will tell you who. It will be those "villains" in the pharmaceutical industry, in partnership with government and academic researchers, unless we hamper their ability to do so, if we do not watch ourselves carefully on this Legislation.

At some point we must put aside this one-dimensional, simplistic vilification of the pharmaceutical industry and examine more closely the actual substance of the pending legislation.

Are the PhRMA companies always right? No, they are not, and neither are the generic companies always right. Hatch-Waxman created a delicate balance so they were competitive against each other, and it has worked very well.

It is my strong preference to conduct the debate over amending the Hatch-Waxman Act with our eyes focused on the policies, not the politics.

As I said last week, the pending legislation, S. 812, addresses important and complex issues of patent law, civil justice reform and antitrust policy. A strong case could be made that Senate consideration of this bill would be improved if the Judiciary Committee were given the opportunity to study the legislation, review the Federal Trade Commission report, and make its voice heard in this debate. It seems unlikely that anything resembling this process will unfold given the decision to rush the HELP Committee patent, antitrust, civil justice reform bill to the floor of the Senate.

As a threshold matter, it seems to me that before we adopt S. 812, we should be certain that this bill is consistent with the longstanding goals of the statute S. 812 seeks to amend, the Drug Price Competition and Patent Term Restoration Act.

Let me remind my colleagues, the goals of this law, passed in 1984, are twofold:

First, to create a regulatory pathway that allows the American public to gain access to more affordable generic drugs; and,

Second, to create incentives for manufacturers of pioneer drug products to see that the American public has access to the latest, cutting-edge medicines.

As I described last week, the 1984 law is a carefully balanced statute and contains features designed to accomplish

these two somewhat conflicting goals. This tension is inherent because of the competing nature of the desire, on one hand, to develop breakthrough drugs and, on the other hand, to make available generic copies of these pioneer products.

As legislation is crafted to address the problems that have arisen up in recent years with respect to the Waxman-Hatch law, we must be careful not to devise a remedy that upsets the delicate balance of the law.

I am concerned that the manner in which the HELP Committee substitute tries to fix the two most widely cited shortcomings of the 1984 law may, in fact, disturb the balance of the statute by, in some areas, overcorrecting and, in other areas, undercorrecting for the observed problems.

Specifically, while the manner in which the Edwards-Collins HELP Committee substitute addresses the 30-month stay issue represents a major improvement over McCain-Schumer bill, I am afraid though, the 30-month stay language represents a case of overcorrection.

Last Thursday, I gave a short summary of the key provisions of the Hatch-Waxman Act. It only took me 1 hour and 32 minutes. After providing this background and context, I explained why I thought that the provisions of the pending legislation relating to patent rights and the 30-month stay went too far. Let me reiterate my concerns with the 30-month stay.

As has been stated by many during this debate, a pioneer drug patent holder, whose patents are under challenge by a generic drug manufacturer, is accorded an automatic 30-month stay. This was not some giveaway to the innovator pharmaceutical industry. We inserted this mechanism to protect the intellectual property of companies that develop patented medications, companies, I might add, that were going to be afforded less intellectual property protections than any other industry as part of the 1984 law. We knowingly added this provision because we wanted to give them a fair opportunity to defend their patents. We know that patent litigation is itself a risky endeavor with the federal circuit court overturning about 40 percent of the trial court decisions in some areas of patent law.

The public policy purpose for this stay is to allow time for the courts to determine the status of validity of drug patents and/or to decide whether valid patents are, or are not, infringed by a generic drug challenger.

That was the intent of the law. Many believe—and I share that view—that the 30-month stay provision has come to present problems in two areas: First, later issued patents that trigger last minute 30-month stays; and, second, multiple uses of the 30-month stay provision in a consecutive, over-lapping manner that work to bar generic competition for as long as the litigation can be made to drag on by lawyers who are paid by the hour.

Some in this debate have characterized that both of these problems are at epidemic proportions. While I think there is evidence that problems have occurred and it is important that we work to modify the law so that the 30-month stay can not be misused in the next few years when so many blockbuster drugs come off-patent we should all take a close look at the FTC report before we conclude that as a general matter the entire research-based pharmaceutical industry has systematically abused the 30-month stay. That is just a speculation at this point until we see all the data.

I will be very interested in what the FTC reports on a number of issues—the frequency of use of multiple 30-month stays; stays stemming from late issued patents; the outcome of litigation on the merits when such multiple stays have been employed; and 11th-hour stays exercised due to late-issued patents.

It seems to me that we should be highly skeptical whenever a patent is listed in the official FDA records, called the Orange Book, years after the FDA approved the drug. One would have to think that all key patents would have been at least applied for prior to the end of the lengthy FDA review.

We all know of the now infamous case of the drug, Buspar. An attempt was made to take advantage of the 30-month stay by listing in the Orange Book a new patent of the metabolite form of the active ingredient of the drug literally in the last day before the original patents were set to expire. A Federal district court stepped in to limit the stay to four months, not 30-months. The appellate court found, however, that this forced de-listing of the patent was improper.

My opinion is that Congress, after getting the better understanding of the facts that the FTC report can provide, should address the consecutive stay and last-minute stay problems.

