

America. This transformation is not without enormous dangers and challenges, but consider how much worse it would have been if a pro-bin Laden movement were fueling this transformation.

It is plain we need more of what we had post-9/11 now. I am not naive. I know it cannot be conjured up or wished into existence. But if we are optimistic, if we are inspired by the Americans who died here, if we truly understand our shared history and the sacred place compromise and rationality hold at the very center of the formation of our Nation and the structure of our Constitution, then we can again take up the mantle of shared sacrifice and common purpose that we wore after 9/11 and apply some of those behaviors to the problems we now confront.

The reality of our current political climate is that both sides are off in their corners; the common enemy is faded. Some see Wall Street as the enemy many others see Washington, DC, as the enemy and to still others any and all government is the enemy.

I believe the greatest problem we face is the belief that we can no longer confront and solve the problems and challenges that confront us; the fear that our best days may be behind us; that, for the first time in history, we fear things will not be as good for our kids as they are for us. It is a creeping pessimism that cuts against the can-do and will-do American spirit. And, along with the divisiveness in our politics, it is harming our ability to create the great works our forbears accomplished: building the Empire State building in the teeth of the Great Depression, constructing the Interstate Highway System and the Hoover Dam, the Erie Canal, and so much more.

While governmental action is not the whole answer to all that faces us, it is equally true that we cannot confront the multiple and complex challenges we now face with no government or a defanged government or a dysfunctional government.

As we approach the 10th anniversary of 9/11, the focus on what happened that day intensifies—what we lost, who we lost, and how we reacted—it becomes acutely clear that we need to confront our current challenges imbued with the spirit of 9/11 and determine to make our government and our politics worthy of the sacrifice and loss we suffered that day.

To return to de Tocqueville, he also remarked that:

The greatness of America lies not in being more enlightened than any other nation, but rather in her ability to repair her faults.

So, like the ironworkers and operating engineers and trade workers who miraculously appeared at the pile hours after the towers came down with blowtorches and hard hats in hand, let's put on our gloves, pick up our hammers and get to work fixing what ails the body politic. It is the least we can do to honor those we lost.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. BROWN of Ohio). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

LEAHY-SMITH AMERICA INVENT'S ACT

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of H.R. 1249, which the clerk will report by title.

The assistant legislative clerk read as follows:

An Act (H.R. 1249) to amend title 35, United States Code, to provide for patent reform.

AMENDMENT NO. 600

Mr. SESSIONS. Mr. President, I ask unanimous consent to call up my amendment No. 600, which is at the desk.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Alabama [Mr. SESSIONS], for himself, Mr. MANGHIN, Mr. COBURN, and Mr. LEE, proposes an amendment numbered 600.

Mr. SESSIONS. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

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

The amendment is as follows:

AMENDMENT NO. 600

(Purpose: To strike the provision relating to the calculation of the 60-day period for application of patent term extension)

On page 149, line 20, strike all through page 150, line 16.

Mr. SESSIONS. Mr. President, the amendment that I have offered is a very important amendment. It is one that I believe is important to the integrity of the U.S. legal system and to the integrity of the Senate. It is a matter that I have been wrestling with and objecting to for over a decade. I thought the matter had been settled, frankly, but it has not because it has been driven by one of the most ferocious lobbying efforts the Congress maybe has seen.

The House patent bill as originally passed out of committee and taken to the floor of the House did not include a bailout for Medco, the WilmerHale law firm, or the insurance carrier for that firm, all of whom were in financial jeopardy as a result of a failure to file a patent appeal timely.

I have practiced law hard in my life. I have been in court many times. I

spent 12 years as a U.S. Attorney and tried cases. I am well aware of how the system works. The way the system works in America, you file lawsuits and you are entitled to your day in court. But if you do not file your lawsuit in time, within the statute of limitations, you are out.

When a defendant raises a legal point of order—a motion to dismiss—based on the failure of the complaining party to file their lawsuit timely, they are out. That happens every day to poor people, widow ladies. And it does not make any difference what your excuse is, why you think you have a good lawsuit, why you had this idea or that idea. Everyone is required to meet the same deadlines.

