multiple employer plan who, for a salary related plan formula, is one of the ten largest contributing sponsors based on required contributions for the plan year ending within the contributing sponsor's information year, or, for an hourly plan formula, is one of the ten largest contributing sponsors based on number of participants for the plan year ending within the contributing sponsor's information years (using the census data as determined under § 4010.8(d)(1)).

(2) *Information year.* For purposes of this paragraph (d) (including determining when a filing is due), if any two contributing sponsors report financial information on the basis of different fiscal years, the information year shall be the calendar year.

(e) *Terminated plans.* A plan may be excluded for purposes of §§ 4010.4(a)(1) and (3), 4010.8, and 4010.11(a) and (d), if, on or before the last day of the information year, all of the assets (excluding excess assets) have been distributed pursuant to a standard termination under Subpart B of part 4041 of this chapter.

§ 4010.12 [Amended]

13. Section 4010.12 is amended by removing the words ''section 4010(c) of ERISA'' and adding in their place the words ''ERISA section 4010(c)''; and by removing the words ''the PBGC'' and adding in their place the word ''PBGC''.

§ 4010.13 [Amended]

14. Section 4010.13 is amended by removing the words ''section 4071 of ERISA'' and adding in their place the words ''ERISA section 4071''; and by removing the words ''the PBGC'' where they appear twice and adding in their place each time the word ''PBGC''.

Issued in Washington, DC, this 14th day of February, 2008.

Charles E.F. Millard,

Director, Pension Benefit Guaranty Corporation.

[FR Doc. E8–3124 Filed 2–19–08; 8:45 am]

BILLING CODE 7709–01–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No.: PTO–P–2005–0027]

RIN 0651–AB99

Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes changes to the rules of practice to require that any deposit of biological material be made before publication of a patent application, and that all restrictions on access to the deposited material imposed by the depositor be removed upon publication. The proposed changes will provide that the public has access to biological materials referenced in the disclosure of a patent application to the same extent that access to the remainder of the disclosure is available. The public policy basis for allowing access to a referenced item is the same whether the item is another patent application or a deposited biological material.

DATES: To be ensured of consideration, written comments must be received on or before April 21, 2008. No public hearing will be held.

ADDRESSES: Comments should be sent by e-mail addressed to *AB99.Comments@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) 273–7754, marked to the attention of Kathleen Kahler Fonda. 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 e-mail 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: Kathleen Kahler Fonda, Legal Advisor, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–7754; by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313–1450; or by facsimile to (571) 273–7754, marked to the attention of Kathleen Kahler Fonda.

SUPPLEMENTARY INFORMATION: Under 35 U.S.C. 112, first paragraph, the disclosure of a patent application must contain a written description that enables a person skilled in the art to make and use the claimed invention. The Supreme Court has consistently recognized that, in exchange for the rights associated with a patent grant, an inventor must disclose his invention in such a manner that would allow the public to make and use it without undue experimentation. *See Universal Oil Prods. Co.* v. *Globe Oil & Refining Co.,* 322 U.S. 471, 484, 61 USPQ 382, 388 (1944) (''But the quid pro quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired * * *.''); *Brenner* v. *Manson,* 383 U.S. 519, 534, 148 USPQ 689, 695 (1966) (''The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.''); *J.E.M. AG Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.,* 534 U.S. 124, 142, 60 USPQ2d 1865, 1873 (2001) (''The disclosure required by the Patent Act is 'the quid pro quo of the right to exclude.' '' (quoting *Kewanee Oil Co.* v. *Bicron Corp.,* 416 U.S. 470, 484, 181 USPQ 673, 679 (1974))).

The American Inventors Protection Act of 1999 (AIPA) (Title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948) as introduced in the 106th Congress on November 17, 1999) was incorporated and enacted into law on November 29, 1999, by 1000(a)(9), Division B, of Public Law 106–113, 113 Stat. 1501 (1999). The AIPA provided for publication of patent applications eighteen months after the earliest date for which priority benefit was sought (amending title 35 of the United States Code to add paragraph (b) to section

122). In exchange for this pre-issue public disclosure, the AIPA also provided a provisional right under 35 U.S.C. 154(d) to obtain a reasonable royalty if the invention as claimed in the published patent application is substantially identical to the invention claimed in any patent that might issue therefrom, and certain other conditions are met.