From what I know today, I am not prepared to conclude that the Edwards-Collins substitute is a measured solution to the cited problems. The bill that passed the HELP Committee and is pending on the floor would limit the 30-month stay to those patents issued within 30-days of FDA approval of the drug. The pending legislation contains major improvements over substantial elements of the McCain-Schumer bill, such as the language that would have completely eliminated the 30-month stay in favor of a system that required case-by-case application of injunctive relief. It is also better than the language the HELP Committee Chairman KENNEDY circulated briefly before the mark-up that would have limited to 30-month stay to certain types of patents.

As I laid out in detail last Thursday, given the facts available at this time, I think a better policy may be to permit one, and only one, 30-month stay to apply to all patents issued and listed with FDA prior to the time a par-

ticular generic drug application is filed with the agency, which cannot occur under the law until at least four years have elapsed in the case of new chemical entities. At a minimum, I do not see what justification exists to differentiate, for the purpose of the 30-month stay, patents issued prior to four years after the FDA first approves a drug.

I would also add that in most European nations and in Japan, it is my understanding that the law provides a 10-year period of data exclusivity—independent of patent term before a generic copy may be approved for marketing. The public policy behind these periods of data exclusivity is to recognize the fact that in approving generic drugs, the government regulatory agency is relying upon the extensive, expensive—and prior to enactment of Hatch-Waxman, generally proprietary, trade secret—safety and efficacy data supplied by the pioneer firm.

At any rate, as I explained last week, current U.S. law does not even allow a generic drug applicant to challenge a pioneer firm's patents until four years have elapsed. Why shouldn't, for example, a formulation patent issued one year after a drug is approved not be protected by the 30-month stay if the challenge cannot be made for 3 more years?

The 30-month stay must be understood in the context of the complexities of the 1984 Waxman-Hatch law that generally provides 5 years of marketing exclusivity to pioneer drug products as part of the recognition for allowing the generic firms to rely on the pioneer's expensive safety and efficacy data. Moreover, I think that any discussion of the 30-month stay is incomplete if it does not include the fact that, under Hatch-Waxman, generic drug firms are given a unique advantage under the patent code that allows them to get a head start toward the market by allowing them to make and use the patented drug product for the commercial and ordinarily patent infringing purpose of securing FDA approval and scaling up production.

Let me quickly review the general rule against patent infringement that is set forth in Title 35 of the United States Code, section 271(a). It says:

... whoever without authority makes, uses, offers to sell, or sells any patented invention ... during the term of the patent ... infringes the patent.

This is a clear, unambiguous protection of property rights, as it should be to protect the creative genius of America's inventors.

Section 271(e) of title 35 contains the so-called Bolar amendment that was added to the patent code by the Hatch-Waxman Act to create a special exception for generic drug manufacturers. Section 271(e)(1) states:

It shall not be an act of infringement to make [or] use ... a patented invention ... solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Essentially, this particular provision I have just read gives generic drug manufacturers a head start over virtually all other producers of generic products. In other words, it gives the generic industry a tremendous advantage. Normally, making and using a patented product for the purpose of securing regulatory approval would be a clear case of patent infringement under section 271(a), but the Bolar Amendment—which overrode a 1984 Federal Circuit Court of Appeals decision that precluded generic drug firms from using on-patent drugs to secure FDA approval or gear up production, in other words, the case overruled that right—allows the generic firms to violate customary patent rights because we put it in Hatch-Waxman. Section 271(e) is the Hatch-Waxman language.

The public policy purpose of the Bolar Amendment meaning the Hatch-Waxman Act is to allow generic drug makers to secure FDA approval and come onto the market the day after the patent on the pioneer drug expires. As I explained last week, there is a balance between the head start that the Bolar Amendment gives to generic manufacturers and the protection that the 30-month stay gives pioneer firms to litigate the validity of their patents.

Given the unique head start that the Bolar Amendment grants generic drug manufacturers over virtually all other generic product manufacturer and the other factors I have discussed, I question whether restricting the 30-month stay to only those patents issued within 30-days of FDA approval is either necessary, fair, or wise.

Moreover, the HELP Committee bill contains file-it-or-lose-it and sue-on-it-or-lose-it provisions as well as a new private right of action which also act to further diminish the value of pharmaceutical patents, or should say pharmaceutical patents, to be more accurate.

Let me first address my concerns regarding the creation of a private right of action, and then move on to the serious and detrimental effects that the file-it-or-lose-it and sue-on-it-or-lose-it provisions would have on pharmaceutical patent holders.

I have two fundamental concerns with authorizing a private cause of action that would allow applicants to bring declaratory actions to correct or delete patent information contained in the FDA "Orange Book."

First, over the past 30 years, the courts have explicitly held that no private right of action is authorized under the Federal Food, Drug, and Cosmetic Act or "FDCA" e.g., "It is well settled . . . that the FDCA creates no private right of action." In re: Orthopedic Bone Screw Products Liability Litigation, 193 F.3d 781, 788 (3d Cir. 1999).

Moreover, the Court of Appeals for the Federal Circuit specifically addressed whether the Waxman-Hatch amendments to the FDCA did not indicate any congressional intent to create

a private right of action, stating that the court could "see nothing in the Hatch-Waxman Amendments to alter" the conclusion that private parties are not authorized to bring suit to enforce the FDCA.

By seeking to create a private right of action, this provision represents a truly unprecedented step that runs contrary to 30 years of judicial interpretation. I believe that this would create an unwise, and potentially dangerous precedent that could be used to justify future legislation authorizing private suits to enforce the numerous and varied provisions of the FDCA. Although I understand—and am sympathetic to—the underlying rationale for this provision, I simply do not think that creating a private right of action is an appropriate answer to the problems cited by the advocates of this provision.