In Alabama they had a situation in which a lady asked a probate judge when she had to file her appeal by, and the judge said: You can file it on Monday. As it turned out, Monday was too late. They went to the Alabama Supreme Court, and who ruled: The probate judge—who does not have to be a lawyer—does not have the power to amend the statute of limitations. Sorry, lady. You are out.

Nobody filed a bill in the Congress to give her relief, or the thousands of others like her every day. So Medco and WilmerHale seeking this kind of relief is a big deal. To whom much has been given, much is required. This is a big-time law firm, one of the biggest law firms in America. Medco is one of the biggest pharmaceutical companies in the country. And presumably the law firm has insurance that they pay to insure them if they make an error. So it appears that they are not willing to accept the court's ruling.

One time an individual was asking me: Oh, JEFF, you let this go. Give in and let this go. I sort of as a joke said to the individual: Well, if WilmerHale will agree not to raise the statute of limitations against anybody who sues their clients if they file a lawsuit late, maybe I will reconsider. He thought I was serious. Of course WilmerHale is not going to do that. If some poor person files a lawsuit against someone they are representing, and they file it one hour late, WilmerHale will file a motion to dismiss it. And they will not ask why they filed it late. This is law. It has to be objective. It has to be fair.

You are not entitled to waltz into the U.S. Congress—well connected—and start lobbying for special relief.

There is nothing more complicated about that than this. So a couple of things have been raised. Well, they suggest, we should not amend the House patent bill, and that if we do, it somehow will kill the legislation. That is not so. Chairman LEAHY has said he supports the amendment, but he doesn't want to vote for it because it would keep the bill from being passed somehow.

It would not keep it from being passed. Indeed, the bill that was

brought to the House floor didn't have this language in it. The first vote rejected the attempt to put this language in it. It failed. For some reason, in some way, a second vote was held, and it was passed by a few votes. So they are not going to reject the legislation if we were to amend it.

What kind of system are we now involved in in the Senate if we can't undo an amendment? What kind of argument is it to say: JEFF, I agree with your amendment, and I agree it is right that they should not get this special relief, but I can't vote for it because it might cause a problem? It will not cause a problem. The bill will pass. It should never have been put in there in the first place.

Another point of great significance is the fact that this issue is on appeal. The law firm asserted they thought—and it is a bit unusual—that because it came in late Friday they had until Monday. We can count the days to Monday—the 60 days or whatever they had to file the answer. I don't know if that is good law, but they won. The district court has ruled for them. It is on appeal now to the court of appeals.

This Congress has no business interfering in a lawsuit that is ongoing and is before an appeals court. If they are so confident their district court ruling is correct, why are they continuing to push for this special relief bill, when the court of appeals will soon, within a matter of months, rule?

Another point: We have in the Congress a procedure to deal with special relief. If this relief is necessary at all, it should go through as a special relief bill. I can tell you one reason it is not going there now: you can't ask for special relief while the matter is still in litigation, it is still on appeal. Special relief also has procedures that one has to go through and justify in an objective way, which I believe would be very healthy in this situation.

For a decade, virtually—I think it has been 10 years—I have been objecting to this amendment. Now we are here, I thought it was out, and all of a sudden it is slipped in by a second vote in the House, and we are told we just can't make an amendment to the bill. Why? The Senate set up the legislation to be brought forward, and we can offer amendments and people can vote for them or not.

This matter has gotten a lot of attention. The Wall Street Journal and the New York Times both wrote about it in editorials today. This is what the New York Times said today about it:

But critics who have labeled the provision "The Dog Ate My Homework Act" say it is really a special fix for one drug manufacturer, the Medicines Company, and its powerful law firm, WilmerHale. The company and its law firm, with hundreds of millions of dollars in drug sales at stake, lobbied Congress heavily for several years to get the patent laws changed.

