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A BILL TO AMEND TITLE 35, UNITED STATES CODE, TO CONFORM CERTAIN FILING PROVISIONS WITHIN THE PATENT AND TRADEMARK OFFICE

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

ON

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A BILL TO AMEND TITLE 35, UNITED STATES CODE, TO CONFORM CERTAIN FILING PROVISIONS WITHIN THE PATENT AND TRADEMARK OFFICE

THURSDAY, SEPTEMBER 14, 2006

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, THE INTERNET,
AND INTELLECTUAL PROPERTY,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 11:14 a.m., in Room 2141, Rayburn House Office Building, the Honorable Lamar Smith (Chairman of the Subcommittee) presiding.

Mr. SMITH. The Subcommittee on Courts, the Internet, and Intellectual Property will come to order.

I am going to recognize myself for an opening statement, then the Ranking Member of the full Judiciary Committee, Mr. Conyers, as well as Mr. Berman and as well as Mr. Jenkins, the author of the legislation on which we are having the hearing today.

Thank you all for your interest. And we will proceed and then get to questions for our panelists as soon as we can.

I will recognize myself for an opening statement.

Today we begin an examination of H.R. 5120, a bill to amend title 35 of United States Code to conform certain filing provisions within the Patent and Trademark Office.

This is an important hearing on a serious subject, and I look forward to the testimony of our witnesses.

It is the tradition of our Subcommittee to ensure all stakeholders have an opportunity to be heard and have their concerns placed on the record. This is a critical step to take before we begin to consider what further steps, if any, may be appropriate.

H.R. 5120 is a highly unusual bill. Its enactment will single out a specific company and their legal counsel for special consideration. I believe the proponents of the legislation have the burden to establish that a change in public law is necessary. At the same time, I want to compliment the company for its commitment to the regular legislative process.

And I appreciate Dr. Meanwell's willingness to respond to tough questions in a public forum, which I believe is necessary to assist the Members of the Subcommittee in understanding the circumstances that led this company and their counsel to this point.

Their view is that the law is inflexible and, in their words, should be conformed to other provisions of the patent code that per-

mit parties who have failed to meet statutory deadlines to be granted an extension. Further, they believe the public interest in spurring innovation and promoting public health is best served by providing for the retroactive application of such a change in the law in their case.

Not unexpectedly, there are countervailing arguments. Opponents of this measure maintain there is no good reason the law requires amendment. They note that since this provision was first enacted more than two decades ago, only three of more than 700 applications have ever been denied in any part for having missed the 60-day filing deadline.

Further, they assert there is substantial precedent in the Patent Act to support the view that no relief should be granted when certain statutory deadlines are not met and that relief should extend only to circumstances where it is objectively demonstrated that the failure to file was unavoidable rather than merely unintentional. In other words, they believe the proposed change would actually make this deadline inconsistent with other precedents in the Patent Act. This is just a preview of the various arguments that the Subcommittee Members will soon hear and need to weigh for themselves.

That concludes my opening remarks. And the gentleman from Michigan, Mr. Conyers, is recognized for his.

Mr. CONYERS. I thank you, Chairman Smith. And I join you in welcoming all the witnesses: the Honorable Jon Dudas, a very dear friend of ours, Dr. Meanwell, and President Jaeger of Generic Pharmaceutical Association, and Professor Thomas.

I wanted you to know as I head for the floor on a judiciary bill that is currently up for consideration that the proposal before us, legislation that would permit the Patent and Trademark Office to consider late applications for an extended term of patent protection or marketing exclusivity, currently if a patent owner files for an extension even 1 day late, then the PTO has no discretion to consider it.

I understand that The Medicines Company faced this problem directly in 2002 when it sought patent term extension for its heart drug, Angiomax. If it was granted, the extension would have permitted the company to exclude competition to Angiomax for a longer period.

The application for additional patent protection was due 60 days after the Food and Drug Administration approved the drug. But the application was filed on the 61st day. Because it has no discretion to review late filings, the PTO summarily rejected its consideration.

Before us today is a proposal that would allow the PTO to consider the application. Contrary to how it has been portrayed, it would not automatically extend the term of exclusivity or automatically prevent competitors from entering the market. And in that regard, the bill appears equitable.

And I look forward to returning to continue the discussion with these very able witnesses that are before us.

And I thank you for your courtesy, Chairman Smith.

Mr. SMITH. Would the gentleman from Michigan yield to the gentleman from California, Mr. Berman, for his opening statement as well?

Mr. CONYERS. Absolutely.

Mr. BERMAN. Thank you, Mr. Chairman.

And thank you, Mr. Ranking Member, for yielding.

I appreciate scheduling this hearing on a bill giving the USPTO additional discretion to extend certain patent deadlines. While similar measures, bills that have specifically extended the Angiomax patent, have been attached to legislative vehicles in the past, I am glad that this issue is finally being reviewed by the Committee with jurisdiction over patent matters. It is important that this Subcommittee be able to analyze the impact of any changes this bill may make on the patent system.

Patents are a cornerstone of innovation. The Constitution provides a limited period of time of protection in order to promote innovation. Therefore, the patent process provides the exclusive right for an invention for 17 to 20 years generating incentives for an inventor to continue to create after which the invention becomes available for public use.

There is a delicate balance here: providing enough of an incentive to the inventor to spend the time, energy and money to create new inventions and on the other hand, the value of allowing the invention to be used by the public enabling others to develop new products or provide similar products for lower cost. Therefore, when considering the effect of allowing the PTO discretion to extend certain patent deadlines there is a natural tension between providing the flexibility to extend the deadline and maintaining a hard date for specific types of filings.

While providing greater elasticity may prevent Draconian results, does that come at the expense of stability in the market? There are to be other instances—there appears to be other instances where the PTO has discretion to extend deadlines. But the situation in this bill is designed to address is not one of those sections. Why? Is there something different about this type of filing that the PTO should not have discretion in this case?

Unfortunately, the PTO, I am sorry to say, Jon, hasn't provided much guidance in its response to the letter from the Chairman and myself about the policy questions posed by this bill. So I look forward to this hearing to hear the witnesses discuss the policy implications of this bill on the patent system and possibly on Hatch-Waxman.

Just to conclude, originally this legislation began as an effort to address one particular late filing of one patent. There has been no demonstrated need or request from any other patent owners, as far as I know, to provide discretion to the PTO for these types of filings. Moreover, from the way the bill has been written, it is clear this bill would affect the late filing of a particular company, which occurred about over 4 years ago. Some have even suggested that the better alternative to this bill is a private bill.

However, this bill and this particular circumstance does raise some questions about why there are inconsistencies in the discretion afforded to the PTO to determine when filings are timely. I look forward to this opportunity to explore those issues.

I yield back, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Berman.

The gentleman from Tennessee, Mr. Jenkins, is recognized for an opening statement.

Mr. JENKINS. Thank you, Chairman Smith, for holding this hearing.

And thank you, Mr. Berman, for your participation. I look forward to the views of our witnesses, like you, sir. And I am grateful for their appearance this morning.

H.R. 5120 has drawn bipartisan sponsorship from 23 of our colleagues, including three Members of the full Judiciary Committee: Mr. Hyde, Mr. Delahunt, and Mr. Meehan. I introduced this measure because I believe it is both good patent policy and sound health care policy. It corrects an inequity in the patent law and will encourage important innovation in medical research, precisely the purpose that Congress sought to accomplish in enacting the Hatch-Waxman Act.

In the course of this hearing, I hope that you will hear several examples of relief that is available for late payments, late filings and deficient filings. By enacting H.R. 5120 we are continuing to promote the basic purpose of Hatch-Waxman, and we are strengthening Hatch-Waxman. It is important to do this so that our nation will continue to lead the way in medical research and so that patients will not be denied promising new, innovative developments.

Mr. Chairman, I am submitting letters from leading medical practitioners and consumer groups, including a letter from the Cleveland Clinic, the University of California at Los Angeles, and the Emory Health Care Center in Atlanta, Georgia, from across our country endorsing H.R. 5120 to include in the Committee report.

Their credentials and their views are impressive. They emphasize the health care advantages of this measure, particularly its effect on opening up new avenues of medical research to prevent and treat strokes.

Mr. Chairman, I would like to ask unanimous consent to introduce these letters and that they be made a part of the record.

Mr. SMITH. Okay. Without objection, those letters will be made a part of the record.

[The letters follow in the Appendix]

Mr. JENKINS. Thank you.

H.R. 5120 is a narrowly tailored bill. It simply confers discretion on the patent office to consider an unintentionally late filed patent term restoration application submitted to the patent office within 5 days of the 60-day deadline in current law. It does not confer any substantive rights on any applicant but merely allows the applicant to present the facts surrounding the late filing to the patent office.

The director of the patent office then has 30 days to rule on the petition. Honest mistakes should not cause irreparable hardship for innovators or patients. A few days unintentional late filing mistake at the patent office should not be a cause for blocking promising medical research that could lead to important health care advances.

Mr. Chairman, I appreciate all the efforts you and the Subcommittee have invested in preparing for this hearing. I hope that

we can move as quickly as possible through the Committee process and proceed with the enactment of H.R. 5120. Thank you.

Mr. SMITH. Thank you, Mr. Jenkins.

And, without objection, other Members' opening statements will be made a part of the record, as well as a statement by Representative Elton Gallegly, a letter from Lawrence Goffney and testimony by Thomas Schatz, president of Citizens Against Government Waste.

Mr. SMITH. Before I introduce our witnesses, I would like to ask you all to stand and be sworn in.

[Witnesses sworn.]

Thank you. Please be seated.

Our first witness is Jon Dudas, who is the Undersecretary for Intellectual Property and Director of the United States Patent and Trademark Office. Mr. Dudas is the lead policy adviser to the Secretary of Commerce, the President of the United States and Administration agencies on intellectual property matters.

As Director of the USPTO, he is responsible for administering the laws that relate to the issuance of patents and trademarks and day-to-day management of the agency's $1.7 billion budget and 8,000 employees.

Prior to joining the Administration, Mr. Dudas served 6 years as Counsel to this Subcommittee and as Staff Director and Deputy General Counsel to the Committee on the Judiciary. Mr. Dudas is a summa cum laude graduate of the University of Illinois where he earned a bachelor of science in finance. He is an honors law graduate from the University of Chicago.

Our second witness is Clive Meanwell, who is the Chairman and Chief Executive Officer of The Medicines Company, a pharmaceutical company based in Parsippany, New Jersey that specializes in acute care hospital medicines. In 1996, Dr. Meanwell co-founded TMC to develop medicines for specialized patient populations.

TMC's only product is marketed under the name Angiomax and is used to prevent blood clots in patients from cardiovascular disease. Dr. Meanwell oversaw the acquisition, development and successful regulatory review of Angiomax, which culminated with the Food and Drug Administration's approval in 2000. Dr. Meanwell holds both an M.D. and a Ph.D. from the University of Birmingham in the United Kingdom.

Our next witness is Kathleen D. Jaeger, who has served as the President and CEO of the Generic Pharmaceutical Association since 2002. Before joining that organization, Ms. Jaeger was a partner in the Washington office of several law firms where she developed a specialty in food and drug practice. In addition to earning her J.D. from Catholic University Law School, Ms. Jaeger also has a bachelor of science in pharmacy and a minor in chemistry, which she earned at the University of Rhode Island.

Our final witness is John R. Thomas, who is a professor of law at the Georgetown University Law Center. Professor Thomas formerly served as an associate or visiting professor on the faculties of George Washington University, Cornell Law School and the University of Tokyo. Professor Thomas has written extensively on intellectual property law co-authoring both a patent law case book and a one-volume treatise on intellectual property.

Welcome to you all.

As you know, we have your entire written statements, which, without objection, will be made a part of the record. But please limit your testimony to 5 minutes.

And, Mr. Dudas, we will begin with you.

TESTIMONY OF JON DUDAS, UNDERSECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY, DIRECTOR OF THE U.S. PATENT AND TRADEMARK OFFICE

Mr. DUDAS. Thank you, Mr. Chairman, Ranking Member Berman, Congressman Jenkins and Congressmen Meehan and Delahunt, for inviting me to testify today on H.R. 5120.

This bill would amend patent law to permit the USPTO to consider certain late-filed applications for patent extension under Hatch-Waxman if such applications are filed no later than 5 days after the current 60-day time period and applicants file a petition showing that the delay was unintentional.

Mr. Chairman, the USPTO does not at this point have a position on this bill. Certainly, there could be some benefits and at least one direct beneficiary of providing the flexibility proposed in the bill. But there are also benefits to maintaining a certainty inherent in the current law.

While we have a sense of the potential impact on the possible direct beneficiary to this legislation and while we know very well our own abilities to enforce the law, we do not yet have a full sense of the impact on other interested parties. Therefore, I commend you for holding this hearing to help determine the potential impact and to otherwise examine the possible merits and limitations of this proposal.

Although I am unable to give you a clear reading of support or opposition, I would like to share with you a number of observations that may be helpful to the Subcommittee as it reviews the bill.

First, this type of legislation is not without precedent. As indicated in my written statement, current patent and trademark law provides the USPTO with discretionary authority to accept late-filed submissions in a number of situations.

Also, while we currently do not believe the legislation requires additional restrictions or limitations in order to ensure a neutral application if enacted, further review of the issue may be helpful as the legislative process continues.

In terms of application, we are aware of one current application for patent term extension that would immediately benefit from enactment of the bill. You will be hearing from the owner of that patent shortly. But our review of the over 700 applications for patent term extensions filed since 1984 indicates that one other application filed 5 days late may have benefited from this bill if it had been in effect.

So after a review of 700 applications since 1984, there are a total of four patent term extension requests that were over 60 days, two that were within 65 days but older than 60 days and one that is currently pending.

I should note that it is not unprecedented for newly enacted patent legislation to apply to issued patents and pending applications. But prospective or retrospective discretionary authority as pro-

posed in this bill should involve a careful balancing of all relevant interests involved. Again, we are pleased that the Subcommittee is reviewing input with an eye toward that balancing.

Mr. Chairman, if granted the authority proposed in the bill, I would not foresee any implementation problems at the USPTO. The USPTO would, of course, follow the policies reflected in our administration of areas currently subject to discretionary review of delayed filings.

Mr. Chairman, in closing I want to thank you, Ranking Member Berman, and the Members of this Subcommittee for your continuing and strong support for the USPTO operations and for your efforts to maintain and improve our system of intellectual property protection and enforcement. And I look forward to answering your questions.

[The prepared statement of Mr. Dudas follows:]

PREPARED STATEMENT OF THE HONORABLE JON W. DUDAS

Chairman Smith, Ranking Member Berman, and Members of the Subcommittee:

Thank you for inviting me to testify today on H.R. 5120, a bill "to amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office."

The bill would amend patent law to permit the USPTO to consider certain late-filed applications for patent extension under section 156 of title 35 if such applications are filed not later than five days after the current 60-day time period and the applicants file a petition that shows that the delay in filing the application was unintentional.

Mr. Chairman, as indicated in our recent letters to you and Ranking Member Berman, the United States Patent and Trademark Office (USPTO) does not at this time have a position on this proposed legislation.

While there could be some benefits, and at least one direct beneficiary, of providing the type of additional flexibility provided by the proposal, there are also benefits to maintaining the certainty inherent in the current law in this area.

While we have a sense of the potential impacts on the possible direct beneficiary to this legislation, we do not yet have a full sense of the impact on others in the invention, manufacturing, consumer, and intellectual property communities.

Accordingly, we commend you for holding this hearing to help determine the potential impact on all interested parties and to otherwise examine the possible merits and limitations of the proposal.

I am pleased to share with you a number of our observations that may be helpful as the Subcommittee reviews the bill.

PRECEDENT

This type of legislation is not without precedent. Currently, patent laws provide the USPTO with discretionary authority to accept late-filed submissions in a number of situations, including: payment of maintenance fees (35 USC § 41(c)(1)); abandonment of applications (35 USC § 133); and payment of issue fees (35 USC § 151). The trademark laws have similar language, for example, regarding timely filing of a verified statement of use (15 USC § 1051(d)(4)) and abandonment of an application for failure to reply or amend (15 USC § 1062(b)).

Similarly, while we currently do not believe the legislation requires additional restrictions or limitations in order to ensure neutral application if enacted, further exploration of the issue may be informative as the legislative process continues.

PREVIOUS APPLICANTS THAT WOULD BENEFIT FROM ENACTMENT

We are aware of one current application for patent term extension that would immediately benefit from enactment of the bill. That application is related to patent number 5,196,404 owned by the company represented at the table here today. More generally, a review of our records indicates that, of the over 700 applications for patent term extension filed since 1984, three other applications were not granted due, at least in part, to timeliness issues. One of these applications was filed within 65 days of the "approval date," and thus may have been eligible for a petition to have the delay excused, if the proposed provision had been in effect.

PROSPECTIVE VS. RETROSPECTIVE

It is not unprecedented for newly enacted patent legislation to apply to issued patents and pending applications. That fact noted, prospective or retrospective discretionary authority, as proposed in the bill, would have to involve a careful balancing of all relevant interests involved. We are unable to make a particular recommendation in this regard because we are unaware of any substantive input by interested parties, other than the 404 patent owner.

EXERCISE OF DISCRETION

With respect to the circumstances under which we would expect to exercise discretion under this bill, we believe it is premature to attempt to list or identify particular examples at this point. We would, of course, if granted the subject authority, be likely to follow the policies reflected in the administration of areas currently subject to discretionary review of delayed filings.

PATENT REFORM

Although our survey of patent term extension applications reveals few issues related to timeliness, this legislation would be of use to at least one current applicant and could be utilized by future applicants who miss the patent term extension application deadline due to unintentional delay. As noted above, the discretionary authority contemplated by H.R. 5120 is similar to other deadline-extending provisions in patent law.

As indicated in testimony before your Subcommittee in April, the USPTO supports enactment of two patent proposals pending before the Subcommittee that are widely supported throughout the intellectual property community, namely, a post-grant review procedure and a new procedure for submission of prior art. We continue to review other proposals before the Subcommittee.

Thank you.

Mr. SMITH. Thank you, Mr. Dudas.

Dr. Meanwell.

TESTIMONY OF CLIVE MEANWELL, CHIEF EXECUTIVE OFFICER, THE MEDICINES COMPANY

Mr. MEANWELL. Thank you, Mr. Chairman and Members of the Committee. I am pleased to be here and appreciate the Committee's invitation to testify. My name is Clive Meanwell. I come before you today both as a physician and as the chairman and CEO of The Medicines Company, a young company devoted to developing medicines for acutely ill patients.

The subject of today's hearing may seem dry and technical, but, as you know, it is actually about ensuring the potential to save lives and reduce health care costs. Our company serves as a poster child for why this legislation is needed. Relying on incentives in the patent law, we spent more than $200 million developing Angiomax, an intravenous blood thinner that has proven to be effective and safe for patients while actually saving hospitals an average of $400 per use compared with more established therapies.

Once FDA approved Angiomax, we applied for patent term restoration to recover time lost while seeking approval. The 60-day deadline was mistaken for a 2-month limit, and the application was filed 1 day late. Unlike most other patent provisions, current law gives the PTO no discretion to accept a late filing. So our application was denied.

This drastic penalty took away 4½ years of patent rights we had earned and cut off our ability to invest tens of millions of dollars more in research to confirm promising new uses of Angiomax in open heart surgery and stroke.

Mr. Chairman, this is a good bill for three principle reasons.

First, the existing deadline provision imposes hugely disproportionate penalty like having your home repossessed when you are a day late with the last mortgage payment. Deadlines are important, but most patent law provisions like Federal court rules recognize that human beings make mistakes and that catastrophic consequences should not flow from them.

Second, this legislation is consistent with most patent laws and regulations, which allow minor mistakes to be excused.

Third, the bill could benefit millions of seriously ill patients. Only companies with a period of exclusivity can make the large-scale investments necessary to develop new uses of the drug beyond the scope of its initial FDA approval.

Some critics suggest this bill will disrupt the decision making process of generic manufacturers who pursue their own applications on relatively tight timelines. I am on the board of a company that sells generics, and I know how important these tight timelines are. But they have nothing to do with the patent term restoration—with when patent term restoration applications are filed. The only dates really important to a generic firm are the date of FDA approval and the date a patent expires.

Similarly, the claim that this bill might interfere with settled expectations is a fallacy. There are no settled expectations 60 days after a drug has been approved, nor would the time added by this bill, a maximum of 35 days, have the slightest impact on a generic's business plans. It is the pioneers' settled expectations that get blown to bits if its patent rights are lost over a minor filing error.

It is also suggested that since the filing of Hatch-Waxman application triggers an elaborate sequence for calculating the registration period—the restoration period, ensuring that this triggering event happens in a seasonable manner is somehow important. But calculating the restoration term typically takes 3 years after the application is filed. So the few extra days this bill could add at the start of the process are just trivial.

This bill will not—and let me repeat that—will not upset the delicate balance that Hatch-Waxman strikes between innovators and generics. In fact, it preserves the balance. Generics retain all their rights. And the patent owners get nothing more than the restoration period that they already earned under Hatch-Waxman. Without this bill, however, an innovator who makes an unintentional filing mistake loses what Congress intended to provide: an opportunity to recover time lost during FDA approval.

I just don't believe that Congress intended to throw this careful balance overboard in the event that an innovator trips on their way to the patent office. Some say this is a single company bill. But that is a red herring. This bill would fix a legal pothole for all other patent holders and could potentially help millions of patients who will benefit from new drugs and new uses of drugs.

In summary, this bill enhances the fundamental bargain struck by Hatch-Waxman. It removes a Draconian penalty for minor error. It is consistent with current law. And it will potentially improve the lives of millions of needy patients.

Thank you very much.

[The prepared statement of Mr. Meanwell follows:]

PREPARED STATEMENT OF CLIVE MEANWELL

Thank you Mr. Chairman and Members of the Committee.

My name is Clive Meanwell, and I am the Chairman and Chief Executive Officer of The Medicines Company, a young pharmaceutical company based in New Jersey where we develop acute care medicines for hospital patients, a small segment of the market often considered unattractive by big drug companies. I am also a doctor. And I am pleased to be here and appreciate the Committee's invitation to testify.

Mr. Chairman, the subject of today's hearing—filing deadlines for certain patent applications—might seem like a dry and technical one, but it is actually about creating the potential to save lives. It is about amending a provision of the Hatch-Waxman Act that, if left unchanged, will right now kill the further development of a drug that is helping thousands of heart disease patients every month and has the promise to help hundreds of thousands more patients with life-threatening cardiovascular conditions, including stroke victims. Beyond our case, if the provision is left unchanged, it will also put at risk the development of other drugs that will save lives in the future.