Second, as the Administration has succinctly stated: "this new cause of action is not necessary to address patent abuses," and may "unnecessarily encourage litigation" surrounding the approval of new drugs. I certainly agree. Authorizing this new cause of action will not effectively address the alleged patent abuses.

Now, I want to emphasize here that I strongly support efforts to halt anti-competitive abuses of the patent laws and the laws and regulations involving the listing of patent information in the FDA "Orange Book." I am willing to work with members from either side of the aisle on this issue. However, I am convinced that creating a private right of action will not only fail to stop the patent abuses at issue, but will likely have substantial unintended detrimental effects on the drug approval process.

The file-it-or-lose-it provision that says patent rights are waived if each new patent is not promptly filed with FDA and the sue-on-it-or-lose-it provision that would result in the forfeiture of patent rights if a pioneer drug firm does not sue within 45 days of being notified of a patent challenge should be contrasted with current law for all other types of patents. Section 286 of the federal patent code establishes a six-year statute of limitations on seeking damages for patent infringement. Why should this usual six-year period be decreased to 45-days for pharmaceutical patents?

I should also note the section 284 of the patent code explicitly authorizes the courts to award treble damages in patent infringement actions. This is a strong signal that Congress wants to protect intellectual property. We should think twice when we are considering adopting measures, such as the Edwards-Collins language, that act to undermine longstanding patent rights such as the six-year statute of limitation on patent damage actions.

As I said last week, I am mindful that the treble damage provision places a generic firm patent challenger in a difficult decision if the firm were

forced to go to market upon a district court decision in a patent challenge situation. That is why I am generally sympathetic to the argument of generic manufacturers that current law should be overturned and any marketing exclusivity a generic firm might earn by beating a pioneer firm's patents should toll from an appellate court decision. In the case of multiple patents and multiple challengers, the policy might have to be refined if the result is that no generic product can reach the market within a reasonable period of time.

As I pointed out, HELP Committee Edwards-Collins language is barely two weeks old, I am not alone in raising concerns about this new language. The Administration opposes this language. The Statement of Administration Policy states, in part, that:

S. 812 would unnecessarily encourage litigation around the initial approval of new drugs and would complicate the process of filing and protecting patents on new drugs. The resulting higher costs and delays in making new drugs available will reduce access to new breakthrough drugs.

That is important.

I look forward in the next weeks to hearing the detailed comments from Administration experts on these matters as we get the FTC report.

We are also starting to hear from others on this new, substantially changed, language. Senator FRIST placed in the RECORD last week a letter from the Biotechnology Industry Organization that complains about the manner in which the bill undermines existing patent protection.

I would just note that the organization representing our nation's cutting edge biotechnology companies, BIO, expressed great dissatisfaction with this new bill language. The July 15th BIO letter says in part:

If enacted, these proposals would significantly erode the measures in Hatch-Waxman to ensure an effective patent incentive for new drug development, and would create undesirable precedents for sound science-based regulations of drug products in the United States.

BIO also has some sharp criticism of the patent forfeiture provisions set forth in the file-it-or-lose-it and sue-on-it-or-lose-it clauses in the bill. BIO says:

This forfeiture will occur without compensation, without a right of appeal and without any recourse. This provision is probably unconstitutional, and in any event is totally unconscionable.

Also adding its voice to the debate over this new, unvetted language is the American Intellectual Property Law Association. The AIPLA is a national bar association representing a diverse group of more than 14,000 individuals from private, corporate, academic and governmental practice of intellectual property law.

Mr. President, I ask unanimous consent to have printed in the RECORD a copy of a July 22, 2002 letter from the AIPLA.

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

AMERICAN INTELLECTUAL PROPERTY  
LAW ASSOCIATION

*Arlington, Virginia*

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

DEAR SENATOR HATCH: I am writing on behalf of the American Intellectual Property Law Association to express our concerns about provisions in S. 812 that would undercut long standing principles of patent law and would set an unfortunate example for other nations to emulate.

The AIPLA is a national bar association of more than 14,000 members engaged in private and corporate practice, in government service, and in the academic community. The AIPLA represents a wide and diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property.

While we take no position on the need for revisions in the practice of "patent listings" in applications for drug approvals before the FDA, AIPLA believes that providing a new civil action to delist patents is ill advised. Such actions would involve the issues of (a) whether the innovator's product is actually covered by the patent-at-issue and (b) potentially, the validity of the patent. Irrespective of the merits of allowing challenges to the listing on the basis of its accuracy, vesting courts with jurisdiction over patent issues in this circumstance where there is no case or controversy is inappropriate. Such proposed new civil actions would be invitations to increased litigation and threats of litigation over such issues without corresponding public benefit.

If a generic drug company wished to challenge the validity of a listed patent, we would suggest that a far better alternative would be to require that it be through the normal procedure of a request for patent reexamination. To the extent that the existing proceedings might not be considered adequate for such challenges, not only are there bills to strengthen them (H.R. 1866, H.R. 1886, and S. 1754), but there is currently a proposal being developed by the U.S. Patent and Trademark Office to establish a post-grant opposition proceeding that would provide a more robust challenge procedure. Such proceedings are not only handled by the experts in the U.S. Patent and Trademark Office in the first instance, but all appeals would go to the Court of Appeals for the Federal Circuit which handles almost all patent appeals from normal infringement litigation.