In amending 35 U.S.C. 122, Congress made it clear that only those patent application publications which provide an enabling disclosure of the claimed invention would be entitled to provisional rights under 35 U.S.C. 154(d). Although the AIPA allowed for certain applications to be published in redacted form, any redacted application was nevertheless required to contain a disclosure that would allow a person skilled in the art to make and use the subject matter of the claim. ''The provisions of section 154(d) shall not apply to a claim if the description of the invention published in the redacted application filed under this clause with respect to the claim does not enable a person skilled in the art to make and use the subject matter of the claim.'' 35 U.S.C. 122(b)(2)(B)(v). By allowing for provisional rights only where the patent publication contains an enabling disclosure, Congress again reinforced the notion that exchange for the rights associated with a patent grant an inventor must disclose his invention in such a manner that would allow the public to make and use it without undue experimentation.

When an invention involves biological material, sometimes words and drawings alone cannot sufficiently describe how to make and use it. As a supplement to the printed written description of an invention, courts have sanctioned a procedure in which biological material may be deposited with an appropriate holding facility under conditions which ensure that the sample is properly maintained, and made available to others when appropriate.

For biological inventions, for which providing a description in written form is not practicable, one may nevertheless comply with the written description requirement by publicly depositing the biological material * * *. Such description is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.

Enzo Biochem, Inc. v. *Gen-Probe, Inc.,* 323 F.3d 956, 970, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Internationally, the deposit of biological materials is governed by the Budapest Treaty.

The proposed rule change brings the Office practice regarding biological deposits in line with the publication of patent applications under AIPA. Courts have consistently recognized that an applicant must have provided the Office with an enabling disclosure no later than the time an invention is disclosed to the public. Prior to publication of patent applications under the AIPA, disclosure occurred simultaneously with patent issuance. Thus, earlier court decisions held that deposits needed to be perfected at the time the patent became public, i.e., at the issue date. For example, in *In re Hawkins* the court stated that ''the function of section 112 in ensuring complete public disclosure is only violated if the disclosure is not complete at the time it is made public, i.e., at the issue date.'' *In re Hawkins,* 486 F.2d 569, 574, 179 USPQ 157, 161 (CCPA 1973). In *In re Argoudelis,* the court specifically referred to the regulation concerning conditions for making a patent application public, 37 CFR 1.14, when it stated, ''The cultures are to be made available to the public upon issuance of a United States patent which refers to such deposit and prior to issuance of said patent under the conditions specified in Rule 14.'' *In re Argoudelis,* 434 F.2d 1390, 1393, 168 USPQ 99, 102 (CCPA 1970).

In the era since *Hawkins* and *Argoudelis* were decided, Congress changed the law to require that most patent applications be published eighteen months after filing, and to grant provisional rights under certain conditions. Publication of patent applications under the AIPA means that the patent issue date is no longer ''the time [the patent disclosure] is made public,'' or the time when ''the conditions of Rule 14 are met.'' At least one commentator has stated that a result of the changes brought about by the AIPA is that there is now a requirement for release of a biological deposit at publication. *See* Michelle Henderson, ''International Harmonization Brought about by the American Inventors Protection Act Compels Early Release of the Biological Deposit,'' 42 IDEA: The Journal of Law and Technology 361 (2002).

In a more recent case involving enablement supported by a biological deposit, the Federal Circuit held that ''the availability of a sample to the public after the patent has issued will meet the enablement requirement.'' *In re Lundak,* 773 F.2d 1216, 1223, 227 USPQ 90, 95 (Fed. Cir. 1985). Although on its face *Lundak* might seem to support delaying public access to a deposit until issue, *Lundak* was decided before provisional rights under the AIPA were instituted. Like the decisions in *Argoudelis* and *Hawkins,* the rule established in *Lundak* is superseded by the AIPA.

