

those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 820-2280 at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 15, 2006.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. E6-19524 Filed 11-17-06; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-P-2006-0034]

Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The Regulatory Flexibility Act permits an agency head to establish, for purposes of Regulatory Flexibility Act analysis and certification, one or more definitions of “small business concern” that are appropriate to the activities of the agency. Pursuant to this authority, the United States Patent and Trademark Office (USPTO) is establishing the Small Business Administration (SBA) business size standard for the purpose of paying reduced patent fees as the size standard for conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations.

DATES: *Effective Date:* November 20, 2006.

FOR FURTHER INFORMATION CONTACT:

Christina T. Donnell, Senior Petitions Attorney, Office of Petitions, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272-3211, 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 Christina T. Donnell.

SUPPLEMENTARY INFORMATION: The USPTO is in this notice establishing the SBA business size standard for the purpose of paying reduced patent fees as the size standard for conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. The USPTO is not changing or proposing to change the definition of small entity for the purpose of paying reduced patent fees.

The patent statute provides that “[f]ees charged under [35 U.S.C. 41](a), (b) and (d)(1) shall be reduced by 50 percent with respect to their application to any small business concern as defined under section 3 of the Small Business Act, and to any independent inventor or nonprofit organization as defined in regulations issued by the Director.” 35 U.S.C. 41(h)(1). The SBA defines a small business concern for the purpose of paying reduced patent fees as one: “(a) Whose number of employees, including affiliates, does not exceed 500 persons; and (b) Which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this section.” 13 CFR 121.802.

The USPTO uses the SBA business size standard for the purpose of paying reduced patent fees in 13 CFR 121.802 as the size standard when conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. *See e.g., Changes To Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan*, 69 FR 56481, 56530 (Sept. 21, 2004) (discussion indicating that small entities for purposes of the Regulatory Flexibility Act are considered a subset of the small entities for purposes of paying reduced patent fees). The USPTO has no business need (other than to conduct an analysis or make a certification under the Regulatory Flexibility Act) to collect information from patentees and patent applicants concerning whether they are a small business concern using the business size standards set forth in 13 CFR 121.201. Thus, the USPTO uses the SBA business size standard set forth in 13 CFR 121.802 as its size standard when conducting an analysis or making a certification under the Regulatory Flexibility Act to avoid the need to gather data from patentees and patent applicants as to whether they are a

small business concern as described in 13 CFR 121.201.

Comments and Responses: Pursuant to the Regulatory Flexibility Act, the USPTO consulted with SBA Advocacy and published a request for comments on the establishment of a business size standard (the business size standard set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees) for the purpose of USPTO Regulatory Flexibility Analysis for patent-related regulations. *See Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 38388 (July 6, 2006), 1309 *Off. Gaz. Pat. Office* 37 (Aug. 1, 2006) (request for comments). SBA Advocacy convened a regulatory roundtable to discuss the USPTO's proposed business size standard (attended by USPTO representatives) on July 19, 2006, and the USPTO received seven written comments (from SBA Advocacy, the Professional Inventors Alliance, and five individuals) in response to the request for comments. The comments and responses to the comments follow:

Comment 1: SBA Advocacy commented, in pertinent part, that:

On July 19, 2006, Advocacy convened a regulatory roundtable to discuss the USPTO's proposed size standard. Participants at the roundtable included industry personnel representing the interests of small businesses and independent inventors, USPTO personnel, representatives from the SBA Office of Size Standards, and Advocacy. During the roundtable, small entity representatives expressed reservations about the proposed size standard. They indicated that the standard would exclude a significant number of small entities. Further, they were concerned that the standard would not provide an accurate estimate of the number of small entities affected by the USPTO's regulations.

Currently, patent applicants must claim small entity status by checking a box on their patent application. However, small entity representatives informed Advocacy that entities often choose not to claim small entity status for a variety of reasons. USPTO data systems track the number of patent applications that claim small entity status. The agency then uses the numbers to estimate the number of small entities affected by its rulemakings. The agency does not collect data on or count the specific entities that are submitting a patent application. As a result, the data collected by the USPTO does not provide an accurate estimate of the number of small entities affected by the agency's rules. Since the proposed size standard only tabulates the number of applicants claiming small entity status, and not actual small entities, Advocacy does not believe that it is the appropriate size standard for [Regulatory Flexibility Act] purposes.

