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In re Hoechst-Roussel Pharmaceuticals Inc.
Request for Patent Term Extension
U.S. Patent No. 4,631,286

:DECISION DENYING
: APPLICATION

An application for extension of the term of U.S. Patent No. 4,631,286 (hereinafter "Hoechst patent") was filed under 35 U.S.C. § 156 in the Patent and Trademark Office (PTO) on November 4, 1993. Petitions under 37 C.F.R. § 1.182 to determine the question of whether the Hoechst patent was eligible for patent term extension were filed on December 13, 1993, November 4, 1994, and March 15, 1995. The application was filed by the assignee of the Hoechst patent, Hoechst-Roussel Pharmaceuticals Inc. (Hoechst-Roussel). The Hoechst patent claims the drug velnacrine and a method of treating a patient in need of memory enhancement by administering velnacrine to the patient.

An extension of the term of the Hoechst patent is sought based on the premarket approval by the Food and Drug Administration (FDA) of the human drug product COGNEX® which was approved for treatment of dementia in patients with Alzheimer's disease. The active ingredient of COGNEX® is tacrine hydrochloride which is claimed in U.S. Patent No. 4,816,456 (hereinafter "Warner patent"). The Warner patent is held by another party, the Warner-Lambert Company (Warner-Lambert). Warner-Lambert sought and obtained approval from the FDA to market COGNEX®. Hoechst-Roussel was not involved in the approval proceeding before FDA. Hoechst-Roussel appears to have no relationship to Warner-Lambert. Tacrine hydrochloride is not literally claimed in the Hoechst patent. Tacrine hydrochloride, when administered, metabolizes within the human body into several compounds. One of these compounds is velnacrine. As noted above, the Hoechst patent claims administering velnacrine to a patient.

The application raises the question of whether Hoechst-Roussel is eligible to file an application for patent term extension based on a regulatory review conducted by its competitor, the marketing applicant Warner-Lambert, wherein Hoechst-Roussel was not associated with the regulatory review that led to FDA approval for commercial marketing of the approved product. If Hoechst-Roussel's request is granted, it would preclude Warner-Lambert

from obtaining an extension of the patent term for the patented chemical that was the subject of Warner-Lambert's original regulatory review. The application also raises the question of whether Hoechst-Roussel's patent "claims" the approved product within the meaning of 35 U.S.C. § 156 as required by the statute. Further, the application raises the question of whether 35 U.S.C. § 156(b)(2) gives petitioner any right to use the approved product during the period of extension.

DISCUSSION

Hoechst-Roussel's arguments in its petition filed December 13, 1993, relating to 37 C.F.R. § 1.785 are not on point. Section 1.785, as presently written, controls when multiple patents are eligible for patent term extension for the same approved product. In the present case 37 C.F.R. § 1.785 does not apply to Hoechst-Roussel's application for patent term extension because, for the reasons set forth below, Hoechst-Roussel's patent is not eligible for patent term extension. To the extent that 37 C.F.R. § 1.785 is confusing, the proposed amendment to 37 C.F.R. § 1.785 clarifies that the applicant for a patent term extension must be the patent owner or its agent, and the patent owner or its agent must be the party that obtained FDA approval. See Amendment to Rules for Extension of Patent Term, 1169 OG 33 (December 13, 1994), 59 FED. REG. 56015 (proposed November 10, 1993) (Fed. Reg. copy enclosed).

Is Hoechst-Roussel eligible to file?

The application states that the patent claims an approved product that was subject to regulatory review under Section 505 of the Federal Food, Drug and Cosmetic Act. The application further states that FDA approval for the product upon which the application for extension is based was obtained by another party, the marketing applicant, Warner-Lambert. While the application does not so state, it does not appear that Hoechst-Roussel participated in or was associated in any manner with the regulatory review that led to FDA approval for commercial marketing of COGNEX for treatment of dementia in patients with Alzheimer's disease.

