

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

FEB 8 1993

In re Sankyo Company Limited :
Request for Patent Term Extension : DECISION DENYING
U.S. Patent No. 4,486,425 : APPLICATION
_____ :

An application for extension of the patent term of U.S. Patent No. 4,486,425 granted on December 4, 1984, was filed under 35 U.S.C. § 156 in the Patent and Trademark Office (PTO) on December 7, 1992. The application for extension was filed by the assignee of record Sankyo Company Limited through its duly authorized agent, The Upjohn Company. Applicant requests a 3.2 year extension of the '425 patent on the basis of new drug applications (NDAs) simultaneously approved by the Food and Drug Administration (FDA) for a product containing the active ingredient cefpodoxime proxetil. The '425 patent claims the active ingredient cefpodoxime proxetil in the drugs VANTIN Tablets, VANTIN Oral Suspension, BANAN Tablets, and BANAN Oral Suspension.

The FDA official records indicate that the product was subject to a regulatory review period before its commercial marketing or use, as required under 35 USC § 156 (a)(4), and that it represents the first permitted commercial marketing or use of the active ingredient cefpodoxime proxetil.

The New Drug Applications were approved on August 7, 1992, which makes the submission of the patent term extension application outside the sixty-day period beginning on the day the NDAs were approved, and accordingly, untimely within the meaning of 35 USC § 156 (d)(1). However, applicant requests that the application be considered as timely filed since the failure to file within the sixty days was "unintentional". Applicant claims that due to a misunderstanding between it and its U.S. licensee, The Upjohn Company, applicant was not aware until December 4, 1992, that the patent extension application had not been filed. Therefore, applicant requests that the sixty-day period referred to in 35 USC § 156 (d)(1) be interpreted as commencing on the date that applicant first became aware of an "unintentional" failure to file an application for extension.

Applicant maintains that public policy supports the requested remedial interpretation of the duration of the sixty-day period, arguing that Congress has twice in the last ten years (1982 and 1992) amended the patent statutes to remedy unintentional failures to act. Applicant notes the court in Unimed v. Quigg, 12 USPQ2d 1644, 1646 (Fed. Cir. 1989) stated that the sixty-day period in section 156 (d)(1) begins on the FDA approval date, but argues the court's decision was before the latest statement from Congress evincing a remedial approach to such matters, and involved different facts than those herein.

Section 156 (a)(3) provides that an application for patent term extension must be submitted by the owner of record of the patent or its agent in accordance with the requirements of subsection (d). Subsection 156 (d)(1) provides:

- (1) To obtain an extension of the term of the patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. ... (emphasis added).

The starting point for statutory interpretation is the plain language of the statute. The statute itself must be regarded as conclusive of the meaning absent a clearly contrary legislative intent. Burlington Northern R.R. Co. v. Oklahoma Tax Comm'n, 481 U.S. 545, 461 (1987); Ethicon v. Quigg, 849 F.2d 1422, 7 USPQ2d 1152 (Fed. Cir. 1988). Statutory words are normally presumed, unless the contrary appears, to be used in their ordinary and usual sense, and with the meaning commonly attributed with them. Calminetti v. United States, 242 U.S. 470, 485 (1917) [the meaning of a statute must, in the first instance, be sought in the language in which the act is framed and, if that is plain, the sole function of the court is to enforce it according to its terms].

The plain language of the statute states that an application for patent term extension is timely only if submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. Read in the light of the definition of "regulatory review period", this language is crystal clear. Unimed v. Quigg, *supra* at 1646. Applicant's application was filed outside the sixty-day period. Clearly it would be inconsistent with the plain language of the statute to make the sixty-day requirement a subjective test based on remedial considerations or on the patent owner's

intent, knowledge or inaction, as the clarity of the statute admits of no other meaning than that the sixty-day period begins on the FDA approval date. Accordingly, the application for patent term extension must be denied because it was not filed within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use.

For the reasons advanced above, the term of U.S. Patent 4,486,425 is not eligible to be extended under 35 USC § 156.

C. E. Van Horn

Charles E. VanHorn
Patent Policy & Projects Administrator
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Re: Vantin Tablets
Docket No. 93E-0009

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