Another aspect of S. 812 which we find troubling is the proposed prohibition against a patentee bringing a patent infringement action against a generic drug company for a patent not listed (and/or not properly listed) in an application for FDA approval. Under current provisions in the law, a patent owner loses the right to file a patent infringement law suit which has the effect of staying the FDA's approval of a generic drug for 30 months to allow resolution of the law suit if (a) the patent is not listed with the FDA or (b) the suit is not brought against the generic drug company within 45 days of receiving an appropriate certification notice that is listed patent is either invalid or not infringed. They do, however, retain the right to bring an infringement suit at a later date. The effect of the present amendments would be to take that right away from the patent holder. This would be an arbitrary denial of

a remedy guaranteed to patent holders in all fields of technology.

We also point out that the denials of relief noted in the preceding paragraph would be limitations on pharmaceutical patents which could implicate certain non-discriminatory obligations of the United States under the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPs), part of the Uruguay Round Agreements. At a time when the Agreement is under challenge from many quarters following the Doha Ministerial Conference, certainly these provisions of S. 812 should be vetted with the Office of the U.S. Trade Representative for their consistency with TRIPs.

In summary, while we take no position on the need for legislation to change the provisions of the 1984 Hatch-Waxman Act or on the merits of the respective positions of innovator drug companies and generic drug companies, we are concerned that these provisions of S. 812 are contrary to good patent law policy and enforcement. Indeed, they would establish principles that would do great harm to the ability of innovators to realize adequate and effective patent protection and set bad examples by the United States when viewed by other nations that are seeking ways to avoid providing such protection. If reform is needed, it should take other forms and directions.

Sincerely,

MICHAEL K. KIRK,  
*Executive Director.*

Mr. HATCH. While taking no position on the need for changing the patent listing provisions of Hatch-Waxman, the AIPLA said that it believes that:

Providing a new civil action to delist patents is ill advised . . . Irrespective of the merits of allowing challenges to the listing on the basis of its accuracy, vesting courts with jurisdiction over patent issues in this circumstance where there is no case or controversy is inappropriate.

The AIPLA also red flags the file-it-or-lose-it patent forfeiture provisions of the pending legislation by pointing out that these, and I quote,

. . . would be limitations on pharmaceutical patents which could implicate certain nondiscriminatory obligations of the United States under the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPs). At a time when the Agreement is under challenge from many quarters following the Doha Ministerial Conference, certainly these provisions of S. 812 should be vetted with the Office of the U.S. Trade Representative for their consistency with TRIPs.

I agree we should hear from United States Trade Representative on this matter. I also agree with the American Intellectual Property Law Association when it closed its letter with the following statement: "If reform is needed, it should take other forms and directions."

Finally, Mr. President, I would like to make my colleagues aware of, and ask unanimous consent to have printed in the RECORD, a statement from the law offices of David Beier.

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

INNOVATION IN HEALTH CARE AND THE RESULTING IMPROVEMENTS IN MORTALITY AND HEALTH OUTCOMES WILL SUFFER FROM THE RETROACTIVE TAKING OF PROPERTY RIGHTS POSED BY THE SENATE H.E.L.P. COMMITTEE PASSAGE OF THE EDWARDS SUBSTITUTE TO S. 812

In the last 50 years there have been dramatic improvements in life expectancy and better health care outcomes, in pertinent part, because of new drugs and therapies. These advances have occurred because the United States, unlike some other nations, has used a strong patent system to help create a balanced set of incentives. That system of incentives for innovation is at risk, if as proposed in the pending bill, the investment backed and settled property rights in patents are retroactively taken away.

The substitute amendment to the Schumer-McCain bill adopted July 11 proposes to deprive property owners—in this case patent holders—of the most fundamental of property rights, the right to exclude others from using their property without just compensation. The bill works this result by taking away the right to sue. As explained in greater detail, the bill proposes to prevent holders of valid patents from suing generic drug companies. This proposal is not only bad policy but poses at least three serious legal problems.

First, the proposed bill takes away an essential attribute of a patent—the right to enforce it against copiers. This deprivation is either a per se taking of property under the relevant Supreme Court case law, or works a taking in light of the case by case constitutional test outlined by the same court. The pending bill would work a per se taking if a Court determined that the loss of a fundamental right—like the right to sue—was the equivalent of a total physical occupation of a piece of real property. There is a good case that a court would so find. But regardless of whether this proposal would meet that test, the courts would most surely find that the loss of the right to sue would be a taking of property that required just compensation under the other applicable constitutional test.

Under current Supreme Court precedent, if enacted, these amendments would be evaluated under a taking analysis that would measure the nature of the property involved, the nature of the economic right and the degree of governmental interference. In this case, it is well settled law that a patent is a property right. It would be absurd to uphold that right and then claim that barring access to the courthouse does not violate that right. Because this amendment would work a fundamental and retroactive deprivation of those economic rights courts would likely hold that these changes are a taking. Such a finding triggers a requirement of government compensation of the property owners. At the President's Council of Economic Advisers recognized in their report to the President earlier this year, the kinds of inventions at risk here—both breakthroughs and incremental improvements in existing products—are critical to improved health outcomes. That same report also recognized that these products require the free market possibility of substantial profits to sustain the magnitude of the R&D necessary to overcome the risk of research failures, and competition from others also racing to be first on the market with new medical innovations. This reality would mean that a successful taking suit would implicate many claims of significant economic loss. Thus, it is likely that any finding would have very serious implications for the Federal budget.

