

## Patent and Trademark Office

### Notice of Hearing and Request for Comments on Changes to a Twenty-Year Patent Term and Its Effects on Patent Expiration Dates and Patent Term Extensions

**AGENCY:** Patent and Trademark Office, Commerce.

**ACTION:** Notice of public hearing and request for comments.

**SUMMARY:** In a Notice published on December 21, 1994 [59 FR 63951], the Patent and Trademark Office ("PTO") announced a public hearing on proposed changes related to the 20-year patent term contained in the Uruguay Round Agreements Act ("URAA"), Pub. L. 103-465.

Concurrently with the hearing scheduled for February 16, 1995, PTO also seeks comments on several additional issues that are relevant to the Food and Drug Administration's interpretation and application of current provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations in light of the changes to title 35, United States Code, effected by passage of the URAA. The specific provisions of the FDCA that would be affected govern the submission of patent information related to new drug applications ("NDAs") and the submission and approval of abbreviated new drug applications ("ANDAs") for generic equivalents of listed drugs in anticipation of the expiration of patent protection for the listed drugs. (See 21 U.S.C. 321; 21 CFR part 314, subparts C and D.) Similarly affected may be FDCA provisions related to the submission of new animal drug applications ("NADAs") and the submission and approval of abbreviated new animal drug applications ("ANADAs"). (See 21 U.S.C. 360b). Because the changes to title 35 may affect the effective date of ANDA and ANADA approval under the FDCA and are relevant to the issues that will be discussed at the public hearing to be held on February 16, 1995, PTO will set aside a portion of the meeting to address these issues.

In addition, PTO seeks comments on the URAA's effect on existing patent term extensions under 35 U.S.C. 156.

**DATES:** The public hearing will be held on February 16, 1995, at 9:30 a.m. in the Commissioner's Conference Room 912, Crystal Park 2, 2121 Crystal Drive, Arlington, Virginia. Oral testimony on issues addressed in this notice will begin at 1:00 p.m. Requests to present oral testimony should be received on or before February 14, 1995. Written

comments must be submitted on or before February 17, 1995.

**ADDRESSES:** Address written comments and requests to present oral testimony to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, Attention: Stephen G. Kunin, Deputy Assistant Commissioner for Patent Policy and Projects, Crystal Park 2, Suite 919, or by fax to (703) 305-8825. Persons with comments on the issues raised in this notice should also forward copies of those comments to the Food and Drug Administration, Attention: Dockets Management Branch (HFA-305), Room 1-23, 12420 Parklawn Dr., Rockville, MD 20857, identified with docket number 95N-0005.

**FOR FURTHER INFORMATION CONTACT:** H. Dieter Hoinkes by telephone at (703) 305-9300, by fax at (703) 305-8885, through electronic mail to hoinkes@uspto.gov, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231. Persons may also contact Brain Malkin by Phone at (301) 443-1382, by fax at (301) 443-0232 or by mail marked to his attention and addressed to the Food and Drug Administration, Office of Health Affairs, HFY-20, 5600 Fishers Lane, Rockville, MD 20857.

#### SUPPLEMENTARY INFORMATION:

#### I. The Effect of URAA on the FDCA's ANDA Approval Process

##### *Background*

As described in detail in the Federal Register notice published on December 12, 1994, the URAA was signed into law on December 8, 1994 (Pub. L. 103-465). The amendments to title 35, United States Code, in the URAA that relate to patent terms will become effective June 8, 1995. Certain provisions of the URAA patent amendments will change the term of existing patents from 17 years from the date of patent grant to 20 years from the date of filing of the patent application. If the patent application contains a specific reference to an earlier application under 35 U.S.C. 120, 121 or 365(c), the patent term will end 20 years from the date on which the earliest application relied on was filed. Patents that are in force on, or applied for by, June 8, 1995, will be entitled to the longer of 17 years from the date of the grant of the patent, or 20 years from the date of filing of the application. In addition, the URAA patent amendments provide for the extension of patents (up to a maximum of five years) in certain specified instances where there was delay in the issuance of the patent. This extension is separate from, and in

addition to, the patent term extension available under 35 U.S.C. 156.