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. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461 (1987); Ethicon v. Quigg, 849 F.2d 1422, 7 USPQ2d 1152 (Fed. Cir. 1988). See also, Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 395, 13 USPQ2d 1628, 1630 (Fed. Cir. 1990)(absent a "clearly expressed legislative intention to the

contrary," the plain meaning of a statute "must ordinarily be regarded as conclusive"). Statutory words are normally presumed, unless the contrary appears, to be used in their ordinary and usual sense, and with the meaning commonly attributed to them. E.g., 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 language of the statute is clear and unambiguous. Section 156(a)(3), when read in combination with Section 156(d)(1)(D), specifically requires that the applicant for patent term extension must also be the party who undertook the activities during the regulatory review period to obtain approval of the product before the FDA. Section 156(a)(3) describes a condition necessary to obtain an extension of a patent:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if...
>
> > (3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d)....

35 U.S.C. § 156(a)(3) (emphasis added).

Thus, only the patent owner or its agent may be an applicant for an extension of the patent term. Section 156(d)(1) reemphasizes this by requiring the owner or its agent to apply for the extension:

> (d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. . . .

35 U.S.C. § 156(a)(3) (emphasis added).

In determining eligibility for and the length of any extension, the activities of "the applicant" during the regulatory review

are made relevant by the statute. Thus, subparagraph 156(d)(1)(D) describes a requirement of an application for extension:

> The application shall contain- . . .
>
> > (D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities . . . .

35 U.S.C. § 156(d)(1)(D) (emphasis added).
The phrase "the applicant" in subparagraph (D) is clearly a reference to the applicant for extension (Hoechst-Roussel). The only antecedent for the phrase in subsection (D) is a reference to the only parties who may be an applicant, "the owner of record of the patent or its agent" in paragraph (d)(1). Hoechst-Roussel's faulty interpretation of the statute would require reporting of Hoechst-Roussel's activities during the Warner-Lambert regulatory review period. It is unclear how the knowledge of Hoechst-Roussel's activities could assist the Commissioner in determining whether the protection for the approved drug should be extended. See 35 U.S.C. § 156(c)(1). Furthermore, 35 U.S.C. § 156(d)(3) defines due diligence as:

> That degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

It is not clear how Hoechst-Roussel's activity of not pursuing tacrine approval would fit within the ambit of due diligence in the pursuit of regulatory approval of tacrine.

Under Section 156(c)(1) of the statute, the length of any extension is dependent upon a variety of factors. One factor is diligence in obtaining approval. The length of the extension is reduced by any period in which there was lack of diligence during the approval process. More specifically, subsection (c) provides:

> (c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review for the approved product which period occurs after the date the patent is issued, except that-
>
> > (1) each period of the regulatory review period shall be reduced by any period determined under subsection

> (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period . . . .

35 U.S.C. § 156(c)(1) (emphasis added).

Pursuant to subparagraph (d)(2)(B) of Section 156, any interested party may ask the appropriate Secretary to make a determination as to whether "the applicant" acted with diligence during the regulatory review period. While subsection (d)(2)(B) does not include the phrase "for the patent extension," the reference in paragraph (c)(1) to subparagraph (d)(2)(B) shows that the phrase "the applicant" means "the applicant for the patent extension."

As noted in Unimed v. Quigg, 888 F.2d 826, 829, 12 USPQ2d 1644, 1647 (Fed. Cir. 1989), 35 U.S.C. § 156 was intended to ameliorate the loss incurred when patent terms tick away while the patented product is awaiting regulatory approval for marketing. A patent owner who does not seek, either directly or indirectly through a licensee or other agent, to market a product protected by its patent does not lose any patent term to the regulatory process. Such a patent owner is not an intended beneficiary of § 156. Granting a patent term extension to a patent owner that did not participate in the regulatory process would constitute an unearned windfall to the patent owner, based on activities before the regulatory agency in which it took no part. An unearned windfall was neither anticipated nor desired by Congress in enacting 35 U.S.C. § 156.

35 U.S.C. § 156(c)(4) states:

> The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent issued, except that -- in no event shall more than one patent extend under subsection (e)(1) for the same regulatory review period for any product.

The present case requests extension of the Hoechst patent. An extension of the Hoechst patent based upon the Warner-Lambert regulatory period would preclude the extension of the Warner patent because there is only a single regulatory period to rely on. Nevertheless, extension of the Warner patent based upon regulatory activities of Warner-Lambert would have no effect on a possible extension of the Hoechst patent if it were based upon activities by Hoechst because they claim entirely different chemical compositions. Under petitioner's viewpoint, although Warner-Lambert spent the time and capital for regulatory

approval, the Warner patent could not be extended. Instead, under petitioner's viewpoint, Hoechst would reap the benefit. Moreover, 35 U.S.C. §156(e)(1) indicates that:

> 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 extension.