The Office did not implement a rule change requiring unrestricted access to biological deposits referenced in published patent applications at the time the patent application publication rules were put in place because a report to Congress required by the AIPA was still pending at that time. Section 4805 of the AIPA required that the Comptroller General (in consultation with the Office) conduct a study and submit a report to Congress on the potential risks to the biotechnology industry in the United States relating to release of biological material deposited in support of biotechnology patents, and that the Office consider the recommendations of such study in drafting regulations affecting deposits of biological material (including any modification of § 1.801 *et seq.*). The study required by Section 4805 of the AIPA was completed in October of 2000. *See Deposits of Biological Materials in Support of Certain Patent Applications,* GAO–01–49 (Oct. 2000). This report may be obtained: (1) By mail addressed to the Government Accountability Office, 441 G Street, NW., Washington, DC 20548; (2) by telephone at (202) 512–6000, facsimile at (202) 512–6061, or TDD (202) 512–2537; or (3) via the Government Accountability Office's Internet Web site at *http://www.gao.gov.*

The Office had previously proposed changes to § 1.809 in order to reduce delays after allowance of a patent application. *See Changes to Implement the Patent Business Goals,* 64 FR 53771 (Oct. 4, 1999), 1228 *Off. Gaz. Pat. Office* 15 (Nov. 2, 1999) (proposed rule). The GAO study did not contain any recommendations related to the Office's proposal to amend § 1.809 to revise the time period within which a deposit of biological material (if needed) must be made after allowance of an application. Accordingly, the Office has already amended § 1.809 to provide that the period of time within which the deposit must be made in order to avoid abandonment is not extendable under § 1.136(a) or (b) if set forth in a ''Notice of Allowability'' or in an Office action having a mail date on or after the mail date of a ''Notice of Allowability.'' *See Changes to the Time Period for Making any Necessary Deposit of Biological Material,* 66 FR 21090 (April 27, 2001), 1246 *Off. Gaz. Patent Office* 42 (May 22, 2001) (final rule).

As to release of the deposit before issuance of the application, the GAO study noted the concern of the

biotechnology industry that the public could obtain the deposit and reproduce the invention with minimal effort and expense, but ''found no documented cases of a person or an organization having ever obtained a sample of a biological deposit and then using it to infringe on the patent.'' GAO–01–49 at 4. Nevertheless, the report concluded that ''the statute does not require an associated release of a biological deposit concurrent with 18-month publication because even though the application may refer to the biological deposit, the deposit itself is not part of the application.'' GAO–01–49 at 5. Although no reference is provided, the report appears to be relying for support of this assertion on the CCPA's statement in *In re Argoudelis* that ''[t]he deposits are not a part of the patent application * * *.'' 434 F.2d 1390, 1394, 168 USPQ 99, 103 (CCPA 1970). The focus in *Argoudelis,* however, appears to have been on an Office position that the Office did not control the deposited material for the purpose of ensuring continued enablement, and in no way implied that the application complied with 35 U.S.C. 112 without the deposit. This passage places the quote in context:

> The only rational ground for concern on the part of the Patent Office appears to be for the permanent availability of the deposited microorganism. The deposits are not a part of the patent application, and the Patent Office exercises no control over them. This concern may be justified in some situations.

Id. at 1393–94, 168 USPQ at 103. Moreover, the *Argoudelis* court recognized that the deposit would be withheld from the public in accordance with the United States Patent Office Rules of Practice, Rule 14. *Id.* at 1391, 168 USPQ at 101 (quoting cover letter from the appellant to the depository accompanying the deposit). As a result, although the deposit was not physically within the application file, the Office's rules related to access to application files still governed access to the deposit. Thus, while the GAO's statement is true insofar as the deposit is not physically part of the application, a deposit is part of the application in the sense that an applicant's disclosure may be non-enabling or not adequately described without it.