Advocacy appreciates the USPTO's challenge in identifying an appropriate size

standard for [Regulatory Flexibility Act] purposes. We agree with the agency's decision to request public comment on the proposed size standard. However, we urge the USPTO not to adopt a size standard that would adversely affect small entities. The proposed standard will not facilitate the USPTO's compliance with the [Regulatory Flexibility Act] since it will not adequately estimate the small entities affected by the agency's regulations. Advocacy suggests that the agency continue to work with our office to identify a more appropriate standard after reviewing public comments on the proposal.

Another individual comment also objected to the use of the SBA business size standard in 13 CFR 121.802 as the size standard when conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. The comment asserted that it was not unusual for a small business concern to file as a large entity to avoid the possibility of the patent being subsequently invalidated because of an improper assertion of small entity status. Additionally, the comment asserted that the number of small business concerns affected by the USPTO's rule making is much greater than the number of small entity applicants assessed by the USPTO. Alternatively, several individual comments supported the USPTO's definition of small business concern for Regulatory Flexibility Act purposes.

Response: The USPTO does not consider the arguments that it significantly undercounts the number of small entities affected by its rule makings to be persuasive. On July 19, 2006, representatives from the USPTO attended SBA Advocacy's roundtable and met with representatives from the SBA, SBA Advocacy, the Intellectual Property Owners Association, the Association for Competitive Technology, the American Intellectual Property Law Association, and the United Inventors Association. The USPTO received anecdotal feedback at the SBA Advocacy roundtable that the USPTO significantly undercounts the number of small entities affected by its rule makings when the USPTO relies upon the small entity data as contained in the USPTO's Patent Application Locating and Monitoring (PALM) system. The USPTO, however, has not been provided with any data or other specific information to substantiate this anecdotal information. In addition, none of the groups whose representatives were present at the SBA Advocacy roundtable (except for SBA Advocacy) submitted a comment in response to the USPTO's request for comments on the USPTO's definition of small business concern for Regulatory Flexibility Act purposes. In support of the contention

that the small entity data in PALM significantly undercounts the number of small entities, the representatives at the SBA Advocacy roundtable and the comments asserted that small entities routinely decline to claim small entity status because: (1) Applicants must claim small entity status by checking a box on a particular USPTO form; (2) small entities consider the fifty percent reduction in patent fees negligible relative to the overall cost of obtaining a patent; and (3) there are negative legal consequences if small entity status is claimed or is claimed improperly.

The small entity data contained in the PALM system is collected from patent applicants on the basis of whether the applicant claims small entity status for the purpose of paying patent fees. Section 4502(b) of the American Inventors Protection Act of 1999 (AIPA) charged the Government Accountability Office (GAO) with conducting a study of the impact of the AIPA's eighteen-month publication provisions, which included a study of any correlation of the status of the applicant (small entity or non-small entity) and the eighteen-month publication of applications. See Public Law 106-113, 113 Stat. 1501, 1501A-552-53 (1999). The GAO analyzed the data in the USPTO's PALM system and deemed it sufficiently reliable for purposes of conducting the study mandated by the AIPA. See *Information about the Publication Provisions of the American Inventors Protection Act*, GAO-04-603 at 14-15 (2004).

The USPTO representatives indicated at the SBA Advocacy roundtable that to collect small entity data with the reliability being urged by SBA Advocacy (or of greater reliability than is currently contained in the USPTO's PALM system) would compel the USPTO to require all patent applicants to affirmatively state whether they are or are not a small entity. No party present at the SBA Advocacy roundtable advocated the adoption of such a requirement. In addition, the SBA Advocacy comment does not suggest any viable alternative to the USPTO's reliance upon the data on small entities contained in the USPTO's PALM system for Regulatory Flexibility Act analysis or certification purposes. Therefore, the USPTO considers the data on small entities in the USPTO's PALM system to be sufficiently reliable (especially in light of the absence of any viable preferable alternatives) for use in conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations.