Section 532(c)(2) of the URAA patent amendments also limits the remedies available to a patent holder for patent infringement under certain circumstances. Specifically, a patent holder may not obtain an injunction or monetary damages, currently provided under title 35, for "acts which (A) were commenced or for which substantial investment was made before [June 8, 1995] and (B) became infringing by reason of [any amendment to a patent term resulting from the new 20-year provision]." Instead, the patent holder may only collect an "equitable remuneration" under such circumstances.

These amendments to title 35 may affect the drug approval process. Under the FDCA, pharmaceutical companies seeking to market pioneer drugs must first obtain FDA approval through the filing of an NDA (see, 21 U.S.C. 355(a) and (b)). In addition to data demonstrating the safety and effectiveness of the drug, an NDA applicant is required to submit to FDA information on any patent which claims the drug or a method of using such drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party (see, 21 U.S.C. 355(b)(1) and (c)(2)). The patent information must include the patent number and date of expiration. FDA publishes this required information in its official publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book").

Under section 505(j)(2)(A)(vii) of the FDCA (21 U.S.C. 355(j)(2)(A)(vii)), an ANDA must include a certification, in the opinion of the applicant and to the best of the applicant's knowledge with respect to each patent which claims the listed drug, (I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. In addition, an ANDA applicant, who certifies that a patent is either invalid or will not be infringed, must provide notice of this filing to each owner of the patent as well as to the holder of the approved NDA for the listed drug which is claimed by the patent (see 21 U.S.C. 355(j)(2)(B)(i)). This notice must contain a statement of the legal and factual grounds that support the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed

(see 21 U.S.C. 355(j)(2)(B)(ii); 21 CFR 314.52(c)(6)).

Under the FDCA, an ANDA approval shall be made effective on the date certified by the ANDA applicant to be the date on which a patent expires (see 21 U.S.C. 355(j)(4)(B)(ii)), or immediately if certified by the ANDA applicant (1) that patent information has not been filed or that the patent has expired (see 21 U.S.C. 355(j)(4)(B)(i)); or (2) that the patent is invalid or will not be infringed, unless an action is brought within 45 days after the ANDA applicant gives notice to the patent holder under section 505(j)(2)(B)(i) of the FDCA (see 21 U.S.C. 355(j)(4)(B)(iii)).

The FDCA and implementing regulations provide no other mechanism by which to stay the effective date of an ANDA approval.

Under the FDCA, similar provisions apply to NADAs and ANADAs. Upon the approval of an NADA, FDA publishes required NADA patent information in its official publication, *FDA Approved Animal Drug Products* (referred to as the "Greek Book"). (See 21 U.S.C. 360b(b)(1)). ANADAs are subject to patent certification requirements (see 21 U.S.C. 360b(n)(1)(H)) and to approval effective dates (see 21 U.S.C. 360b(c)(2)(D)), similar to the ANDA provisions described above. The effective approval date of an ANADA, similar to an ANDA, is stayed only if an action is brought within 45 days after the ANADA applicant gives notice to the patent holder under 21 U.S.C. 360(n)(2)(B)(i), that the patent is not valid or will not be infringed. The FDCA provides no other mechanism by which to stay the effective date of an ANADA.

#### *Issues Upon Which Comments Are Sought*

Comments are requested regarding the effect of the URAA patent amendments upon the filing and approval of ANDAs and ANADAs. Specifically, comments are requested on the following questions:

1. Should FDA revised the patent term expiration dates currently listed in the Orange Book and Green Book for those patents entitled to a longer term under the URAA, because they are in force on June 8, 1995?

