TESTIMONY OF
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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.