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."
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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.

Biography

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

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

Jay Thomas is a member of the faculty of the Georgetown University Law Center. He has served as a law clerk to Chief Judge Helen W. Nies of the Court of Appeals for the Federal Circuit, visiting fellow at the Max Planck Institute in Munich, Germany, and visiting researcher at the Institute of Intellectual Property in Tokyo, Japan. Professor Thomas has also served as a member of the visiting faculty at the Cornell Law School and the University of Tokyo, a member of the faculty of the George Washington University Law School, and an instructor at the USPTO Patent Academy.

Professor Thomas holds a B.S. in computer engineering from Carnegie Mellon, a J.D. *magna cum laude* from the University of Michigan Law School, and an LL.M. with highest honors from the George Washington University Law School. He is admitted to the Maryland state bar and to the patent bar. In his capacity as visiting researcher at the Congressional Research Service, he has authored or co-authored over twenty CRS reports concerning the patent law. He recently published his fifth book concerning intellectual property, the one-volume treatise *Pharmaceutical Patent Law*.