That is what the Wall Street Journal said in their editorial. The Wall Street Journal understands business reality and litigation reality. They are a critic

of the legal system at times and a supporter at times. I think they take a principled position in this instance. The Wall Street Journal editorial stated:

We take no pleasure in seeing the Medicine Company and WilmerHale suffer for their mistakes, but they are run by highly paid professionals who know the rules and know that consistency of enforcement is critical to their businesses. Asking Congress to break the rules as a special favor corrupts the law.

I think that is exactly right. It is exactly right. Businesses, when they are sued by somebody, use the statute of limitations every day. This law firm makes hundreds of millions of dollars in income a year. Their partners average over \$1 million a year, according to the New York Times. That is pretty good. They ought to be able to pay a decent malpractice insurance premium. The New York Times said WilmerHale reported revenues of \$962 million in 2010, with a profit of \$1.33 million per partner.

Average people have to suffer when they miss the statute of limitations. Poor people suffer when they miss the statute of limitations. But we are undertaking, at great expense to the taxpayers, to move a special interest piece of legislation that I don't believe can be justified as a matter of principle. I agree with the Wall Street Journal that the adoption of it corrupts the system. We ought not be a part of that.

I love the American legal system. It is a great system, I know. I have seen judges time and time again enter rulings based on law and fact even if they didn't like it. That is the genius and reliability and integrity of the American legal system. I do not believe we can justify, while this matter is still in litigation, passing a special act to give a wealthy law firm, an insurance company, and a health care company special relief. I just don't believe we should do that. I oppose it, and I hope my colleagues will join us.

I think we have a real chance to turn this back. Our Congress and our Senate will be better for it; we really will. The Citizens Against Government Waste have taken an interest in this matter for some time. They said:

Congress has no right to rescue a company from its own mistakes.

Companies have a right to assert the law. Companies have a right to assert the law against individuals. But when the time comes for the hammer to fall on them for their mistake, they want Congress to pass a special relief bill. I don't think it is the right thing to do.

Mr. President, let's boil it down to several things. First, if the company is right and the law firm is right that they did not miss the statute of limitations, I am confident the court of appeals will rule in their favor, and it will not be necessary for this Senate to act. If they do not prevail in the court of appeals and don't win their argument, then there is a provision for private relief in the Congress, and they

ought to pursue that. There are special procedures. The litigation will be over, and they can bring that action at that time.

That is the basic position we ought to be in. A bill that comes out of the Judiciary Committee ought to be sensitive to the legal system, to the importance of ensuring that the poor are treated as well as the rich. The oath judges take is to do equal justice to the poor and the rich.

How many other people in this country are getting special attention today on the floor of the Senate? How many? I truly believe this is not good policy. I have had to spend far more hours fighting this than I have ever wanted to when I decided 10 years ago that this was not a good way to go forward. Many battle this issue, and I hope and trust that the Members of the Senate who will be voting on this will allow it to follow the legitimate process. Let the litigation work its way through the system.

If they do not prevail in the litigation, let a private relief bill be sought and debated openly and publicly to see if it is justified. That would be the right way to do it—not slipping through this amendment and then not voting to remove it on the basis that we should not be amending a bill before us. We have every right to amend the bill, and we should amend the bill. I know Senator GRASSLEY, years ago, was on my side. I think it was just the two of us who took this position.

I guess I have more than expressed my opinion. I thank the chairman for his leadership. I thank him and Senator GRASSLEY for their great work on this important patent bill. I support that bill. I believe they have moved it forward in a fair way.

The chairman did not put this language into the bill; it was put in over in the House. I know he would like to see the bill go forward without amendments. I urge him to think it through and see if he cannot be willing to support this amendment. I am confident it will not block final passage of the legislation.

I yield the floor.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. LEAHY. Mr. President, I will speak later about the comments made by the distinguished Senator from Alabama. He has been very helpful in getting this patent bill through. He is correct that this amendment he speaks to is one added in the other body, not by us. We purposely didn't have it in our bill. I know Senator GRASSLEY will follow my remarks.