The statement that patent applicants must claim small entity status by checking a box on a particular USPTO form is not correct. The USPTO revised 37 CFR 1.27 in September of 2000 to provide that patent applicants may claim small entity status by: (1) Providing a written assertion of entitlement to small entity status (37 CFR 1.27(c)(1)); or (2) paying the basic filing or basic national fee in the small entity amount (37 CFR 1.27(c)(3)). See *Changes to Implement the Patent Business Goals*, 65 FR 64603, 54609-15, 54659-61 (Sept. 8, 2000) (final rule). The USPTO includes a box next to a written assertion of entitlement to small entity status on its application transmittal form, which patent applicants may use to claim small entity status when filing a patent application (37 CFR 1.27(c)(1)). The USPTO, however, does not require applicants to check this box on the application transmittal form (or even use the application transmittal form) to claim small entity status. Therefore, the USPTO does not believe that small entities routinely decline to claim small entity status due to the USPTO's requirements for establishing small entity status.

The argument that small entities consider the fifty percent reduction in patent fees to be negligible is likewise unpersuasive. As introduced and reported out of the House Committee on the Judiciary, the United States Patent and Trademark Fee Modernization Act of 2003 did not contain a small entity reduction for the patent search fee. See *The United States Patent and Trademark Fee Modernization Act of 2003*, H.R. 1561, 109th Cong., § 2 (2003). During the floor debate on the United States Patent and Trademark Fee Modernization Act, the following amendments were necessary to address small entity concerns and secure passage of this legislation by the House of Representatives: (1) A fifty percent reduction in the patent search fee for small entities; (2) a seventy-five percent reduction in the patent filing fee for small entities who file electronically; and (3) a study of the effects of patent fees on the ability of small entities to file patent applications. See *United States Patent and Trademark Fee Modernization Act of 2004*, 150 Cong. Rec. H793, H803 (daily ed. Mar. 3, 2004) (floor debate and passage of United States Patent and Trademark Fee Modernization Act of 2004 by the House of Representatives). The USPTO does not believe that small entities would have sought these changes to the United States Patent and Trademark Fee

Modernization Act of 2004 if a substantial number of small entities considered the fifty percent reduction in patent fees to be negligible.

The argument concerning negative legal consequences if small entity status is claimed or is claimed improperly is similarly not persuasive. The rules of practice provide that: “[i]f status as a small entity is established in good faith, and fees as a small entity are paid in good faith, in any application or patent, and it is later discovered that such status as a small entity was established in error, or that through error the Office was not notified of a loss of entitlement to small entity status as required by § 1.27(g)(2), the error will be excused upon compliance with the [requirements of 37 CFR 1.28(c)].” 37 CFR 1.28(c). In the mid-1990s, there were District Court decisions in which a patentee faced negative legal consequences for erroneously or improperly claiming small entity status. See *Haden Schweitzer Corp. v. Arthur B. Myr Industries, Inc.*, 901 F. Supp. 1235, 36 U.S.P.Q.2d 1020 (E.D. Mich. 1995) (failure to pay maintenance fee in the correct amount results in intervening rights under 35 U.S.C. 41(c)(2)); and (2) *DH Technology, Inc. v. Synergstex International, Inc.*, 937 F. Supp. 902, 40 U.S.P.Q.2d 1754 (N.D. Cal. 1996) (failure to timely pay issue fee in the correct amount results in patent lapse under 35 U.S.C. 151); but see *Jewish Hospital of St. Louis v. Idexx Laboratories*, 951 F. Supp. 1, 42 U.S.P.Q.2d 1720 (D. Me. 1996) (correction of improper small entity fee payment in compliance with 37 CFR 1.28 does not result in patent lapse). In light of the uncertainty that existed in the mid-1990s concerning the consequences of erroneously claiming small entity status, the Office advised applicants and patentees at that time that they could avoid this uncertainty by not claiming small entity status unless it is absolutely certain that the applicant or patentee is entitled to small entity status (*i.e.*, resolving any doubt, uncertainty, or lack of information in favor of payment of the full fee). See *Changes to Patent Practice and Procedure*, 62 FR 53131, 53135 (Oct. 10, 1997); see also *DH Technology*, 937 F. Supp. at 910, 40 U.S.P.Q.2d at 1761 (“where there is the slightest doubt about an applicant’s entitlement to claim small entity status, the applicant would be foolish not to pay the full * * * fee”).

