

**§ 803.55 If I am a manufacturer, in what circumstances must I submit a baseline report, and what are the requirements for such a report?**

(a) You must submit a baseline report for a device when you submit the first report under § 803.50 involving that device model. Submit this report on FDA Form 3417 or an electronic equivalent approved under § 803.14.

(b) You must update each baseline report annually on the anniversary month of the initial submission, after the initial baseline report is submitted. Report changes to baseline information in the manner described in § 803.56 (i.e., include only the new, changed, or corrected information in the appropriate portion(s) of the report form). In each baseline report, you must include the following information:

(1) Name, complete address, and establishment registration number of your reporting site. If your reporting site is not registered under part 807, we will assign a temporary number for use in MDR reporting until you register your reporting site in accordance with part 807. We will inform you of the temporary MDR reporting number;

(2) FDA registration number of each site where you manufacture the device;

(3) Name, complete address, and telephone number of the individual who you have designated as your MDR contact, and the date of the report. For foreign manufacturers, we require a confirmation that the individual submitting the report is the agent of the manufacturer designated under § 803.58(a);

(4) Product identification, including device family, brand name, generic name, model number, catalog number, product code, and any other product identification number or designation;

(5) Identification of any device that you previously reported in a baseline report that is substantially similar (e.g., same device with a different model number, or same device except for cosmetic differences in color or shape) to the device being reported. This includes additional identification of the previously reported device by model number, catalog number, or other product identification, and the date of the baseline report for the previously reported device;

(6) Basis for marketing, including your 510(k) premarket notification number or PMA number, if applicable, and whether the device is currently the subject of an approved postmarket study under section 522 of the act;

(7) Date that you initially marketed the device and, if applicable, the date on which you stopped marketing the device;

(8) Shelf life of the device, if applicable, and expected life of the device;

(9) The number of devices manufactured and distributed in the last 12 months and an estimate of the number of devices in current use; and

(10) Brief description of any methods that you used to estimate the number of devices distributed and the number of devices in current use. If this information was provided in a previous baseline report, in lieu of resubmitting the information, it may be referenced by providing the date and product identification for the previous baseline report.

**§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?**

If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to us within 1 month of the day that you receive this information. On a supplemental or followup report, you must:

(a) Indicate on the envelope and in the report that the report being submitted is a supplemental or followup report. If you are using FDA form 3500A, indicate this in Block Item H-2;

(b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (e.g., your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and

(c) Include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s) for reports that cross reference previous reports.

**§ 803.58 Foreign manufacturers.**

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50;

(3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(4) Maintain complaint files in accordance with § 803.18; and

(5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

Dated: February 17, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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BILLING CODE 4160-01-S

**DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**37 CFR Part 1**

[Docket No.: 2005-P-055]

RIN 0651-AB87

**Changes to the Practice for Handling Patent Applications Filed Without the Appropriate Fees**

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** Among other changes to patent and trademark fees, the Consolidated Appropriations Act, 2005 (Consolidated Appropriations Act), splits the patent application filing fee into a separate filing fee, search fee and examination fee, and requires an additional fee (application size fee) for applications whose specification and drawings exceed 100 sheets of paper, during fiscal years 2005 and 2006. The United States Patent and Trademark Office is in this notice proposing changes in the Office's practice for handling patent applications filed without the appropriate filing, search, and examination fees. The Office has implemented the changes to the patent fees provided in the Consolidated Appropriations Act in a separate rulemaking.

**DATES:** *Comment Deadline Date:* To be ensured of consideration, written comments must be received on or before March 30, 2005. No public hearing will be held.

**ADDRESSES:** Comments should be sent by electronic mail message over the Internet addressed to [AB69Comments@uspto.gov](mailto:AB69Comments@uspto.gov). Comments may also be submitted by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, or by facsimile to (571) 273–7735, marked to the attention of Robert W. Bahr. Although comments may be submitted by mail or facsimile, the Office prefers to receive comments via the Internet. If comments are submitted by mail, the Office prefers that the comments be submitted on a DOS formatted 3½ inch disk accompanied by a paper copy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (<http://www.regulations.gov>) for additional instructions on providing comments via the Federal eRulemaking Portal.