The proposed requirement for unrestricted access to a deposited biological material upon publication of a patent application that makes reference to it will ensure that the public has the same level of access to the disclosure of an invention involving biological materials as it does to the disclosure of any other category of invention. With few limited exceptions, the patent statutes do not distinguish among different fields of endeavor. Significantly, section 122 of Title 35 does not authorize the Office to refrain from making some portion of an applicant's disclosure public simply because it is in the form of a deposit of biological material. Parity of treatment regardless of the type of invention involved has been espoused by the Federal Circuit, which stated recently that this court accords the same treatment to all forms of invention. *Eolas Techs Inc.* v. *Microsoft Corp.*, 399 F.3d 1325, 1339, 73 USPQ2d 1782, 1794 (Fed. Cir. 2005) (citing TRIPs Agreement, Part II, Section 5 (1994) (''[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention[ ][and] the field of technology * * *.'')). By providing for unrestricted access to deposited material upon publication, the Office will ensure that uniform standards for public release of a patent disclosure apply regardless of the field of the invention.

In order to ensure that the public receives a meaningful disclosure of an invention in a patent application publication, provisional rights may accrue to the patentee only if the claims in the patent are substantially identical to those in the published application. *See* 35 U.S.C. 154(d). The specification of a patent application must also comply with 35 U.S.C. 112. *See* 35 U.S.C. 111(b)(1)(A). If a deposit of biological material to comply with 35 U.S.C. 112 is necessary to preserve the availability of provisional rights under 35 U.S.C. 154(d), the disclosure of the invention must contain a specific reference to a depository accession number of the biological material, or be amended to contain such a reference in sufficient time to allow for the accession number to be included in the patent application publication. A reference to an accession number which appears in papers related to a patent application but not in the disclosure itself is not sufficient. Although application-related papers are generally made available to the public upon publication of the application, *see* § 1.14(a)(1)(ii) and (iii), such papers are not part of the disclosure of the patent or patent application publication itself. As a result, if the patent application itself is not originally filed with a reference to the accession number, a substitute specification in compliance with § 1.125(b) should be filed at least four months before the projected publication date of the patent application publication in order to ensure that the reference to the deposit is included in the patent application publication.

The Office serves as a guardian of the public interest when it examines patent applications and issues those which meet statutory requirements, including the requirement of an adequate disclosure. *See In re Russell*, 439 F.2d 1228, 1230, 169 USPQ 426, 428 (CCPA 1971) (''[T]here is a public interest in *granting* valid patents * * * .''). By instituting the proposed rule changes, the Office will ensure that patent application publication documents requiring a deposit of biological material to comply with the disclosure requirements of 35 U.S.C. 112, first paragraph, will be fully available as prior art as of the date of publication. If a patent application publication does not comply with the disclosure requirements of 35 U.S.C. 112, first paragraph, as of its publication date, the patent application publication cannot serve as anticipatory prior art under 35 U.S.C. 102(a) and (b), and possibly (e). *See Elan Pharms., Inc.* v. *Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1375 (Fed. Cir. 2003) (''To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.'') (quoting *Amgen, Inc.* v. *Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003) (''A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.''); *Bristol-Myers Squibb* v. *Ben Venue Labs., Inc.,* 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) (''To anticipate, the reference must also enable one of skill in the art to make and use the claimed invention.''); *PPG Indus., Inc.* v. *Guardian Indus. Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) (''To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.'').

Absent a requirement for deposit prior to publication coupled with release of the deposited material upon publication, an otherwise anticipatory patent application publication could fail to qualify as prior art. It is not in the public interest to allow arbitrariness in the date of deposit to disqualify a patent application publication as prior art, when the publication otherwise fully discloses an invention. The proposed rule changes take steps to ensure that patent application publications will be available as prior art as of their publication date, and can therefore be used to prevent issuance of patents which do not represent a contribution to

public knowledge. *See Constant* v. *Advanced Micro-Devices, Inc.,* 848 F.2d 1560, 1564, 7 USPQ2d 1057, 1059 (Fed. Cir. 1988) (''Public policy requires that only inventions which fully meet the statutory standards are entitled to patents.'').

A requirement for deposit of the biologic material prior to publication would be a significant step toward harmonizing United States practice with that of the European Patent Office (EPO). The proposed rules require that a deposit necessary for compliance with 35 U.S.C. 112 be made before technical preparations for publication of the application as a patent application publication have begun, whereas in Europe any deposit necessary for compliance with the disclosure requirement of Article 83 of the European Patent Convention (EPC) must have been made at or before filing. EPC Rule 28(1)(a). Thus the timing requirements for deposits are not identical, and even under the proposed rules it would remain the case that an EP application risks losing benefit of a United States priority application unless the deposit had been made at or before filing in the United States. However, under the proposed changes to § 1.809(e), as well as under EPC Rule 28(2)(a), an amendment to a patent application to make reference to a deposit must be made in sufficient time so that the reference will be included in the patent application publication. Thus members of the interested public, for both U.S. applications and those filed in the EPO, will be informed of the existence of the deposited material and be able to request its release upon publication at eighteen months.