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit), however, reversed the District Court’s decision in *DH Technology* and held that an applicant may correct an

erroneous payment of patent fees in the small entity amount under 37 CFR 1.28 without penalty, such as patent lapse, as long as small entity status was established in good faith and the small entity fees were paid in good faith. See *DH Tech. v. Synergstex Int’l*, 154 F.3d 1333, 1343, 47 U.S.P.Q.2d 1865, 1872 (Fed. Cir. 1998). Thus, subsequent to the Federal Circuit’s decision in *DH Technology*, the only patent applicants or patentees who face negative legal consequences from claiming or erroneously claiming small entity status are those applicants who have no basis for making a good faith claim to small entity status. Therefore, the USPTO does not believe that a significant number of small entities currently decline to claim small entity status to avoid negative legal consequences (*i.e.*, the patent being invalidated) due to the applicant claiming or erroneously claiming small entity status.

Finally, no party to the SBA Advocacy roundtable or other comment suggested that the USPTO should use the business size standards set forth in 13 CFR 121.201 for purposes of conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations.

Comment 2: One comment requested clarification as to whether a license to a non-small entity that arises only impliedly negates small entity status for an applicant or patentee. The comment stated that the situation of an implied license to a non-small entity frequently occurs when the invention is embodied in software, and the software is mass-marketed under a standard shrink-wrap license. The comment asserted that a shrink-wrap agreement typically grants a “license” without indicating the intellectual property rights for which the “license” is granted. The comment contended that frequently the licensee cannot use the software without using the patented invention and that the law often implies a license under these circumstances. Additionally, the comment asserted that the current definition of small business concern excludes any small entity that licensed the invention to a non-small entity; however, the definition does not limit the exclusion to only those small business concerns that explicitly licensed the invention. Therefore, the comment suggested that the USPTO adopt the following language: “(b) which has not assigned, granted, conveyed, or explicitly licensed (and is under no obligation to do so) any rights in the invention * * *.” Lastly, the comment averred that some practitioners do not claim small entity

status for software-embodied inventions, even though the applicant or patentee is entitled to the benefit of small entity status, because the applicant or patentee is usually unaware if or when the mass-market software production is licensed by a non-small entity.

Response: The scope of the term “license” in the context of entitlement to small entity status was previously discussed in the SBA rule making to define small entity for purposes of a reduction in patent fees for such a small entity. Specifically, the SBA responded as follows:

Two comments raised questions about the intended scope of the term “license.” It was suggested that clarification is needed as to what is included within the scope of the term. One comment suggested that, “[a]t the very least, the record should reflect that the definition is not intended to reach implied licenses to use and resell patented articles purchased from a small business.” The comment is correct insofar as it suggests that such “implied licenses” are not intended to be included within the scope of the term. Likewise, an order by the applicant to a firm to build a proto-type machine or product for the applicant’s own use is not considered to constitute a license for purposes of the definition.

Another suggestion was that the regulation be reworded to deny small business status where revenue above a certain dollar amount was received from licensing rights under the invention to a concern which could not qualify as a small entity. It was also suggested that the term “exclusive license of any of the rights in the invention” be used instead of the term “license.” The latter two suggestions have not been adopted. Adoption of these suggestions would cause the regulation to become more complicated, and does not appear necessary to aid small concerns in accord with the purposes of the legislation. In addition, it could substantially broaden the number of concerns which could qualify with a resulting excessive loss of revenue to the Patent and Trademark Office. It is not seen likely that the restriction on licensing would unduly or adversely affect the ability of the small business concern to participate in the patent system.

Definition of Small Business for Paying Reduced Patent Fees Under Title 35, United States Code, 47 FR 43272 (Sept. 30, 1982) (final rule). The USPTO did not propose to change the definition of a small business concern for the purpose of paying reduced patent fees. Rather, the USPTO was inviting public comment on the establishment of the SBA business size standard in 13 CFR 121.802 as the size standard when conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. Therefore, the suggested change is not adopted.