Second, there is a strong argument that this amendment interferes with the right of

patent holders to petition their government through the judicial system for a redress of their grievances. In this case, much like the efforts of others in an earlier time, seeks to prevent courts from enforcing rights guaranteed by the Constitution. This approach can not be justified in light of the compelling constitutional right to have full and fair access to redress grievances.

Third, and finally, this amendment makes artificial and illegal distinctions between types of patents in violation of the United States' obligations under international law. One of the important advances in law, secured at the request of the United States, in the World Trade Organization's Trade Related Intellectual Property system was a bar on discrimination between different technologies. In this case, the amendment proposes to withdraw significant patent rights from the holders of certain innovative drug patents that continue to be guaranteed to all other patent holders. Imagine if another nation proposed to cut off the right to sue for infringement for the violation of an aerospace, computer or computer software patent, we certainly would assert that it violated our Nation's rights under TRIPS. The pending amendment offers the same kind of flawed and illegal approach. In the case of a TRIPS violation the penalty could, after adjudication in the WTO, result in the imposition of retaliatory tariffs on American exports.

In sum, the pending amendment is a bad idea on policy grounds, procedurally suspect and legally subject to challenge. Congress should carefully consider the risks to the Federal Treasury that could result if this bill were enacted and the courts uphold a strong "taking" of property claim. Moreover, legislators should also be cognizant of the bad precedent they would be creating by barring access to judicial remedies. Finally, Congress should recognize that if approaches to international obligations like this are adopted, other countries will be more likely to punish American inventions in other sectors, including information technology and aerospace.

**Mr. HATCH.** Mr. Beier was a member of the staff of the House Judiciary Committee when Hatch-Waxman was adopted in 1984. After that, for many years he headed the Washington office of the biotechnology company, Genentech. Mr. Beier then spent four years serving as the chief domestic policy advisor for Vice President Gore. He is recognized as an expert in high technology issues and is now a partner in highly respected Washington law firm. David is certainly not a conservative Republican although I still have my hopes for him!

In Mr. Beier's view, "the pending amendment is a bad idea on policy grounds, procedurally suspect and legally subject to challenge." Mr. Beier lays out the Takings Clause problems, the procedural due process concerns, and the TRIPS considerations.

With respect to the potential for negative impact on foreign trade Mr. Beier warns:

Imagine if another nation proposed to cut off the right to sue for infringement for the violation of an aerospace, computer or computer software patent. We would certainly assert that it violated our Nation's rights under TRIPS. The pending Amendment offers the same kind of flawed and illegal approach. In the case of a TRIPS violation the penalty could, after adjudication in the

WHO, result in the imposition of retaliatory tariffs on American exports.

Mr. President, I share these concerns. I urge my colleagues to consider the views of BIO, the AIPLA, and David Beier, as well as the other organizations cited by Senator FRIST last week, before we rush to adopt this virtually unvetted, far-reaching language that has not been the subject of a hearing in any committee of Congress. Not the HELP Committee, not the Judiciary Committee, not the Commerce Committee, and not the Finance Committee which has jurisdiction over matters of international trade.

But more important than any payments that the Treasury might be compelled to pay due to judgments related to the Takings Clause or than any retaliatory trade sanctions that the WHO may impose on the United States down the road, we need to consider what the public health consequences might be if we unjustifiably lower protections on pharmaceutical patents.

Don't get me wrong. I am in favor of fierce price competition in the pharmaceutical marketplace. I favor not just less expensive general drugs today, but also better breakthrough drugs tomorrow. We need to keep in mind the relationship between public health and intellectual property. As David Beier has observed with respect to this linkage and the threat of this bill:

In the last 50 years there have been dramatic improvements in life expectancy and better health care outcomes, in pertinent part, because of new drugs and therapies. These advances have occurred because the United States, unlike other nations, has used a strong patent system to help create a balanced set of incentives. That system of incentives for innovation is at risk, if as proposed in the pending legislation, the investment backed and settled property rights in patents are retroactively taken away.

In short, while better in some key respects than McCain-Schumer, I am afraid that the HELP Committee-reported bill goes too far with respect to the 30-month stay. As I testified before the HELP Committee in May, if the problems we are trying to solve are the multiple use of 30-month stays and 11th hour-issued patents that unfairly trigger the stay, it seems to me that a more appropriate—and more narrowly-tailored—legislative response might be a rule that allows one stay, and one stay only.

Further, it might be appropriate to restrict the use of the sole stay only with respect to those patents listed in the FDA Orange Book at the time when a particular generic drug application is submitted. I will be interested if such a rule satisfies the problems that the FTC finds with respect to abuses of the 30-month stay and how the FTC, FDA, DOJ and other experts and interested parties think about this perspective.

I am open to other alternatives as more information becomes available and more discussion takes place among interested parties.

For now at least, I am forced to conclude that this new NDA-plus 30-day

rule coupled with the file-it-or-lose-it and sue-on-it-or-lose-it provisions and the new private right of action amounts to legislative overkill that creates a host of new problems.

In contrast to this over-correction with regard to the 30-month stay, I am concerned that the Edwards-Collins HELP Committee Substitute under-corrects in fixing the 180-day marketing exclusivity issue.