There is no question in my mind that if the amendment of the Senator from Alabama were accepted, it in effect will kill the bill. Irrespective of the merits, it can come up on another piece of legislation or as freestanding legislation. That is fine. But on this bill, after 6 years of effort to get this far, this bill would die because the other body will not take it up again.



## HURRICANE IRENE

Mr. LEAHY. Mr. President, I will use my time to note some of the things happening in my own very special State of Vermont, the State in which I was born.

As Vermonters come together and continue to grapple with the aftermath of storm damage from Irene, I wish to focus today on the agriculture disaster that has hit us in Vermont and report to the Senate and our fellow citizens across the Nation about how the raging floodwaters wreaked havoc on our farming lands and infrastructure in Vermont.

It was 12 days ago now that this enormous, slow-moving storm hit Vermont and turned our calm, scenic brooks and creeks into raging gushers. In addition to our roads and historic covered bridges that were destroyed or carried away, we had barns, farmhouses, crops, parts of fields, and livestock washed away in the rising floodwaters. I recall the comments of one farmer who watched his herd of cows wash down the river, knowing they were going to die in the floodwaters.

Now the cameras have begun to turn away, but the cleanup and urgent repairs are underway. For major parts of Vermont's economy, the worst effects of this storm are yet to come. For our dairy farmers, who are the bedrock of our economy and keystones of our communities, the toll of this disaster has been heavy and the crises has lasted longer as they have struggled to take care of their animals while the floodwaters recede.

This is a photograph of East Pittsford, VT, taken by Lars Gange just over a week ago. The water we see is never there. It is there now. Look at this farm's fields, they are destroyed. Look at homes damaged and think what that water has done.

As I went around the state with our Governor and Vermont National Guard General Dubie the first couple of days after the storm hit, we went to these places by helicopter and I cannot tell you how much it tore at my heart to see the state, the birthplace to me, my parents, and grandparents. To see roads torn up, bridges that were there when my parents were children, washed away. Historic covered bridges, mills, barns, businesses just gone and what it has done to our farmers, it is hard, I cannot overstate it.

Our farmers have barns that are completely gone, leaving no shelter for animals. They are left struggling to get water for their animals, to rebuild fencing, to clean up debris from flooded fields and barns, and then to get milk trucks to the dairy farms. Remember, these cows have to be milked every single day. We also have farmers who do not have any feed or hay for their animals because it all washed away. As one farmer told me, the cows need to be milked two or three times every day, come hell or high water. This farmer thought he had been hit with both, hell and high water.

While reports are still coming in from the farms that were affected, the list of damages and the need for critical supplies, such as feed, generators, fuel, and temporary fencing is on the rise. As we survey the farm fields and communities, we know it will be difficult to calculate the economic impacts of this violent storm on our agriculture industry in Vermont.

Many of our farmers were caught by surprise as the unprecedented, rapidly rising floodwaters inundated their crops, and many have had to deal with the deeply emotional experience of losing animals to the fast-moving floodwaters. We have farms where whole fields were washed away and their fertile topsoil sent rushing down river. The timing could not have been worse. Corn, which is a crucial winter feed for dairy cows, was just ready for harvest, but now our best corn is in the river bottoms and is ruined. Other farms had just prepared their ground to sow winter cover crops and winter greens; they lost significant amounts of topsoil.

River banks gave way, and we saw wide field buffers disappear overnight, leaving the crops literally hanging on ledges above rivers, as at the Kingsbury farm in Warren, VT. Vegetable farming is Vermont's fastest growing agricultural sector, and, of course, this is harvest season. Our farmers were not able to pick these crops, this storm picked many fields clean.

Many Vermonters have highly productive gardens that they have put up for their families to get through the winter by canning and freezing. Those too have been washed away or are considered dangerous for human consumption because of the contaminated floodwaters. Vermont farmers have a challenging and precarious future ahead of them as they look to rebuild and plan for next year's crops, knowing that in our State it can be snowing in 1½ or 2 months.