Comment 3: One comment suggested that part (b) of the SBA's definition of a small business concern, specifying an entity "which has not assigned, granted, conveyed or licensed * * * any rights in the invention" to a large entity should be deleted from the definition as being inappropriate. The comment stated that a license or other agreement between a small entity and a large entity does not typically result in substantial income to the small entity. The comment further asserted that in most cases the small entity retains the financial responsibility to pay the patent prosecution and maintenance fees, without any additional income from the large entity. The comment contended that if the license or other agreement is later terminated, the termination agreement often allows the large entity to retain some rights without further payment. Additionally, the termination agreement may be so complex that the small entity may not be able to overcome a charge of inequitable conduct by a third party. Alternatively, one of the comments stated that the adopted size standard does not unfairly burden small entities because a large entity typically pays the cost of patent prosecution when a small entity licenses its technology to the large entity.

Response: 13 CFR 121.802 is the substantive provision for determining whether an entity is a small business concern for purposes of paying reduced patent fees. The USPTO did not propose to change the definition of a small business concern for the purpose of paying reduced patent fees. Rather, the USPTO was inviting public comment on the establishment of the SBA business size standard in 13 CFR 121.802 as the size standard when conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations.

Moreover, the suggestion was previously considered and rejected in the rule making to implement the reduction in patent fees for small entities. Specifically, a past comment suggested that 37 CFR 1.27 should be corrected to indicate that a small business concern would be entitled to pay reduced patent fees even though the small business concern may grant a non-exclusive or an exclusive license to a non-small entity. The USPTO responded as follows:

Section 1.27 requires that the concern qualify as a small business concern as defined in § 1.9(d). Section 1.9(d) defines a small business concern by incorporating 13 CFR 121.3-18, which in turn defines a small business concern as one not exceeding a particular size "which has not assigned,

granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section." The intent of both 13 CFR 121.3-18 and 37 CFR 1.9(d) and 1.27(c) is to limit the payment of reduced fees under section 41(a) and (b) of Title 35, United States Code, to those situations in which all of the rights in the invention are owned by small entities, i.e., independent inventors, small business concerns, or nonprofit organizations. To do otherwise would be clearly contrary to the intended purpose of the legislation which contains no indication that fees are to be reduced in circumstances where rights are owned by non-small entities. Adopting the suggestion might, for example, permit a non-small entity to transfer patent rights to a small business concern which would pay the reduced fees and grant an exclusive license to the non-small entity.

Revision of Patent and Trademark Fees, 47 FR 43273 (Sept. 30, 1982) (final rule). Therefore, the suggested change is not adopted.

Comment 4: One comment noted an error in the following text: "The SBA Advocacy, however, has questioned whether the USPTO's size standard is under-inclusive because it excludes any business concern that has assigned, granted, conveyed, or licensed (and is under no obligation to do so)." The comment suggested the following correction: "The SBA Advocacy, however, has questioned whether the USPTO's size standard is under-inclusive because it excludes any business concern that has assigned, granted, conveyed, or licensed (or is under an obligation to do so)."

Response: The USPTO notes that the text at issue should have read: "The SBA Advocacy, however, has questioned whether the USPTO's size standard is under-inclusive because it excludes any business concern that has assigned, granted, conveyed, or licensed (or is under an obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under [13 CFR 1.802]."

Establishment of a Definition of "Small Business Concern" for Purposes of the USPTO Conducting an Analysis or Making a Certification under the Regulatory Flexibility Act for Patent-Related Regulations: The Regulatory Flexibility Act permits an agency head to establish, for purposes of Regulatory Flexibility Act analysis and certification, one or more definitions of

"small business concern" that are appropriate to the activities of the agency, after consultation with the Office of Advocacy of the Small Business Administration and opportunity for public comment. See 5 U.S.C. 601(3) and 13 CFR 121.903(c). The USPTO consulted with SBA Advocacy and published a request for comments on the establishment of a business size standard (the SBA business size standard set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees) for USPTO Regulatory Flexibility Analysis for patent-related regulations. See *Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR at 38388-89, 1309 Off. Gaz. Pat. Office at 37-38. Therefore, the USPTO is establishing the following definition of small business concern for purposes of the USPTO conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations: A small business concern for Regulatory Flexibility Act purposes for patent-related regulations is a business or other concern that: (1) Meets the SBA's definition of a "business concern or concern" set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) Whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition.

Dated: November 9, 2006.

Jon W. Dudas,

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

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BILLING CODE 3510-16-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Office of the Secretary of Defense (Health Affairs)/TRICARE Management Activity

AGENCY: Department of Defense.

ACTION: Notice of a TRICARE demonstration project for the State of Alaska