Discussion of Specific Rules

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

Section 1.77: Section 1.77 is proposed to be amended by revising paragraph (b)(1) to delete '', which may be accompanied by an introductory portion stating the name, citizenship, and residence of the applicant (unless included in the application data sheet),'' by redesignating paragraphs (b)(6) through (b)(12) as paragraphs (b)(7) through (b)(13), adding a new paragraph (b)(6), and revising paragraph (c). Having the name, citizenship and residence of each applicant on the title page suggests that such information should be changed if the information changes, and to avoid any need for an amendment, this information should not be included on the title page. New paragraph (b)(6) would provide a section heading for a reference to a deposit of biological material. Paragraph (c) is proposed to be revised to refer to paragraph (b) in general rather than each of the numbered paragraphs of (b) so that if paragraph (b) is amended in the future, no amendments would be required to paragraph (c).

Section 1.163: Section 1.163 is amended by revising paragraph (c)(1) to delete '', which may include an introductory portion stating the name, citizenship, and residence of the applicant,'' redesignating paragraphs (c)(6) through (c)(11) as paragraphs (c)(7) through (c)(12), and adding a new paragraph (c)(6) to provide a section heading for a reference to a deposit of biological material.

Section 1.804: Section 1.804 is proposed to be amended to provide that if a biological material is necessary to preserve the availability of provisional rights under 35 U.S.C. 154(d), the deposit of the biological material must be made prior to filing an application or during the pendency of an application, provided that the deposit is made before technical preparations for publication of the application as a patent application publication have begun (*see* § 1.215(a)).

Section 1.808: Section 1.808(a)(1) is proposed to be amended to change ''122'' to ''122(a)'' and to make grammatical corrections. Section 1.808(a)(2) is proposed to be amended to provide that all restrictions imposed by the depositor will be irrevocably removed upon the earlier of publication of the application under § 1.211 and 35 U.S.C. 122(b) or grant of the patent, and to indicate that the rule applies regardless of whether the deposit was made to satisfy a statutory provision.

Section 1.808(b) is amended to add ''before the patent is granted or'' before ''term of the patent.''

Section 1.808(c) is amended to provide that the Office will, on request, certify that an application referring to the deposit has been filed, that the subject matter of that application involves the deposited biological material or the use thereof, that the application has been published or patented or is otherwise open to public inspection, and that the requesting party has a right to a sample of the biological material. This is the certification called for in Rule 11.3 of the Regulations Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. A form, BP/12, is provided on the World Intellectual Property Organization's Internet Web site (*http://www.wipo.int*) for this purpose.

Section 1.808(c)(3) is also proposed to be revised to require the application number referring to the deposit, as well as either the patent application publication number and publication date, or the patent number and issue date of the patent, instead of only the patent number and issue date.

Section 1.809: Section 1.809(a) is proposed to be amended to clarify that the examiner's rejection may be under any appropriate statutory provision.

Section 1.809(b)(1) is proposed to be amended to delete ''either'' and '', or assuring the Office in writing that an acceptable deposit will be made.'' Section 1.809(b)(2) is proposed to be amended to delete the text after ''nonresponsive'' and to insert in place thereof ''A request to hold the making of the deposit in abeyance will not be considered a bona fide attempt to advance the application to final action (§ 1.135(c)).''

Section 1.809(c) is proposed to be amended to delete ''and the Office has received a written assurance that an acceptable deposit will be made.''