Thus, a direct result of Hoechst-Roussel's position is that an individual, A, who sought regulatory approval could be without the potential for extension of A's patent term if a competitor sought benefit of A's regulatory period. The individual that originally labored to obtain regulatory approval would not even have the right to present his case before the Commissioner. Hoechst-Roussel's position would not appear to comport with the due process requirements of the Constitution. Moreover, Hoechst-Roussel's position provides a patent holder with an incentive not to rapidly seek FDA approval if a competitor has sought such approval for a similar drug. A statute must be construed, if possible, to avoid absurd results. United States v. Turkette, 452 U.S. 576, 580 (1981). Accordingly, Hoechst-Roussel's argument, that a patentee can select any approval period, including that of another marketing applicant, is unpersuasive.

The legislative history clearly shows that Congress assumed that the patent term extension applicant, the patent owner or its agent, would also be the marketing applicant. In addressing proposed Section 156(d)(1), which section requires the patent owner to be the applicant for extension, the House Report states:

> Proposed section 156(d) sets forth procedures for applying for an extension. To obtain an extension, subsection (d)(1) requires the patent owner or its agent [to] submit an application to the Commissioner of Patents and Trademarks within 60 days of approval of the approved product. The application shall contain the following information: . . . (F) a brief description of the activities undertaken by the applicant during the regulatory period with respect to the approved product and when . . . .

H.R.Rep.No.98-857, Part II, 98th Cong. 2d Sess. (1984), reprinted in 1984 U.S. Code Cong. & Admin. News 2647, 2707 (emphasis added).

As noted above, subsection (c) specifically requires the extension applicant (patent owner or its agent) to be the

marketing applicant. The House Report, when addressing proposed subsection 156(c)(1) states:

> Subsection (d)(2)(B) authorizes any interested person to petition the Secretary for a determination regarding whether the applicant for an extension acted with due diligence during the regulatory review period of the approved drug.

1984 U.S. Code Cong. & Admin. News at 2708 (emphasis added). Thus, the activities made relevant by the statute are those of the applicant for extension, i.e., the patent owner or its agent. The "brief description of the activities undertaken by the applicant during the applicable regulatory review period" required by Section 156 (d)(1)(D) are the activities of the patent owner or its agent. Similarly, the activities that may result in a reduction of the term of the extension are those of the applicant for the extension, the patent owner or its agent. E.g., see 35 U.S.C. § 156(d)(2)(B)(i) and (ii). One principal underlying purpose of the statute is to encourage research and development of new products by permitting the patent owner to recoup some of the time lost on the life of the patent while pre-marketing approval of the product was obtained. The House Report states:

> Title II of this bill would extend the amount of time for which certain patents are issued to include some or all of the time required for a manufacturer to test a product for safety and efficacy and to receive market approval. . . . FDA would also monitor diligence in product testing which must be shown in order for a manufacturer to receive . . . patent term extension.

1984 U.S. Code Cong. & Admin. News at 2716. When addressing the Summary of the Statute, the House Report states:

> In general, the bill provides that a patent may be extended for a period of up to five years if the patented drug (or other item subject to regulatory review by the FDA) has undergone regulatory review. The bill provides several general rules for calculating the period of extension.... Finally, any part or all of the patent extension may be canceled if the applicant for an extension failed to act with due diligence in conducting tests or in the submission of data to the FDA.

1984 U.S. Code Cong. & Admin. News at 2690 (emphasis added). It is apparent the Congress intended to provide partial compensation to patent owners for the time and expense of FDA marketing approval incurred by the patent owner or its agent; not

to provide an unearned windfall to the holder of a different patent for the regulatory review efforts of a third party where the patent owner did not participate, either directly or indirectly, in the regulatory approval process. Manifestly, the applicant for the extension and the marketing applicant do not have to be the same. However, one party must be the agent of the other to fall within the scope of the statute. The activities of a totally unrelated party are of no concern under the statute.