The purpose of this hearing, at least as I see it, is to weigh the distinct benefit of the proposed filing amendment against whatever benefit there may be to retaining the existing, inflexible provision. In my view, what H.R. 5120 does, in a nutshell, is to preserve the fundamentally sound bargain Congress struck in the Hatch-Waxman Act between encouraging innovation and bringing generic drugs to market. In preserving Hatch-Waxman's incentive to develop new drugs and new uses for drugs—without curtailing provisions that benefit generic manufacturers—this bill also stands solidly on the side of patients.

BACKGROUND

To date, The Medicines Company's only marketed product is a new blood thinning drug called Angiomax. The FDA has already approved Angiomax for use in angioplasty—a procedure often used to treat coronary artery disease, including heart attacks. Catheters, inflatable balloons, and stents are used to open up a coronary artery that is narrowed or blocked by arteriosclerosis or blood clots. Approximately one million angioplasties are performed each year in the United States, and in this setting Angiomax has been shown effective and safe, and is also associated with a significant reduction in bleeding complications compared to other treatments. More than 250,000 patients benefited from Angiomax last year alone. These positive results have been seen in both clinical trials and real-world use, in many different groups of patients, from diverse ethnic backgrounds, with a range of risk factors and a variety of life-threatening coronary artery disease states. And Angiomax—a product of high technology research—is particularly useful for people who cannot tolerate heparin, an extract of pig intestines discovered in 1916, that until the last decade was the only injectable anticoagulant available.

In addition to its established effectiveness in coronary angioplasty, Angiomax may also have important uses in patients undergoing cardiac surgery, those with pre-heart attacks and those with strokes. Each of these conditions represents enormous public health problems in the United States today. Coronary artery disease and stroke combine to kill well over a half million Americans each year—more than the deaths caused by all cancers combined, and therefore by far the leading cause of death in this country. The initial promise of Angiomax in these new research areas is exciting. For example, results of an Angiomax pilot trial in open heart surgery were reported in the *Annals of Thoracic Surgery* in 2004, where an expert commentator stated, "bivalirudin [*i.e.,* Angiomax] could be the 'holy grail' eagerly sought by cardiac surgeons and anesthesiologists (and hematologists). . . ." Ann. Thorac. Surg. 2004; 77:925–31. In another example, early studies involving carotid artery stenting—a procedure used to unblock the arteries in the neck that can throw off blood clots to the brain—have shown that Angiomax can reduce the risks of bleeding and effectively prevent embolic strokes during this delicate life-saving procedure.

We have already committed, and hope to continue committing, substantial resources to research and development of these significant new uses for Angiomax. And that brings me to the point of my testimony today.

Our company serves, I am sorry to say, as a poster child for why this bill is needed.

In developing Angiomax, we did what research-based biotech and pharmaceutical companies regularly do in responding to the incentives of the U.S. patent system: we spent large amounts of time and money to bring a new product to market. In total, development of Angiomax for angioplasty took eight years and cost more than $200 million. We anticipate that the clinical trials needed to establish the safety and effectiveness of Angiomax in patients for cardiac surgery and for stroke will take

at least 4 more years and cost tens of millions of dollars. These investments are not viable without the patent exclusivity provided by the Hatch-Waxman Act.

As you know, the U.S. patent law framework—including Hatch-Waxman—is designed to provide incentives for the investment of such time and money. Hatch-Waxman, of course, enables research-based pharmaceutical companies to recoup some of the time spent in the FDA approval process so that the patent exclusivity period is not unfairly curtailed. Often, it is the possibility of qualifying for Hatch-Waxman patent term restoration that provides innovators with the incentive to invest in drugs that no one else wants to develop. Moreover, once such restoration has been granted, innovators have added incentive to pursue further research on drugs to broaden their approved use, an important step in the development process, since it is not unusual for FDA to grant a narrow approval in the first instance.

The FDA approved Angiomax for the narrow initial use in coronary angioplasty on December 15, 2000. Under the Hatch-Waxman formula, we calculated that we were entitled to a restoration period of approximately 4½ years. We quickly set about preparing our application for patent restoration, completing a first draft of the 100-plus page application package by the first week of January 2001 and then working steadily along with our counsel on further drafts. But then human error intervened. The current filing provision of Hatch-Waxman requires an application to be filed within 60 days of FDA's approval of the drug in question. Unfortunately, the 60-day requirement was evidently mistaken for a two-month requirement, and our patent restoration application was filed on February 14, 2001, within a two-month window, but one day late for the actual 60-day deadline. Unlike other filing provisions of the patent laws, this provision of Hatch-Waxman does not allow for any discretion to accept late applications, no matter the reason and no matter how close to the actual deadline. So, the Patent and Trademark Office denied the petition as untimely. We filed a motion for reconsideration which is still pending, but the PTO lacks the authority to grant it.

So, because of an inadvertent administrative error, The Medicines Company—and the patients who could be helped by Angiomax—are facing a drastic and disproportionate penalty. The basis for a $200 million investment that powered development of a life-saving drug in coronary angioplasty has been completely cut out from under us. And our hope of extending the benefit of Angiomax into critically important new areas is in tatters. Without patent restoration, our patent will expire in 2010, not nearly enough time to make possible the investment of years and tens of millions of dollars needed to confirm the efficacy of Angiomax in treating stroke and serious heart disease to the satisfaction of ourselves, the FDA and medical practitioners. And others who make accidental filing mistakes in the future, may face a similar predicament.

Making the consequences of a minor mistake so catastrophic, both to a patent owner and the public, simply cannot be good or wise public policy.

H.R. 5120-WEIGHING THE BENEFITS

H.R. 5120 is a modest bill that would correct this unduly harsh result for us and for any other innovators who make the same mistake. The bill would not give a patent owner anything other than what it has already earned under the Hatch-Waxman system—a credit for the portion of a patent term effectively lost while seeking FDA approval. The bill would not, by its own terms, grant patent term restoration. It would simply give the PTO authority to accept an application that was filed late on account of an unintentional error.

Mr. Chairman, I think a reasoned analysis of the potential costs and benefits of this legislation argues powerfully in its favor. Let me begin with the benefits of modifying the existing deadline provision.

First, the effect of the existing provision is like having your home repossessed for making your mortgage payment a day late—a completely disproportionate punishment for a minor, administrative mistake. As a matter of wise public policy, this does not make sense. Years of highly valuable, hard earned patent rights—in our case more than a third of our total patent period—should not be forfeited on account of a minor clerical error.

Second, this legislation is entirely consistent with typical patent law and practice and supports the purpose of Hatch-Waxman. Recognizing the obvious importance of patent rights and the national interest in promoting pharmaceutical innovation, the great majority of relevant patent laws and regulations actually do give the PTO discretion to excuse inadvertent mistakes. For example: if an applicant files an incomplete application for patent term restoration, the PTO can grant up to two extra months to correct the errors in the application. This is not an isolated example. There are more than 30 such examples where the PTO has the authority

to excuse errors that could otherwise deprive an applicant of its rights. We have submitted a memorandum detailing these examples to the Committee. Thus, the rigid statutory 60-day deadline, allowing PTO no discretion to excuse an inadvertent error is, in fact, an anomaly, which this bill would rightly correct. Moreover, by preventing the automatic forfeit of years of patent protection for minor clerical errors, the bill supports an important purpose of the Hatch-Waxman system—to make sure patent owners have an opportunity to recover the portion of their exclusivity period that would otherwise be lost while awaiting FDA approval.

Third, this bill would potentially benefit millions of seriously ill patients. Only a company that can assure itself of a significant period of exclusivity will take the risks and make the substantial investment necessary to obtain the approval of new uses of a drug beyond the scope of its initial FDA approval. In our case, no generic manufacturer would do what we are prepared to do—invest years and tens of millions of dollars to test promising new uses of Angiomax for heart disease and stroke—because the manufacturer would have no financial incentive to do so. If the initial promise we have seen for such applications is realized, Angiomax could potentially provide vital help to hundreds of thousands of seriously ill patients. And what is true for us will be true for others in the future. So this is an important, potentially life-saving bill for patients.

Now, I understand that concerns have also been raised about this bill, but they do not, individually or together, begin to measure up to the bill's substantial benefits.

Settled expectations/certainty. First, it has been said that H.R. 5120 might interfere with settled expectations about when a drug would come off patent, and that there are legitimate benefits to maintaining the certainty inherent in current law. In principle, there are of course benefits to certainty in laws. But the interest of "settled expectations" is more effectively served by this bill than by the status quo.

The fact that a patent owner might get an additional 5 days to file a patent restoration application, and that the PTO could take 30 days to decide whether to grant this additional time, will not have the slightest impact on the business plans a generic manufacturer has or has not made to enter a new market. The truth is that neither generics manufacturers nor anyone else can know what the duration of a possible patent term restoration period might be until the proposed patent term extension is published for public comment, often years after the application is filed. That is the first notice that a generic manufacturer is likely to rely on in terms of its own planning, and this bill would have no impact on the content or timing of such notice.

I am very sympathetic to the value of generics companies in our healthcare system—indeed I sit on the board of directors of one, and I am proud of what we do there. But the claimed disturbance to certainty and settled expectations entailed in H.R. 5120 would not even amount to a ripple upon the water for a generic firm.

By contrast, the settled business expectations that are obliterated are those of a patent holder that devises its business and investment strategy in reliance on the opportunity for Hatch-Waxman restoration, if those rights are lost on account of a minor filing error.

The delicate balance. Second, some have said that enacting this bill would upset the delicate balance in Hatch-Waxman between (a) spurring innovation by assuring that a patent holder retains its exclusivity rights despite the years it takes to get FDA approval, and (b) allowing generic manufacturers to produce cheaper drugs. I'm neither a lawyer nor a legislator, but it seems to me that the "balance" argument cuts in favor of H.R. 5120, not against it.

The Hatch-Waxman balance was premised, as I understand it, on the following five elements: first, a generic manufacturer can study a drug during the patent term without infringing the patent; second, a generic manufacturer can rely upon the investment and testing done by the innovator, rather than incurring the time and expense required to test the drug itself; third, a generic manufacturer who files an ANDA (Abbreviated New Drug Application) successfully challenging an existing patent is eligible for a six-month period of marketing exclusivity; and fourth, generic manufacturers benefit from the five-year limit on the patent restoration term and the 14-year cap on the overall patent term; while, fifth, the innovator is provided an incentive—through the grant of patent term restoration—to undertake the risk, expense, and delay of drug testing and FDA approval.

Under H.R. 5120, this balance is fully preserved. Generic manufacturers would retain all of the benefits I just described—study during patent term, benefiting from others' R&D investments, ANDA opportunity, and limited patent terms—and the innovator would retain its benefit of term restoration in exchange for conducting clinical testing. *Without* this bill, however, an innovator who makes a minor, inad-

vertent filing error loses its entire Hatch-Waxman benefit—the opportunity to seek the patent term restoration that was already earned.

I simply cannot believe that, as Congress constructed this careful balance, it meant to throw it overboard in the event that the innovator tripped on the way to the Patent Office. That was manifestly not part of the bargain Congress intended to strike.

Deadlines. Third, some say simply that 60 days means 60 days, full stop. I understand the importance of deadlines, and I understand that penalties are an important way to enforce deadlines. But, the problem here is that the punishment does not remotely fit the crime. As I have noted, the PTO has extensive discretion to extend deadlines in most situations encountered in patent examinations. And I understand that a similar rule applies in federal civil litigation, where the relevant rule (6(b)) gives judges broad discretion to extend a deadline or permit a filing "where the failure to act was the result of excusable neglect." The flexibility found in the patent law and the rules of civil procedure is built on a fundamental and simple recognition—that people are human and sometimes make inadvertent mistakes, and thus draconian consequences ought not to flow from such errors. An argument that comes down to the claim that a rule is a rule and should not be changed no matter how inappropriate its effect seems to me unworthy of this great legislative body. The PTO, of course, cannot change such a rule in a statute, but Congress can if it concludes, as a matter of policy, that a wise amendment is available. I think H.R. 5120 constitutes just such an amendment.

Single company. Fourth, the notion that this is just a bill to help one company is a red herring. Of course, our company would potentially be helped by the bill, since the PTO would then have the discretion to accept our filing and consider our application on the merits if it so chose. But, as the PTO has noted, others in the past have had timeliness problems with regard to Hatch-Waxman filings, and, because people will always make mistakes, others will have this problem in the future. Our company is the one that has stumbled, inadvertently, into this legal pothole. But that does not change the reality that the pothole ought to be fixed. Most laws passed by Congress benefit some companies and disadvantage others—that is just a fact of life. If there is any difference here, it is that most of the beneficiaries of this law will be found in the future and no one is likely to be disadvantaged.

Going to court. Finally, some have said to me that we should just file a lawsuit rather than advocating an amendment to Hatch-Waxman. But that course of action would fail in fundamental ways that I care about a great deal. First, there is a *bona fide* public policy problem here. This really is not just one company's concern. The immense disproportion between a relatively trivial mistake and the enormous consequences that flow from it is just not right—not for us and not for any other companies that follow in our wake.

In addition, I care deeply about pursuing the promise of Angiomax to heart and stroke applications, which as I have explained, we will not be able to do absent patent term restoration. As I said at the outset, I am not just a businessman, I am also a doctor. I have made a lifelong commitment to improve patient care, and I would hate to let that promise go unexplored. Money that we might recover in a lawsuit would be useful to the company, but it would not save a single life. So that is not the answer to this problem even for us, much less for future patent owners.

CONCLUSION

In summary, this is a small but important piece of legislation. I think the answer to the question I posed at the start of my of my testimony—whether the benefits of the bill outweigh the benefits of the status quo—is clear. H.R. 5120 would provide palpable benefits both to innovators and to patients in a manner that is fully consistent with patent law and practice. The only harms identified—a negligible effect on certainty and the loss of an unintended, unplanned and unearned windfall for generic manufacturers—in my judgment are definitively outweighed by those benefits.

Mr. Chairman, I have been impressed by the thorough and diligent manner in which this Subcommittee has carried on its work. I hope that, with a single-minded focus on the public interest, the Subcommittee will see fit to move the bill forward toward ultimate enactment.

Thank you very much and I look forward to your questions.

Mr. SMITH. Thank you, Dr. Meanwell.

Ms. Jaeger.

TESTIMONY OF KATHLEEN JAEGER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENERIC PHARMACEUTICAL ASSOCIATION

Ms. JAEGER. Chairman Smith, Ranking Member Berman and Members of this Committee, my name is Kathleen Jaeger, and I am the president and CEO of the Generic Pharmaceutical Association. On behalf of GPhA and our 130 members, I want to thank you for convening this hearing and allowing GPhA to express its views on H.R. 5120.

Mr. Chairman and Members of this Committee, what we are essentially discussing here this morning is playing by the rules and whether Congress is willing to turn its back on the rules because one company decided it just didn't want to play by those rules.

The fact is that Congress established specific criteria in both title 1 and title 2 of the Hatch-Waxman amendments on how brand and generic pharmaceutical companies should operate when in the Hatch-Waxman system, including how and when a brand company could apply for a patent term extension, or a PTE.

Congress worked hard to ensure that they established a system that addressed two competing yet equally important goals: encouraging innovation and expediting the public's access to more affordable generic medicine. The system was designed to foster both goals, and a process was put in place that hundreds of companies have been following since 1984.

As with any system, the Hatch-Waxman system is replete with rules and deadlines. And they need to be followed to achieve these important public health goals. In the case of The Medicines Company, it simply chose not to follow the rules that says there is a deadline for submitting the PTE application. And now it is asking for a change of the rules because it didn't follow them.

Mr. Chairman, that is simply not the way the system works. We all know the rules, and we all know that if we don't play by them we could be benched, we could be penalized or lose an extraordinary opportunity.

Congress cannot create a system where if a company misses a deadline it can come running to Congress to fix it. If that was the case, I daresay this Committee would have an even busier hearing calendar than it does now.

For example, several brand companies have lost the opportunity to secure a 30-month automatic stay under title 1 of Hatch-Waxman because the brand companies failed to file a lawsuit against a generic patent challenger within the statutory mandated 45-day deadline.

Likewise on our side of the industry, a generic company is eligible for 180 days of generic exclusivity provided that among other things, the company is the first to file a generic application with FDA that contains a paragraph four patent challenge. If another company files 1 day after the first generic company filed its application, that subsequent firm gets nothing because those are the rules.

If Congress approves this legislation, rules go out the window. You would basically be saying that the deadlines don't mean anything. Under this legislation, the PTO would be given a discretion to accept a P.T. application filed up to 5 days after expiration of

statutory deadline. And by its terms, this bill would have the practical effect of automatically extending a deadline to 65 days.

This extension not only undermines the intent of Congress, it ultimately delays the ability of more affordable generic drugs to be brought to consumers. And this Committee needs to ask itself what happens when some other company misses the new deadline and files on day 66. Do we extend the deadline again? And what are the consequences to the health care system when several of the Hatch-Waxman system deadlines get extended and the system unravels?

Now, this legislation has been labeled, "Sorry I am Late, the Dog Ate My Homework Act," by Citizens Against Government Waste. While this label is quite amusing, there is nothing funny about the consequences of this legislation. It isn't as simple as saying my dog ate my homework.

This is a major change in the law with enormous negative implications, a change that would offset the delicate balance Congress created under the Hatch-Waxman Act between the brand and generic pharmaceutical companies. That balance has stimulated pharmaceutical innovation while ensuring that consumers are able to receive safe, effective and affordable medicines in a timely manner.

In the end, statutory deadlines have meaning. They have consequences. Allowing 5 extra days to file a patent term extension application renders that deadline meaningless and treats certain patentees differently than everyone else who respects statutory deadlines. And all to the benefit of one company who by its own inactions failed to file a simple form within the statutory timeframe.

Mr. Chairman and Members of this Committee, we thank you for giving GPHA the opportunity to present our concerns about this legislation. This legislation opens a Pandora's Box that simply should not be opened because one company didn't get its paperwork done on time. Thank you.

[The prepared statement of Ms. Jaeger follows:]

PREPARED STATEMENT OF KATHLEEN JAEGER

TESTIMONY OF
KATHLEEN JAEGER

BEFORE THE

SUBCOMMITTEE ON COURTS, THE INTERNET AND INTELLECTUAL PROPERTY,
COMMITTEE ON THE JUDICIARY,
U.S. HOUSE OF REPRESENTATIVES, CONGRESS OF THE UNITED STATES

INTRODUCTION

Chairman Smith, Ranking Member Berman, and members of the Committee, my name is Kathleen Jaeger and I am the President of the Generic Pharmaceutical Association ("GPhA"). I am pleased to testify today on behalf of GPhA.

On behalf of the Association and its nearly 130 members, I want to thank you for convening this hearing and allowing GPhA to express its views on H.R. 5120, a bill introduced to benefit a single brand pharmaceutical company at significant expense to all Americans, as well as the generic pharmaceutical industry. Specifically, H.R. 5120 would give the U.S. Patent & Trademark Office ("PTO") discretion to accept an application for a patent term extension ("PTE") filed up to five days *after* expiration of the statutory deadline for the submission of such applications. By its terms, the proposal would, in practice, automatically extend the 60-day filing deadline by five days. Before enacting legislation that would severely harm consumers and taxpayers, both Congress and the public should understand the genesis of H.R. 5120, a bill that the Council for Citizens Against Government Waste has appropriately labeled the "Sorry I'm Late, the Dog Ate My Homework Act."

BACKGROUND

In 1997, The Medicines Company filed a new drug application ("NDA") for Angiomax™ (bivalirudin) injection. On December 15, 2000, FDA approved that application, and The Medicines Company began marketing in January 2001. While it began marketing promptly after receiving approval, the company inexplicably waited to file its request for a PTE with the PTO. Not until February 14, 2001 did The Medicines Company finally get around to submitting an application seeking a PTE for U.S. Patent No. 5,196,404 ("the '404 patent"). Unfortunately, waiting until what it thought was the last day had significant consequences for The Medicines Company.

February 14, 2001 is 61 days from the date of NDA approval. As a result, after confirming the NDA approval date with FDA, the PTO correctly determined that the '404 patent is not eligible for a PTE under 35 U.S.C. § 156 because that statutory provision requires PTE applications to be filed within 60 days of NDA approval. *See* 35 U.S.C. § 156(d)(1).

Upon learning of the PTO's decision, The Medicines Company immediately sought to avoid the consequences of its delayed filing. Specifically, The Medicines Company attempted to convince the PTO that the application had been timely filed. The Medicines Company could not deny that FDA had, in fact, approved the NDA on December 15, 2000. Nor could The Medicines Company argue that they lacked the information necessary to submit the application on time, or that the application was too complicated to complete within 60. Instead, the company could only argue that FDA allegedly had not signed the approval letter until after the agency's normal business hours on December 15, 2000 and that, as a result, the approval date should be considered December 18, 2000, the next business day. Changing the approval date in this way would have made The Medicines Company's application timely. Nearly four years

later, The Medicines Company's October 2002 request for reconsideration apparently remains pending before the PTO.

In the years since its untimely PTE filing, The Medicines Company has acknowledged that, despite having 60 days to complete this simple application, its representatives failed to get the application in on time. As GPhA understands it, The Medicines Company's representative assumed that the company had two months to file the PTE application. But as the statute says on its face, such applications must be filed within *60 days* of NDA approval. Two months and 60 days are not the same thing and, in this case, The Medicines Company's decision to wait until the very last minute and to rely on an assumption, rather than consult the statute itself, caused the company to miss the filing deadline by a day. While a mistake and, perhaps, even an understandable mistake, mistakes have consequences.

With hundreds of millions of dollars in sales at stake, and a dubious request for reconsideration pending, The Medicines Company embarked on a more ambiguous plan to secure a PTE – lobbying heavily for new federal legislation to fix the company's mistake. While The Medicines Company undoubtedly has made other efforts, GPhA knows that the company attempted to have language included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"). Those efforts failed, however, when various members of Congress refused to support such a proposal.

