Commissioner of Patents and Trademarks
Patent and Trademark Office (P.T.O.)

IN RE HERBERT DUBNO, PETITIONER
June 30, 1989

Donald J. Quigg

Commissioner of Patents and Trademarks

Decision on Petition

***1** Herbert Dubno petitions the Commissioner under 37 CFR § 1.183 to suspend rule 1.765(d) to permit consideration of his third-party protest to a patent term extension application.

Background

Petitioner filed a protest under 37 CFR § 1.291 on April 10, 1989. The protest was against a patent term extension application which petitioner alleged to be incomplete or erroneous. The protest papers were returned without consideration on April 12, 1989 pursuant to 37 CFR § 1.765(d). Petitioner filed this petition on April 24, 1989, seeking suspension of 37 CFR § 1.765(d) claiming extraordinary circumstances.

Opinion

Petitioner contends that 35 U.S.C. § 156, which provides for patent term extension, does not bar third-party intervention or protest. However 37 CFR § 1.765(d) prohibits such protests:

> (d) The duty of disclosure pursuant to this section rests on [the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantially involved on behalf of the patent owner] and no submission on behalf of third parties, in the form of protests or otherwise, will be considered by the Office. Any such submissions by third parties to the Office will be returned to the party making the submission, or otherwise disposed of, without consideration by the Office.

Section 1.765(d) states there is no third-party participation in a patent term extension. However, 37 CFR § 1.183 allows for the suspension or waiver of the rules "in an extraordinary situation, when justice requires". Pursuant to 37 CFR § 1.183 petitioner contends that there are extraordinary circumstances warranting suspension or waiver of the prohibition against protests by third parties in this case.

The extraordinary circumstances petitioner relies upon are:

> 1. Unique circumstances under which Applicant is attempting to extend the term of the patent which does not cover specifically the composition which Applicant claims to be the basis for the regulatory review delay, but rather a component of the composition which was not

subject to that delay; and

2. the collateral effort by Applicant to cover the composition utilized as a basis for the application in a further patent application which may extend a monopoly through two patent lives.

These circumstances appear to go to the merits of petitioner's protest. Assuming these contentions are true, they fall within the scope of the facts reviewed in making the determination on patent term extension eligibility. Accordingly, no extraordinary situation has been shown which justifies a waiver of § 1.765(d). Further, a waiver of the rule would not be justified in view of the intent of the legislation and rules to make patent term extension an ex parte proceeding without third-party participation.

***2** The patent term extension legislation provides for extensions when a very specific set of criteria have been fully met. If those criteria are not met, a patent is not eligible for extension. The criteria and procedures set out in the statute are designed to guard against the circumstances petitioner appears concerned about. Among the requirements of 35 U.S.C. § 156 is subsection (d)(4) which provides:

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner. The disclosure requirements are set out in 37 CFR § 1.765(d). The duty of disclosure falls squarely on the shoulders of the patent holder and his agents. It does not contemplate disclosure by "interested" third parties.

The rules track the statutory intent of providing a closely circumscribed procedure for obtaining a patent term extension. The statute only allows for third-party participation before the appropriate Secretary charged with determining the regulatory review period. See 35 U.S.C. § 156(d)(2)(B)(ii).

The ex parte nature of the matter before the Commissioner is stated in 35 U.S.C. § 156(e)(1):

A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension....

The ex parte nature of the proceedings are also reflected in H.Rep. No. 857, 98th Cong., 2d Sess., Part 1, 42-43 (1984), reprinted in 1984 U.S.Code Cong. & Admin.News 2647, 2675-76

The Commissioner's decision regarding a patent's eligibility for extension under the rules of section 156(a) may be based solely on the information contained in the application. The burden is on the applicant to show that all patents which are relevant to the eligibility determination have been considered and do not prevent the requested extension.

While the Commissioner would be responsible for evaluating the applicant's determination regarding the patents listed in the application, the Committee expects that most reviews would be ministerial in nature. Since the applicant is under a duty to disclose all relevant information (see section 156(d)(4)), the application should be so well documented that a substantive review by the Commissioner would usually not be necessary.

In discussing section 156(d), the House Report provides:

To obtain an extension, the patent owner or its agent would submit an application to the Commissioner of Patents and Trademarks within 60 days of approval of the approved product. The application would contain

the information described in subparagraphs (A)-(G) of section 156(d)(1). The applicant would be subject to any disclosure requirements prescribed by the Commissioner. The Committee expects that those requirements would subject the applicant to at least the same duty of disclosure, and the penalties and loss of rights for violation of the duty of disclosure, which governs all patent application proceedings before the Patents and Trademarks Office.
***3** Id. at 2674.

A waiver of the rules in the present case to permit a third party submission would not be justified in view of the intent of the legislation and rules to make patent term extension essentially an ex parte proceeding. Further, the circumstances set forth in this petition do not rise to the level of extraordinary in that they fall clearly within the scope of the determination made based upon the face of the application in conjunction with the duty of disclosure.

In light of the foregoing, the protest filed by petitioner on April 10, 1989 is an improper submission under 37 CFR § 1.765(d). Further, petitioner has not set forth an extraordinary situation sufficient to warrant waiver of 37 CFR § 1.765(d). The petition is DENIED.

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