Hoechst-Roussel's assertion that the FDA regulatory approval requirements deprived them of royalties from Warner Lambert does not affect this analysis. The intent of 35 U.S.C. § 156 was to reward the patent owner for the efforts and time required to obtain regulatory approval. Hoechst-Roussel obtained a consent judgment indicating that Warner-Lambert infringed the '286 patent. Therefore, Hoechst-Roussel's position is that but-for the regulatory approval process, their competitor would have initiated the tortious act of infringement sooner and they would be entitled to additional royalties. This does not justify extension of the '286 patent. The fact that the regulatory review period precluded the tortious act of infringement would appear to be a benefit of the regulatory review process. The PTO will not presume that in the absence of a regulatory approval period, the tortious act of infringement would have occurred sooner.

Does U.S. Patent No. 4,631,286 claim the approved product or the method of using or making the approved product?

35 U.S.C. § 156 states:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if-
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use . . . .
>
> (f) For the purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of-
> (A) a new drug, antibiotic drug, . . . as those terms are used by the Federal Food, Drug, and Cosmetic Act. . . including any salt or ester or the active ingredient . . . .

Accordingly, one requirement of the statute is that the patent

must claim the approved product or a method of using or manufacturing the product. Hoechst-Roussel's patent, U.S. Patent No. 4,631,286, includes claim 1, that encompasses velnacrine, and claims 138[1], 140 and 142, that encompass the use of velnacrine. The chemical name of velnacrine is 9-amino-1,2,3,4-tetrahydroacridin-1-ol (1-hydroxy-THA or 1-OH-THA). The chemical name of COGNEX® (tacrine hydrochloride), the approved product, is 9-acridinamine, 1,2,3,4-tetrahydro-monohydrochloride or 9-amino-1,2,3,4-tetrahydroacridine monohydrochloride. The two compounds are not the same, and velnacrine is neither a salt nor an ester of the active ingredient, i.e. tacrine hydrochloride, of the approved drug product. Therefore, the claims of the patent that encompass velnacrine do not encompass COGNEX®, the approved product. Claim 138 claims that velnacrine is "administered to the patient." Velnacrine is not an ingredient of COGNEX®, the approved product. Since administering COGNEX® to a patient is not the same as administering velnacrine, claim 138 does not literally claim the use of the approved product.

Hoechst-Roussel's argument that the use of COGNEX® infringes its patent is inapposite. Whether a patent is infringed and what is being claimed are different issues. The fact that the body of a patient who has taken COGNEX® may make the claimed product[2] is not relevant to the issue of whether Hoechst-Roussel has met the statutory requirement of claiming the active ingredient of the approved product or the method of use or manufacturing of the active ingredient of the approved product.

To be eligible for patent term extension, the patent must claim an active ingredient of the approved product or the method of use or

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[1]Claim 138, for example, recites "[a] method of treating a patient in need of memory enhancement, wherein an effective memory enhancing amount of a compound defined in claim 1 is administered to the patient." The compound of claim 1 is understood to include velnacrine.

[2]It is not disputed that tacrine hydrochloride metabolizes into velnacrine, among other substances. Researchers have shown that tacrine hydrochloride metabolizes into not only velnacrine (9-amino-1,2,3,4-tetrahydroacridin-1-ol (1-OH-THA), but also 9-amino-1,2,3,4-tetrahydroacridin-2-ol (2-OH-THA), 9-amino-1,2,3,4-tetrahydroacridin-4-ol (4-OH-THA) and N-methoxy-1,2,3,4-tetrahydroacridin-9 (10*H*)-imine. Robert S. Hsu et al., Note, High-performance liquid chromatography for the determination of tacrine and its metabolites in plasma, 530 J. Chromatogr. 170,171 (1990) (Exhibit L to petitioner's application for patent term extension).

manufacturing of the active ingredient. 35 U.S.C. § 156(f)(2)(A). "[A]n 'ingredient' must be present in the drug product when administered." Glaxo Operations UK, Ltd. v. Quigg, 706 F. Supp. 1224, 1227-28, 10 USPQ2d 1100, 1103 (E.D. Va. 1989), aff'd 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990). Velnacrine is not present in COGNEX® and thus is not present when that drug product is administered. Accordingly, velnacrine cannot be an active ingredient as defined by the statute.