I have been heartened, however, by the many stories I have heard from communities where people are coming together to help one another. For instance, at the Intervale Community Farm on the Winooski River, volunteers came out to harvest the remaining dry fields before the produce was hit by still rising floodwaters.

When the rumors spread that Beth and Bob Kennett at Liberty Hill Farm in Rochester had no power and needed help milking—well, people just started showing up. By foot, on bike, all ready to lend a hand to help milk the cows. Fortunately for them and for the poor cows, the Vermont Department of Agriculture had managed to help get them fuel and the Kennetts were milking again, so asked the volunteer farm hands to go down the road, help somebody else and they did.

Coping with damage and destruction on this scale is beyond the means and capability of a small State such as ours, and Federal help with the rebuilding effort will be essential to

Vermont, as it will be to other States coping with the same disaster. I worry the support they need to rebuild may not be there, as it has been in past disasters, when we have rebuilt after hurricanes, floods, fires and earthquakes to get Americans back in their homes, something Vermonters have supported even though in these past disasters Vermont was not touched.

So I look forward to working with the Appropriations Committee and with all Senators to ensure that FEMA, USDA and all our Federal agencies have the resources they need to help all our citizens at this time of disaster, in Vermont and in all our states. Unfortunately, programs such as the Emergency Conservation Program and the Emergency Watershed Protect Program have been oversubscribed this year, and USDA has only limited funds remaining. We also face the grim fact that few of our farms had bought crop insurance and so may not be covered by USDA's current SURE Disaster Program.

But those are the things I am working on to find ways to help our farmers and to move forward to help in the commitment to our fellow Americans. For a decade, we have spent billions every single week on wars and projects in far-away lands. This is a time to start paying more attention to our needs here at home and to the urgent needs of our fellow citizens.

I see my friend from Iowa on the floor, and I yield the floor.

The PRESIDING OFFICER. The senior Senator from Iowa.

## AMENDMENT NO. 600

Mr. GRASSLEY. Mr. President, I rise to rebut the points Senator SESSIONS made, and I do acknowledge, as he said on the floor, that 2 or more years ago I was on the same page he is on this issue. What has intervened, in the meantime, that causes me to differ from the position Senator SESSIONS is taking? It is a district court case giving justice to a company—as one client—that was denied that sort of justice because bureaucrats were acting in an arbitrary and capricious way.

Senator SESSIONS makes the point you get equal justice under the law from the judicial branch of government and that Congress should not try to override that sort of situation. Congress isn't overriding anything with the language in the House bill that he wants to strike because that interest was satisfied by a judge's decision; saying that a particular entity was denied equal justice under the law because a bureaucrat, making a decision on just exactly what counts as 60 days, was acting in an arbitrary and capricious way. So this language in the House bill has nothing to do with helping a special interest. That special interest was satisfied by a judge who said an entity was denied equal justice under the law because a bureaucrat was acting in an arbitrary and capricious manner.

This amendment is not about a special interest. This amendment is about

uniformity of law throughout the country because it is wrong—as the judge says—for a bureaucracy to have one sort of definition of when 60 days begins—whether it is after business hours, if something goes out, or, if something comes in, it includes the day it comes in. So we are talking about how we count 60 days, and it is about making sure there is a uniform standard for that based upon law passed by Congress and not upon one judge's decision that applies to one specific case.

I would say, since this case has been decided, there are at least three other entities that have made application to the Patent Office to make sure they would get equal justice under the law in the same way the entity that got help through the initial decision of the judge. So this is not about special relief for one company. This is about what is a business day and having a uniform definition in the law of the United States of what a business day is, not based upon one district court decision that may not be applied uniformly around our Nation.

So it is about uniformity and not about some bailout, as Senator SESSIONS says. It is not about some ferocious lobbying effort, as Senator SESSIONS has said. It is not just because one person was 1 hour late or 1 day late, because how do you know whether they are 1 hour late or 1 day late if there is a different definition under one circumstance of when 60 days starts and another definition under other circumstances of when a 60-day period tolls?