Apparently, The Medicines Company decided not to give up its legislative efforts. Now, some three years later, Congress is again entertaining legislative language that would allow The Medicines Company to avoid the consequences of its admitted failure to comply with the plain language of § 156 to the detriment of consumers and taxpayers. This time, unfortunately, the harm to the public would be astronomically higher. The 2003 proposal that Congress rejected only would have applied to The Medicines Company's PTE on the '404 patent. In stark contrast, H.R. 5120 would apply to any late-filed PTE application, in essence extending the statutory deadline from 60 days to 65 days. Such a statutory change would have serious anti-consumer consequences when the American public can least afford it. GPhA strongly urges Congress not to enact H.R. 5120, or any similar legislation.

DISCUSSION

Congress should not enact H.R. 5120. First, the legislation would disrupt the balance created with the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act in a way that harms consumers and the generic drug companies. Second, the legislation is unnecessary. As discussed above, it came about solely because one brand company failed to meet a clear-cut filing deadline established by statute back in 1984. Third, the legislation would put more pressure on the generic pharmaceutical industry – an industry already under attack by such brand company tactics as "authorized generics" and abuse of the FDA's citizen petition process. Fourth, amending the PTE provisions in the way The Medicines Company seeks runs contrary Congress' historical treatment of statutory deadlines for the expansion or extension of

patent rights. Indeed, by setting a firm deadline (one that the PTO cannot extend), the PTE filing deadline of § 156 is consistent with other statutory provisions that establish deadlines for patentees seeking to expand the scope or lengthen the terms of their patents.

I. Congress Must Preserve The Balance Created By The Hatch-Waxman Amendments.

H.R. 5120 would disturb the delicate balance that Congress struck between generic and brand pharmaceutical companies in the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Amendments or Hatch-Waxman.

Hatch-Waxman represents a carefully-crafted balance between two competing, yet equally important goals – encouraging innovation and expediting the public's access to more-affordable generic drug products. Congress enacted Hatch-Waxman as "the best possible compromise between [these] two competing economic interests." (H.R. Rep. No. 98-857, pt. II at 7 (1984)). To expedite generic market entry, Congress created a statutory scheme whereby generic companies could file Abbreviated New Drug Applications ("ANDAs") and litigate patent infringement during FDA review. Congress also enacted a 180-day generic exclusivity period as the incentive needed to get generic companies to challenge drug patents. To encourage innovation, Congress enacted many benefits for brand companies, including a wide variety of regulatory exclusivity periods and the opportunity to extend the terms of certain patents. Disturbing these provisions threatens the balance that Congress created and, in the process, threatens to harm a public that desperately needs increased and expedited access to lower-priced generic drug products.

A. H.R. 5120 Would Upset Hatch-Waxman's Balance At A Time When Consumers And Taxpayers Need Increased Access To Affordable Generic Medicines.

GPhA fully supports both of the intended purposes of Hatch-Waxman. The public needs both innovative new medicines and increased access to affordable generic drug products. This precisely is why Congress should reject H.R. 5120.

The PTE application deadlines of 35 U.S.C. § 156 are part of the "encouraging innovation" portion of the Hatch-Waxman Amendments. H.R. 5120 would enlarge the benefits found in that provision by allowing more brand companies to obtain PTEs. Allowing brand companies greater opportunities to obtain PTEs necessarily threatens the public's access to lower-priced generic alternatives because more patents – patents that block generic competition – will be entitled to extensions. H.R. 5120 also unbalances Hatch-Waxman in that it changes just one of many deadlines found in those amendments. Before enacting such legislation, Congress must ask at least two questions: first, whether such legislation truly is necessary and, second, whether this is the best course of action now, at a time when the need for affordable health care and prescription medication is so great.

First, the legislation most assuredly is not necessary. As discussed above, H.R. 5120 came about because a single brand company failed to meet the 60-day PTE filing deadline after (1) waiting until the last minute to file a simple, 7-page application; and (2) making an incorrect assumption about the law, rather than consulting the statutory language which has remained the same since September 1984.[1] An attorney myself, I personally am sympathetic to The Medicines Company's plight. Indeed, every practicing attorney can understand how The Medicines Company and its representatives feel, as we all fear of making the same type of mistake made here. But deadlines are a key part of the balanced statutory scheme that Congress created with Hatch-Waxman. Sympathy and understanding simply are not sufficient reasons to pass a law that would have such enormous, negative consequences for consumers and taxpayers for the sole purpose of rectifying a mistake that never should have happened.

Further, any sympathy felt for The Medicines Company should be tempered by the knowledge that company has legal recourse to obtain compensation for any damage that it believes that it has suffered. According to the company's public SEC filings, The Medicines Company has "entered into agreements with the counsel involved in the filing that suspend the statute of limitations on our claims against them for failing to make a timely filing."[2] And, of course, The Medicines Company's Angiomax™ already has generated sales exceeding over half a billion dollars since launch, according to IMS Health data, and the '404 patent does not expire until March 2010, even without the extension that the company seeks.[3]

Second, now is not the time for such blatant special interest legislation. Everyone recognizes that America today faces a healthcare crisis, with the skyrocketing cost of prescription drugs eating up an ever-increasing part of the available funds. For example, in one recent survey, 26% of senior citizens surveyed stated that that they did not fill a prescription, skipped doses, or took smaller doses of medications due to the high cost of drugs.[4] Generic pharmaceuticals, which provide the same medicines and the same results, are critical to helping contain healthcare costs. Specifically, while generic drugs provide the same results, they do so at prices ranging from 30 to 80 percent *less* than their brand counterparts.[5] Thus, "[w]hile generics accounted for 56 percent of prescriptions dispensed, Americans spent $22.3 billion on them last year, compared with $229.5 billion for branded drugs . . . ."[6] Such savings add up to billions and billions of dollars each year.[7] As a result, the availability of generic pharmaceuticals is of the

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[1] The Medicines Company would benefit from H.R. 5120 because the PTO apparently has not ruled upon the company's 2002 request for reconsideration. GPhA finds it unusual that the PTO has not acted on this request at some point over the last four years. If the PTO has not, in fact, ruled on the reconsideration request, GPhA encourages the Committee to look into why the PTO apparently is assisting The Medicines Company in its effort to obtain a PTE for the '404 patent.

[2] The Medicines Company 12/31/05 10-K at 33.

[3] The Medicines Company seeks to extend the '404 patent's term by 1,773 days, until January 29, 2015.

[4] *See* National Survey of Seniors and Prescription Drugs, April 19, 2005, The Kaiser Family Foundation.

[5] *See* GPhA Press Release, 8/16/05.

[6] "Dose of Relief: Are Generic Drugs Just What the Cost-cutters Ordered? As Healthcare Prices Spiral Upward, Some Are Encouraged by an Emerging Trend: Key Drugs Are Losing Patent Protection. Now They Look to the FDA to Unclog the Approval Pipeline for Generics," *The Boston Globe*, April 30, 2006).

[7] *See, e.g.*, Express Scripts Research Study Findings, 2005 Generic Drug Usage Report, available at www.express-scripts.com (finding that consumers had the potential to save $21.7 billion in 2005, and an estimated $24.7 billion in 2006, through the use of generic drugs).

utmost importance to consumers, taxpayers, and federal and state governments.[8] Indeed, as one member of Congress recently explained: "***It is now more important than ever that we speed less expensive generic drugs to market.***"[9]

As of January 2006, the MMA's prescription drug benefit was estimated to account for roughly 4 out of every 10 prescriptions dispensed in the United States.[10] The Congressional Budget Office has estimated the plan will cost $850 billion over its 10-year life span, although some lawmakers have predicted the costs will top $1 trillion.[11] Because generic drugs are critical both to consumers and taxpayers, Congress must carefully consider any legislation that would make it harder for affordable medicines to reach the market. This is especially true for special interest legislation like H.R. 5120.

In the end, statutory deadlines have meaning. They must be followed and failing to do so has consequences. Here, rather than face the consequences of its mistakes, The Medicines Company has spent considerable time and money lobbying for federal legislation that would harm consumers and taxpayers. Because the legislation reaches all PTE applications, the negative consequences for the public would, of course, extend far beyond just this one patent and this one drug.

B. H.R. 5120 Would Add To The Growing Number Of Forces Currently Working Against Hatch-Waxman's Goal Of Providing Timely Consumer Access To Generic Pharmaceuticals.

Generic pharmaceutical companies' ability to provide consumers with access to affordable generic drugs increasingly has come under attack. This special interest legislation is just another tool that would delay generic pharmaceuticals from timely entering the market.

In recent years, brand companies have employed various tactics to undermine the purpose of Hatch-Waxman. Such tactics include the marketing of authorized generics, the filing of frivolous citizen petitions with FDA, and failure to bring suit on listed patents during FDA's review of the ANDA. Moreover, other forces impede consumer access to lower priced generic drugs. For example, currently, the United States Trade Representative ("USTR") is including provisions in Free Trade Agreements ("FTAs") that fail to promote access to lower-priced generics. Congress should not add to the impediments to the introduction of affordable generic medicines by enacting H.R. 5120.

In recent years, the brands embarked on a widespread practice of launching "authorized generics" during the 180-day generic exclusivity period that Congress created as a

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[8] *See* Congressional Budget Office report, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (July 1998), available at www.cbo.gov.

[9] "Sen. Kohl Pushes HHS Secretary Leavitt to Accelerate Generic Drug Approvals," *US Fed News* (May 3, 2006) (emphasis added).

[10] *See* "Medicare Rx Formularies Likely to Satisfy Drugmakers," *FDANews Drug Daily Bulletin*, 6/23/05, Vol. 2, No. 123; "Lawmakers Push Bush to Repeal Medicare Part D," *FDANews Drug Daily Bulletin*, 10/10/05, Vol. 2, No. 199.

[11] *See* "Lawmakers Push Bush to Repeal Medicare Part D," *FDANews Drug Daily Bulletin*, 10/10/05, Vol. 2, No. 199.

reward for the first company to challenge the patents blocking the entry of generic drugs. *See* 21 U.S.C. § 355(j)(5)(B)(iv). An authorized generic merely is the brand's own product repackaged and sold through traditional generic drug distribution channels. By diminishing Hatch-Waxman's incentive for generic drug companies to develop generic drugs and to challenge suspect brand patents, authorized generics have a chilling effect on the patent challenges that must happen for generics to enter the market prior to patent expiration. More specifically, when brands sell authorized generics during the 180-day exclusivity period, they compete with the true ANDA generic and siphon off funds and other market advantages that Congress intended the true generic to receive. In this way, authorized generics create a disincentive for generics to challenge patents and get their products on the market sooner. In the long run, this tactic slows competition, to the disadvantage of the public.

Unfortunately, as AARP recently has explained, the "practice of authorized generics is just one growing trend in the industry's arsenal of anticompetitive practices."[12] Another anti-competitive tactic that has re-emerged in recent years is rampant brand company abuse of FDA's citizen petition. These generic blocking petitions ask FDA to withhold ANDA approval unless applicants carry out time-consuming and scientifically unnecessary tests and studies. Because FDA virtually always delays ANDA approval until it deals with even the most frivolous petitions, ANDA approvals are significantly delayed, as it takes the Agency months and even years to complete its evaluation. In the meantime, the public is forced to pay millions of dollars for brand name products because FDA has not approved a generic alternative. While the brand petitions are without merit, the delay they cause is very real. For example, of the 35 or so generic blocking petitions that brand representatives filed in 2004 and 2005, FDA had only ruled on about half as of the end of July 2006. Yet, because no one has held brand companies accountable for this anti-competitive behavior, they have everything to gain and nothing to lose by continuing to file these blocking petitions. Indeed, as one GPhA member aptly explained in recent Congressional testimony, "[f]rivolous citizen petitions given brand companies an undeserved patent extension, at no cost and with no consequences" to the brand.

Yet another delay tactic involves brand companies obtaining and listing patents with FDA, but refusing to bring suit when confronted with a generic applicant seeking immediate ANDA approval. Brand companies have found that delaying suit can delay generic market entry because few generic companies will launch product before patent issues have been fully resolved. The reason a generic would delay launch is a matter of simple economics – infringement damages calculated on the basis of the enormous monopoly profits associated with blockbuster drugs would ruin most generic companies. As a result, few generic companies can risk going to market before a final judicial resolution of its patent invalidity and/or non-infringement claims. Thus, by refusing to bring suit immediately, brand companies create paralyzing uncertainty that allows them to continue selling drugs at monopoly prices.

As this Committee is aware, Congress recognized this problem and sought to prevent such a scenario by specifically providing generic applicants with the right to bring declaratory judgment actions if they are not sued by the patentee or NDA-holder within 45 days of receiving the generic applicant's notice that the Orange Book listed patent is invalid and/or

[12] AARP's 6/5/06 Comments to FTC's Authorized Generic Study at 2; *see also* Prescription Access Litigation Project's 6/5/06 Comments to FTC Study at 4.

not infringed. *See* Medicare Act § 1101(a)(2)(C) (codified at 21 U.S.C. § 355(j)(5)(C)). In doing so, Congress directed the courts to exercise jurisdiction over such declaratory judgment actions "to the extent consistent with the Constitution." *Id.* § 1101(d) (codified at 35 U.S.C. § 271(e)(5)). The Federal Circuit, however, issued a decision in 2005 that effectively guts these important declaratory judgment provision. Thus, despite Congress' attempt to provide the generic industry with a mechanism for obtaining patent certainty and avoiding delays in marketing, generic companies nevertheless have been unable to take advantage of these provisions.

Finally, other forces are working against generic drug companies and, in turn, against the introduction of affordable medicines. For instance, the USTR is including provisions in FTAs that fail to promote access to lower-priced generics. Moreover, these provisions often are inconsistent with U.S. law. Such provisions serve to: (1) block generic drug exports in foreign territories; (2) significantly delay the availability of affordable drugs in those territories; and (3) create an avenue to delay domestic generic competition. Many FTAs, for example, have provisions that require patent "linkage" provisions. In other words, these provisions mandate that the United States' trading partner establish a generic approval system that is identical to the one in the United States. But these same provisions do not provide a means for generic companies to challenge drug patents and, as a result, block generic competition. Thus, there is no incentive for the early resolution of patent disputes, nor is there a limit on the types of drug patents that can be listed for a drug product. Such measures grant brand companies *de facto* patent extensions, encourage lower quality patents, and unnecessarily delay the availability of affordable generic drugs. They not only are inconsistent with U.S. law, but they also thwart generic competition both domestically and abroad. The USTR should be required to modify provisions in current and future FTAs so that they are consistent with U.S. law and ensure that foreign and domestic consumers have timely access to affordable drugs.

As this discussion amply demonstrates, generic companies currently face significant obstacles. H.R. 5120 only would serve as yet another barrier to generic market entry – a barrier created because one brand company failed to comply with a statutory deadline in existence since 1984. Neither the public nor the generic drug industry upon which the public relies so heavily deserve better.

II. The Current Statutory Deadline Is Consistent With Other Statutory Provisions Setting Deadlines For Patentees.

As GPhA understands it, proponents of H.R. 5120 have argued that "the hard and fast 60-day deadline for filing Hatch-Waxman applications for patent term restoration runs counter to" the PTO's "general philosophy" of giving extensions to patent applicants. Not so. As an initial matter, if the PTO has a "general philosophy" of granting extensions to patent applicants, that philosophy is limited to deadlines in PTO rules, and *not* to the deadlines found in statutory enactments of Congress. The PTO created its rules and the deadlines contained therein. Should it wish to give extensions, the PTO can do so. The PTO cannot, however, extend statutory deadlines set by Congress. Indeed, the rule which allows the PTO to extend deadlines states that "in no situation may an applicant reply later than the maximum period set by statute"

and must reply at "the earlier of any maximum period set by statute or five months after the time period set for reply." 37 U.S.C. § 1.136.

More importantly, Congress historically has set firm statutory deadlines by which a patentee must act in order to expand or extend patent rights. The patent term extension statute of 35 U.S.C. § 156 is no exception. That statute mandates that a party seeking to extend the term of its patent must submit an application for extension "within the sixty day period" proscribed. 35 U.S.C. § 156(d)(1). In this material respect, PTE filing deadline is entirely consistent with other substantive, statutory provisions that establish deadlines for patentees seeking to *expand the scope or lengthen the terms* of their patents. For example, a patentee seeking to enlarge the scope of the claims of its original patent by invoking the PTO's reissue procedure must apply within two years from the grant of the original patent. *See* 35 U.S.C. § 251. Similarly, a patentee seeking to claim priority to the date of an earlier-filed foreign patent must file its patent application in the U.S. within twelve months from the earliest date on which such foreign application was filed. *See* 35 U.S.C. § 119(a). The governing statutes do not allow the PTO to extend these deadlines. Thus, while Congress has seen fit to provide the PTO with discretion as to the purely ministerial act of paying a patent maintenance fee (35 U.S.C. § 41), such leniency is in stark contrast to the statutes which set deadlines for patentees to act to substantively expand or extend their patent rights. Congress should give careful consideration to changing this precedent in the manner found in H.R. 5120.

In the end, statutory deadlines have meaning. They have consequences. Either they are followed or penalties ensue. Citizens, for example, must file their tax returns or ask for an extension by April 15. Here, allowing five extra days to file an application makes the deadline essentially meaningless, and treats patentees differently than anyone else to whom statutory deadlines apply. And all to benefit one company that, by choice, waited until the last minute to file a simple form that hundreds and hundreds of other companies have timely filed since 1984.

CONCLUSION

Thank you, Mr. Chairman, Ranking Member Berman, and Members of the Committee, for giving GPhA the opportunity to explain its views and concerns about this important issue. The Association again urges Congress to refuse to enact this special interest legislation that does nothing but help one company to the detriment of all consumers and taxpayers.

Mr. SMITH. Thank you, Ms. Jaeger.
Professor Thomas.

TESTIMONY OF JOHN THOMAS, PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER

Mr. THOMAS. Thank you, Mr. Chairman and other distinguished Members of the Subcommittee. I am pleased to testify today on my personal behalf. My views are my own rather than those of Georgetown University or other institutions with which I am affiliated.

The Hatch-Waxman Act represents an effort to refine within the pharmaceutical industry the central problem of any intellectual property regime: encouraging the labors that lead to innovation on one hand and disseminating the fruits of those labors on the other. Thus the Hatch-Waxman Act created an expedited generic marketing approval protocol, but also called for term extensions for patents on approved drugs.

Patent term extension is unquestionably a fundamental part of the Hatch-Waxman Act, a statute that for all its perceived flaws has been highly successful in both encouraging the generic drug industry and promoting the discovery and development of new drugs by brand name firms.

As the Committee considers modifications to the 60-day period provided by section 156, the term extension statute, a few basic subjects and points may be worthy of review.

First, the Federal circuit has long interpreted the 60-day deadline strictly. Its 1989 decision in *Unimed v. Quigg* held that an NDA holder was not entitled to patent term extension even though it filed promptly after having the drug cleared by the Drug Enforcement Administration.

It held that, in fact, the date for term extension calculation was the FDA approval date, which had occurred more than a year before. It is a 17-year-old case, and I simply know of no other circumstance during that period in which anyone has come to Congress requesting a term extension.

Second, U.S. PTO regulations already provide some flexibility in meeting the deadline standards. And so, there is already some ability for NDA holders to follow an expedited application that can then be filled out.

Third, term extension determinations do not entail merely a ministerial calculation. The filing of an application for term extension potentially triggers a fairly elaborate proceeding potentially involving the USPTO, Secretary of Health and Human Services, Secretary of Agriculture, the patent proprietor and third hearings—third parties. There may even be an informal hearing to discuss qualifications for the term extension.

And that somewhat distinguishes this case from other sorts of deadlines that the USPTO deals with, for example, responding to an office action. So ensuring that these deadlines are met promptly would arguably serve important administrative goals.

Finally, it is true that some deadlines of the USPTO can be waived or extended. Though, of course, many of those extensions entail third party rights, for example, user rights in favor of those who may have a reliance interest on the expiration of diminution of patent rights.

As you know, the Patent Reform Act of 2005 retains the 1-year deadline. Anyone who discloses an invention more than a year before filing forfeits their patent rights. And that is a provision that can work very hard against independent inventors and small firms.

The Hatch-Waxman Act is replete with deadlines that impose even tighter timeframes. A brand name firm has to file a patent infringement suit within 45 days of receipt of notice of a paragraph four ANDA, otherwise it loses its entitlement to a 3-month stay by the FDA.

On the generic side, a paragraph four ANDA applicant who files 1 day after another such applicant potentially loses its entitlement to a 180-day period of generic exclusivity. So there already are a lot of tight deadlines and even shorter deadlines in the Hatch-Waxman Act.

Now, in view of those principles, allow me to offer a few observations.

First, one question is the extent of the problem. How many times has this occurred? Is this a recurring issue or one that we think might change?

Second, what is the standard for the USPTO to resolve whether there ought to be an extension or not? The statute right now says the delay in—or the bill says that whether the delay in filing the application is unintentional.

I am sort of reminded of Aristotle and the Nicomedian ethics. No one can suffer injustice voluntarily because no one can wish to be harmed, Aristotle says. Well, if that is so, what does this mean? Is this an automatic 5-day deadline for everyone? If that is so, better just to change the period to 61 days, 65 days or something else.

If, in fact, the USPTO is supposed to do a malpractice style inquiry, I would suggest this is not a situation where the USPTO is well suited. And it ought to retain its core responsibilities.

There are a lot of other section 156 issues that seem to me to be more compelling. For example, the applicability of patent term extension to combination therapies. And the Committee may wish to consider that.

Thank you again for the opportunity to submit this testimony. I would be delighted to answer any questions.

[The prepared statement of Mr. Thomas follows:]

PREPARED STATEMENT OF JOHN R. THOMAS

United States House of Representatives
Committee on the Judiciary
Subcommittee on Courts, the Internet, and Intellectual Property

Legislative Hearing on H.R. 5120, "To amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office."
September 14, 2006

Statement of John R. Thomas
Professor of Law
Georgetown University

Thank you for the opportunity to submit this statement before the subcommittee today. These comments reflect my personal views, rather than those of Georgetown University or other institutions with which I am affiliated.

Patent Term Extension Within the Hatch-Waxman Act

The Hatch-Waxman Act represents an effort to refine, within the pharmaceutical industry, the central problem of any intellectual property regime: Encouraging the labors that lead to innovation, on one hand, and disseminating the fruits of those labors, on the other. Thus, the Hatch-Waxman Act codified an expedited generic marketing approval protocol, but also provided for term extension for patents on approved drugs.[1] Patent term extension is unquestionably a fundamental part of a statute that, for all of its perceived flaws, has been highly successful in both encouraging the generic drug industry and promoting the discovery and development of new drugs by brand-name firms.