Perhaps no single provision of the 1984 law has caused so much controversy as the 180-day marketing exclusivity rule.

As I explained last week, the statute contains this incentive to encourage challenges that help test the validity of pioneer drug patents and to encourage the development of non-patent infringing ways to produce generic drugs. The policy motivation behind the 180-day rule is to benefit consumers by earlier entry of cost-saving generic products onto the market in situations where patents were invalid or could be legally circumnavigated.

For many years as we intended and envisioned FDA awarded this 180-day exclusivity only to a generic drug applicant that was successful in patent litigation against the pioneer firm. In 1997, FDA's longstanding successful defense requirement was struck down by the D.C. Circuit Court of Appeals in the case of *Mova Pharma v. Shalala*.

The next year, the D.C. Circuit issued its opinion in *Purepac Pharm v. Shalala* which 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. Also in 1998, the Fourth Circuit Court of Appeals held in *Granotec v. Shalala* that a court decision with respect to a second or third filer could trigger the exclusivity period of a first filer.

Taken together, these decisions, which strictly construed the statutory language, awarded the exclusivity to the first filer of a generic drug application. As a co-author of the legislation, I will be the first to concede that we drafters of the 1984 law came up short in this area because we were attempting to reward the first successful challenger, not the first to file papers with the FDA.

Once the successful defense requirement was struck down, the mismatch between first filers of generic drug applications and the generic drug firms actually litigating the patents resulted in a number of controversial contractual arrangements in which generic firms in the first-to-file blocking position were paid by pioneer firms not to go to market. These agreements prevented the 180-day marketing exclusivity clock from ever starting, and the statute prevented FDA from approving second and subsequent filers from going to market.

Here is how my good friend, Bill Haddad, an astute political analyst, generic drug manufacturer, gifted writer, incorrigible liberal, and participant in



the 1984 negotiations recalled the intent of the 180-day marketing exclusivity provision:

There was never any doubt that the goal .. was to bring generics to the market earlier using the route of legal challenge with a reward to be paid to the entrepreneur with the courage and facts to successfully challenge.

It was and is very clear that the law was not designed to allow deals between brand and generic companies to delay competition.

Unfortunately, the string of court decisions that interpreted these imprecisely drafted statutory clauses has resulted in a wholly unintended result.

As David Balto, a former senior official at the FTC, has described the problem:

The 180-day exclusivity provision appears to have led to strategic conduct that has delayed and not fostered the competitive process.

Mr. Balto assessed:

The competitive concern is that the 180-day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws and the Hatch-Waxman Act by delaying generic entry for a substantial period.

He is right. He is absolutely right.

This wholly unintended dynamic has properly brought intense antitrust scrutiny. As a matter of fact, in May of 2001, the Judiciary Committee examined the antitrust implications of pharmaceutical patent settlements inspired by the 180-day rule.

The Federal Trade Commission has been very active in this area. The FTC has brought and settled three of these cases in which brand name companies pay generic firms not to compete. At this point I will not go into the details of the consent decrees in the Abbott—Geneva case, the Hoescht—Andrx agreement, and the FTC's settlement with American Home Products. FTC Chairman Tim Muris provided a great deal of information in his testimony before the Senate Commerce Committee in April.

The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws. Probably in no small part due to the FTC's vigorous enforcement under the existing antitrust laws and the development of Senator LEAHY's Bill, The Drug Competition Act, S. 754, I understand that no more of these type of anti-competitive agreements have been initiated for over two years. The FTC report will no doubt shed light on this area. In a post-Enron, post-WorldCom environment, who would be so reckless as to enter into such an agreement? Nevertheless, I must also point out that the agency recently suffered a set back when the FTC administrative law judge issued a ruling in the on-going K-Dur litigation that reminds us that not all pharmaceutical patent settlements are per se violations of federal antitrust law.

In any event, the McCain-Schumer bill addressed the 180-day collusive re-

verse payments situation by adopting a so-called rolling exclusivity policy. 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.

As I testified before the HELP Committee, I do not favor rolling exclusivity. Here's what Gary Buehler, then Acting Director of FDA's Office of Generic Drugs, said before 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.

In 1999, FDA proposed a rule which embraced a use it or lose it policy whereby 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. 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 FDA's use it or lose it policy over the McCain-Schumer brand of rolling exclusivity.

In that regard, I must again commend the sponsors of the Edwards-Colins 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 was alarmed to learn that during mark-up Senator EDWARDS responded to a question by stating it was conceivable that his modified use-it-or-lose-it language might actually roll indefinitely. This disturbs me. Every time the exclusivity would roll to another drug firm, consumers will be further away from the day when multi-firm generic price competition can begin in the marketplace.

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. 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 am supportive of the general concept. But 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 use-it-or-lose-it proposal.

As I stated earlier, I am generally 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 or attacking on non-infringement.

I must say I am troubled by the provision of the bill that appears to grant each generic firm that qualifies for the benefit of the 18-month marketing exclusivity incentive a 30-month period to secure FDA approval, measured from the time of the filing of the generic drug application.

Let's say that the first firm eligible to take advantage of the 180-day benefit drops out for some reason. Assume also that the next firm eligible under the terms of Section 5 is in the midst of, for example, a negative good manufacturing inspection and can't go to market, but has say 14 months remaining on the 30-month clock. It would hardly seem like an appropriate outcome if, for example, the next firm eligible on the list already has satisfied all of the FDA requirements and has received tentative final approval, but must wait until the 30-month clock runs out.