Also, I would suggest to Senator SESSIONS that this is not Congress interfering in a court case that is under appeal because the government lost this case and the government is not appealing. Now, there might be some other entity appealing for their own interests to take advantage of something that is very unique to them.

But just in case we have short memories, I would remind my colleagues that Congress does sometimes interject itself into the appeal process, and I would suggest one time we did that very recently, maybe 6 years ago—and that may not be very recent, but it is not as though we never do it—and that was the Protection of Lawful Commerce Act of 2005, when Congress interjected itself into an issue to protect gun manufacturers from pending lawsuits. It happens that 81 Senators supported that particular effort to interject ourselves into a lawsuit.

So, Mr. President, in a more formal way, I want to repeat some of what I said this past summer when I came to the Senate floor and suggested to the House of Representatives that I would appreciate very much if they would put into the statutes of the United States a uniform definition of a business day and not leave it up to a court to maybe set that standard so that it might not be applied uniformly and, secondly, to make sure it was done in a way that

was treating everybody the same, so everybody gets equal justice under the law, they know what the law is, and they don't have to rely upon maybe some court decision in one part of the country that maybe they can argue in another part of the country, and also to tell bureaucrats, as the judge said, that you can't act in an arbitrary and capricious way. But bureaucrats might act in an arbitrary and capricious way, in a way unknown to them, if we don't have a uniform definition of what a business day is.

So I oppose the effort to strike section 37 from the patent reform bill for the reasons I have just given, but also for the reasons that were already expounded by the chairman of this committee that at this late date, after 6 years of trying to get a patent reform bill done—and we haven't had a patent reform bill for over a decade, and it is badly needed—we shouldn't jeopardize the possible passage of this bill to the President of the United States for his signature by sending it back to the other body and perhaps putting it in jeopardy. But, most important, I think we ought to have a clear signal of what is a business day, a definition of it, and this legislation and section 37 makes that very clear.

This past June, I addressed this issue in a floor statement, and I want to quote from that because I wanted my colleagues to understand why I hoped the House-passed bill would contain section 37 that was not in our Senate bill but that was passed out of the House Judiciary Committee unanimously. Speaking as ranking member of the Senate Judiciary Committee now and back in June when I spoke, I wanted the House Judiciary Committee to know that several Republican and Democratic Senators had asked me to support this provision as well.

Section 37 resulted from a recent Federal court case that had as its genesis the difficulty the FDA—the Food and Drug Administration—and the Patent Office face when deciding how to calculate Hatch-Waxman deadlines. The Hatch-Waxman law of the 1980s was a compromise between drug patent holders and the generic manufacturers. Under the Waxman-Hatch law, once a patent holder obtains market approval, the patent holder has 60 days to request the Patent Office to restore the patent terms—time lost because of the FDA's long deliberating process eating up valuable patent rights.

The citation to the case I am referring to is in 731 Federal Supplement 2nd, 470. The court found—and I want to quote more extensively than I did back in June. This is what the judge said about bureaucrats acting in an arbitrary and capricious way and when does the 60 days start.

The Food and Drug Administration treats submissions to the FDA received after its normal business hours differently than it treats communications from the agency after normal business hours.

Continuing to quote from the decision:

The government does not deny that when notice of FDA approval is sent after normal business hours, the combination of the Patent and Trademark Office's calendar day interpretation and its new counting method effectively deprives applicants of a portion of the 60-day filing period that Congress expressly granted them . . . Under PTO's interpretation, the date stamped on the FDA approval letter starts the 60-day period for filing an application, even if the Food and Drug Administration never sends the letter . . . An applicant could lose a substantial portion, if not all, of its time for filing a Patent Trademark Extension application as a result of mistakes beyond its control . . . An interpretation that imposes such drastic consequences when the government errs could not be what Congress intended.