The comments will be available for public inspection at the Office of the Commissioner for Patents, located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia, and will be available via the Office Internet Web site (address: <http://www.uspto.gov>). Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

**FOR FURTHER INFORMATION CONTACT:**

Robert W. Bahr, Senior Patent Attorney, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–8800, by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, or by facsimile to (571) 273–7735, marked to the attention of Robert W. Bahr.

**SUPPLEMENTARY INFORMATION:** Among other changes, the Consolidated Appropriations Act (section 801 of Division B) provides that 35 U.S.C. 41(a), (b), and (d) shall be administered in a manner that revises patent application fees (35 U.S.C. 41(a)) and patent maintenance fees (35 U.S.C. 41(b)), and provides for a separate filing fee (35 U.S.C. 41(a)), search fee (35 U.S.C. 41(d)(1)), and examination fee (35 U.S.C. 41(a)(3)) during fiscal years 2005 and 2006. The Consolidated Appropriations Act also provides that the provisions of 35 U.S.C. 111(a) for payment of the fee for filing the application apply to the payment of the examination fee (35 U.S.C. 41(a)(3)) and search fee (35 U.S.C. 41(d)(1)) in an

application filed under 35 U.S.C. 111(a), and that the provisions of 35 U.S.C. 371(d) for the payment of the national fee apply to the payment of the examination fee (35 U.S.C. 41(a)(3)) and search fee (35 U.S.C. 41(d)(1)) in an international application filed under the Patent Cooperation Treaty (PCT) and entering the national stage under 35 U.S.C. 371. See 35 U.S.C. 41(a)(3) and 41(d)(1)(C). Thus, the examination fee and search fee are due on filing in an application filed under 35 U.S.C. 111(a) or on commencement of the national stage in a PCT international application, but may be paid at a later time if paid within such period and under such conditions (including payment of a surcharge) as may be prescribed by the Director. See H.R. Rep. 108–241, at 16 (2003) (H.R. Rep. 108–241 contains an analysis and discussion of an identical provision in H.R. 1561, 108th Cong. (2004)).

In view of the revised patent fee structure during fiscal years 2005 and 2006 set forth in the Consolidated Appropriations Act, the Office is proposing the following changes in Office practice for handling patent applications filed without the appropriate fees: That is, the filing fee, search fee, and examination fee.

The Office is proposing to: (1) Require the surcharge under § 1.16(f) in any application filed under 35 U.S.C. 111(a) in which the search fee or examination fee is paid on a date later than the filing date; and (2) require the surcharge under § 1.492(h) in any application filed under the PCT in which the search fee or examination fee is paid on a date later than thirty months from the priority date. This change is because the Consolidated Appropriations Act splits the former patent application filing (or national) fee into a separate filing (or national) fee, search fee and examination fee during fiscal years 2005 and 2006. The filing of an application which lacks any of the basic filing (or national) fee, the search fee, the examination fee, or oath or declaration requires the Office to issue a notice to file the missing parts (or requirements) of the application.

The Office is also proposing to eliminate the processing and retention fee (§ 1.21(l)) practice. The processing and retention fee practice permits an applicant to file an application without the basic filing fee (which formerly covered the cost of the initial processing of an application and part of the cost of the search and examination of an application) and pay only the processing and retention fee set forth in § 1.21(l) in order for the application to be used as a basis for foreign filing and

benefit claims under 35 U.S.C. 120 and § 1.78(a). Under the revised patent fee structure set forth in the Consolidated Appropriations Act, the basic filing fee covers only the cost of the initial processing of an application. Thus, the Office is proposing to require payment of the basic filing fee (rather than just the current processing and retention fee set forth in § 1.21(l)) to retain the application. Since the Office must retain an application to permit benefit of the application to be claimed under 35 U.S.C. 120 and § 1.78 in a subsequent nonprovisional or international application, the Office is also proposing to require payment of the basic filing fee (rather than just the current processing and retention fee set forth in § 1.21(l)) to permit benefit of the application to be claimed under 35 U.S.C. 120 and § 1.78 in a subsequent nonprovisional or international application.