Codified at 35 U.S.C. § 156, the patent term extension provision of the Hatch-Waxman Act stands among the most unwieldy statutes in the federal code. One portion of that statute is relatively clear, however. An application for term extension "may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use."[2]

As this Committee considers modifications to this period, a few basic substantive points may be worthy of review. First, the Federal Circuit has interpreted the 60-day deadline strictly. Second, provided that an application is filed within the statutory period, existing USPTO rules already accord

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[1] I use the phrase "patent term extension" loosely. The Hatch-Waxman Act does not go so far as to provide a patent term extension in the usual sense–that is to say, a temporal extension of the original right to exclude others from practicing the patented invention. During the period of term extension, the rights provided by the patent are instead limited, generally speaking, to the specific use that the FDA has approved. *See* 35 U.S.C. § 156(b)(1) (2006). *See* John R. Thomas, PHARMACEUTICAL PATENT LAW 299-300 (Bureau of National Affairs 2005).

[2] 35 U.S.C. § 156(d)(1) (2006).

applicants for term extension some relief in complying with regulatory requirements. Third, term extension determinations do not entail merely a ministerial calculation. The filing of an application for patent term extension potentially triggers a fairly elaborate proceeding involving the USPTO, FDA, and patent proprietor and possibly third parties as well. Fourth, generic firms reach decisions about pursuing their own applications, along with patent challenges, in a relatively tight time frame that is governed by FDA-administered marketing exclusivities. Because the duration of proprietary rights is obviously significant concern for these stakeholders, determining entitlement to patent term extension in a seasonable manner serves important regulatory goals. Finally, both the Patent Act in general, and the Hatch-Waxman Act in particular, provide that failure to meet certain deadlines is irremediable. These comments discuss each of these points in further detail below.

Judicial Precedent. Longstanding judicial precedent has interpreted the 60-day statutory time period strictly. Notably, in its 1989 decision in *Unimed, Inc. v. Quigg*,[3] the Court of Appeals for the Federal Circuit considered an application for term extension of U.S. Patent No. 3,668,224. The '224 patent described and claimed a process for making dibenzo-pyran. That compound, known under the trademark MARINOL®, is the synthetic equivalent of an isomer of delta-9-tetrahydrocannabinol (THC), the principal psychoactive substance in *Cannabis sativa L.* marijuana.

The exclusive licensee of the '224 patent, Unimed, submitted an NDA to the FDA on June 24, 1981, pursuant to the Federal Food, Drug, and Cosmetic Act.[4] The FDA approved the NDA on May 31, 1985, but reminded Unimed that "MARINOL may not be legally marketed until the Drug Enforcement Administration has completed rescheduling activities as required by the Controlled Substances Act."[5] This latter step took place on May 13, 1986, when the Drug Enforcement Administration ("DEA") finalized the removal of MARINOL® from Schedule I to Schedule II of the Controlled Substances Act.[6] Unimed filed its application for extension of the '224 patent term under 35 U.S.C. § 156 at the USPTO 14 days later. By that point, more than one year had elapsed since the FDA had issued marketing approval for MARINOL®.[7]

The USPTO denied Unimed's application, concluding that it had not been filed within sixty days of receipt of FDA marketing approval. Although the District Court for the District of Columbia reversed the USPTO's decision,[8] on appeal the Federal Circuit again reversed. Judge Mayer stated

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[3]888 F.2d 826 (Fed. Cir. 1999).

[4]*See* 21 U.S.C. § 355 (2006).

[5]888 F.2d at 827.

[6]21 U.S.C. § 812 (2006).

[7]888 F.2d at 827.

[8]707 F. Supp. 17 (D.D.C. 1989).

the issue crisply: "The timeliness issue boils down to whether the 60-day period specified in section 156(d)(1) began, as the [USPTO] Commissioner argues, when the FDA sent its approval letter, on May 31, 1985, or, as Unimed argues, when the DEA rescheduled Marinol nearly a year later."[9] Siding with the USPTO, the Court of Appeals reasoned that the sixty-day period identified in 35 U.S.C. § 156(d)(1) commenced "on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." 35 U.S.C. § 156(g)(1)(B) in turn defined the "applicable regulatory review period" as section 505 of the Federal Food, Drug, and Cosmetic Act, which governs the approval of new drugs by the FDA, and nowhere mentioned the role of the DEA. The Federal Circuit therefore agreed with the USPTO that the 60-day period began upon the FDA approval date. As a result, the '224 patent term extension application was considered to have been untimely filed and was therefore rejected.[10]

It should be appreciated that both the patent laws and food and drug laws have been amended numerous times during the 17-year period since the Federal Circuit decided *Unimed v. Quigg*. Further, this subcommittee has spent significant time in recent years contemplated further reforms to the patent laws. To my knowledge, this is the first occasion where the Congress has considered altering 35 U.S.C. § 156.

USPTO Regulations. Agency regulations allow New Drug Application (NDA) holders to assemble somewhat truncated applications for term extension, with the remainder of the material to follow. Rulemaking therefore already affords brand-name drug companies the ability to submit a somewhat condensed application that is more readily prepared during the 60-day statutory period.

In particular, the USPTO has employed its rule-making authority[11] to provide that each application for term extension under 35 U.S.C. § 156 include some fifteen elements.[12] The USPTO will assign a filing date to an application for term extension that falls somewhat short of its regulatory standards, however. If the application (1) identifies the approved product; (2) identifies each federal statute under which regulatory review occurred; (3) identifies the patent for which an extension is being sought; (4) identifies each claim of the patent which claims the approved product or a method of using or manufacturing the approved product; (5) provides sufficient information to enable the USPTO to determine whether the patent is eligible for extension, and the rights that will be derived from the extension, and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and (6) includes a brief description of the activities undertaken by the marketing applicant

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[9] 888 F.2d at 828.

[10] *Id.* at 828-29.

[11] 35 U.S.C. § 156(d)(1)(E) (2006).

[12] 37 C.F.R. § 1.740(a) (2006).

during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities, then the USPTO will accord the application a filing date.[13] This USPTO policy is based on the obligatory nature of these six elements in a term extension application under 35 U.S.C. § 156(d)(1)(A)-(D), while the remainder of the USPTO requirements were established via regulation.

If the USPTO determines that the term extension application should be accorded a filing date, but that it does not fully comply with its regulations, the applicant ordinarily has two months to complete the application.[14] The applicant may extend this period through the payment of additional surcharges in accordance with usual USPTO practice.

The USPTO therefore already provides NDA holders with some flexibility in assembling their term extension applications, provided of course that the 60-day deadline is met.

Subsequent Proceedings. The submission of a complete application for term extension under 35 U.S.C. § 156 commences a fairly elaborate proceeding involving the USPTO, FDA, and patent proprietor and possibly third parties as well. In short, within 60 days of receiving the application, the USPTO will request either the Secretary of Agriculture (if the product is subject to the Virus-Serum-Toxin Act) or the Secretary of Health and Human Services (in all other cases) to calculate the applicable "regulatory review period," which is then published in the *Federal Register*.[15]

The date of publication is followed by a 180-day period during which any interested party may file a petition contending that the applicant has not acted with due diligence.[16] The appropriate secretary must determine within 90 days of filing whether the applicant has acted with due diligence or not, and then publish this determination in the *Federal Register*.[17] An interested person may then request an informal hearing on this determination within 60 days of publication, which is held within 60 days of the request.[18] Following the hearing, the appropriate Secretary is allotted 30 days to

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[13] 37 C.F.R. § 1.741 (2006).

[14] 37 C.F.R. § 1.741(b) (2006)

[15] 35 U.S.C. § 156(d)(2)(A) (2006). *See* Aktiebolaget Astra v. Lehman, 71 F.3d 1578, 1580-81 (Fed. Cir. 1995).

[16] 35 U.S.C. § 156(d)(2)(B)(i) (2006).

[17] *Id.*

[18] 35 U.S.C. § 156(d)(2)(B)(ii) (2006).

affirm or modify its original decision and then notify the USPTO Director.[19]

The USPTO then forwards a Notice of Final Determination to the applicant. The applicant may make a single request for reconsideration of the determination within one month, or such other time period set forth in the determination.[20] If no such request for reconsideration is filed, or upon the completion of its review of such a request, the USPTO will then issue a Certificate of Extension of Patent Term to the applicant.[21]

In view of these statutory procedures, it should be appreciated that the filing of an application under 35 U.S.C. § 156 does not merely trigger the ministerial calculation of a particular number of days. Rather, such a filing potentially commences an elaborate multi-party proceeding. Ensuring that the triggering event for this procedure commences in a seasonable manner would appear to be an important administrative aspiration.

Generic Responses. FDA approval of an NDA in many cases triggers a response by generic firms that might be interested in entering that market. Although the Hatch-Waxman Act includes provisions that create marketing exclusivity for certain FDA-approved drugs,[22] these periods are relatively short in view of the time required for preparation and regulatory review of an ANDA or § 505(b)(2) application. As a result, generic firms reach decisions about pursuing their own applications, along with patent challenges, within a relatively tight time frame. Between the duration of proprietary rights is obviously significant concern for these stakeholders, determining entitlement to patent term extension in a prompt manner serves important regulatory goals.

Timeliness Within the Patent Law. Given its focus upon novelty, and its requirement of government intervention to secure rights, the patent law is a temporally focused discipline. The Patent Act includes numerous deadlines that, if not followed, lead to the irrevocable forfeiture of

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[19]*Id.*

[20]USPTO, MANUAL OF PATENT EXAMINING PROCEDURE § 2755 (May 2004).

[21]37 C.F.R. § 1.780 (2006).

[22]In brief, the length of marketing exclusivity is contingent on whether or not the drug is considered a "new chemical entity" (NCE). The Hatch-Waxman Act defines an NCE drug as an approved drug that consists of active ingredients, including the ester or salt of an active ingredient, none of which has been approved in any other full NDA. 21 U.S.C. § 355(j)(4)(D)(i), (ii) (2006). If the approved drug is not an NCE, then the FDA may not approve an ANDA for a generic version of the approved drug until three years after the approval date of the pioneer NDA. 21 U.S.C. § 355(j)(4)(D)(iii) (2006). In contrast, if the approved drug is an NCE, then a would-be generic manufacturer cannot submit an ANDA until five years after the date of the approval of the pioneer NDA. The effect of this provision is to restrict a potential generic manufacturer from bringing a product to market for five years plus the length of the FDA review of the ANDA. 21 U.S.C. § 355(c)(3)(d)(ii) (2006).

patent rights. Most significant among these is the one-year grace period of 35 U.S.C. § 102(b). That public disclosure even one day outside that grace period voids all patent rights has a severe impact upon individuals unfamiliar with the patent system, including individuals, small firms, and academics. In contrast, applications for patent term extension are commonly filed by sophisticated enterprises that have just achieved obtained FDA marketing approval–an occasion that is often a watershed in the life of their firms.

The Hatch-Waxman Act further conditions a number of other benefits upon observance of fairly tight deadlines. For example, a brand-name firm must file a patent infringement suit against a paragraph IV ANDA or § 505(b)(2) applicant within 45 days in order to obtain the right to a 30-month stay of marketing approval.[23] A generic applicant must notify the NDA holder and patent proprietor within 20 days of filing its paragraph IV ANDA or § 505(b)(2) application; otherwise, that application will presumably be considered incomplete.[24] A paragraph IV ANDA applicant that files even one day after another may forfeit entitlement to a 180-day period of generic marketing exclusivity.[25] In the context of the Hatch-Waxman Act, the 60-day period established by 35 U.S.C. § 156 stands as just one relatively short time frame among many.

Comments on H.R. 5120

In view of this statutory, regulatory, and industrial backdrop, allow me to offer some observations on H.R. 5120.

The Extent of the Problem. Although I am unsure how many applicants the 60-day filing deadline for term extension has impacted, to the best of my knowledge this issue has not been a recurring one. I am uncertain that legislative intervention is required with respect to this issue. It should also be appreciated that the Hatch-Waxman Act stipulates numerous deadlines that impose significant obligations over even more compact time frames. The creation of an additional 5-day window for complying this deadline, as compared to many others, may strike many observers as anomalous.

The Standard for Obtaining 5-Day Period. H.R. 5120 would require the USPTO to determine whether "the delay in filing the application was unintentional." Although I have no doubt

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[23] 21 U.S.C. § 355(c)(3)(C) (2006) (with respect to § 505(b)(2) applications); 21 U.S.C. § 355(j)(5)(B)(iii) (2006) (with respect to ANDAs).

[24] 21 U.S.C. § 355(b)(3)(B)(I) (2006) (with respect to § 505(b)(2) applications); 21 U.S.C. § 355(j)(2)(B)(ii)(I) (2006) (with respect to ANDAs).

[25] 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

that the USPTO will administer any standard that Congress stipulates at a high level of professional ability, the lack of an objective basis for assessing entitlements to patent term extension strikes me as troubling. If the Congress means to say that obviously no rational actor would intentionally waive valuable periods of term extension, then I would encourage a simple extension of the deadline to 61, 65, or some other period of days that is greater than 60. Alternatively, if Congress wishes to compel a substantive inquiry into the fulfillment of professional obligations by the applicant or its counsel, I would suggest that this inquiry would undoubtedly be a thorny one. The USPTO plainly has more important tasks at hand, and should be allowed to pursue its core responsibilities without having to engage in this manner of endeavor.

The Potential Advantages of Prospective Application. I am unsure how many other stakeholders have established a reliance interest based upon the events of any one failure to comply with the statutory deadline. To the extent that legislation is considered desirable, the common mandate that the legislation applies only on a prospective basis strikes me as a superior alternative.

Other Section 156 Issues. Now that the subcommittee has extended its gaze to 35 U.S.C. § 156, it should be aware that this statute has raised other thorny issues that may be amenable to legislative reform. Following the Federal Circuit opinion in *Cardiac Pacemakers, Inc. v. St. Jude Medical*,[26] brand-name firms possess a greater ability to select individual patents for term extension with respect to medical devices than with respect to pharmaceuticals. In addition, in *Arnold Partnership v. Dudas*,[27] the Federal Circuit has interpreted the statute in such a way effectively to eliminate the possibility of patent term extension for combination therapies. Although the court of appeals read the precise language of § 156 fairly in both cases, in my opinion this reading unfairly limits the availability of term extension both for pharmaceuticals in general, and for combination therapies in particular. The subcommittee may wish to address these issues as it considers reforming the Hatch-Waxman Act's term extension provisions.

Legislative Alternatives. Finally, to the extent that H.R. 5120 is motivated by a single incident, a different legislative alternative might be more appropriate. Another option is to promote a private term extension bill in favor of the particular patent involved. Such legislation might more effectively convey to the public the motivation for the legislation and focus attention upon relevant stakeholders in this particular circumstance.

Thank you again for the opportunity to submit this statement.

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[26] 381 F.3d 1371 (Fed. Cir. 2004).

[27] 362 F.3d 1338 (Fed. Cir. 2004).

Mr. SMITH. Thank you. Thank you, Professor Thomas.

And let me say this is the first panel where every witness has kept within their 5-minute limit. So that is appreciated. It is appreciated in part because we have a Judiciary Committee bill on the House floor right now. We are actually trying to expedite this hearing.

Mr. Dudas, let me direct my first question to you. The PTO has had under consideration for 4 years now a request by The Medicines Company for reconsideration. You have also said that the statute is clear and you have your hands tied. Why is it that the PTO has not acted in 4 years on the request by The Medicines Company?

Mr. DUDAS. Thank you. We have acted within 4 years, and I will explain.

This is a rather administrative procedure back and forth between the USPTO and other agencies, the FDA and Department of Agriculture. But that question came up in my mind as well. How many of these do we have that are over 4 years old? How long does this process take?

I talked to the woman who is in charge of this process. The average time period is a little bit over 3 years. It is a series of back and forths with the FDA and the Department of Agriculture. We now have 30 cases. I have a list of them that I had compiled—30 cases where they are active over 4 years old.

The second question is, well, do we want things to be active for 4 years. We are very careful in every case measuring everything at the USPTO to make certain we protect rights.

Mr. SMITH. And you are just as careful in issuing patents as well, right?

Mr. DUDAS. Absolutely, absolutely. And so, the answer to that is basically both referred to it here. These are patent term extensions. The date that really matters is when the patent term originally expires. So you look at this case. It is the year 2010, 2015, et cetera.

Mr. SMITH. Yes, right.

Mr. DUDAS. So the back and forth—certainly, if we get close to that time period we accelerate the process.

Mr. SMITH. Okay. Thank you, Mr. Dudas.

Mr. DUDAS. Sure.

Mr. SMITH. Dr. Meanwell, this is a particularly litigious society that we have today. I am sure there are any number of plaintiff's attorneys who would be happy to file a malpractice suit, contingency fee or not, on your behalf. Why haven't you simply resorted to those means and filed a malpractice suit?

Mr. MEANWELL. Mr. Chairman, a lawsuit won't solve this problem. We will still be left with the underlying pothole in the law. I think there is a real policy problem to solve here.

Of course, I would like the money. The money would be useful to help me build my company. But it wouldn't save a single life. I don't think at this stage that a lawsuit is going to move any of us forward. Certainly, it is not going to move forward the well-being of any patient.

So for us, at this point, we would rather come here and debate the merits of fixing this hole in the law than suing our law firm.

Mr. SMITH. Okay. Thank you, Dr. Meanwell.

Ms. Jaeger, you said in your written and opening statement that severe harm would be caused to both consumers and taxpayers if this legislation were to be passed. That is in distinction to what Dr. Meanwell has said where he said that actually consumers would be benefited by having an extension to the patent.

You made that assertion. Can you support it with evidence that consumers and taxpayers would be harmed by passing this legislation?

Ms. JAEGER. Absolutely, Mr. Chairman.

There are two issues here. The first one is the broader piece on harm having to do with the statutory framework of Hatch-Waxman. As I said in my testimony, the Hatch-Waxman system is a very complex system. And it is based on an intellectual property-based generic approval system. In that system, there are numerous rules and deadlines.

We were very concerned that with respect to this particular issue we start moving deadlines, they start to be very clouded. We do not, well, actually we will not have a system. The system will totally unravel to the detriment of the generic industry and to consumers. These deadlines need to be met, and they need to be there for the administration of the orderly conduct of all parties in the system.

Mr. SMITH. Right. But wouldn't consumers be benefited by the continuing research and development of additional benefits that might accrue from this particular type of drug? And would that be halted by The Medicines Company not getting their extension or reconsideration?

Ms. JAEGER. I think the broader issue is that the rules need to be followed is more imperative to consumers. Again, we have had situations where other deadlines in the Hatch-Waxman system have been missed by brand companies even by 1 day. Yet they did not get the benefit and the opportunity of that other provision.

And again, it goes to the benefit of consumers and ensuring that everyone plays by the rules. And in this instance, what we are talking about also, getting down to more of a specific issue, is we do have a situation where the patent will expire in 2010.

Our members do a lot of research and development many years prior to bringing a generic to the marketplace. They rely on that information that has been posted. They are relying on the information that the PTE extension has been rejected. They have made business decisions on reliance on that decision.

Mr. SMITH. Okay. Thank you, Ms. Jaeger.

Professor Thomas, would you respond to two issues that I brought up so far, that being the possibility of and the advisement of filing a malpractice suit? And second of all, whether you think real harm is being done to consumers if we do not grant discretion to the patent holder.

Mr. THOMAS. Yes, sir. The malpractice suit is part of patent practice. As someone who used to spend his time prosecuting patent applications, my experience was the docketing clerk was the most important colleague I had. And he would come and tell me, "Look, you have got a deadline up here, and it is irremediable."

And so, any first-year associate at a patent law firm is advised about this in no uncertain terms. And you can read the law books.

They are full of malpractice cases where regrettably deadlines have been missed. So that has traditionally been the method of compensation for those who have missed deadlines. Alternatively, shareholder suits against company management——

Mr. SMITH. And what about harm?

Mr. THOMAS. Harm to patients?

Mr. SMITH. Harm to consumers if extension is not granted.

Mr. THOMAS. Well, we are deciding here, I guess, essentially is wealth transfer between patient populations that will pay lower prices for generic versions of drugs versus, you know, surplus that would go to the firm due to its super-competitive profits that are based on a patent. Harm to patients, it is hard to say. We have already got this medication in hand.

But the patent law is about incentives. We have got the patent in hand. The question is how The Medicines Company chooses to use its resources and whether, in fact, it is the best actor to further develop this medication.

Mr. SMITH. Okay. Thank you, Professor Thomas.

The gentleman from California, Mr. Berman, is recognized for his questions.

Mr. BERMAN. Well, thank you, Mr. Chairman. I guess I have a set of questions for Dr. Meanwell and Ms. Jaeger.

Ms. Jaeger, I thought maybe your testimony went a little far in saying that the company chose not to meet the deadline. My guess is they don't feel they chose not to meet the deadline. Somebody screwed up big time. Maybe somebody at the company screwed up by not watching who was in charge of not screwing up. And bad things happened. And this is clearly a case.

But the central public policy point from not the company's well-being or the shareholders' well-being—but, Dr. Meanwell, when you came a long time ago, I think it was, to my office, you made the point, which you have repeated here, that not having what was your settled expectation regarding the delays caused by the FDA and added on to your patent term is going to keep you from investing the funds to do the trials and the research in the trials to find where you think there are beneficial uses from this drug or some slight variation of this drug and that you believe that that is the real harm to the public in a way that you see, apart from your own interests, your company's interests, your shareholders' interests, that a new use of this drug will be precluded.

And I guess what I am asking is you originally developed Angiomax based on raising funds to do the research and trial runs for the blood thinning use that it is now used for. Why can't you do that same process for the new uses of this particular drug, even though I recognize a huge amount of revenue, if nothing changes, is going to be lost to you by not having what was your settled expectation of exclusivity?

And maybe, because my time might run out, let me just ask Ms. Jaeger very specifically. Apart from all the generalized talk, what generic drug company thought that this patent term would expire 4, 4½ years earlier than you would have normally assumed and has made an investment based on what didn't happen on the 60th day to produce an alternative that is going to end up in a lower cost drug?

I would like you to be specific about your members that you sort of generalized have made investments based on their, what you claim to be, their settled expectation of when this thing would come on the market, especially given that at least for, it seems like, years, but maybe it is only two since there has been a great deal of public discussion about this issue that would unsettle anyone's expectations about anything.

So those are my two questions.