So the judge is telling us in the Congress of the United States that because we weren't precise, there is a question as to when Congress intended 60 days to start to toll. And the question then is, if it is treated one way for one person and another way for another person, or if one agency treats it one way and another agency treats it another way, is that equal justice under the law? I think it is very clear that the judge said it was not. I say the judge was correct. Congress certainly should not expect nor allow mistakes by the bureaucracy to up-end the rights and provisions included in the Hatch-Waxman Act or any other piece of legislation we might pass.

The court ruled that when the Food and Drug Administration sent a notice of approval after business hours, the 60-day period requesting patent restoration begins the next business day. It is as simple as that.

The House, by including section 37, takes the court case, where common sense dictates to protect all patent holders against losing patent extensions as a result of confused counting calculations. Regrettably, misunderstandings about this provision have persisted, and I think you hear some of those misunderstandings in the statement by Senator SESSIONS.

This provision does not apply to just one company. The truth is that it applies to all patent holders seeking to restore the patent term time lost during FDA deliberations—in other words, allowing what Hatch-Waxman tries to accomplish: justice for everybody. In recent weeks, it has been revealed that already three companies covering four drug patents will benefit by correcting the government's mistake.

It does not cost the taxpayers money. The Congressional Budget Office determined that it is budget-neutral.

Section 37 has been pointed out as maybe being anticonsumer, but it is anything but anticonsumer. I would quote Jim Martin, chairman of the 60-Plus Association. He said:

We simply can't allow bureaucratic inconsistencies to stand in the way of cutting-edge medical research that is so important to the increasing number of Americans over the age of 60. This provision is a common-sense response to a problem that unnecessarily has ensnared far too many pharmaceutical companies and caused inexcusable delays in drug innovations.



We have also heard from prominent doctors from throughout the United States. They wrote to us stating that section 67 “is critically important to medicine and patients. In one case alone, the health and lives of millions of Americans who suffer from vascular disease are at stake . . . Lives are literally at stake. A vote against this provision will delay our patients access to cutting-edge discoveries and treatments. We urgently request your help in preserving section 37.”

So section 37 improves our patent system fairness through certainty and clarity, and I urge my colleagues to join me in voting to preserve this important provision as an end in itself, but also to make sure we do not send this bill back to the House of Representatives and instead get it to the President, particularly on a day like today when the President is going to be speaking to us tonight about jobs. I think having an updated patent law will help invention, innovation, research, and everything that adds value to what we do in America and preserve America’s greatness in invention and the advancement of science.

In conclusion, I would say it is very clear to me that the court concluded that the Patent and Trademark Office, and not some company or its lawyers, had erred, as is the implication here. A consistent interpretation ought to apply to all patent holders in all cases, and we need to resolve any uncertainty that persists despite the court’s decision.

I yield the floor.

The PRESIDING OFFICER. The senior Senator from Vermont is recognized.

Mr. LEAHY. Mr. President, I thank the distinguished Senator from Iowa for his words, and I join with the Senator from Iowa in opposing the amendment for two reasons. First, as just simply as a practical matter, the amendment would have the effect, if it passed, of killing the bill because it is not going to be accepted in the other body, and after 6 years or more of work on the patent bill, it is gone. But also, on just the merits of it, the provision this amendment strikes, section 37 of H.R. 1249, simply adopts the holding of a recent district court decision codifying existing law about how the Patent and Trademark Office should calculate 5 days for the purpose of considering a patent term extension. So those are the reasons I oppose the amendment to strike it.

The underlying provision adopted by the House is a bipartisan amendment on the floor. It was offered by Mr. CONYERS, and it has the support of Ms. PELOSI and Mr. BERMAN on the Democratic side and the support of Mr. CANTOR, Mr. PAUL, and Mrs. BACHMANN on the Republican side. I have a very hard time thinking of a wider range of bipartisan support than that.

The provision is simply about how they are calculating filing dates for patent extensions, although its critics

have labeled it as something a lot more. A patent holder on a drug is entitled by statute to apply for an extension of its patent term to compensate for any delay the Food and Drug Administration approval process caused in actually bringing the drug to market. The patent holder not only has to file the extension within 60 days beginning on the date the product received permission for marketing, but there is some ambiguity as to when the date is that starts the clock running.