I 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, because I think it would be wise for Congress to step back and reassess the wisdom of retaining the 180-day marketing exclusivity provision in essentially the same form as enacted in 1984. Why not take this opportunity to re-think the 180-day rule?

At one extreme are those who have suggested that the 180-day marketing exclusivity provision may not even be necessary at all. Liz Dickinson, a top-notch career attorney at FDA, 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 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.”

At the Judiciary Committee hearing on May 24, 2001, Gary Buehler, FDA's top official in the Office of Generic Drugs agreed with his colleague's assessment:

... 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.

Keep in mind that both of these FDA officials are career civil servants with no political axe to grind. I personally favor retaining some financial incentive to encourage patent challenges, but in light of this testimony and other factors, I do not think we need to be wedded to the current form of the 180-day exclusivity benefit.

Frankly, I am surprised that neither the McCain-Schumer bill, nor the Kennedy mark, nor the Edwards-Collins amendment, proposed any changes in the current regime in light of the views of the FDA officials among other considerations. But, of course, neither the FDA nor FTC nor any representatives from the Administration testified at the HELP Committee hearing on May 8th.

Senator SCHUMER argues that the task of this legislation is to curb excesses in order to return to the original balance in the 1984 law. But what if conditions have changed and the original balance of the 1984 need to be reassessed? Or what if there was 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 identically under the 180-day marketing exclusivity rule. But invalidity and non-infringement are two very different theories of the case. Here is what Al Engelberg, a smart and tenacious 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.

As one of the drafters, I must accept my share of responsibility for not fully appreciating the implications of this distinction. I think what Mr. ENGELBERG is pointing out that the 180-day rule acts as only a floor in non-infringement cases. As long as any patents stand, a particular non-infringer's marketing exclusivity can extend well beyond 180 days until such time as an

other non-infringer comes along. Conversely, doesn't the 180-day floor work to the detriment of consumers whenever it acts to block market entry of a second non-infringer 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 would reap immediate benefits for price competition.

I hope that my colleagues working on the bill will consider the distinction between invalidity and non-infringement as this debate continues over the next week. While I am of the mind to retain a strong financial incentive to encourage vigorous patent challenges by generic drug firms, we must ask why identical rewards are granted for successful invalidity and non-infringement claims. I welcome the comments and suggestions of my colleagues and other interested parties on this matter.

Frankly, I think we need more public discussion and debate about the wisdom of retaining—lock, stock, and barrel—the old 180-day exclusivity award.

For example, even if we adopt the modified use it or lose it approach of the HELP Committee bill and the first qualified generic manufacturer cannot, or will not, commence marketing and the exclusivity moves to the next qualified applicant, why should the second manufacturer get the full 180-days? Why not 90 days? Why not 60 days?

After all, once the exclusivity begins to roll and roll and we move away from granting the marketing exclusivity to the successful generic litigant and Americans always prefer actual winners—we may end up with a mere second filer—and since when does our society grant such lucrative rewards to someone who merely files some papers?

And what is so sacrosanct about 180-days in the first place? It is my information that in 1984 the number-one selling drug in the United States was Tagamet, with domestic sales of about \$500 million. I am told that today the cholesterol-controlling medicine, Lipitor, has domestic U.S. sales of over \$5 billion. Lipitor sales are 10-times higher in the U.S. than domestic Tagamet sales were in 1984. I understand that worldwide sales of Lipitor are about \$7 billion.

Even adjusting for inflation, it seems clear that 180-days of marketing exclusivity is worth more, and a lot more, today than it was worth in 1984.

What might 180-days of marketing exclusivity for today's blockbuster drugs be worth in profits to the generic firm holding the 180-day marketing exclusivity rights?

Let's be frank about what is going on here: Retention of the 180-day marketing exclusivity provision is one of those areas in which both the generic sector and the R&D sector have something of a mutual interest. And when all is said and done, I think that the joint interest of the generics and the pioneer firms is not in perfect alignment with the interests of consumers.

This is so because during the 180-day time frame, when there is only one generic competitor, the pioneer firm does not take anywhere near the hit on market share and profits that occurs when multiple generic firms enter the market. Similarly, the first generic on the market is under no pressure to cut the price anywhere near as much as when there is competition from multiple generic firms.

The report, *Drug Trend: 2001*, published by Express Scripts, notes this dynamic:

The AWP [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. It seems likely that the value of the 180-day marketing exclusivity award today may be worth much more than it was back in 1984—perhaps several hundred million dollars more per blockbuster drug.

Given the dramatic increase in drug sales for today's blockbuster products, it does not seem far-fetched to project that the 180-marketing exclusivity reward can amount to hundreds of millions of dollars—and perhaps over one billion dollars—in profits to the fortunate generic drug manufacturer. 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 excess profits back to consumers?

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 at least some of those funds earmarked for attorneys' fees, be channeled to help citizens lacking access to prescription drugs?

Shouldn't we get the 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.

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 organization, state Medicaid agencies, and insurers, whether there is interest in discussing the advisability of passing on more of the value associated with the marketing exclusivity to consumers if it appears it is fair 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.

I think we can and should explore this area further.

Let us not too quickly and too blindly retain the basic structure of reward



under the 180-day marketing exclusivity provision. 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.