Mr. MEANWELL. Thank you for the question. Indeed, there has been quite a lot of public disclosure about this. It is not so much the loss of money and revenue, Mr. Berman. It is the loss of time that is the critical component in research here.

By not having the extension that we had expected, I cannot launch the kind of programs that are required today to prove that this drug, to my satisfaction, to the satisfaction of the FDA, to the satisfaction of doctors and their patients, will meet the needs of patients with, for example, stroke or undergoing open heart surgery. I need several years to do that in.

It was our plan that we would follow—and this is not unusual for hospital products—the initial research program with the FDA.

Mr. BERMAN. Explain that to me.

Mr. MEANWELL. Yes, sir.

Mr. BERMAN. Why does the fact that the patent will expire in 2010 if nothing is done have anything to do with the time needed to run the clinical tests to determine if there are other uses?

Mr. MEANWELL. Because, sir, if I start the trials today—and some of them have preliminarily started—and then we held it, I would have 2, 3, 4 years to do it, 1 year to get it through the FDA and, at that point, would happily hand over those indications to my colleagues in the generic industry. I would not benefit from them at all. And I simply don't have time to get them done.

Mr. BERMAN. Don't you need a patent for new uses of——

Mr. MEANWELL. No, sir. But I need an FDA approval in order to promote those new uses, and I don't have that today. I need to work hard to get a new indication for the drug beyond its existing use. And I don't have time to do that unless the patent term is restored, which, of course, is what under Hatch-Waxman we believe we had earned in the normal way.

So our expectations were to get that. We set our programs up sequentially. We now cannot pursue that research in what looked like very promising new indications in important illnesses.

Mr. BERMAN. Thank you. I have to say, I think it is me, but I am not fully understanding why. But just to get my second question answered——

Ms. JAEGER. May I just add, Ranking Member Berman, regarding that issue, is that a number of companies, a lot of brand companies, do actually pursue their brand products to subsequent clinical trials and do get new indications of use. When they do bring those indications of use, and the Food and Drug Administration does approve those new indications of use, they will get 3 years of exclusivity under the Hatch-Waxman system.

At the same time, there are also generally speaking, on average, there are also some patents that also will be issued protecting that particular product for that new indication of use. Generally speak-

ing, there will be new I.P. protection for those new indications of use as they bring those products to the marketplace.

As to your question, I cannot sit here and tell you specifically one company, or if there are 10 companies in our industry. Unfortunately, our pipelines, our companies' pipelines, are proprietary information.

What I can tell you is what they do utilize for business decisions and that is the CEOs and their R&D teams are looking at what we call the Orange Book, which is a publication by FDA that puts forth all the products as approved by FDA, the market exclusivity that is generated that protects the brand company, the 5 years to 3 years, as well as all patents that the brand company claimed this particular—that claim to protect this particular product and that are eligible for listing in that system. We look at those patents based upon that information, we then turn around and make business decisions on what products we will start our R&D investment on.

A 2010 product is something our companies are considering and have been considering for many years. That is something they are now looking at and will bring a product through the appropriate R&D process and do the necessary application process to have something ready to go when that, when that patent expires in 2010.

Mr. BERMAN. —perhaps 10 generic drug companies are spending money on research in developing this generic product in the hope that one of those 10—each one of those 10 will be the first guy to file that thing and get the 180 days exclusivity? That seems like high-risk ventures.

Ms. JAEGER. No, there is two different issues here in Hatch-Waxman. What happens is there is a patent challenge process. And what the patent challenge process is, that Congress, in their wisdom, basically said the brand companies are to file all patents they deem that claim that particular drug product with FDA.

If there is a patent that gets filed with the Food and Drug Administration that a generic company believes is either filed wrongly, or it is frivolous, or it is questionable, meaning that they believe their product will be outside the scope of that patent, then they will file a paragraph four challenge, which means they are challenging the patent. And then we go into a very complicated Hatch-Waxman patent challenge process. However, if a generic company looks at a patent and believes it is valid, it may not challenge it.

What the companies are going to do then is under the statute file a paragraph three patent certification, which basically says to the Food and Drug Administration, we will not be seeking approval until that patent expires. But indeed, these companies are looking at the patents. They are looking at the market, and they are making determinations many years prior to the patent expiring.

As you imagine, our generic companies want to get FDA approval the day the relevant patent expires. So they are going to back in at least 2 years of FDA review of a generic application, which is 2008.

Their application has to be in by 2008. We are in 2006 now. That means a lot of R&D work has to be done now or could have been done last year as well.

So our systems are, we back in from where patent expiration and the market exclusivity periods will expire. We back in at least 2 years for FDA review of a generic application. And then we back in our R&D schedules.

Mr. SMITH. Thank you, Mr. Berman.

The gentleman from Tennessee, Mr. Jenkins, is recognized for his questions.

Mr. JENKINS. Thank you, Mr. Chairman.

Mr. Dudas, you mentioned several instances in which relief can be given for the late payment of fees, late filings or deficient filings. I have been told that there may be as many as 30 instances under our patent law in which this is the case. Is that a pretty accurate number of cases where relief can be given for late filings?

Mr. DUDAS. We have not compiled each and every one of them, but that seems very much a reasonable estimate of how many there are.

Mr. JENKINS. Now, well, let me ask Ms. Jaeger.

Ms. Jaeger, you have been in law school much more recently than I have. But my memory is—and I am sure you will correct me if I misspeak—but in England, there was a court known as the keeper of the king's conscience. What was it, exchequer came to us in our country as the chancellory system. And it was basically a system where there was no laches adequate remedy at law. And it brought with it the doctrine of—now, I am not recommending that be applied in this instance.

But I would ask you with the prospect of this particular medicine—and it has not been denied, and there is ample medical evidence that the prospects for it in the treatment of strokes and heart disease are very promising.

So I would ask you, what is wrong with 30 instances under our patent laws where relief can be given, what is wrong with us departing from the rigidity that you stick with and going to a more humane situation where we can go ahead, this company can spend those tens of millions of dollars that they spoke about and get on with the prospect of benefiting?

You know, some of us—and you may feel this way when you get older, but some of us have family backgrounds that kind of indicate that we need to be on the lookout for strokes coming on one of these days. And millions and millions of Americans would welcome any prospect to have their prospects for the future improved.

So what is wrong with us departing from rigidity? We already have flexibility in the law in, I say, at least 30 instances. So what is wrong with us departing and seizing this opportunity that we have? We seize too few in this country in advancing genuine and good. We seize many, but there are many that we miss.

What is wrong with us departing from rigidity and going to a more humane system? Would you not, would you not be an advocate of a—and perhaps we are the keeper in this instance of the king's conscience. And so, would you fault us then if we went to a more humane system?

Ms. JAEGER. To that question I have three points. And I think the first point is, it is quite important that with respect to the PTE filing deadline, it is truly consistent with other substantive statu-

tory provisions that establish deadlines for patentees seeking to expand the scope or lengthen the term of the patent.

For example, a patentee seeking to enlarge the scope of the claims in the original patent by invoking PTO's reissuance proceedings must apply within 2 years from the grant of the original patent. Likewise, a patentee seeking to claim priority to the date of an early filed foreign patent must file with the U.S. within 12 months of the earliest day on such foreign application was filed. And these governing statutes do not allow PTO to extend those deadlines much like the PTE applications.

And then, too, these statutes don't have what we call equitable tolling provisions. Now, GPHA is not supporting nor endorsing the concept of moving forward an equitable tolling statute for this particular situation. But even assuming that there was an equitable tolling statute here, this situation would not rise to that level.

Unfortunately, it is an administrative error. An administrative error would not rise to a level of inequitable conduct, in an equitable tolling statute, much like that for the Federal circuit, and there we are talking about the Federal rules of civil procedures, which state a failure to take the proper steps at the proper time not in consequence of the party's own carelessness, inattention or willful disregard of the process of the court but in consequence of some unexpected or unavoidable hindrance or accident or reliance on the care of his counsel or a promise made by an adverse party. In that situation, we apply just a general equitable tolling statute or this particular civil rule of procedure.

Under either scenario, this situation doesn't rise to that level. And therefore, redress was not appropriate. We do believe—my third point is that redress should not be found here with respect to a retroactive amendment, but that there are other recourses that the company can pursue outside this Committee.

Mr. SMITH. Thank you, Mr. Jenkins.

The gentleman from Massachusetts, Mr. Meehan?

Mr. MEEHAN. Thank you, Mr. Chairman.

And to the Ranking Member, thank you very much for putting this hearing together. I think we all can agree that somebody didn't file a form on time, whether it is incompetently or—I doubt they intentionally didn't file it. And I can only assume that whoever failed to file is somewhere in an unemployment line somewhere.

I am interested—because we all agree it wasn't filed on time. And we could go on and on about that, although I am—it is interesting how when we have a Conference Committee how we reach these magical numbers, whether it be 50 or 60 or 45. I can assure you it is usually the House wants one number, the Senate wants another, and we split the difference in the middle.

But in any event, I think it would be important, Dr. Meanwell, just for the record, that you could talk about the public health benefits of this drug and what it means for the future. Because I really haven't heard it for the record here. And if you could do that.

Mr. MEANWELL. Yes, I will do that. I would like to also add something I said to Mr. Berman, which I missed in my attempt to be brief. But let me first get to the point of the drug.

This is an intravenous blood thinner. It is a very unique, high-technology product. It is one which has proven in heart procedures

called angioplasty to be highly effective and to substantially reduce the risk of bleeding among these patients. Typically patients today are receiving a mix of powerful blood thinners in a hospital intravenously. And the big risk is bleeding. And the other big risk is having a heart attack. And then there is a minor risk, if you wish, of dying.

This drug has reduced all of those: bleeding, dying and heart attacks relative to the alternative therapy, which in this case is heparin, which is a 60-year-old product made of pig intestines and which has a lot of side effects, most notably, bleeding and allergies. We have basically knocked out all of those issues.

Now, we found in the course of our research in coronary angioplasty that doctors started to try to experiment with the drug in stroke and cardiac surgery. One report from a doctor described this drug as—and I quote, and I am willing to put this into the record—"the holy grail of drugs for cardiac surgery in patients who are allergic to heparin."

We cannot complete that research right now because we don't have the money, the time, the incentive that Hatch-Waxman originally saw we would and which we expected to get but for our error in filing.

As far as stroke is concerned, it is one of the biggest causes of death in Americans today. It affects all ethnic groups, particularly African-Americans, as we know. It is a deadly disease, of course, and something that really needs to be worked on. We have shown that this drug in preliminary trials can enable the positioning of the carotid stents, stents in the neck to prevent stroke better than any other product that is currently out there. Most experts believe this is a drug that should be developed extensively in that situation.

Mr. MEEHAN. Thank you.

Secretary Dudas, I want to make sure that I understand the current law correctly. As I understand it, an application which contains a number of technical errors submitted on time within the 60 days can be returned to the applicant who has a number of months to correct these mistakes. But a perfectly filed and complete patent resolution application mistakenly filed 1 day late—and I have been counting how many days have—how many months have 30 days and how many have 31, which apparently is part of the problem. Do you know quickly how many have 30 days?

Mr. DUDAS. I have to count it on my hand.

Mr. MEEHAN. Right. But I am interested is that case. In other words, in other words, if you file an application with mistakes on time, can you make corrections?

Mr. DUDAS. Yes, you can.

Mr. MEEHAN. How does that work?

Mr. DUDAS. Well, there is a variety of different instances.

Mr. MEEHAN. So, in other words, so even if somebody files with mistakes, as long as they file within the 60 days, they will get a period of months to correct those mistakes?

Mr. DUDAS. There is an opportunity to correct mistakes in some cases with applications and also in other areas in the office, yes.

Mr. MEEHAN. Do you, do you believe that PTO can waive the 60-day filing requirement on its own inherent authority? Or is it your

belief that an extension must be legislated through a measure such as H.R. 5120?

Mr. DUDAS. It is our belief that it would have to be legislated.

Mr. MEEHAN. Do you agree with the discretionary authority in 5120? Do you agree that it is similar to other deadline-extending provisions presently in patent law? And if so, approximate—well, I think the question was asked. But you said maybe 30. But you agree that there is already discretionary authority with other deadlines?

Mr. DUDAS. There is definitely discretionary authority with some other deadlines. And this is not in some way that we find to be fundamentally inconsistent with some of the other deadlines.

Mr. MEEHAN. Okay. So there are other deadlines that it is okay, this discretion that you guys have? There are other mistakes that are filed that somebody has a period of months to correct. Would you agree with the description of H.R. 5120 that the bill simply gives the PTO the discretion to review a patent term restoration application filed a few days late to determine whether that filing was delayed intentionally? Would you agree?

Mr. DUDAS. I think that is correct, as I read it. It would depend on what—and I am not familiar with the legal standard of unintentional. And we have folks in our office that could determine, whether or not it would be automatic. But the bill on its face says discretion to determine whether it is unintentional.

Mr. MEEHAN. Would you agree that the legislation doesn't by itself add any additional patent term restoration?

Mr. DUDAS. The bill itself does not add any patent term restoration.

Mr. MEEHAN. Finally, some people have characterized this bill as automatically extending—I heard some of the witnesses say that it automatically extends the 60-day filing deadline by 5 days. Do you agree with that?

Mr. DUDAS. I think the only way that would be true is if the term unintentional—no, it can't be that, because if someone did it intentionally it wouldn't be automatic, either. So I think a lot depends on the standard of unintentional. But, no, there is at least that standard there.

Mr. MEEHAN. And I read it, and I share Mr. Berman's feeling. I read the material from you, the letter from you. One thing I think we can be clear is the PTO doesn't have any reason to oppose this legislation. Is that correct?

Mr. DUDAS. From a PTO perspective, an administrative perspective and an ability to carry it out, no, we don't have a reason to oppose.

Mr. MEEHAN. Thank you, Mr. Chairman.

Mr. SMITH. Okay. Thank you, Mr. Meehan.

I am going to ask, Mr. Dudas, you another question and in doing so, give other witnesses, if they so desire, an opportunity to answer the question as well. And what I am trying to do here in asking a question about precedent is to find out exactly what the facts are, and be a little bit more specific when we talk about those precedents.

I have a list in front of me which may or may not be entirely comprehensive of all the instances where discretion has been al-

lowed in the case of unintentional mistakes. And so far as I can see from this list in front of me, which, as I say, may not be completely extensive, is that in all the instances where discretion has been allowed in the case of unintentional mistakes that deal with the statute as opposed to PTO rules generally fall into two categories: discretion being allowed in the case of late fees and discretion being allowed in the case of failure to reference earlier applications.

Clearly, discretion in those instances don't rise to the level of significance of discretion in the case of extending a patent. Do you know of any instance where there would be a precedent directly on point where discretion would be allowed in the case of an unintentional mistake dealing with the approval of a patent and dealing with discretion being allowed in the case of the statute as opposed to PTO rules?

Mr. DUDAS. I am not aware of that, but I would give the following caveat that we have in our deputy office of operations and policy within Patent and Trademark Office—I would like to follow-up——

Mr. SMITH. Okay. It would probably be useful to the Committee to realize two things. One, most of the discretion that is being given is of relatively minor infractions or deadlines dealing with PTO rules, not the statute. And if you have any case in point, I think that would be helpful. But there is precedent perhaps on both sides. I just haven't seen the precedent yet on the side of extending a patent.

Dr. Meanwell, do you have any examples you could give? And then we will ask Ms. Jaeger and Professor Thomas.

Mr. MEANWELL. I would like to say that the hard and fast deadlines that we have reviewed—and I am no patent attorney, so I am——

Mr. SMITH. Neither am I.

Mr. MEANWELL. The ones that seek to expand the scope of a patent, the breadth of the intellectual property, are indeed often hard and fast. I know at least of three. In fact, they were mentioned earlier, I think, 102-B, 251 and 119-A are the things related to establishing a patent, either here or in foreign territories. But actually, that is establishing new grounds for a patent. That is establishing the breadth of a patent.

Here we are talking about the time life of a patent. We are not talking about the breadth of the patent in any way. The breadth of the Angiomax patent will remain exactly the same.

And one of the things I should have said to Mr. Berman is that that means that we are not looking for a new patent to do what we are doing. We are hoping to use this one as long as we need. And we will need to invest $100 million to do so. So we obviously would like to recoup that with exclusivity thereafter. So just to clarify.

But there are certainly situations where expanded the scope of a patent is hard and fast. But this is a procedural situation, in my opinion, not expanding the scope of the patent in any way. And by the way, the revision here would not in any way give us a single day more on our term than would be normally envisioned under Hatch-Waxman. And, you know, frankly for such a Draconian pen-

alty to be hammered out for the sake of this dumb mistake, we feel would be, would be inequitable.

Mr. SMITH. Okay. Thank you, Dr. Meanwell.

Ms. Jaeger or Professor Thomas, any precedents to cite or examples to give?

Mr. THOMAS. Mr. Chairman, I believe the most apt analogy would be with respect to maintenance fees, which may well be the first element on the chart you have referenced. As you know, the patent 20-year term is not automatic. You have to pay periodic annuities essentially to the patent office to retain the term and the 3 and-a-half, 7 and-a-half and 11 and-a-half years from the date of issuance. Some of those deadlines aren't met, so there are provisions for coming in late and asking for your patent to be maintained in a sense, sort of a term extension.

Mr. SMITH. You are right. Okay.

Mr. THOMAS. However, and those applications are entertained by the U.S. PTO. However, if there is a late maintenance fee accepted, that gives some right with respect to third parties that are rather vaguely defined by the statute, for example, something that would be akin to the first inventor Defense Act, which you are considering modifying to encompass all sorts of inventions, not just——

Mr. SMITH. Okay. Thank you, Professor Thomas.

Mr. THOMAS. You are welcome.

Mr. SMITH. Ms. Jaeger?

Ms. JAEGER. I just want to reiterate for the record, I know we see three particular situations where patentees are seeking to expand the scope or lengthen the term that do not, do not have any discretion for PTO. And, of course, that is the——

Mr. BERMAN. Expand the scope.

Ms. JAEGER. Expand the scope of patent with a reissuance proceeding or a PTE, which is extending the length of the patent as well as, of course, you know, the foreign early filed foreign patent provision as well.

Mr. SMITH. Okay, okay. Thank you, Ms. Jaeger.

Let me explain to the panelists that I have to leave for another engagement. I am going to ask the gentleman from Tennessee to chair the rest of the hearing. And thank you all again for being here.

Mr. JENKINS. [Presiding.] Mr. Berman, were you finished?

I am sorry. Go ahead.

Mr. BERMAN. I was just interrupting somebody else.

Actually, now I understand, Dr. Meanwell, you are not seeking a new patent. You will need to get FDA approval for the new uses. You won't need to get a new patent. And it makes a heck of a difference whether it expires in 2010 or 2014 whether you have some exclusive period for marketing this drug that FDA would have approved for additional uses. Okay. I have got it. It is not about a new patent.

Professor Thomas, you made a point in your initial testimony. I forget exactly how you put it, but a policy reason perhaps to not provide discretion in this provision is because it implicates not just the patent office, but the Secretary of HHS and the head of FDA and the Secretary of Agriculture. And I don't know what other agencies you mentioned.

But realistically, what is the difference if under the limited nature of this extension in terms—I am trying to understand why is that a policy argument against doing it when in the limited nature of the relief proposed in this legislation.

Mr. THOMAS. It is a good point. It is only 5 days. But it does create a lot of reliance interest upon other actors. And that is something that is not as commonly the case with other missed PTO deadlines. So in short, there are a host of actors out there that have to engage in a fair amount of steps.

Another distinction that may be salient to you—and again, let me first once more acknowledge you are right about the 5 days. It is only 5 days from that perspective. But there are any number of other deadlines that if missed are irremediable under the Patent Act. And again, they often impact small entities that are not sophisticated players in the patent system. They have long been a part of our law. That really——

Mr. BERMAN. That are not, that are not——

Mr. THOMAS. That cannot be correctable. And that is really not the case here. Right? We are really talking about very sophisticated actors that are well-advised. And that may be why this is not a situation that has recurred.

One of my colleagues at Georgetown often uses the phrase "big boys" that I don't like because of its gender implications. But nonetheless, do we need in a sense really a protection statute for sophisticated actors who have just been gifted with a watershed event for their firm, FDA marketing approval?

Mr. BERMAN. Well, no, look, one cannot help but avoid the notion that in life there are a lot of deadlines that every day because some little person or company or whatever missed them and opportunity was lost or harm was done and, I mean, you can't, you can't but avoid thinking at this. And at the same time, it is hard to avoid thinking about the enormity of, you know—I mean, there is a disproportional aspect of what has happened here, too, on the other side in terms of just nature of mistake versus money lost. So I guess that is part of the consideration.

Ms. Jaeger, my last question—in the context of, somewhere companies in your association, unknown to you because of the proprietary interests may have spent money, and in some cases considerable money, thinking that notwithstanding all the hullabaloo in 2010 this thing is coming out there and we want to be ready to fill that void with a lower cost consumer benefit therefore protection.

Are there situations—somebody mentioned in the context of some other statute the maintenance fees. In the context of things, are compensation for money spent in reliance on something that Congress subsequently changed—is there any precedent for those kinds of arrangements?

Ms. JAEGER. Well, I think when we are looking at this retroactively—we are looking at this retroactive bill. And in so doing, the job, I think, of everyone here is to sort of do the analysis of weighing the benefits and the risks.

And here, yes, absolutely, the benefit would inure to The Medicines Company and would provide them with 5 additional years of market exclusivity in the United States. It is adding to their patent that they have today, which expires in 2010. It is not taking away

their patent. It is just going to extend the terms of that particular patent and give them this extraordinary benefit.

At the same time, the burden that would be placed on our industry would be that we relied upon the 2010 patent expiration date. We went through and did some performance research and development, which costs money from our industry side.

At the same time, we also have a downstream effect of the others in the health care distribution channel, which are the insurers and the PBMs and the consumers, that have relied upon that date as well for forecasting and in trying to figure out what health insurance premiums will be in 2010 and the like. So this does have a negative implication downstream in the health care distribution channels.

At the same time, among the broader issue, we are just very concerned about the many, many deadlines in Hatch-Waxman. And, you know, we say, we all hope to move the deadline to, 65 days. When we get to another situation when someone comes in at 67, 68, are we going to move it again? And then do we move the 45-day window? And does that move——

Mr. BERMAN. We are very good at saying it is this time only, never again until——

Ms. JAEGER. And we think it is a Pandora's Box that doesn't need to be opened, sir.