The Office is also implementing the provision in 35 U.S.C. 41(a)(1)(G) for the Office to prescribe the paper size equivalent of an application filed in whole or in part in an electronic medium for purposes of the application size fee specified in 35 U.S.C. 41(a)(1)(G) (§ 1.16(s) and § 1.492(j)). A 21.6 cm by 27.9 cm (8½ by 11 inches) sheet of paper with a top margin of 2.0 cm (¾ inch), a left side margin of 2.5 cm (1 inch), a right side margin of 2.0 cm (¾ inch), and a bottom margin of 2.0 cm (¾ inch), will contain about 30 lines of double-spaced text, with each line having about 50 to 65 characters. An ASCII text (the only format permitted by § 1.52(e)) document containing 30 lines of text, each line having about 50 to 65 characters, will be slightly less than two kilobytes in size. Therefore, the Office is proposing that each two kilobytes of content submitted on an electronic medium shall be counted as a sheet of paper for purposes of the application size fee specified in 35 U.S.C. 41(a)(1)(G) (§ 1.16(s) and § 1.492(j)).

### Discussion of Specific Rules

Title 37 of the Code of Federal Regulations, Part 1, is proposed to be amended as follows:

*Section 1.16:* Section 1.16(f) is proposed to be amended to require a surcharge if any of the basic filing fee, the search fee, the examination fee, or oath or declaration is filed in a nonprovisional application on a date later than the filing date of the application. Section 1.16(s) is proposed to be amended to include a cross reference to § 1.52(f).

*Section 1.21:* Section 1.21 is proposed to be amended to remove and reserve paragraph (l), which set forth the fee for

processing and retaining an application in which the basic filing fee has not been paid.

*Section 1.52:* Section 1.52(f)(1) is proposed to be amended to provide that for purposes of determining the application size fee required by § 1.16(s) or § 1.492(j), for an application the specification and drawings of which (excluding any sequence listing in compliance with § 1.821(c) or (e), and any computer program listing filed in an electronic medium in compliance with §§ 1.52(e) and 1.96) are submitted in whole or in part on an electronic medium other than the Office electronic filing system, each two kilobytes of content submitted on an electronic medium shall be counted as a sheet of paper.

*Section 1.53:* Section 1.53(f)(5) is proposed to be amended to provide that if the applicant does not pay the basic filing fee during the pendency of the application, the Office may dispose of the application.

*Section 1.78:* Section 1.78(a)(1) is proposed to be amended to provide that to claim the benefit of a prior-filed nonprovisional application under 35 U.S.C. 120 and § 1.78(a) in a subsequent nonprovisional or international application, the prior-filed nonprovisional application must be entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and have paid therein the basic filing fee set forth in § 1.16 within the pendency of the application.

*Section 1.492:* Section 1.492(h) is proposed to be amended to require a surcharge if any of the search fee, the examination fee, or the oath or declaration is filed later than thirty months from the priority date. Section 1.492(j) is proposed to be amended to include a cross reference to § 1.52(f).

### Rulemaking Considerations

*Administrative Procedure Act:* The changes proposed in this notice relate solely to the procedures to be followed in prosecuting a patent application: *i.e.*, the procedures for paying the fees due upon filing an application for patent. This notice does not propose any change to the amount of fees charged by the Office. Specifically, the changes proposed in this notice concern the procedures for payment of the filing fee, search fee, and examination fee, and setting forth which fees must be paid in order for a nonprovisional application to be processed and retained by the Office such that it may be used as the basis for foreign filing and for benefit claims under 35 U.S.C. 120 and § 1.78(a). Therefore, these rule changes involve interpretive rules, or rules of

agency practice and procedure under 5 U.S.C. 553(b)(A). *See Bachow Communications Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are “rules of agency organization, procedure, or practice” and are exempt from the Administrative Procedure Act’s notice and comment requirement); *see also Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549–50, 38 USPQ2d 1347, 1351 (Fed. Cir. 1996) (the rules of practice promulgated under the authority of former 35 U.S.C. 6(a) (now in 35 U.S.C. 2(b)(2)) are not substantive rules (to which the notice and comment requirements of the Administrative Procedure Act apply)), and *Fressola v. Manbeck*, 36 USPQ2d 1211, 1215 (D.D.C. 1995) (“it is doubtful whether any of the rules formulated to govern patent and trade-mark practice are other than ‘interpretive rules, general statements of policy, \* \* \* procedure, or practice.’”) (quoting C.W. Ooms, *The United States Patent Office and the Administrative Procedure Act*, 38 Trademark Rep. 149, 153 (1948)).