Hoechst-Roussel also argues that the Hoechst patent claims the approved drug because a letter to Hoechst-Roussel from Ronald L. Wilson, Director of the Health Assessment Policy Staff, of the FDA states that the product claimed in the patent is COGNEX®. This letter was generated in response to a letter from the Patent and Trademark Office requesting confirmation that the product identified in the application was subject to a regulatory review and that the review was before its first commercial marketing and use. It is not FDA's responsibility to determine what drugs are claimed in the listed patent. This information is simply taken from the application for patent term extension: an application prepared by Hoechst-Roussel. Whether a patent claims the approved product is one requirement of eligibility for a patent term extension. The Patent and Trademark Office is charged with the responsibility of determining whether a patent is eligible for extension. 35 U.S.C. 156(d)(1)(C). See also Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 399, 13 USPQ2d 1628, 1633 (Fed. Cir. 1990)("Congress left to the Commissioner's technical expertise . . . determin[ation of] whether any patented chemical compound named in a patent term extension application fell within the statutory definition of 'product'" (emphasis omitted)). This view is mirrored in the legislative history which states that the

> PTO would be responsible for handling patent extension applications and for determining extension eligibility.

1984 U.S. Code Cong. & Admin. News 2647, 2707. Accordingly, the fact that Mr. Wilson names COGNEX® as the product claimed is neither controlling nor relevant. Similarly, the fact that the FDA'a Approved Drug Products Book lists United States Patent No. 4,631,286 in the Patent-Use Code for tacrine hydrochloride is not controlling in the PTO's determination.

As the Hoechst patent does not claim the subject product or the method of use or manufacturing of the subject product of the FDA regulatory review at issue, it is not eligible for patent term extension under the provisions of 35 U.S.C. § 156(a).

Does 35 U.S.C. § 156 (b)(2) give petitioner the right to use the product as approved?

35 U.S.C. § 156 (b) states:

> Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended - . . .
> (b) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product . . . .

Hoechst-Roussel has not shown any right to use the approved product, COGNEX®. Hoechst-Roussel's patent does not claim the method of using the approved product and instead claims the method of administering a metabolite (velnacrine) of the approved product. The FDA, however, approved the use of COGNEX®, not velnacrine, in treatment of Alzheimer's disease. The purpose of the statute is to extend a patentee's right to use an approved product for the duration of the patent term extension. Accordingly, it would be meaningless to grant a patent term extension to a party who has not been granted the right by the FDA to use the approved product. A statute must be construed, if possible, to avoid absurd results. Turkette, 452 U.S. at 580 (1981). Accordingly, Hoechst-Roussel is not entitled to a patent term extension as its grant would be contrary to the intent of the statute. Hoechst-Roussel's drug has not, at present, been approved by the FDA and does not fall within the ambit of subject matter addressed by 35 U.S.C. § 156.

CONCLUSION

In view of all of the above, the application for patent term extension is denied because: (1) the application does not set forth any activities undertaken by the "applicant" -- the patent owner or its agent, as required by the statute; (2) the patent does not claim the approved product or a method or use or manufacturing of the approved product as required by Section 156(a); and (3) the statute does not provide Hoechst-Roussel any rights under § 156(b).

To the extent that the noted petitions request denial of an application under 35 U.S.C. § 156 by Summers for extension of the term of the Warner patent, the petitions constitute a third party protest, and are therefore denied. 37 C.F.R. § 1.765(d). See also In re Dubno, 12 USPQ2d 1153 (Comm. Pat. & Tm. 1989) (stating that an application for patent term extension is intended to be an ex parte proceeding in the Patent and Trademark Office, where participation by third parties is not allowed).

Finally, the request for a stay of proceedings in both the

Hoechst-Roussel and Summers applications pending the outcome of litigation in the United States District Court for the District of Delaware between Hoechst-Roussel and Warner-Lambert Company is dismissed as moot since the matter has been settled.

Accordingly, the application under 35 U.S.C. § 156 by Hoechst-Roussel for extension of the term of U.S. Patent No. 4,631,286 cannot be granted.

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for Patent Policy and Projects

cc: RONALD L. WILSON, DIRECTOR
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RE: COGNEX®
FDA DOCKET NO: 93E-0454