Section 1.809(e) is proposed to be amended to delete ''before or with the payment of the issue fee (*see* § 1.312)'' and to insert ''(1) within a period of sixteen months after the date of filing of the application or, if the benefit of an earlier filing date is sought under 35 U.S.C. 119(e), 120, 121, or 365(c), within the later of four months of the actual filing date of the later-filed application and sixteen months from the filing date of the prior-filed application; and (2) before or with any request for early publication (§ 1.219).'' Of course, § 1.312 continues to apply, and the amendment cannot be filed after payment of the issue fee. By providing that the amendment should be filed at a set time related to publication of the application, the application should be published with the required deposit information.

Rulemaking Considerations

Administrative Procedure Act: This notice does not propose to add any new fees or new requirements to the rules of practice. Rather, this notice proposes to change the time period for compliance with existing requirements of the rules of practice in 37 CFR 1.801 *et seq.* Therefore, the changes proposed in this notice involve only rules of agency practice and procedure under 5 U.S.C. 553(b)(B). *See Bachow Communications Inc.* v. *FCC*, 237 F.3d 683, 690 (DC 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) and *JEM Broadcasting Co.* v. *FCC*, 22 F.3d 320, 327 (DC Cir. 1994)

(rule under which any flawed application is summarily dismissed without allowing the applicant to correct its error is merely procedural despite its sometimes harsh effects on applicants); *see also Fressola* v. *Manbeck*, 36 USPQ2d 1211, 1215 (D.D.C. 1995) (''it is extremely doubtful whether any of the rules formulated to govern patent or 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)). 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 seeking public comment on proposed changes to these rules of practice to obtain the benefit of such input.

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), neither an initial regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are required. *See* 5 U.S.C. 603. Nevertheless, for the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the changes proposed in this notice will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

The principal impacts of the changes proposed in this notice are changes to the rules of practice to: (1) Require that any deposit of biological material be made before publication of a patent application; and (2) provide that all restrictions on access to the deposited material imposed by the depositor be removed upon publication. The Office estimates that there are approximately 1,000 patent applications filed each year (both small entity and other than small entity) that are supplemented (either on filing or later) by a deposit of biological material. This notice does not propose any new fees or new requirements for such applications, but is simply proposing to change the time period for compliance with existing requirements of the rules of practice to ensure that the public has access to biological materials referenced in the disclosure of a patent application to the same extent that access to the remainder of the disclosure is available. Therefore, the changes proposed in this notice will not have a significant economic impact on a substantial number of small entities.

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 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 0651–0022 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 principal impacts of the changes proposed in this notice are changes to the rules of practice to: (1) Require that any deposit of biological material be made before publication of a patent application; and (2) provide that all restrictions on access to the deposited material imposed by the depositor be removed upon publication.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Robert A. Clarke, 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, Inventions and patents, Lawyers.

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 1.77 is amended by redesignating paragraphs (b)(6) through (b)(12) as paragraphs (b)(7) through (b)(13), adding a new paragraph (b)(6), and revising paragraphs (b)(1) and (c) to read as follows:

§ 1.77 Arrangement of application elements.

* * * * *

(b) * * *

(1) Title of the invention.

* * * * *

(6) Reference to a deposit of biological material.

* * * * *

(c) The text of the specification sections defined in paragraph (b) of this section, if applicable, should be preceded by a section heading in uppercase and without underlining or bold type.

3. Section 1.163 is amended by redesignating paragraphs (c)(6) through (c)(11) as paragraphs (c)(7) through (c)(12), revising paragraph (c)(1), and adding a new paragraph (c)(6) to read as follows:

§ 1.163 Specification and arrangement of application elements in a plant application.

* * * * *

(c) * * *

(1) Title of the invention.

* * * * *

(6) Deposit of biological material.

* * * * *

4. Section 1.804 is amended by revising paragraph (a) to read as follows:

§ 1.804 Time of making an original deposit in order to preserve availability of provisional rights under 35 U.S.C. 154(d).

(a) If deposit of a biological material is necessary to preserve the availability of provisional rights under 35 U.S.C. 154(d), an original deposit of the biological material must be made either before the application is filed or during pendency of the application provided that the deposit is made before technical preparations for publication of the application as a patent application publication have begun (see § 1.215(a)).

* * * * *

5. Section 1.808 is revised to read as follows:

§ 1.808 Furnishing of samples.