Under the Office’s pre-existing “missing parts” or “missing requirements” practice, an applicant was required to pay a surcharge if the basic filing fee was not present on filing in an application filed under 35 U.S.C. 111 or if the basic national fee was not present on the date of commencement of the national stage of processing in a PCT application entering the national stage under 35 U.S.C. 371. The Consolidated Appropriations Act split the patent application filing (or national) fee into a separate filing (or national) fee, search fee and examination fee. Therefore, the proposed replacement of the basic filing (or national) fee in §§ 1.16 and 1.492 with the basic filing (or national) fee, the search fee, or the examination fee is simply a procedural change that is necessary to maintain (or restore) the *status quo ante* with respect to the Office’s pre-existing “missing parts” or “missing requirements” practice.

The processing and retention fee practice allows applicants to file an application without the filing fee and to pay only a processing and retention fee in order for the application to be used as a basis for foreign filing and for priority under 35 U.S.C. 120. Under the revised patent fee structure set forth in the Consolidated Appropriations Act (which split the filing fee into a separate filing, search fee and examination fee), the filing fee covers the cost of the initial processing and retention of an application. Thus, requiring payment of the basic filing fee under the Consolidated Appropriations Act in order for an application to be used as a

basis for foreign filing and for priority under 35 U.S.C. 120 is more compatible with the filing fee scheme set forth in the Consolidated Appropriations Act than is continuing the processing and retention fee practice.

The Consolidated Appropriations Act provides for the Office to prescribe the paper size equivalent of an application filed in whole or in part in an electronic medium for purposes of the application size fee specified in 35 U.S.C. 41(a)(1)(G). Thus, setting a paper size equivalent based upon the number of kilobytes of content that can fit onto a sheet of paper (given the current requirements for applications filed in part on CD and for paper size and margins) simply sets forth the procedures for determining the paper size equivalent of an application filed in whole or in part in an electronic medium for purposes of the application size fee.

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law). Nevertheless, the Office is providing this opportunity for public comment on the changes proposed in this notice because the Office desires the benefit of public comment on these proposed changes.

*Regulatory Flexibility Act:* As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law), an initial regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is not required. *See* 5 U.S.C. 603.

*Executive Order 13132:* This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

*Executive Order 12866:* This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

*Paperwork Reduction Act:* This notice involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information involved in this notice have been reviewed and previously approved by OMB under OMB control numbers: 0651–0021, 0651–0031, and 0651–0032. The United States Patent and Trademark Office is not resubmitting any information collection package to OMB for its review and approval because the changes in this notice do not affect the information collection requirements associated with the information collection under these OMB control

numbers. The changes proposed in this notice concern the procedures for payment of the filing fee, search fee, examination fee, and the application size fee, including setting forth which fees must be paid in order for an application to be processed and retained by the Office such that it may be used as the basis for foreign filing and for benefit claims under 35 U.S.C. 120 and § 1.78(a).

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Robert J. Spar, Director, Office of Patent Legal Administration, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Patent and Trademark Office.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

**List of Subjects in 37 CFR Part 1**

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, 37 CFR part 1 is proposed to be amended as follows:

**PART 1—RULES OF PRACTICE IN PATENT CASES**

1. The authority citation for 37 CFR part 1 continues to read as follows:

**Authority:** 35 U.S.C. 2(b)(2).

2. Section 1.16 is amended by revising paragraphs (f) and (s) to read as follows:

**§ 1.16 National application filing, search, and examination fees.**

\* \* \* \* \*

(f) Surcharge for filing any of the basic filing fee, the search fee, the examination fee, or oath or declaration on a date later than the filing date of the application, except provisional applications:

By a small entity (§ 1.27(a))—\$65.00  
By other than a small entity—\$130.00

\* \* \* \* \*

(s) Application size fee for any application under 35 U.S.C. 111 filed on

or after December 8, 2004, the specification and drawings of which exceed 100 sheets of paper, for each additional 50 sheets or fraction thereof (see § 1.52(f) for applications submitted in whole or in part on an electronic medium):

By a small entity (§ 1.27(a))—\$125.00  
By other than a small entity—\$250.00

\* \* \* \* \*

3. Section 1.21 is amended by removing and reserving paragraph (l):

**§ 1.21 Miscellaneous fees and charges.**

\* \* \* \* \*

(l) [Reserved]

\* \* \* \* \*

4. Section 1.52 is amended by revising paragraph (f)(1) to read as follows:

**§ 1.52 Language, paper, writing, margins, compact disc specifications.**

\* \* \* \* \*

(f)(1) Any sequence listing in an electronic medium in compliance with §§ 1.52(e) and 1.821(c) or (e), and any computer program listing filed in an electronic medium in compliance with §§ 1.52(e) and 1.96, will be excluded when determining the application size fee required by § 1.16(s) or § 1.492(j). For purposes of determining the application size fee required by § 1.16(s) or § 1.492(j), for an application the specification and drawings of which, excluding any sequence listing in compliance with § 1.821(c) or (e), and any computer program listing filed in an electronic medium in compliance with §§ 1.52(e) and 1.96, are submitted in whole or in part on an electronic medium other than the Office electronic filing system, each two kilobytes of content submitted on an electronic medium shall be counted as a sheet of paper.

\* \* \* \* \*

5. Section 1.53 is amended by revising paragraph (f)(5) to read as follows:

**§ 1.53 Application number, filing date, and completion of application.**

\* \* \* \* \*

(f) \* \* \*

(5) If applicant does not pay the basic filing fee during the pendency of the application, the Office may dispose of the application.

\* \* \* \* \*

6. Section 1.78 is amended by removing paragraph (a)(1)(iii) and revising paragraph (a)(1)(ii) to read as follows:

**§ 1.78 Claiming benefit of earlier filing date and cross references to other applications.**

(a)(1) \* \* \*

(ii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and have paid

therein the basic filing fee set forth in § 1.16 within the pendency of the application.

\* \* \* \* \*

7. Section 1.492 is amended by revising paragraphs (h) and (j) to read as follows:

**§ 1.492 National stage fees.**

\* \* \* \* \*

(h) Surcharge for filing any of the search fee, the examination fee, or the oath or declaration later than thirty months from the priority date pursuant to § 1.495(c):

By a small entity (§ 1.27(a))—\$65.00  
By other than a small entity—\$130.00

\* \* \* \* \*

(j) Application size fee for any international application for which the basic national fee was not paid before December 8, 2004, the specification and drawings of which exceed 100 sheets of paper, for each additional 50 sheets or fraction thereof (see § 1.52(f) for applications submitted in whole or in part on an electronic medium):

By a small entity (§ 1.27(a))—\$125.00  
By other than a small entity—\$250.00

Dated: February 22, 2005.

**Jon W. Dudas,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 05-3743 Filed 2-25-05; 8:45 am]

**BILLING CODE 3510-16-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[R05-OAR-2004-IN-0007; FRL-7875-4]

**Approval and Promulgation of Air Quality Implementation Plans; Indiana**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The EPA is proposing to approve revisions to the particulate matter (PM) and sulfur dioxide (SO<sub>2</sub>) emission requirements for Pfizer, Inc. (Pfizer). Pfizer operates a medicinal chemical manufacturing facility in Vigo County, Indiana. On October 7, 2004, Indiana submitted a request for PM and SO<sub>2</sub> emission limit revisions as an amendment to its State Implementation Plan (SIP). Pfizer has removed five boilers from its facility. Indiana has requested the deletion of the site-specific PM and SO<sub>2</sub> emission limits for all five removed boilers. A new boiler has replaced three of the removed boilers. It is subject to the applicable