2. Should PTO, at the request of NDA or NADA holders, certify (or alternatively, verify) new patent expiration dates under the URAA for patents currently listed in the Orange Book and the Green Book?

3. Should NDA and NADA holders be required to submit to FDA revised patent expiration dates for those patents

currently listed in the Orange Book and Green Book that will have a longer term under URAA? If so, should such submissions be required to be made (1) by June 8, 1995, (2) only after PTO certifies or verifies the claimed patent term expiration date, or (3) within some other specified time period?

4. If revised patent term expiration dates are published in the Orange Book and the Green Book, then if PTO does not certify or verify the patent term expiration date identified by the NDA or NADA holder, what submission, if any, should FDA require to verify the date? Should FDA publish the revised patent term expiration date submitted by the NDA or NADA holder without verification?

5. If revised patent term expiration dates are published in the Orange Book and the Green Book, what revisions to patent certifications, if any should applicants with pending ANDAs or ANADAs be required to make? When should such revisions to patent certifications be made? What type of information related to substantial investment, if any, should ANDA and ANADA applicants be required to make with such revisions?

#### **II. The Effect of URAA on Existing Patent Term Extensions Under 35 U.S.C. 156**

Under 35 U.S.C. 156, patent term extensions are issued for eligible patents from the original expiration date of the patent. Since this provision was enacted in 1984, the PTO has issued 195 certificates of patent term extension in accordance with section 156. Under the URAA, patents in force on June 8, 1995, are entitled to a patent term of 17 years from grant or 20 years from filing, whichever is longer. The PTO estimates that 93 patents whose terms were extended under section 156 would be entitled to such longer patent term. The PTO has assumed, for the purpose of evaluating the number of extending patents that may be affected by the 20-year patent term, that a patent that would have expired (under the original 17-year patent term) before June 8, 1995, but has received a patent term extension for a period beyond June 8, 1995 (with the rights prescribed in 35 U.S.C. 156(b)), is a patent "in force" on June 8, 1995.

There are several ways to interpret the provision of the URAA that grants the longer of a 17 or 20-year patent term to patents in force on June 8, 1995, and that have been or will be extended under section 156. First, the extension already issued by the PTO could simply be added to the longer of the 17 or 20-year patent term. No action would be

required by the PTO. Second the extension already issued by the PTO could be interpreted to operate from "the original expiration date of the patent" (35 U.S.C. 156(a)), which could be interpreted as the expiration date of the 17-year patent term. Again, no action would be required by the PTO. A third interpretation could be that the appropriate extension under section 156 would be added to the longer of the 17 or 20-year patent term. This third interpretation would require the PTO to revise the extension granted in some cases as the 14-year limitation of a patent term counted from the date of market approval (35 U.S.C. 156(c)(3)) would be applicable to the extended patent term regardless of whether the original expiration date of the patent was 17 years from grant or 20 years from the filing date. The PTO seeks comments from the public on the appropriate course of action with respect to patents that have been or will be issued term extensions under section 156 of title 35, United States Code.

#### *Questions*

1. Should PTO take any action with respect to existing patent term extensions under section 156?

2. What approach should PTO take with respect to the calculation of new patent term extensions under section 156 where the patent is entitled to the longer of the 17 or 20-year patent term under the URAA?

Comments on any other issues relevant to the relationship between the URAA and the FDCA or existing patent term extensions under 35 U.S.C. 156 are also invited.

Dated: January 11, 1995.

**Michael K. Kirk,**

*Deputy Assistant Secretary of Commerce and Deputy Commissioner of Patents and Trademarks.*

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#### **COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS**

##### **Adjustment of Import Limits for Certain Wool Textile Products Produced or Manufactured in the Slovak Republic; Correction**

January 10, 1995.

The letter to the Commissioner of Customs published in the **Federal Register** on December 16, 1994 (59 FR 65019) should be corrected as follows:

1. In column 2, paragraph 1, line 3, change "June 10, 1993" to read "June 7, 1994."