I 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 integrity of the old Hatch-Waxman Act. But why should we be governed by the world of 1984 when, for example, the best selling drugs in this country have increased sales by a factor of 10? Why should the value of the marketing exclusivity reward increase in direct proportion?

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 I still have problems with the floor vehicle as I have laid out in some detail. I commend them again today.

I hope to return to the floor before this debate ends to offer a few suggestions for a more comprehensive approach to reforming the Drug Price Competition and Patent Term Restoration Act.

This in no way minimizes the importance of the matters that are the subject of the pending legislation, because they are important areas. I do not believe, however, that these are the most important issues we can address.

Rather than focusing on how best to bring the law back to the old days of 1984, as Senator SCHUMER suggests, I want to discuss ways to modify the law to help usher in a new era of drug discovery while, at the same time, increasing patient access to the latest medicines.

Mr. President, I yield the floor.

#### ORDER OF PROCEDURE

Mr. REID. Mr. President, I ask unanimous consent that following disposition of H.R. 5121, the legislative branch appropriations bill, Rockefeller amendment No. 4316 be agreed to, and the motion to reconsider be laid on the table.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. REID. Mr. President, I ask unanimous consent that immediately following action on adoption of the Rockefeller amendment, the Senate proceed to the consideration of the conference report to accompany H.R. 3763, the Corporate and Auditing Accountability, Responsibility, and

Transparency Act of 2002, and that it be considered under the following limitations: That there be a time limitation of 2 hours equally divided and controlled between the chair and ranking member of the committee or their designees; that upon the use or yielding back of time, without further intervening action or debate, the Senate proceed to vote on adoption of the conference report.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

#### LEGISLATIVE BRANCH APPROPRIATIONS ACT, 2003—Resumed

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to vote on H.R. 5121, the Legislative Branch Appropriations Act.

Mr. REID. Mr. President, I ask for the yeas and nays on the legislative branch appropriations bill.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The question is on agreeing to the conference report. The clerk will call the roll.

The legislative clerk called the roll.

Mr. NICKLES. I announce that the Senator from North Carolina (Mr. HELMS) is necessarily absent.

The PRESIDING OFFICER (Mrs. CARNAHAN). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 85, nays 14, as follows:

[Rollcall Vote No. 191 Leg.]

#### YEAS — 85

Akaka	Durbin	McConnell
Allen	Edwards	Mikulski
Baucus	Feingold	Miller
Bennett	Feinstein	Murkowski
Biden	Frist	Murray
Bingaman	Graham	Nelson (FL)
Bond	Grassley	Nelson (NE)
Boxer	Gregg	Nickles
Breaux	Hagel	Reed
Burns	Harkin	Reid
Byrd	Hatch	Rockefeller
Campbell	Hollings	Santorum
Cantwell	Hutchinson	Sarbanes
Carnahan	Hutchison	Schumer
Carper	Inouye	Sessions
Chafee	Jeffords	Shelby
Cleland	Johnson	Smith (OR)
Clinton	Kennedy	Snowe
Cochran	Kerry	Specter
Collins	Kohl	Stabenow
Corzine	Kyl	Stevens
Craig	Landrieu	Thompson
Crapo	Leahy	Thurmond
Daschle	Levin	Torricelli
Dayton	Lieberman	Warner
DeWine	Lincoln	Wellstone
Dodd	Lott	Wyden
Domenici	Lugar	
Dorgan	McCain	

#### NAYS — 14

Allard	Ensign	Roberts
Bayh	Enzi	Smith (NH)
Brownback	Fitzgerald	Thomas
Bunning	Gramm	Voinovich
Conrad	Inhofe	

#### NOT VOTING—1

Helms

The bill (H.R. 5121) was passed, as follows:

(The bill will be printed in a future edition of the RECORD.)

Mr. DURBIN. Madam President, I move to reconsider the vote.

Mr. REID. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. Under the previous order, the Senate insists on its amendments and requests a conference with the House on the disagreeing votes of the two Houses.

The PRESIDING OFFICER appointed Mr. DURBIN, Mr. JOHNSON, Mr. REED of Rhode Island, Mr. BYRD, Mr. BENNETT, Mr. STEVENS, and Mr. COCHRAN conferees on the part of the Senate.

#### GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001—Continued

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of S. 812. The Rockefeller amendment No. 4316 is agreed to, and the motion to reconsider that vote is laid on the table.

The amendment (No. 4316) was agreed to.

#### SARBANES-OXLEY ACT OF 2002—CONFERENCE REPORT

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to the consideration of the conference report to accompany H.R. 3763, which the clerk will report.

The legislative clerk read as follows:

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 3763), to protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws, and for other purposes, having met, have agreed that the House recede from its disagreement to the amendment of the Senate, and agree to the same with an amendment, and the Senate agree to the same, signed by a majority of the conferees on the part of both Houses.

The PRESIDING OFFICER. The Senate will proceed to the consideration of the conference report.

(The report is printed in the House proceedings of the RECORD of July 24, 2002.)

The PRESIDING OFFICER. The Senator from Nevada is recognized.

Mr. REID. Madam President, I suggest the absence of a quorum and ask that the time not be charged against either manager.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. SARBANES. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. SARBANES. Madam President, parliamentary inquiry of the Chair: What is pending before the Senate?

The PRESIDING OFFICER. The debate on the conference report is limited to 2 hours equally divided.