Mr. BERMAN. Just in closing, Mr. Chairman, as I heard Dr. Meanwell describe the drug, I realized that this fit perfectly with what happened to my father, who died from an allergic reaction to heparin during a heart surgery where he had to have a blood thinner at that time. This is 16 years ago or something. Not from the heart surgery, not from the heart attack, but from not having—so I could personally testify there is something valuable about what you have produced here.

And I yield back.

Mr. JENKINS. Professor Thomas, let me go back to the flexibility that you spoke about with respect to the payment of fees for continuation. If that flexibility was not in the law, then this patent continuation would be just as dead as any of the other instances that could kill its continued life. Isn't that true? If we had the same rigidity in the law with respect to the payment of those fees that we have, let us say, in this instance, then that would put an end to that patent and its continuation just as surely.

Mr. THOMAS. Sir, I don't know all the facts of the case. I am not aware of how long the patent has been extant and whether they have paid maintenance fees or not. So in good faith I can't answer that, sir.

Mr. JENKINS. Well, let me ask it not on a comparative basis, but just on the basis of if the law was different and said you had to pay these fees on time, you couldn't pay them a day late, then your continuation would be just as dead, would it not? It would be dead.

Mr. THOMAS. That is right, if the maintenance fees were paid late, right.

Mr. JENKINS. Okay.

Mr. Meehan, do you have any questions, sir?

Mr. MEEHAN. Mr. Chairman, I just want to point out on this issue of unintentional error in standards that are, that are used by

the PTO, there is a letter in the record from Lawrence Goffney that specifically says that the agency is extremely familiar with the unintentional error standard that is being proposed in H.R. 2150. Indeed, this is a standard most commonly used by the PTO in determining whether to accept late filings under the statutory provisions. And I would refer that to Members of the Committee.

Just one more thing that I want to ask Ms. Jaeger. So you can't provide us with a company that is ready to develop this drug or has had an investment or anything of that nature?

Ms. JAEGER. No, sir, not at this time I cannot because, again, our companies' pipelines are proprietary. As you can imagine, they are fierce competitors. And so, it is not something they are about to disclose, what products they are or are not going to bring to the market in a few years.

Mr. MEEHAN. Right. And that is basically for some of us—the question is, you know, what is the future going to be of this particular drug and the advances that have been made?

It is my understanding that clinical data demonstrates that up to 23,000 transfusions could be saved if these results move forward, more than 1 million of these performed each year, these procedures. So from my perspective, that is why we are balancing interests here.

We are balancing a lawyer at a firm who messed up with what the public health effect would be in the end. And for me, that is a significant thing that we should weigh.

So I thank the Chairman. I just want to point out those unintentional error standards into the record.

Mr. JENKINS. Thank you, Mr. Meehan.

Does any other Member of the Committee have any additional questions?

Mr. Berman?

Mr. BERMAN. No.

Mr. JENKINS. Any?

Well, the Chairman has already complimented this panel of witnesses. And let me add to that and say that your remarks were very informative. Your answers were very direct and cogent, and we certainly appreciate that.

I think that this Committee has learned quite a bit today. I hope that we can use it to the benefit of the people across the United States of America. It is a difficult situation.

And, Ms. Jaeger, let me say I have the utmost respect for you and what your association members are doing. We shouldn't let it pass without saying that your members provide a really valuable service to millions and millions of Americans.

As I understand it, Dr. Meanwell is also on the board of directors of a generic company. Was that brought out? Is that true?

Mr. MEANWELL. Yes, I am, sir. I am on the board of a company that sells generics. I absolutely agree with your remarks.

Mr. JENKINS. All right. Well, thank you very much for coming. And the Committee will be adjourned.

[Whereupon, at 12:35 p.m., the Subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

STATEMENT OF THE HONORABLE HOWARD BERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND RANKING MEMBER, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

Mr. Chairman,

Thank you for scheduling this hearing on a bill giving the USPTO additional discretion to extend certain patent deadlines. While similar measures (bills that have specifically extended the Angiomax patent) have been attached to legislative vehicles in the past, I am glad that this issue is finally being reviewed by the committee with jurisdiction over patent matters. It is important that this Subcommittee be able to analyze the impact of any changes this bill may make on the patent system.

Patents are the cornerstone of innovation. The Constitution provides for a limited period of time of protection in order to promote innovation. Therefore, the patent process provides the exclusive right for an invention (for 17 to 20 years) generating incentives for an inventor to continue to create after which the invention becomes available for public use. There is a delicate balance of - on the one hand- providing enough of an incentive to the inventor to spend the time, energy and money to create new inventions - and on the other- the value of allowing the invention to be used by the public enabling others to develop new products or provide similar products for lower cost.

Therefore, when considering the effect of allowing the PTO discretion to extend certain patent deadlines, there is a natural tension between providing the flexibility to extend a deadline and maintaining a hard date for specific types of filings. While providing greater elasticity may prevent seemingly draconian results does it come at the expense of stability in the market? There appear to be other instances where the PTO has discretion to extend deadlines but the situation this bill is designed to address is not among them. WHY? Is there something different about this type of filing that the PTO should NOT have discretion in this case?

Unfortunately, the PTO has not provided much guidance in its response to the (letter from the Chairman and myself about the) policy questions posed by this bill. I look forward to hearing from the other witnesses to discuss the policy implications of this bill on the patent system and possibly Hatch-Waxman.

Originally this legislation began as an effort to address one particular late filing, of one patent - there has been no demonstrated need nor request from any other patent owners to provide discretion to the PTO for these type of filings. Moreover, from the way the bill has been written it is clear that this bill would effect the late filing of a particular company which occurred over 4 years ago. Some have even suggested that the better alternative to this bill is a private bill. However, this bill and this particular circumstance does raise some questions about why there are inconsistencies in the discretion afforded to the PTO to determine when filings are timely. As such I look forward to further exploring the issues.

STATEMENT OF THE HONORABLE ELTON GALLEGLY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND MEMBER, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

Mr. Chairman, I would like to begin by thanking you for holding this hearing on H.R. 5120. I appreciate your interest in this important issue. I would also like to commend Congressman Jenkins for the introduction of this legislation.

H.R. 5120, which I strongly support, deals with what seems to be a narrow issue in our nation's patent law, namely the question of patent term restoration applica-

tions submitted to the Patent and Trademark Office. However, although the change to the law is relatively minor, the passage of this legislation would both provide greater fairness to patent holders and encourage innovation by companies in the medical research field and in other industries.

H.R. 5120 would amend the Hatch-Waxman Act to provide the U.S. Patent and Trademark Office with modest discretion to accept late-filed patent term restoration applications. In a recent letter to the Subcommittee, the Director of the Patent and Trademark office confirmed that under current law the PTO already enjoys discretion in numerous instances to accept late-filed applications. However, Congress has not given the PTO similar discretion to accept late-filed patent restoration applications.

This strikes me, and other cosponsors of H.R. 5120, as an unfortunate and undeserved inconsistency in our patent law.

Mr. Chairman, failure to allow an innovator that has earned patent term restoration to qualify merely because of a clerical or other unintentional error discourages innovation and ultimately harms patients who rely on research into new medicines. We must keep in mind that for a company to qualify for patent term restoration, it must already have successfully completed an incredibly rigorous drug testing and development regime, ultimately obtaining FDA approval of its drug. The Hatch-Waxman Act offers patent term restoration as an incentive for innovators to invest their time, effort, and resources in this arduous drug development and approval process.

I can think of no area in the patent law where permitting discretion on the part of the PTO too accept late-filed applications is more important that in the case of patent restoration applications. Yet, this is one area where Congress has not granted the PTO such discretion. It is imperative that we correct this situation by the passage of H.R. 5120.

I understand that some oppose H.R. 5120, arguing that giving the PTO any discretion will somehow disadvantage generic manufacturers.

In my view, the Hatch-Waxman Act provides generic manufacturers with clear, enumerated benefits. However, Congress never intended one of those benefits to be the ability to take advantage of unintentional clerical errors, thereby gaining years of marketing time at the expense of innovative companies that have satisfied all of the many processes required by Hatch-Waxman.

Mr. Chairman, I want to thank you again for holding this hearing today.

A LETTER TO THE HONORABLE JONATHAN W. DUDAS, UNDER SECRETARY FOR INTELLECTUAL PROPERTY AND DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE (USPTO) FROM THE HONORABLE LAMAR SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS AND CHAIRMAN, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY, AND THE HONORABLE HOWARD BERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND RANKING MEMBER, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

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ONE HUNDRED NINTH CONGRESS

Congress of the United States
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May 23, 2006

The Honorable Jonathan W. Dudas
Under Secretary for Intellectual Property and Director
U.S. Patent and Trademark Office (USPTO)
Madison West Building
600 Dulany Street
Suite AW 10-d-44
Alexandria, Virginia 22313

Dear Jon:

Please find enclosed a copy of H.R.5120, a bill referred to the Subcommittee, which seeks to amend the Patent Act to provide the Director of the United States Patent & Trademark Office (USPTO) with new authority to waive the operation of title 35 U.S.C. §156(d)(1).

Specifically, H.R. 5120 proposes, under circumstances shown "to the satisfaction of the Director" to permit the Director to declare such delay to be "unintentional" and "accept" an application for extended patent term that is filed:

1) "not later than 5 days after the expiration of the 60-day period" specified by statute[1] for applications not submitted on the date of enactment ;or
2) "not later than 5 days after [the] date of enactment" in the case of an application that is pending at USPTO, subject to a request for reconsideration, or has been denied an extension under this section but whose period for seeking reconsideration has not expired.

[1] 35 U.S.C. § 156(d)(1) provides, "[t]o obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use."

In support of this proposal, proponents have noted that the USPTO has ex ante discretionary authority[2] to permit an application, which is incompletely or improperly filed within the 60-day statutory period, to be deemed "informal" and to grant the applicant additional time to make corrections.

They assert that the USPTO has no authority under statute or regulation to permit a properly completed application, which was filed late due to an applicant's inadvertence[3], to be granted an extension. In their view, the interests of equity would be served if Congress granted the Director with statutory discretion to waive or extend the deadline in certain instances.

In considering amendments to the Patent Act, we are mindful that ensuring the predictable application of our law can promote a number of beneficial purposes. The presence of clearly articulated standards contributes to increased entrepreneurial activity, which can lead to the availability of innovative new products and technologies.

The certainty associated with a clearly defined statute may act as an incentive for parties to conduct their affairs in reliance upon the occurrence of outcomes that are reasonably foreseeable. And a demonstrably consistent application of the law inspires public confidence in the objectivity of administrative decision-making.

In sum, the reliance upon variable and uncertain factors may result in unsettling the reasonable expectations of parties, as a disincentive to innovation, and as a bar to potential competition.

Notwithstanding the considerations above, there are those who believe the USPTO needs new administrative flexibility to waive the requirements of 35 U.S.C. §156(d)(1). It is argued this is required to ensure that the strict application of a "bright line" rule in every circumstance does not lead to counter-productive outcomes that have the unintended and undesired effects of actually discouraging innovation and imposing on inventors draconian and unforeseeable costs.

Due to the technical nature of these issues and the importance we attach to ensuring all relevant views are fully and properly considered, we would appreciate your providing the Subcommittee with your analysis and assessment of H.R. 5120.

If, as the Director of the USPTO, you determine that you wish to request that Congress grant the authority intended by H.R. 5120, then we would appreciate your providing us with a written response that includes recommendations for any restrictions or limitations that you believe ought to be included to ensure the neutral application of such a provision, a discussion of

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[2] 37 CFR § 1.740

[3] A non-dispositive but arguably persuasive authority for similar equitable principles may be found in FED. R. CIV P. 6(b), which provides, subject to some restrictions that a "court for cause shown may at any time in its discretion ... order the period [of time for an act to be done] enlarged, or ... permit the act to be done where the failure to act was the result of excusable neglect."

the status of any pending matter that USPTO foresees may be impacted by such a change, the identification of any parties who may be aggrieved by such a change, and an explanation of the manner in which the USPTO would anticipate implementing such a proposal.

We are aware of one instance where a company might benefit from the enactment of legislation and the exercise of administrative flexibility in this area. The Medicines Company manufactures the pharmaceutical Angiomax® (bivalirudin), an anticoagulant approved in the U.S. for use by patients who are undergoing coronary angioplasty procedures. The company believes Angiomax® may be useful in treating other conditions. Due to uncertainty over the final expiration date of the underlying patent the company has, thus far, been reluctant to fund new clinical trials. The current patent for Angiomax®, U.S. Patent No. 5,196,404, (herinafter the "404" patent) was issued March 23, 1993. Absent an extension, it will expire in 2010.

We understand that attorneys who represent The Medicines Company applied for an additional 4.5 years of extended patent term but that the request was denied due to a failure to meet the 60-day statutory filing requirement contained in 35 U.S.C. §156(d)(1). We are told that an attorney filed a motion for reconsideration in this matter with the USPTO on October 4, 2002, and that the motion, as of today's date, has not yet been acted upon by the USPTO.

Further, we understand that the law, as of December 2004, permits a generic manufacturer to be eligible to file a "paragraph 4 certification" to challenge the validity of the "404" patent.

While we are not aware of an expressed intention by a generic manufacturer to file such a challenge, we are concerned about the possible effect that the operation of such a statutory and administrative change could have on the inchoate interests of potential generic competitors.

We would appreciate your analysis and opinion as to whether the changes proposed in H.R. 5120 could, under any circumstances, operate to retroactively delay the ability of a generic manufacturer to file a challenge to a patent granted by the USPTO.

In addressing our concerns, please be sure to include answers to the following specific questions:

- If USPTO was granted statutory discretion to extend the deadline of an application for an extended patent term, how many previous applicants could benefit? How many current applicants could be expected to take advantage of such discretion?

- If discretion was granted, should it be prospective and not apply to any current case rather than retroactive since that would be consistent with the way new laws are generally applied?

- What are examples of the USPTO's having been "given wide discretion to excuse late filings" in other areas?

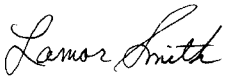
- Under what circumstance would you expect such discretion to be exercised in regard to patent term restoration applications filed in an "untimely manner"? What are specific examples of "unintentional delay" in filing such applications? Would "unintentional delay" cover "human error"?

- Finally, do you feel this legislation is needed?

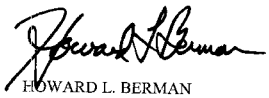
After conducting a thorough review of H.R. 5120 and the circumstances it is intended to address, we would appreciate your recommendations, if any.

The Committee's points of contact for this matter are David Whitney, Counsel to the House Judiciary Committee's Subcommittee on Courts, the Internet, and Intellectual Property and Shanna Winters, Minority Counsel to the Subcommittee on Courts, the Internet, and Intellectual Property.

Sincerely,



LAMAR SMITH
Chairman, Subcommittee on Courts,
The Internet, and Intellectual Property



HOWARD L. BERMAN
Ranking Member, Subcommittee on Courts,
The Internet, and Intellectual Property

109TH CONGRESS
2D SESSION

H. R. 5120

To amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2006

Mr. JENKINS (for himself, Mr. DELAHUNT, Mr. DUNCAN, and Mr. MEEHAN) introduced the following bill; which was referred to the Committee on the Judiciary

A BILL

To amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FINDINGS.

The Congress finds the following:

(1) The Congress historically has provided vigorous support for innovation in the useful arts by establishing a system of patent protection for products and processes.

(2) Through section 156 of title 35, United States Code, the Congress sought to promote the de-

velopment of innovative drugs by granting patent term restoration to companies to recover a portion of the patent term for such drugs that was consumed during the approval process conducted by the Food and Drug Administration.

(3) Consistent with the historic purpose of promoting innovation, patent legislation, and subsequent rules promulgated by the United States Patent and Trademark Office (PTO), have routinely given the PTO wide discretion to excuse late filings and other mistakes that might otherwise result in the forfeiture of underlying patent rights.

(4) Contrary to this routine practice, however, under section 156 of title 35, United States Code, the PTO has no discretion to excuse a filing that is even one day late.

(5) In order to be consistent with the intent of protecting patent rights and promoting further innovation, the PTO should be granted limited, circumscribed discretion to consider patent term restoration applications filed in an untimely manner.

SEC. 2. FILING OF APPLICATIONS FOR EXTENSIONS OF A PATENT TERM.

(a) IN GENERAL.—Section 156 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(i) UNINTENTIONAL DELAY.—The Director may accept an application under this section that is filed not later than 5 days after the expiration of the 60-day period provided in subsection (d)(1) if the applicant files a petition showing, to the satisfaction of the Director, that the delay in filing the application was unintentional. Such petition must be filed with the application in the case of an application filed on or after the date of the enactment of this subsection and must be filed not later than 5 days after such date of enactment in the case of an application which, on such date of enactment, is pending, is the subject of a request for reconsideration of a denial of a patent term extension under this section, or has been denied a patent term extension under this section in a case in which the period for seeking reconsideration of such denial has not yet expired. The Director shall make a determination on a petition under this subsection not later than 30 days after the date on which the petition is received. If no determination has been made on the petition within that 30-day period, the petition shall be deemed to be denied.".

(b) REVIVAL FEES.—Section 41(a)(7) of title 35, United States Code, is amended—

(1) by striking "or for an" and inserting "for an"; and

(2) by inserting after "reexamination proceeding," the following: "or for an unintentionally delayed application for patent term extension,".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act, and shall apply to any application for patent term extension under section 156 of title 35, United States Code, which—

(1) is filed on or after the date of the enactment of this Act; or

(2) on such date of enactment—

(A) is pending;

(B) is the subject of a request for reconsideration of a denial of a patent term extension under section 156; or

(C) has been denied a patent term extension under such section 156 in a case in which the period for seeking reconsideration of such denial has not yet expired.

○

A LETTER TO THE HONORABLE LAMAR SMITH, A REPRESETATIVE IN CONGRESS FROM THE STATE OF TEXAS, AND CHAIRMAN, SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY, IN RESPONSE TO A LETTER REQUESTING THE UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO) ANALYSIS AND ASSESSMENT OF H.R. 5120

UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

AUG 30 2006

The Honorable Lamar Smith
Chairman, Subcommittee on Courts,
The Internet, and Intellectual Property
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your co-signed letter requesting the United States Patent and Trademark Office's (USPTO) analysis and assessment of H.R. 5120, a bill "to amend title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office."

We appreciate the Committee's interest in the USPTO's views on this bill. This type of legislation is not without precedent. Currently, patent laws provide the USPTO with discretionary authority to accept late-filed submissions in a number of situations, including: payment of maintenance fees (35 U.S.C. § 41(c)(1)), abandonment of applications (35 U.S.C. § 133); and payment of issue fees (35 U.S.C. § 151). The trademark laws have similar language, for example, regarding timely filing of a verified statement of use (15 U.S.C. § 1051(d)(4)) and abandonment of an application for failure to reply or amend (15 U.S.C. § 1062(b)).

At this time, however, we do not have a position on this proposal. As the Committee recognizes, there could be some benefits, and at least one direct beneficiary, of providing the type of additional flexibility provided by the proposal. However, as the Committee also recognizes, there are also benefits to maintaining the certainty inherent in current law in this area. While we have a sense of the potential impacts on the possible direct beneficiary to this legislation, we do not yet have a full sense of the impact on others in the invention, manufacturing, consumer, and intellectual property communities. As the legislative process continues, we would encourage the Committee to explore these issues, as the views of a range of parties may help elucidate the merits and limitations of the proposal. Similarly, while we currently do not believe the legislation requires additional restrictions or limitations in order to ensure neutral application if enacted, further exploration of the issue may help inform this question as well.

We are pleased to provide information below that is responsive to various questions posed in your letter.

Previous Applicants that Would Benefit from Enactment
We are aware of one current application for patent term extension that would immediately benefit from enactment of the bill. That application is related to patent number 5,196,404 owned by the company named in your letter. More generally, a review of our records indicates that, of the over 700 applications for patent term extension filed since 1984, three other applications were not granted due, at least in part, to timeliness issues. One of these applications was filed within 65 days of the "approval date," and thus may have been eligible for a petition to have the delay excused, if the proposed provision had been in effect.

Prospective vs. Retrospective
It is not unprecedented for newly enacted patent legislation to apply to issued patents and pending applications. That fact noted, prospective or retrospective discretionary authority, as proposed in the bill, would have to involve a careful balancing of all relevant interests involved. We are unable to make a particular recommendation in this regard because we are unaware of any substantive input by interested parties, other than the '404 patent owner.

Exercise of Discretion
With respect to the circumstances under which we would expect to exercise discretion, we believe it is premature to attempt to list or identify particular examples at this point. We would, of course, if granted the subject authority, be likely to follow the policies reflected in the administration of areas currently subject to discretionary review of delayed filings.

Patent Reform
Although our survey of patent term extension applications reveals few issues related to timeliness, this legislation would be of use to at least one current applicant and could be utilized by future applicants who miss the patent term extension application deadline due to unintentional delay. As noted above, the discretionary authority contemplated by H.R. 5120 is similar to other deadline-extending provisions in patent law.

As indicated in testimony before your Subcommittee in April, the USPTO supports enactment of two patent proposals pending before the Subcommittee that are widely supported throughout the intellectual property community, namely, a post-grant review procedure and a new procedure for submission of prior art. We continue to review other proposals before the Subcommittee.

The Office of Management and Budget has advised that there is no objection to the transmittal of these views from the standpoint of the Administration's program.

Sincerely,

JON W. DUDAS
Under Secretary and Director

A LETTER TO THE HONORABLE JON W. DUDAS, UNDER SECRETARY FOR INTELLECTUAL PROPERTY AND DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE (USPTO) FROM JANE A. AXELRAD, ASSOCIATE DIRECTOR FOR POLICY, CENTER FROM DRUG EVALUATION AND RESEARCH, DEPARTMENT OF HEALTH & HUMAN SERVICES IN REGARD TO THE MARCH 24, 2003 LETTER FROM KARIN FERRITER REQUESTING FDA'S ASSISTANCE IN PREPARING A RESPONSE TO A REQUEST FOR RECONSIDERATION IN THE APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT NO. 5, 196, 404 FILED BY THE MEDICINES COMPANY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 2 2006

Re: Angiomax
Docket No. 01E-0213

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the March 24, 2003, letter from Karin Ferriter requesting FDA's assistance in preparing a response to a request for reconsideration in the application for patent term extension for U.S. Patent No. 5,196,404 filed by The Medicine Company under 35 U.S.C. § 156. The human drug product claimed by the patent is Angiomax (bivalirudin), which was assigned new drug application (NDA) No. 20-873.