(a) A deposit must be made under conditions that assure that:

(1) Access to a deposit will be available during pendency of a patent application making reference to the deposit to one determined by the Director to be entitled thereto under § 1.14 and 35 U.S.C. 122(a), and

(2) Subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the earlier of publication of the application under § 1.211 and 35 U.S.C. 122(b) or grant of the patent, and any deposit referenced in a patent application publication or patent will be available to the public upon publication or patenting, regardless of whether the deposit was necessary for compliance with any statutory provision.

(b) The depositor may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, before the patent is granted or during the term of the patent:

(1) Is in writing or other tangible form and dated;

(2) Contains the name and address of the requesting party and the accession number of the deposit; and

(3) Is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.

(c) Upon request made to the Office, the Office will certify that an application referring to the deposit has been filed and that the subject matter of that application involves the deposited biological material or the use thereof, that the application has been published or patented or is otherwise open to public inspection, and the certified party has a right to a sample of the biological material, provided the request contains:

(1) The name and address of the depository;

(2) The accession number given to the deposit;

(3) The application number referring to the deposit and any patent application publication number and publication date, or patent number and issue date of the patent; and

(4) The name and address of the requesting party.

6. Section 1.809 is amended by revising paragraphs (a), (b), (c), and (e) to read as follows:

§ 1.809 Examination procedures.

(a) The examiner shall determine pursuant to § 1.104 in each application for patent, application for reissue patent or reexamination proceeding if a deposit is needed, and if needed, if a deposit actually made is acceptable for patent purposes. If a deposit is needed and has not been made or replaced or supplemented in accordance with these regulations, the examiner, where appropriate, shall reject the affected claims under the appropriate statutory provision, explaining why a deposit is needed and/or why a deposit actually made cannot be accepted.

(b) The applicant for patent or patent owner shall reply to a rejection under paragraph (a) of this section by:

(1) In the case of an applicant for patent, making an acceptable original, replacement, or supplemental deposit; or, in the case of a patent owner, requesting a certificate of correction of the patent which meets the terms of paragraphs (b) and (c) of § 1.805, or

(2) Arguing why a deposit is not needed under the circumstances of the application or patent considered and/or why a deposit actually made should be accepted. Other replies to the examiner's action shall be considered nonresponsive. A request to hold the making of the deposit in abeyance will not be considered a bona fide attempt to advance the application to final action (§ 1.135(c)).

(c) If an application for patent is otherwise in condition for allowance except for a needed deposit, applicant will be notified and given a period of time within which the deposit must be made in order to avoid abandonment. This time period is not extendable under § 1.136(a) or (b) if set forth in a ''Notice of Allowability'' or in an Office action having a mail date on or after the mail date of a ''Notice of Allowability'' (see § 1.136(c)).

* * * * *

(e) An amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section for a biological deposit that is necessary to preserve provisional rights under 35 U.S.C. 154(d) must be filed:

(1) Within a period of sixteen months after the date of filing of the application or, if the benefit of an earlier filing date is sought under 35 U.S.C. 119(e), 120, 121, or 365(c), within the later of four months of the actual filing date of the later-filed application and sixteen months from the filing date of the of the prior-filed application; and

(2) Before or with any request for early publication (§ 1.219).

Dated: February 13, 2008.

Jon W. Dudas,

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

[FR Doc. E8–3084 Filed 2–19–08; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2007–0633; A–1–FRL–8517–5]

Approval and Promulgation of Air Quality Implementation Plans; Maine; Conformity of General Federal Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maine for the purpose of making the SIP consistent with recent additions to the Federal general conformity regulation. This revision incorporates by reference new definitions and establishes de minimis emission levels for fine particular matter ($PM_{2.5}$) into Maine's existing general conformity criteria and procedures previously approved into the Maine SIP.

DATES: Written comments must be received on or before March 21, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2007–0633 by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: arnold.anne@epa.gov.*

3. *Fax:* (617) 918–0047.

4. *Mail:* ''EPA–R01–OAR–2007–0633'', Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, One Congress Street, Suite 1100 (mail code CAQ), Boston, MA 02114–2023.

5. *Hand Delivery or Courier. Deliver your comments to:* Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, One Congress Street, 11th floor, (CAQ), Boston, MA 02114–2023. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.