Only in Washington, DC, could the system produce such absurd results that the word “date” means not only something different between two agencies—the PTO and the FDA—but then it is given two different constructions by the FDA. If this sounds kind of esoteric, it is. I have been working on this for years and it is difficult to understand. But the courts have codified it. Let’s not try to change it yet again.

What happens is that the FDA treats submissions to it after normal hours as being received the next business day. But the dates of submissions from the FDA are not considered the next business day, even if sent after hours. To complicate matters, the PTO recently changed its own method of defining what is a “date.”

If this sounds confusing even in Washington, you can imagine how it is outside of the bureaucracy. Confusion over what constitutes the “date” for purposes of a patent extension has affected several companies. The most notable case involves the Medicines Company’s ANGIOMAX extension application request.

The extension application was denied by the PTO because of the difference in how dates are calculated. MedCo challenged the PTO’s decision in court, and last August the federal district court in Virginia held the PTO’s decision arbitrary and capricious and MedCo received its patent term extension.

Just so we fully understand what that means, it means PTO now abides by the court’s ruling and applies a sensible “business day” interpretation to the word “date” in the statute. The provision in the America Invents Act simply codifies that.

Senator GRASSLEY has spoken to this. As he said a few weeks ago, this provision “improves the patent system fairness through certainty and clarity.”

This issue has been around for several years and it was a controversial issue when it would have overturned the PTO’s decision legislatively. For this reason Senator GRASSLEY and others opposed this provision when it came up several years ago. But now that the court has ruled, it is a different situation. The PTO has agreed to accept the court’s decision. The provision is simply a codification of current law.

Is there anyone who truly believes it makes sense for the word “date” to receive tortured and different interpretations by different parts of our govern-

ment rather than to have a clear, consistent definition? Let’s actually try to put this issue to bed once and for all.

The provision may solidify Medco’s patent term extension, but it applies generally, not to this one company, as has been suggested. It brings common sense to the entire filing system.

However, if the Senate adopts the amendment of the Senator from Alabama, it will lead to real conflict with the House. It is going to complicate, delay, and probably end passage of this important bipartisan jobs-creating legislation.

Keep in mind, yesterday I said on the floor that each one of us in this body could write a slightly different patent bill. But we do not pass 100 bills, we pass 1. This bill is supported by both Republicans and Democrats across the political spectrum. People on both sides of the aisle have been working on this issue for years and years in both bodies. We have a piece of legislation. Does everybody get every single thing they want? Of course not. I am chairman of the Senate Judiciary Committee. I don’t have everything in this bill I want, but I have tried to get something that is a consensus of the large majority of the House and the Senate, and we have done this.

In this instance, in this particular amendment, the House expressly considered this matter. They voted with a bipartisan majority to adopt this provision the amendment is seeking to strike. With all due respect to the distinguished Senator from Alabama, who contributed immensely to the bill as ranking member of the committee last Congress, I understood why he opposed this provision when it was controversial and would have had Congress override the PTO. But now that the PTO and court have resolved the matter as reflected in the bill, it is not worth delaying enactment of much-needed patent reform legislation. It could help create jobs and move the economy forward.

We will have three amendments on the floor today that we will vote on. This one and the other two I strongly urge Senators, Republicans and Democrats, just as the ranking member has urged, to vote them down. We have between 600,000 and 700,000 patents applications that are waiting to be taken care of. We can unleash the genius of our country and put our entrepreneur class to work to create jobs that can let us compete with the rest of the world. Let’s not hold it up any longer. We have waited long enough. We debated every bit of this in this body and passed it 95 to 5. On the motion to proceed, over 90 Senators voted to proceed. It has passed the House overwhelmingly. It is time to stop trying to throw up roadblocks to this legislation.

If somebody does not like the legislation, vote against it. But this is the product of years of work. It is the best we are going to have. Let us get it done. Let us unleash the ability and inventive genius of Americans. Let us go forward.

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