The applicant argues that the approval date for NDA 20-873 should be December 18, 2000, not December 15, 2000 (a Friday), because the approval letter was signed after FDA's normal business hours on December 15.

The FDA reiterates that NDA 20-873 for Angiomax was approved on December 15, 2000.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Hollie Baker
Wilmer, Cutler, Pickering, Hale and Dorr, LLP
60 State Street
Boston, MA 02109

Paul Antinori
The Medicine Company
8 Campus Drive
Parsippany, NJ 07054

Bcc:
BCC:
Chron
Hard Copy to B.Friedman for Patent File : Angiomax Patent No. 5,196,404

Scanned Copy to:

J. Axelrad
L. Jaffe/G. Ortega/J. Butler for Docket # 20016-0213
Mary_Till@PTO.gov for Angiomax Patent No. 5,196,404

I:\Patent98\PRODUCTS\Angiomax\Response to request for reconsideration v2.doc

A PAPER ON CRITICAL ACTIONS THAT RELATE TO THE MEDICINES COMPANY APPLICATION FOR PATENT TERM EXTENSION FOR U.S. PATENT 5, 196, 404

Critical Actions That Relate to The Medicines Company Application for Patent Term Extension for U.S. Patent 5,196,404

DAY	DATE	ACTION
0	December 15, 2000	FDA approves New Drug Application (NDA).
3-19	December 18, 2000 – January 3, 2001	Application preparations underway (drafting, beg collection and preparation of appendices); meetin on January 3, 2001 at The Medicines Company (MDCO) w/ Hale & Dorr (H&D) to discuss application.
21	January 5, 2001	First draft of (substantially complete) 100 + page application prepared and sent by H&D to MDCO for review.
42	January 26, 2001	Meeting at H&D to review application.
56	February 9, 2001	Review next to final draft of application at MDCC
59	February 12, 2001	Application sent by Hale & Dorr to Fish & Neave (patent counsel of record) for filing.
60	February 13, 2001	Application arrived at Fish & Neave.
61	February 14, 2001	Fish & Neave files application with PTO (by Express Mail procedure).
	March 2, 2001	PTO asks FDA to confirm that PTE application w. not filed within sixty days after the product was approved as required by 35 USC §156(d)(1).
	September 6, 2001	FDA transmits letter confirming that PTE was file untimely.
	March 4, 2002	Final Determination of Ineligibility issued.
	October 2, 2002	H&D Counsel files MDCO Request for Reconsideration for Patent Term Extension by USPS with Commissioner for Patents.

REQUESTED SUBMISSION FROM THE HONORABLE WILLIAM JENKINS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE; LETTERS FROM LEADING MEDICAL PRACTITIONERS AND CONSUMER GROUPS

06/15/2006 16:52 4046864824 CARDIOLOGY PAGE 02/05

EMORY HEALTHCARE
HEART CENTER

The Carlyle Fraser Heart Center
at Crawford Long Hospital
550 Peachtree Street NE
Atlanta Georgia 30308
Phone 404 686-5051

June 15, 2006

Congressman John Lewis
United States House of Representatives
343 Cannon House Office Building
Washington, DC 20515

Dear Representative Lewis,

I received a phone call today from Clive Meanwell, Chief Executive Officer of The Medicines Company, regarding HR 5120, relating to the patent restoration provisions of the Hatch-Waxman law I am the Director of Interventional Cardiology at Emory Crawford Long Hospital and have been on the faculty of Emory University School of Medicine for thirteen years I am also the President of the Greater Atlanta Division of the American Heart Association (A H A), and a medical reporter for FOX-5 television The major focus of my profession is the care of patients with advanced and complex cardiovascular disease, particularly those undergoing interventional procedures (commonly known as stents) of the arteries of their heart and elsewhere in the body

I am writing in support of HR 5120 because I understand that, if it passes, the anticoagulant drug Angiomax may become eligible for patent term restoration. This would allow for further investment in clinical development. Angiomax is a critically important product which is used in the overwhelming majority (thousands) of the interventional procedures at Emory Angiomax is an important therapy because it provides safe, effective, and cost-effective anticoagulation during interventional procedures In addition, several Emory physicians have performed extensive research on Angiomax. Emory was one of the leading U.S. centers in a recent trial studying this product. I am perhaps one of the nation's leading experts and researchers in this area and have lectured internationally and published extensively in this area Within the last month, we submitted approximately twenty individual research abstracts on Angiomax to the American Heart Association and Transcatheter Cardiovascular Therapeutics national meetings Our research shows that Angiomax provides equal efficacy to other drugs, costs less, is easier to use, and causes less risk of bleeding complications Bleeding complications have been shown to increase mortality and are particularly common in

patients who are: elderly, female, African-American, and those with kidney disease, anemia, and high-blood pressure. I have attached two of our abstracts highlighting the consequences of bleeding complications. These types of patients make up the majority of the patients at our institution. Better outcomes and a reduction in healthcare costs with Angiomax is what we want for the patients of our community.

But that is only part of the story. Patent term restoration for Aagiomax is important because preliminary experience suggests that Angiomax may be useful in preventing and treating stroke but more studies are needed. Stroke is the nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year--one every 45 seconds; over 165,000 die and many thousands more are disabled for life. I know that you are aware that Georgia is part of the high-risk "stroke belt" In my capacity with the A.H.A., one of our major initiatives is reducing the risk of stroke. Unfortunately, the blood thinning and clot-busting agents currently utilized to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Angiomax may be useful in the prevention and treatment of strokes with fewer bleeding side effects. But the very costly and time-consuming clinical trials (which Emory will likely be involved with) which will be needed to explore this and other promising new uses (such as patients undergoing open-heart surgery) will not be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

It is vital that HR 5120 be enacted so that research in stroke is undertaken to evaluate the use of Angiomax in the treatment and prevention of this debilitating disease. I would be happy to discuss this matter further with you at your convenience; my direct office number is 404-686-2663.

Very truly yours,

Steven V. Manoukian, M.D., F.A.C.C
Director, Interventional Cardiology
Emory Crawford Long Hospital
Emory University School of Medicine

Bivalirudin Significantly Reduces Bleeding While Maintaining Efficacy Compared to Either Abciximab or Eptifibatide in Percutaneous Coronary Intervention: Lessons from REPLACE-2

Michael D. Voeltz, Emory University School of Medicine, Atlanta, GA; A. Michael Lincoff, Cleveland Clinic, Cleveland, OH
Frederick Feit, New York University Sch ool of Medicine, New York, NY; Robert V. Marcoulian, Emory University School of Medicine, Atlanta, GA

ABSTRACT

[illegible]

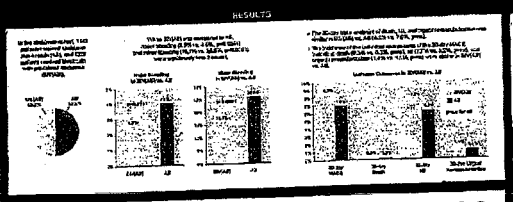
BACKGROUND

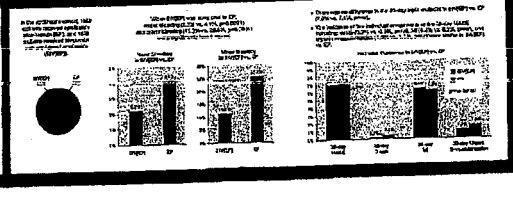
- [illegible]
- [illegible]
- [illegible]

METHODS

- [illegible]

RESULTS





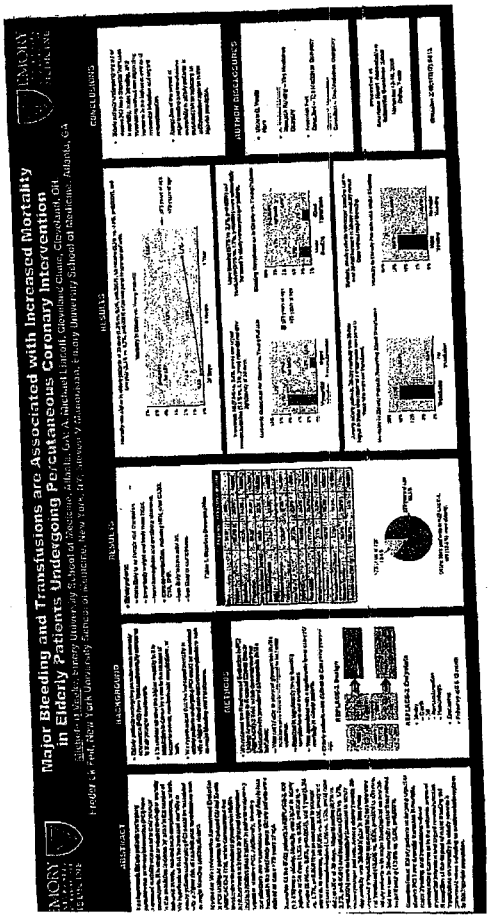
CONCLUSIONS

- [illegible]
- [illegible]

AUTHOR DISCLOSURES

- [illegible]
- [illegible]
- [illegible]
- [illegible]

Presented at American Heart Association Scientific Sessions 2005
November 13-16, 2005
Dallas, Texas


Major Bleeding and Transfusions are Associated with Increased Mortality in Elderly Patients Undergoing Percutaneous Coronary Intervention
ABSTRACT
BACKGROUND
METHODS
RESULTS
CONCLUSIONS
AUTHOR DISCLOSURES

THE CLEVELAND CLINIC FOUNDATION

Heart Center

April 24, 2006

Deepak L. Bhatt, MD, FACC, FSCAI, FESC
Director, Interventional Cardiology Fellowship
Cardiac, Peripheral, and Carotid Intervention
Department of Cardiovascular Medicine / F25
Office: 216/445-6042
Appts: 216/444-6697
Fax: 216/445-8531

Congresswoman Stephanie Tubbs Jones
United States House of Representatives
1009 Longworth House Office Building
Washington, DC 20515

Dear Representative Tubbs Jones:

I understand that you are considering a bill, HR 5120, related to the patent restoration provisions of the Hatch-Waxman law. I am an interventional cardiologist practicing at the Cleveland Clinic. I engage in the clinical care of patients with cardiovascular disease as well as in clinical research related to this complex and unique group of patients.

I am writing in support of HR 5120 because I understand that, if it passes, the anticoagulant drug Angiomax may become eligible for patent term restoration. This would allow for further investment in clinical development. I use Angiomax and have been involved in the study of Angiomax in acute care cardiovascular procedures, including heart attack and angina. Angiomax is an important therapy that provides safe and effective anticoagulation in interventional procedures with less bleeding than other treatments. These advantages also save the health care system money by reducing bleeding and providing single drug therapy versus combination drug therapy.

Patent term restoration for Angiomax is important because preliminary experience suggests that Angiomax may be useful in preventing and treating stroke, but more studies are needed. Stroke is the nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year--one every 45 seconds; over 165,000 die and many thousands more are disabled for life. Unfortunately, the blood thinning and clot-busting agents now available to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Angiomax may be useful in the prevention and treatment of strokes with fewer side effects. But the very costly and time-consuming clinical trials needed to explore this promising new use won't be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

9500 Euclid Avenue, Cleveland, OH 44195

It is vital that HR 5120 be enacted so that research on Angiomax in the prevention and treatment of strokes is undertaken to evaluate the drug in the treatment and prevention of this debilitating disease. I am available to discuss this matter further with you at your convenience.

Very truly yours,

Deepak L. Bhatt M.D

Deepak L. Bhatt, MD, FACC, FSCAI, FESC, FACP
Associate Director, Cleveland Clinic Cardiovascular Coordinating Center
Staff, Cardiac, Peripheral, and Carotid Intervention
Associate Professor of Medicine
Department of Cardiovascular Medicine
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Cleveland, OH 44195 USA
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UNIVERSITY OF CALIFORNIA, LOS ANGELES

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SANTA BARBARA • SANTA CRUZ

DEPARTMENT OF MEDICINE
UCLA SCHOOL OF MEDICINE
CENTER FOR THE HEALTH SCIENCES

Please Reply to:

CARDIOLOGY SECTION (111E)
V.A. HOSPITAL (WADSWORTH)
11301 WILSHIRE BOULEVARD
LOS ANGELES, CALIFORNIA 90073

September 6, 2006

Congresswoman Nancy Pelosi
United States House of Representatives
H-204 The Capitol
Washington, DC 20515-6537
Fax: 202 225-4188

Dear Congresswoman:

I understand that the Subcommittee on Courts, the Internet and Intellectual Property of the Judiciary Committee of the House of Representatives is considering a bill, HR 5120, relating to the patent restoration provisions of the Hatch-Waxman law. I am an interventional cardiologist practicing at The UCLA Medical Center and the Greater Los Angeles Veterans Administration Medical Center. I engage in the clinical care of patients with cardiovascular disease as well as in clinical research related to this complex and unique group of patients.

I am writing in support of HR 5120 because I understand that, if it passes, the anticoagulant drug Angiomax may become eligible for patent term restoration. This would allow for further investment in clinical development. I use Angiomax and have been involved in the study of Angiomax in acute care cardiovascular procedures. Angiomax is an important therapy that provides safe and effective anticoagulation in interventional procedures with less bleeding than other treatments. These advantages also save money by reducing bleeding and providing single drug therapy versus combination drug therapy.

Patent term restoration for Angiomax is important because preliminary experience suggests that Angiomax may be useful in preventing and treating stroke but more studies are needed. Stroke is the nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year--one every 45 seconds; over 165,000 die and many thousands more are disabled for life. Unfortunately, the blood thinning and clot-busting agents now available to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Angiomax may be useful in the prevention and treatment of strokes with fewer side effects. But the very costly and time-consuming clinical trials needed to explore this promising new use won't be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

It is vital that HR 5120 be enacted so that research in stroke is undertaken to evaluate the use of Angiomax in the treatment and prevention of this debilitating disease. I am available to discuss this matter further with you at your convenience.

Very truly yours,

Ramin Ebrahimi, M.D., FACC, FCCP, FSCAI
Associate Clinical Professor University of California Los Angeles
Director Cardiac Catheterization Laboratory Greater Los Angeles VA Medical Center
Assistant Director Nuclear Cardiology Greater Los Angeles VA Medical Center

September 13, 2006

The Honorable F. James Sensenbrenner, Jr.
Chairman, Committee on the Judiciary
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, DC 20515

The Honorable John Conyers, Jr.
Ranking Member, Committee on the Judiciary
2426 Rayburn Building
Washington, DC 20515

Dear Chairman Sensenbrenner and Ranking Member Conyers,

On behalf of the 800,000 members of FreedomWorks, I am writing to urge your support for H.R. 5120, a bill that would address a concern that has arisen in patent law and provide an environment that facilitates innovation and continued development of products that are beneficial to potentially millions of Americans. FreedomWorks has a long history of involvement with issues arising from the drug approval process, promoting policies that eliminate unnecessary delays that limit consumer access to important new therapies. In addition, FreedomWorks believes that at times the patent process may be abused and generics provide an important source of competition that generates substantial benefits to consumers. This legislation, however, is not an abuse of the system; it is an adjustment to the process that will ensure continued research and development. This issue also highlights the burden imposed by the drug approval process and I would urge Congress to also consider reforms in this area as well to ensure Americans have the access to the best care possible.

Briefly, H.R. 5120 would grant the U.S. Patent Office the discretion to consider an application for patent term restoration that unintentionally has been filed late, but within five days of the expiration of the 60-day filing period established in the Hatch-Waxman Act (see 35 U.S.C. Section 156(d)(1). The U.S. Patent Office has the discretion to accept late-filed submissions in a variety of patent and trademark proceedings, but it does not in instances of patent term restoration filings. H.R. 5120 would correct this anomaly.

Under the Hatch-Waxman Act, patent term restoration is an inducement for innovators and firms to undertake risky, time-consuming, and costly drug development and the FDA approval processes. Without patent term restoration, incentives for drug innovation are diminished and consumers would bear the costs as fewer resources are devoted to important lifesaving drug therapies.

As an example, the Medicines Company failed to receive patent restoration because its filing was unintentionally filed one day late. The firm was in the process of conducting important additional research on Angiomax, a drug initially approved as a blood thinning agent. New research, however, suggests that Angiomax may be beneficial for use in the prevention and treatment of stroke, which is the leading cause of disability and third leading cause of death in the

1775 Pennsylvania Ave., NW, 11th Floor Washington, DC 20006 PH: 202.783.3870 www.freedomworks.org

United States. Unfortunately, without patent restoration, the ability to conduct the additional research and commit to the costly approval process are eliminated, leaving consumers with fewer choices for critical health care decisions.

Unlike other areas of patent law, the inflexible filing deadline is clearly draconian. The Hatch-Waxman act provides incentives to invest in the costly and time-consuming drug approval process, yet the inflexibility built into the current law can destroy those incentives and have a disproportionate impact on the process, and reduce opportunities for innovation. H.R. 5120 brings this application of patent law more in line with the broader process for patent and trademark proceedings. Given the importance of innovation in the field of health care, and the potential impact on the lives of Americans, I urge you to support this important legislation.

Sincerely,

Matt Kibbe
President and CEO
FreedomWorks

cc: Subcommittee on Courts, the Internet, and Intellectual Property

Hon. Lamar S. Smith, Chairman	Hon. Howard L. Berman, Ranking Member
Hon. Henry J. Hyde	Hon. Rick Boucher
Hon. Elton Gallegly	Hon. Zoe Lofgren
Hon. Bob Goodlatte	Hon. Maxine Waters
Hon. William L. Jenkins	Hon. Martin T. Meehan
Hon. Spencer Bachus	Hon. Robert Wexler
Hon. Robert D. Inglis	Hon. Anthony D. Weiner
Hon. Ric Keller	Hon. Adam B. Schiff
Hon Darrell E. Issa	Hon. Linda T. Sánchez
Hon. Chris Cannon	
Hon. Mike Pence	
Hon. J. Randy Forbes	

RetireSafe

Preserving Your Retirement. Securing Your Benefits.

September 13, 2006

The Honorable F. James Sensenbrenner
Chairman
House Committee on the Judiciary
2138 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Sensenbrenner,

On behalf of the almost 400,000 senior citizens represented by RetireSafe, I am writing to inform you of our support of H.R. 5120, legislation that would correct a troubling anomaly in the patent law that can hinder innovation and stymie life-saving research. Currently, the Hatch Waxman Act allows the owner of a drug patent to obtain time restored to its patent to make up for time lost while awaiting FDA approval. H.R. 5120 would permit the Patent and Trademark Office to accept an application within five days of the deadline if the PTO determines the filing de ay was unintentional.

RetireSafe urges the House Judiciary Committee to support this much needed legislation that can benefit millions of seriously ill patents. It's unfortunate, but when years of patent protection on a drug are forfeited due to a minor clerical error, the benefits of further research and development of critical drugs is often lost. Ironically, there are more than 30 patent laws and regulations on the books giving the PTO the discretion to accept minor application errors and late filings, but not under Hatch-Waxman. We believe such rigid rules undermine the intent and basic purposes of the patent law.

Furthermore, there are absolutely no downsides to fixing this problem. The bill would not upset the balance of Hatch-Waxman; it would simply avoid a premature cutoff of earned patent rights due to minor clerical error. Generic manufactures will also still have the same right they now enjoy to file an application to bring out a new drug, and this right would still be keyed to the date FDA approves the patent owner's drug use.

For instance, take the case of the drug Angiomax, made by a small drug company, which had earned the right to patent restoration but missed the filing deadline by *one* day. Research into promising new applications of Angiomax for cardiac and stroke patients – applications which are critical to older Americans -- will be cut short if this legislation is not passed. If Angiomax loses its patent protection prematurely, this critical research opportunity will be lost entirely as it will *never* be conducted by generic manufacturers. The end result will mean that 13 million Americans including the millions of seniors with coronary artery disease will never benefit from this potentially life-saving drug.

Angiomax is just one example of a drug that has faced this filing deadline issue. Two

1900 Campus Commons Drive, Suite 100 • Reston, VA 20191 • 703-766-6360
www.retiresafe.org

other companies have missed the Hatch-Waxman filing deadline by *one* day and others will doubtless make minor filing errors in the future. Cardiac and stroke patients will clearly benefit from this bill. H.R. 5120 is good public policy that will help save lives and provide a better quality of life for seriously ill patients, and it should be enacted immediately.

In short, H.R. 5120 does not give anything to patent owners that the Hatch-Waxman law did not intend to give them and does not take anything away from the generic manufactures that the Hatch-Waxman law intended to provide. It merely gives PTO the discretion to consider whether or not to accept an application for patent term restoration after hearing all the facts.

I urge you and your committee to support H.R. 5120 and help millions of seniors in this country who are currently suffering or at risk for coronary artery disease and need innovative life-saving medications. It is my hope you will agree that H.R. 5120 is good public policy with an overriding public health benefit.

Sincerely,

Michelle Plasari

Michelle Plasari
RetireSafe

RetireSafe
1900 Campus Commons Drive, Suite 100 • Reston, VA 20191 • 703-766-6360
www.retiresafe.org

CENTER FOR INDIVIDUAL FREEDOM

113 S. Columbus St., Suite 310 •Alexandria, VA 22314 • (703) 535-5836 • (703) 535-5838 (fax) • www.cfif.org

September 12, 2006

Chairman F. James Sensenbrenner, Jr.
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

Congressman John Conyers, Jr.
Ranking Member
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Sensenbrenner and Congressman Conyers:

On behalf of the Center for Individual Freedom and its more than 250,000 supporters and activists nationwide, I am writing to urge you to support H.R. 5120. This bill grants the Patent and Trade Office Director the discretion, where fair and appropriate, to accept slightly overdue patent-term restoration applications under the Hatch-Waxman law.

Under current law, an application unintentionally filed even one day late *must* be denied – the Director possesses absolutely no discretion whatsoever. Such a rigid command creates unfair outcomes, and arbitrarily jeopardizes enormously valuable property rights.

Throughout other realms of business, legal, and personal life, equitable grace periods exist. For example, other federal agencies such as the Internal Revenue Service possess discretion to accept slightly overdue submissions. If even the "Tax Man" can have a heart, the Patent and Trademark Office should also be allowed similar discretion.

