

U.S. PATENT FILINGS AND THE PITFALLS OF CLAIMING SMALL ENTITY STATUS

Protection of proprietary technology via obtaining patent protection is a crucial yet expensive necessity across the competitive landscape of pharma, whether the company in question is big pharma or a start-up specialty pharma concern.

The decision to not incur the costs to investigate the possibility and/or to pursue adequate patent protection for a core technology is often a mistake that is realized too late. A serious issue that arises with cost-conscious companies that often does not receive adequate attention concerns the payment of small entity fees to the USPTO. The determination of whether an entity is entitled to make reduced fee payments to the USPTO during the prosecution of its patents is much more complex than many inventors, corporate decision-makers, and patent practitioners realize. As I will explain in the following paragraphs, the determinative factor as to whether an entity qualifies as a small entity for the purpose of paying reduced (small entity) fees is much more complex than merely determining the number of employees of that entity. Rather, that is only the starting point of the analysis.

The laws concerning the applicability of small entity status for patent filings are found in Title 13 of the Code of Federal Regulations (CFR). SBA size standards (found at 13 CFR 121) define whether a business concern qualifies for reduced Government fees, e.g., patent fees.

1. Determining Your Status

To be eligible for reduced patent fees under 13 CFR 121.802 (Small Business Size Regulations) a business concern must:

1. have less than 500 employees, including affiliates; and

2. 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 title.

However, certain businesses with less than 500 employees, may not qualify for small entity status depending on their primary industry and income.

A. Determining the Number of Employees

Employees counted for determining size include the total number of people employed by the concern. This number may be calculated by taking the average number of employees on payroll for each pay period of the prior year including part-time, full-time, temporary, and independent contractors. Where the concern has been operating for less than twelve months, the average number of employees on the payroll for the pay periods the concern has operated is used.¹

Part of the analysis concerning the number of employees includes the issue of whether the business concern has affiliated concerns. The employees of such concerns are counted for purposes of determining small entity status. Affiliates are defined in 13 CFR 121.103 as all subsidiaries, over which the concern has control, and parent companies which exercise, or have the capacity to exercise, control over the concern are affiliates and need to be considered when calculating the total number of employees in the next step. There are some exceptions, most of which can be categorized as investors without a controlling interest.²

¹ 13 CFR 121.106

² Further explanation can be found at 13 CFR 121.103(b).

If the number of employees is over 500, then the concern is a large-entity and does not qualify for reduced fees. No further consideration is necessary, the concern is considered a large-entity. If however, the number of employees is less than 500, the concern does not automatically qualify for small-entity status. Further steps must be taken and additional information must be gathered to determine the status of the concern, e.g., calculation of annual receipts

B. Calculation of annual receipts

If the number of employees of a business concern does not exceed 500 persons, then the next step in determining whether a concern qualifies for small entity status is to calculate annual receipts depending on the businesses' primary industry according to the North American Industry Classification System (NAICS).³

To determine the primary industry of the concern, a business concerns activities for the most recently completed fiscal year need to be examined. The industry generating the bulk of earnings, the employees' area of expertise and experience, and expenditures in the industries where the concern operates are all relevant in addition to the distribution of patents, contract awards and assets.⁴

Annual receipts are defined as "total income" plus "cost of goods sold" (profits) as the terms are defined by the IRS.⁵ Where the business has been operating for more than three years, the annual receipts are equal to the receipts over the preceding three years divided by three. For less than three years of operation, annual receipts are calculated by taking the receipts for the period the business has operated, divided by the number of weeks in the period of operation multiplied by 52. In other words, the average weekly receipts for the period of operation is multiplied by 52. It should be noted that the receipts of all affiliates are included when calculating annual receipts.

³ A list of the SBA Standards by NAICS Industry is set out at 13 CFR Sec. 121.201.

⁴ 13 CFR 121.107

⁵ 13 CFR Sec. 121.104

C. **Third Party Interests in the Patent Filing**

If any right in the patent filing has been given to a third party (e.g., via an assignment or license), such right must not have been given to a large entity in order to maintain small entity status. For example, if there has been an assignment or license, the size of the assignee concern must be evaluated as discussed above (e.g., affiliates and number of employees).

2. **Assertion of Small Entity Status for Paying Reduced Patent Fees**

Title 37 CFR 1.27 establishes the rules governing assertion of small entity status for payment of reduced patent fees. Any party (person, small business concern, or nonprofit organization) entitled to reduced patent fees must make an assertion of entitlement to small entity status in the application or patent in which small entity fees are to be paid.⁶

The assertion may be by writing or by payment of the small entity basic filing or basic national fee. Status as a small entity must always be established by an assertion in any related, continuing or reissue application, if so appropriate and desired. Also, once small entity status has been established in an application, a new determination of entitlement to small entity status is needed when the issue fee and maintenance fees are due.

3. **Good Faith Error in Asserting Small Entity Status**

Small entity status established in good faith that is later found to be in error will be excused upon compliance with the requirements set forth in the rules and the

⁶ 37 CFR 1.27(c)

deficiency payment required.⁷ Improper payment of a maintenance fee paid as a small entity when small entity status has been established, but the small entity status is no longer appropriate will not be considered to involve expiration of the patent. However, payment of a maintenance fee as a small entity where small entity status was not established will result in expiration of the patent, unless the full maintenance fee due or a written assertion of small entity status is timely filed.

4. Fraudulent Assertion of Small Entity Status on the Patent Office

Any attempt to fraudulently establish or improperly establish with intent to deceive status as a small entity, or pay fees as a small entity, shall be considered as a fraud practiced or attempted on the Office. Fraudulent or improper establishment with intent to deceive small entity status may result in the patent being found invalid.

Correction of an erroneously paid small entity issue fee is addressed at 37 C.F.R. § 1.28(c)(2). Correction may be accomplished at any time so long as the payment is accompanied by a statement of how the error occurred in good faith and when the error was discovered. (Id.). The Court of Appeals for the Federal Circuit has further noted that “these regulations permit correction of honest mistakes, but prevent attempts to fraudulently pay the small entity issue fee while maintaining an enforceable patent.” See, *DH Technology, Inc., v. Synergystex International, Inc.*, 154 F.3d 1333 at 1343 (Fed. Cir. 1998). Allegations of unenforceability or expiration of patents due to incorrect payment of patent maintenance fees as a small entity have been raised in federal court patent infringement actions. In situations where the error was made in good faith, the Federal Circuit has ruled that such errors do not render the patent unenforceable or expired. (See, *Ulead Systems Inc. v. Lex Computer & Management Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003); *Cardiac Pacemakers, Inc. v. St. Judes Medical, Inc.* 381 F.3d 1371 (Fed. Cir. 2004)).

⁷ See, 37 CFR 1.28(c)(1) and (c)(2).

Conclusion

The decision to save costs by paying small entity patent fees to the USPTO is one which requires more thought and attention than most business concerns, and in fact most patent practitioners, realize. A determination that a business concern is entitled to small entity status and a reduction of patent fees should be made carefully and with consideration of all of the above issues. Further, if a determination of small entity status is made, this determination should be periodically reviewed, particularly in the situation where the possibility of company growth, co-development agreements or out-licensing exists.

By: Cliff Davidson, Esq.
Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, New York, NY 10018
Telephone: (212) 736-1940
Facsimile: (212) 736-2427
Email: cdavidson@ddkpatent.com
www.ddkpatent.com