





regulations generally define small businesses as those with fewer than a maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code. The Office, however, has formally adopted an alternate size standard as the size standard for the purpose of conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. See *Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 67109 (Nov. 20, 2006).<sup>1</sup>

Unlike the SBA small business size standards set forth in 13 CFR 121.201, this size standard is not industry-specific. Specifically, the Office's definition of small business concern for Regulatory Flexibility Act purposes 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. See *Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR at 67112.

The proposed rule will apply to any such small entity who files a patent application and chooses to use alternative language in claiming his or her invention. To estimate the number of applications containing alternative language that are submitted by small entities, Office staff analyzed applications filed in fiscal year 2005 (FY05) (the most recent year for which complete eighteen-month publication data are available). Using the preceding

definition of small entity, the Office screened these published applications for commonly used alternative language (e.g., "contains one selected from the group consisting of") and identified 20,824 small entity applications as containing alternative language and, therefore, as potentially affected by the proposed rule. The Office estimates that this represents approximately 31 percent of total applications containing alternative language.

As anticipated, a larger proportion of applications containing alternative language is concentrated in the biotechnology/chemical arts (an estimated 9,186 of the 21,187 small entity applications in the biotechnology/chemical arts or 43.4 percent). The remaining applications with alternative language are distributed throughout the electrical and mechanical arts (an estimated 11,638 of the 73,831 small entity applications in the electrical/mechanical arts or 15.8 percent). These results are summarized in Table 1.

TABLE 1.—SMALL ENTITY APPLICATIONS (FY05)

| Type of art                               | Number of small entity applications | Number of small entity applications containing alternative language | Percent |
|---|-------------------------------------|---|---------|
| Biotechnology/Chemical Applications ..... | 21,187                              | 9,186   | 43.4    |
| Electrical/Mechanical Applications .....  | 73,831                              | 11,638  | 15.8    |
| Total Applications .....                  | 95,018                              | 20,824  | 21.9    |

4. *Description of the projected reporting, recordkeeping and other compliance requirements of the proposed rules, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record:* The proposed rule could potentially impact applicants in two ways. First, it would require that a claim must be limited to a single invention. Consequently, if a submitted application contains a single claim that defines multiple independent and distinct inventions, then the examiner may apply a restriction requirement. See *Examination of Patent Applications That Include Claims Containing Alternative Language*, 72 FR

at 44995. In this case of an intra-claim restriction, applicants who wish to pursue patent protection for the full scope covered by their initial application would have to file a divisional application for each additional invention defined in that original claim. For example, if a single claim contains three independent and distinct inventions and the Office requires restriction, the applicant could file two divisional applications to prosecute the full scope of the original claims. Alternatively, the applicant could elect not to file any divisional applications, in which case he or she would be limited to the one invention elected in the initial application.

To estimate the costs of one divisional application, the Office is using unit cost data from the American Intellectual Property Law Association (AIPLA) Report of the Economic Survey<sup>2</sup> and the Office fee schedule for fiscal year 2007. Based on these data, the Office estimates that the cost of filing one divisional application is \$10,258 (expressed in present value terms using a 7 percent discount rate). The cost faced by applicants could be greater than this amount if the applicant files more than one divisional.

Second, the proposed rule allows examiners to require applicants to simplify the presentation of claims with alternative language so that:

<sup>1</sup> This alternate small business size standard is the previously established size standard that identifies the criteria entities must meet to be entitled to pay reduced patent fees. See 13 CFR 121.802. If patent applicants identify themselves on the patent application as qualifying for reduced patent fees,

the Office captures this data in the Patent Application Location and Monitoring (PALM) database system, which tracks information on each patent application submitted to the Office.

<sup>2</sup> AIPLA Report of the Economic Survey 2007. Table Q33g, Third Quartile, "Patent application

amendment/argument, relatively complex, biotechnology/chemical (Preparation and Filing)." Page I-74; Table Q33l, Third Quartile, "Issuing an allowed application (all post-allowance activity)." Page I-81; Table Q33n, Third Quartile, "Pay a Maintenance Fee." Page I-76.