It is also important to put H.R. 5120 into perspective: the bottom line is that a company should not have to pay the price of millions or even billions of dollars in revenue due to a simple and unintentional clerical error. Companies invest billions of dollars in product research and development, and recouping those investments through patent protection is what allows our innovative economy to thrive.

Moreover, other patent laws and regulations allow the Patent and Trade Office discretion to excuse minor mistakes, such as filing documents or making payments. Thus the current Hatch-Waxman deadline provision stands as an anomaly by prohibiting any type of discretion. In our view, this anomaly should be fixed, and H.R. 5120 does just that.

If an individual unintentionally pays their mortgage payment one day late, does the bank seize their home? No. If property taxes are paid one day late due to a bank disbursement error,

does the government automatically seize your property? Obviously not. Should a different standard apply to a company whose very existence depends upon a patent that they hold?

Opponents of this rational legislation claim that it would somehow benefit one particular company, but that is incorrect. Rather, any company that can prove that its slight delay was unintentional would be treated more fairly. This is simply good public policy.

Indeed, the only beneficiaries of perpetuating the current regulations are generic companies who stand to gain an unfair windfall by pouncing whenever a patent owner accidentally files a few days late. Perpetuating such inequitable windfalls for generic companies is an inappropriate public policy result. Maintaining the Hatch-Waxman mandate as-is will lead to the further loss of highly valuable patent rights for no good reason. In contrast, fixing it through H.R. 5120 will help all innovators, both present and future.

Further, H.R. 5120 does not give the patent holder a "carte blanche, no questions asked" grace period. It does not allow for indefinite patents, nor does it imply continued protections due to intentional negligence. Rather, it allows a five-day grace period for a patent restoration filing that was unintentionally delayed. Five days.

Finally, Congress routinely revisits statutes in order to fix loopholes and anomalies. Very simply, mistakes happen, as does the law of unintended consequences. In the case of Hatch-Waxman, allowing a simple five-day grace period will not undermine or compromise the growth of the generics market in the United States. Rather, H.R 5120 will merely align patent restoration filing rules with the other discretions enjoyed by the Patent and Trademark Office.

Accordingly, the Center for Individual Freedom urges you and all members of the Judiciary Committee to pass H.R. 5120, allowing it full consideration by the U.S. House of Representatives. Fairness and equity demands it, and we will monitor members' votes on this critical matter and communicate them to our constituency.

Thank you very much for your time and consideration.

Sincerely,

Timothy H. Lee, Esq.
Director of Legal and Public Affairs

CC:
The Honorable Lamar S. Smith
The Honorable Henry J. Hyde
The Honorable Elton Gallegly
The Honorable Bob Goodlatte
The Honorable William L. Jenkins
The Honorable Spencer Bachus
The Honorable Bob Inglis
The Honorable Ric Keller
The Honorable Darrell Issa
The Honorable Chris Cannon
The Honorable Howard L. Berman
The Honorable Mike Pence
The Honorable Randy Forbes
The Honorable Rick Boucher
The Honorable Zoe Lofgren
The Honorable Maxine Waters
The Honorable Marty Meehan
The Honorable Robert I. Wexler
The Honorable Anthony D. Weiner
The Honorable Adam Schiff
The Honorable Linda T. Sanchez

LETTER FROM LAWRENCE GOFFNEY

Lawrence J. Goffney
120 Waterford Place
Alexandria, VA 22314-3860

(703) 518-0214
LGoffney@comcast.net

September 13, 2006

The Honorable Lamar Smith, Chairman
The Honorable Howard Berman, Ranking Member
Subcommittee on Courts, The Internet, and Intellectual Property
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman and Mr. Berman,

My name is Lawrence J. Goffney, Jr., perhaps I am better known as "Larry Goffney." I am a former Acting Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks and a former Assistant Commissioner for Patents (now known as the "Commissioner of Patents") with the United States Patent and Trademark Office (the "PTO"). In connection with the hearing that you are holding tomorrow on H.R. 5120, it has come to my attention that there are a number of issues that warrant clarification with respect to this legislation.

Simply put, H.R. 5120 is perfectly consistent with both the Hatch-Waxman system and the general authority to excuse unintentional errors in patent practice.

The bill would provide the Director with the authority to excuse a late filing under 35 U.S.C. § 156 caused by an unintentional error. This authority, however, is limited to filings within a very short period of five days after the original due date that are accompanied with a petition explaining to the Director's satisfaction the unintentional error. The short window for forgiveness in the bill ensures that errors that could be corrected by this authority will in no way disrupt the handling of patent term extension applications within the PTO. Indeed, virtually no formal or substantive review will have occurred within the PTO within five days of the original deadline for filing of a § 156 application.

The provision of a 5-day grace period to address an unintentional late filing will not affect, in any manner, the decision-making process that generic firms follow regarding filing of Abbreviated New Drug Applications ("ANDA"), the marketing of generic drugs, or the initiation of patent challenges under the Hatch-Waxman system. Simply put, the date on which an application for patent term restoration is filed has no relevance to the decisions made by the generic company as to whether to market a generic drug. Rather, those decisions are based on factors such as the size of the market of a pioneer drug, the strength or coverage of a patent, and

the business risks the generic manufacturer is willing to undertake in seeking early marketing of a generic copy of a drug product.

In addition, the precedent for an "unintentional error" standard for § 156 applications in the rest of the patent system is overwhelming. Few firm deadlines are present in the patent laws; instead the PTO has been granted the discretion to extend deadlines that would affect substantive rights in a number of circumstances. The agency is extremely familiar with the "unintentional error" standard being proposed in H.R. 5120. Indeed, this is the standard most commonly used by the PTO in determining whether to accept late filings under other statutory provisions. There is thus little basis for concluding that H.R. 5120 is inconsistent with or anomalous to the patent laws or that the "unintentional error" is not an objective standard that will prove difficult for the PTO to apply.

Finally, there is considerable precedent for having patent legislation apply to issued patents and pending applications rather than having only a prospective effect. Most patent legislation that Congress has passed in the last twenty years has applied at least in part to pending applications or existing patents.

1. The Present Statutory Scheme Contemplates Delays Greater Than 60 Days in the Filing of a Completed Patent Term Restoration Request

The PTO has exercised its rule-making authority to provide that an application for patent term extension must include 15 elements. 37 C.F.R. § 1.740(a). Notwithstanding this exercise of its rule-making authority, the PTO has further exercised its rule-making authority to provide that an application containing less than all of the required 15 elements will be treated as timely filed if it provides certain of the required information. These elements roughly correspond to those specified in 35 U.S.C. § 156(d)(1). If that information is provided, the patentee has two months—plus the additional time available upon the payment of surcharges pursuant to the PTO's usual practice—to provide the missing or incomplete elements of the application. 37 C.F.R. § 1.741(b).

Arguments that the five day grace period that would be provided by H.R. 5120 will disrupt the orderly processing of § 156 applications, or will cause other unprecedented disruptions, ignore both the existing authority to correct informal errors already in the system, and the broader experience under PTO practice. H.R. 5120 would provide a grace period of 5 days (and would afford the PTO 30 days to determine whether the patentee is entitled to the grace period). This period is significantly shorter than the period already allotted for initial review of §156 applications. For example, the system already contemplates a potential delay in processing of two months, plus the additional time available upon the payment of a surcharge, before the request for patent term extension will be substantively processed. Moreover, 37 C.F.R. § 1.741(b)'s use of two months to establish the time within which the application must be completed underscores that a difference of a few days is inconsequential to the process. For example, if the two-month period includes December and January, 62 days are afforded the patentee. If, on the other hand, the two-month period is measured by January and February the patentee is afforded 58 days in the normal year but 59 days in a leap year. Indeed, it is likely that nothing more than initial processing by the PTO mailroom will have occurred within 5 days of the 60 day statutory deadline provided by 35 U.S.C. § 156.

2. Determining the Amount of Patent Term Restoration is a Lengthy Process.

Similarly, introducing a 5-day grace period will not lengthen the time it takes to process a request for patent term restoration. That is because, although the Secretary of the Department of Agriculture (for certain veterinary drugs) or the Secretary of Health and Human Services (in the case of human drugs) must be asked to calculate the applicable "regulatory review period" within 60 days of receiving the application, there is no set period within which that calculation must be made.

Research into the average time it takes to make that calculation reveals the calculation period is far longer than the fixed time periods specified in these regulations. For example, a review of all of the available requests for patent term extension filed between 1996 and 2005 reveals that the average time taken by the Secretary of Health and Human Service to make a determination was 1121 days—3.08 years. In context, the 5-day grace period provided by H.R. 5120 is 0.44% of that period. Those who point to the deadlines for subsequent proceedings frequently omit the fact that by far the largest amount of time consumed in that process is the period taken by the Secretary of Health and Human Services to make its determination.

3. The Date of Filing of A Request for Patent Term Restoration is Irrelevant to Generics.

Suggestions that the *timely* filing of a § 156 application somehow factors into the decision-making process of a generic drug manufacturer are disingenuous. The only dates having any importance to third parties, such as generics, are the dates of FDA approval of the drug (from which the time to file a paragraph 4 certification under Hatch-Waxman is computed) or the date on which the patent (including any restored term) expires. In fact, until recently, there was virtually no information made available to the public about these filings. A person wishing to determine if a § 156 application has been filed at that date had to travel to a small filing room at the Office of Patent Legal Administration at the PTO and hand search the paper records. Today, information on patent term extension applications is still only sporadically available through the PTO's Patent Application Information Retrieval system. The lack of ready access to the information is hardly surprising in light of the fact that the mere filing of a § 156 application has no significance.

4. Granting The PTO The Discretion To Accept A Late Extension Filing Would Align The Patent Term Extension Process With Other Patent Deadlines

One of the other main clarifications to make about H.R. 5120 is that it corrects an anomaly in the patent law. It has been noted by some of the opponents of the bill that certain provisions of the Patent Act and the Hatch-Waxman Act include deadlines that are not flexible. Contrary to these suggestions, the norm is flexibility, not punitive inflexibility.

The few fixed deadlines that exist in the Patent Act are directed almost exclusively to a person's decision to pursue patent protection or from obligations the United States has under treaties. When it comes to granting an inventor the right to exclude the public from an invention, or the right to claim an even broader invention than what was claimed in his original patent, the patent laws require prompt action. Statutes such as 35 U.S.C. § 102(b) and 35 U.S.C. § 251

force the prospective patentee to file a patent or an amendment to a patent within a specific time frame to avoid upsetting settled expectations of the public, who had access to the invention for over a year before the application claiming the invention was filed, in the case of 35 U.S.C. § 102(b), or had access to a patent limiting the scope of its claims for two years, in the case of 35 U.S.C. § 251. The patent laws are therefore protective of the public when information is being removed from the public domain.

The patent term extension provision of 35 U.S.C. § 156 is not analogous to statutes that increase the scope of the patent owned by an inventor. There is no new intellectual knowledge that is removed from the public or called into question when a patent applicant files for an extension. Instead, the term of the patent increases in order to compensate the patentee for the delay it experienced during the FDA approval process. Congress approved this increase in the patent term as part of the Hatch-Waxman Act in 1984; it thus has already decided that the extension is worth the cost to the public.

Once a patent application has been filed, the Patent Act provides for extraordinary flexibility in the prosecution and administration of the patent. As noted by the PTO in its letter dated August 30, 2006, the PTO currently has discretionary authority in a "number of situations" to accept late-filed submissions. This discretion extends to the ability to correct patent term extension applications, as discussed above, 37 C.F.R. § 1.741(b); revive abandoned applications, 37 C.F.R. § 1.137; pay required maintenance fees, 35 U.S.C. § 41, and claim the benefit of earlier foreign filing or priority dates, 35 U.S.C. § 119(b)(2), 35 U.S.C. § 120. Research has shown that there are at least thirty examples of such flexibility in the patent laws and regulations, most of which could otherwise result in the loss of substantive rights due to an unintentional error.

With respect to the Hatch-Waxman Act, the consequence for failing to file a patent term extension with 60 days is orders of magnitude more harsh than the penalties incurred by missing the other fixed deadlines in the Act. For example, Section 505(b)(2) requires the patentee to file a lawsuit against an ANDA applicant within 45 days of receiving notice that the application has been filed. The consequence for missing that deadline is not to eliminate the right to sue, however. Instead, the patentee is not granted an automatic 30-month stay of approval of the ANDA that challenges the patent. The loss of the 30-month stay does not foreclose the ability of the patentee to sue the generic manufacturer or enjoin its marketing of the generic product. Similarly, while the ANDA applicant has 20 days to give notice to the patent holder, there are no prescribed consequences if this deadline is not met. The other provision of the Hatch-Waxman Act that has been identified –the 180-day generic exclusivity period granted to the first ANDA filer to include a patent challenge–is more aptly termed a "race to the FDA" than a deadline. Indeed, the failure of an ANDA filer to file its ANDA with a patent challenge on the first day possible does not automatically lead to an inability of that filer to receive 180-day exclusivity. Instead, exclusivity remains a possibility as long as there is no earlier filer. Comparing a race to win exclusivity to a loss of an earned patent term restoration period attempts to compare apples and oranges.

5. The PTO Is Familiar With The Standard Used In H.R. 5120.

The PTO is not only familiar with having discretion to accept late-filed submissions, it is also familiar with the standard that H.R. 5120 asks them to apply: unintentional delay. Contrary to concerns raised by some commentators, unintentional delay has a well-defined meaning within the PTO. According to our research, the unintentional error standard is the most common standard used by the PTO to determine whether to excuse a late filing. The standard is used by the PTO for example to determine whether to revive an abandoned patent, 37 C.F.R. § 1.137(b); revive a patent that has expired because of a failure to pay maintenance fees, 35 U.S.C. § 41(c); file tardy responses in reexamination proceedings, 37 C.F.R. § 1.550 and § 1.958, among others. The term "unintentional delay" has even been defined in the MPEP, which is the authority for handling applications for patents within the PTO. The MPEP definition is that such a delay is one that is not the result of a "deliberately chosen course of action on the part of the applicant." M.P.E.P. § 711.03(c). With all such standards, the agency has ample experience in evaluating the merits of the case before it and applying the appropriate standard.

6. The PTO Is Familiar With The Standard Used In H.R. 5120.

H.R. 5120 has also been questioned because it applies not only to prospective applications, but also to applications that are currently pending. This is common practice in patent legislation, however—Congress routinely permits patent holders and patent applications to take advantages of the benefits granted by new legislation. Research has shown that nearly every bill amending the patent statute has applied to pending applications and pending patents in at least some respects. This includes provisions in the Cooperative Research and Technology Enhancement Act ("CREATE") (Pub.L.108-453); the American Inventors Protection Act ("AIPA") of 1999 (Pub. L. 106-113); Biotechnology Process Patent Amendments Act (Pub. L. 104-41), and the Uruguay Round Agreements Act ("URAA") (Pub. L. 103-465).

Sincerely,

Lawrence J. Goffney, Jr.

Lawrence J. Goffney, Jr. has, since January 2000, consulted on intellectual property and serves as an expert witness on patent issues, including proceedings before the United States Patent and Trademark Office. Since January 2000, he has testified in court or by deposition in over 50 cases, many involving ANDA litigation. He is registered to practice before the U.S. Patent and Trademark Office, and he is licensed to practice before the state and federal courts in the State of Michigan and before other federal courts, including the U.S. Court of Appeals for the Federal Circuit

Until January 2000,he was a partner with Akin, Gump, Strauss, Hauer & Feld, L.L.P., in Washington, where he was a member of the firm's intellectual property practice.

From 1996 until 1998, prior to joining Akin, Gump, Mr. Goffney was the Acting Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks at the USPTO, a position to which he had been designated by the Secretary of Commerce.

In 1994, he had been appointed by the President and confirmed by the Senate to the position of Assistant Commissioner for Patents, in which capacity he ran the entire U.S. official patent process (the "Patent Office") from application to issue. In this capacity, and later as Deputy Commissioner, he attended Trilateral Meetings officials

Prior to entering government service as a senior official in January, 1994, Mr. Goffney was a partner in the Michigan based law firm of Dykema Gossett. From 1974 until 1983, he was a law professor on the faculties of the University of Texas and the University of Detroit, a visiting professor at the University of Wisconsin and a Harvard Fellow in Law and the Humanities.

Mr. Goffney received a B.S. with honors in 1970 from Oakland University. He attended Carnegie Institute of Technology (now Carnegie-Mellon University). He received a J.D. in 1974 from the University of Detroit and an LL.M. in 1974 from Columbia University, where he was a Burton Fellow in Intellectual Property. In 1975, Mr. Goffney received a certificate from the Parker School in Foreign and Comparative Law at Columbia University.

Testimony from Thomas Schatz, President, Citizens Against Government Waste

Testimony

Thomas A. Schatz,
President,
Citizens Against Government Waste
before the
House Committee on the Judiciary,
Subcommittee on Courts, the Internet, and Intellectual Property
September 14, 2006

H.R. 5120
A bill to amend title 35 of the United States Code, to conform certain filing provisions within the Patent and Trademark Office

or

"The Dog Ate my Homework Act"

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Mr. Chairman, members of the subcommittee, thank you for having this hearing to discuss H.R. 5120 and allowing me to submit testimony on behalf of the more than 1.2 million members and supporters of Citizens Against Government Waste (CAGW). We hope that this hearing will shed light on what we believe is an irresponsible attempt to change U.S. patent law and throw a cog into the wheel of the landmark Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, that governs the approval process for generic drugs. Hatch-Waxman seeks to balance two important but highly competitive goals: provide quick market access for generic manufacturers and encourage brand-name drug manufacturers to incur the high cost of drug research by providing patent term restoration to compensate for the Food and Drug Administration (FDA) regulatory review time.

CAGW was created in 1984 By J. Peter Grace and Jack Anderson after Mr. Grace presented to President Ronald Reagan the 2,478 findings and recommendations of the Grace Commission (formally known as the President's Private Sector Survey on Cost Control). If all of the Grace Commission's recommendations had been implemented, it would have saved $424.4 billion over three years. In fact, savings from Grace Commission and other CAGW-proposed recommendations have saved $825 billion over 22 years.

CAGW is classified as a Section 501(c)(3) organization under the Internal Revenue Code of 1954, has not received any federal money, and does not plan to receive any federal funds in the future.

H.R. 5120 has no specific title, but should be called, "The Dog Ate My Homework Act." Simply put, this legislation will allow the Director of the U.S. Patent and Trademark Office (PTO) to accept an application for an extension of the term of a patent if an application is filed no more than 5 days late and if the applicant files a petition showing that the delay in filing the application was unintentional. If no attention had been paid to this legislation, it might have been added to an appropriations bill in the dead of night. There would have been no hearing or analysis of how it would drastically change current drug approval law. We therefore appreciate the effort being made to address this matter in an open hearing.

As you know, The Medicines Company acquired the anti-coagulant drug Angiomax from Biogen in 1997, received their New Drug Application (NDA) from the FDA on December 15, 2000, and began to sell the drug in January 2001. The company filed for a patent extension until December 15, 2014. Current patent law states that a company has 60 days from the day of NDA approval to file a patent term extension. That day came and went on February 13, 2001. Unfortunately for The Medicines Company,

their representative waited until they thought was the last minute to file this simple application. By filing the extension on February 14, 2001, The Medicines Company missed the statutory deadline. The PTO said precisely this in a letter to the company, dated March 4, 2002: "The NDA was approved on December 15, 2000, which makes the submission of the patent term extension application on February 14, 2001, untimely within the meaning of 35 U.S.C. 156(d)(1)..."

CAGW is concerned that the PTO has left this matter pending for several years in order to provide The Medicines Company with the opportunity to explore avenues to extend the term of its patent. According to patent lawyers with whom we have spoken, this is unusual. CAGW is also concerned that the PTO is under pressure to keep this application open, possibly anticipating that H.R. 5120 will be enacted.

H.R. 5120 is special interest legislation at its worst. It would allow the Director of the PTO to accept an application for an extension of the term of a patent if an application is filed no more than 5 days late, if the applicant files a petition showing that the delay in filing the application was unintentional. Why? Because one company missed a statutory deadline that has existed since 1984. As it states in H.R. 5120, it would apply to any application that, "is pending on the date of enactment, is the subject of a request for reconsideration of a denial of a patent extension, or has been denied a patent term extension in a case in which the period for seeking reconsideration of such denial has not yet expired." The PTO admits as much when it states in its letter to the Subcommittee on Courts, the Internet, and Intellectual Property that, "We are aware of one current application for patent term extension that would immediately benefit from enactment of the bill."

Of further concern is the legislative language that states, "if the applicant files a petition showing, to the satisfaction of the Director, that the delay in filing the application was unintentional." How does one prove that a delay was "unintentional?" Talk about opening up a can of worms and prompting numerous lawsuits! At best, the phrase exposes PTO to all sorts of political shenanigans and lobbying pressure. At worse, it is an automatic 5-day extension on patent term extension applications. It is far better to have certainty on patent extension applications. The current statute provides that certainty without burdening the public with additional patent extensions – extensions that delay generic competition.

As CAGW stated in a June 19 letter to the Judiciary Committee, timelines written into laws have meaning. Furthermore, how likely is it that a company that has its product regulated under the Food, Drug, and Cosmetic Act will miss this kind of important deadline? Again, the PTO provides insight. Of the 700 applications for patent term

extensions filed since 1984, when Hatch-Waxman was enacted, only three other applications were not granted due, at least in part, to timeliness issues. That is 0.4 percent of total applications. Surely this doesn't warrant legislation that will provide a window to cover delays in patent extension filings. In other words, making a law to cover an exception benefits the one to the detriment of the many who have complied with the regulatory deadlines.

CAGW understands and appreciates the importance of patents, property rights and the role research pharmaceutical companies play in our nation's health and economy. We have long fought against legislation that jeopardizes the vital work pharmaceutical companies do, such as price controls and the re-importation of prescription drugs.

But CAGW also appreciates the vital role that the generic industry plays in health care. Generics encourage competition and lower the price of pharmaceuticals for all Americans.

The bottom line is H.R. 5120 gives an unfair advantage to one company and dramatically changes patent law. It is in fact private relief legislation disguised as public law.

CAGW believes any changes to Hatch-Waxman and patent exclusivity deserve close examination. We appreciate this hearing, but other committees need to review this legislation before it goes forward, such as the House Energy and Commerce Committee, and it deserves a full review in the appropriate Senate committees.

Neither Congress, nor taxpayers and consumers, should be used to cover-up and correct any company's errors. H.R. 5120 sets a dangerous precedent and it should not become law.

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