894 F.2d 392

58 USLW 2480, 13 U.S.P.Q.2d 1628

GLAXO OPERATIONS UK LIMITED, Plaintiff-Appellee,
v.
Donald J. QUIGG, Assistant Secretary of Commerce
and
Commissioner of Patents and Trademarks,
Defendant-Appellant.

No. 89-1407.

**United States Court of Appeals,
Federal Circuit.**

Jan. 24, 1990.

Donald O. Beers, Arnold & Porter, Washington, D.C., argued for plaintiff-appellee. With him on the brief were Stuart J. Land, John Agar and David E. Korn. Also on the brief was Richard E. Fichter, Bacon & Thomas, Alexandria, Va., of counsel.

Irene M. Solet, Dept. of Justice, Washington, D.C., argued for defendant-appellant. With her on the brief were Stuart E. Schiffer, Acting Asst. Atty. Gen., Henry E. Hudson, U.S. Atty. and John F. Cordes. Also on the brief were Fred E. McKelvey, Sol., Charles E. Van Horn, Deputy Sol. and John C. Martin, Associate Sol., Patent and Trademark Office, Arlington, Va., of counsel.

Before ARCHER and MICHEL, Circuit Judges, and BALDWIN, Senior Circuit Judge.

MICHEL, Circuit Judge.

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Donald J. Quigg, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks (Commissioner), appeals the Order of the United States District Court for the Eastern District of Virginia, dated February 28, 1989, granting summary declaratory judgment to Glaxo Operations U.K. Ltd. (Glaxo). See Glaxo Operations UK Ltd. v. Quigg, 706 F.Supp. 1224, 10 USPQ2d 1100 (E.D.Va.1989). The court declared in its Order that Glaxo's application for patent term extension for U.S. Patent No. 4,267,320 satisfies the requirements of 35 U.S.C. Sec. 156(a) (Supp. V 1987), a provision of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Act), tit. II, Sec. 201(a), 98 Stat. 1598. Because the district court correctly construed and properly applied the operative terms of the Act, we affirm.

Background

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Glaxo is the assignee of U.S. Patent No. 4,267,320 ('320), issued May 12, 1981, which claims cefuroxime axetil, an antibiotic drug. In 1985, Glaxo sought approval from the Food and Drug Administration (FDA) to market a form of this drug, CEFTIN[1] tablets, and received approval on December 28, 1987. The active ingredient of CEFTIN tablets is cefuroxime axetil. The properties

of this compound are such that it becomes therapeutically active and effective when orally administered. Cefuroxime axetil is an ester[2] of cefuroxime, an organic acid.

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Cefuroxime and its salts[3] are claimed in Glaxo's U.S. Patent No. 3,974,153. Cefuroxime and two of its salts, marketed as ZINACEF and KEFUROX, are therapeutically active antibiotics only when administered intramuscularly or intravenously. None of these compounds are effective if orally administered. FDA approved ZINACEF in 1983 and various dosage strengths of KEFUROX in 1986 and 1987, but the acid cefuroxime has not been approved.

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Glaxo sought a patent term extension for its '320 patent (cefuroxime axetil) because of the lost marketing time due to the lengthy FDA review process. The Commissioner denied the extension asserting that the 1987 FDA approval of CEFTIN was not the first permitted commercial marketing or use of the "product" because ZINACEF and KEFUROX had previously been approved, and therefore the '320 patent was not eligible for a term extension under the Act. See In re Glaxo Operations UK Ltd., Request for Patent Term Extension Under 35 U.S.C. Sec. 156 for U.S. Patent No. 4,267,320 (Sept. 9, 1988).

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Glaxo sought declaratory and injunctive relief under the Administrative Procedures Act (APA), 5 U.S.C. Sec. 702 (1988), for which the federal district court had jurisdiction under 28 U.S.C. Sec. 1338(a) (1982). Glaxo then filed a motion for summary judgment. In responding to that motion, the Commissioner modified his grounds for rejection of Glaxo's patent term extension application. See Glaxo, 706 F.Supp. at 1226, 10 USPQ2d at 1102. The dispute between Glaxo and the Commissioner, however, remains focused entirely on the proper interpretation of one statutory eligibility requirement for patent term extension. Its application in this case, once properly construed, is not in dispute.

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For a patent to be eligible for a term extension, among other things the product must have been "subject to a regulatory review period" and "the permission for the commercial marketing or use of the product after such regulatory review period [must have been] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." 35 U.S.C. Sec. 156(a)(4) & (5) (Supp. V 1987) (emphasis added). Moreover, the Act explicitly defines "product" as "the active ingredient of a new drug, ... including any salt or ester of the active ingredient...." Id. Sec. 156(f)(2).

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It is undisputed that cefuroxime axetil is the active ingredient of CEFTIN tablets. Moreover, the Commissioner does not appear to contest that ZINACEF and KEFUROX are neither salts nor esters of cefuroxime axetil. Consequently, Glaxo argues that the "product" as defined by the Act has not been previously approved or used before CEFTIN tablets were approved because neither ZINACEF nor KEFUROX fell within the definition. Accordingly, Glaxo contends that because CEFTIN is the "first permitted commercial marketing or use" of the product patented, the '320 patent is eligible for term extension.

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The Commissioner, on the other hand, argues that "product" was not intended by Congress to have a literal meaning, only encompassing three categories of compounds: (1) an active ingredient; (2) a salt of an active ingredient; or (3) an ester of an active ingredient. He asserts that Congress intended the definition to mean any "new chemical entity," i.e., "new active moiety," which would encompass all acid, salt, or ester forms of a single therapeutically active substance even if the drug before being administered contained only other substances. In this case, because after being orally administered CEFTIN tablets combine with digestive substances in the human body to produce the same therapeutically active substance contained in both ZINACEF and KEFUROX, then under the Commissioner's interpretation, Glaxo has already had a prior approval of the "product" before it sought a term extension for its '320 patent.

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The trial court reviewed the Commissioner's interpretation of section 156 under the standard enunciated in the APA, 5 U.S.C. Sec. 706(2)(A) (1988),[4] and concluded that his action was "contrary to law." Accordingly, the trial court granted Glaxo summary judgment. We hear the Commissioner's appeal under 28 U.S.C. Sec. 1295(a)(1) (1982).

OPINION

I.

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In reviewing a grant of summary judgment, an appellate court must determine whether the strict standard set forth in Rule 56(c) of the Federal Rules of Civil Procedure has been satisfied. Chula Vista City School Dist. v. Bennett, 824 F.2d 1573, 1579 (Fed.Cir.1987), cert. denied, 484 U.S. 1042, 108 S.Ct. 774, 98 L.Ed.2d 861 (1988). In the instant case, both parties concede that there are no genuine issues of material fact. Consequently, this court need only decide the same question of law decided by the district court on summary judgment. That question is one of statutory interpretation, one that an appellate court can independently determine without deference to the trial court's interpretation. See Madison Galleries, Ltd. v. United States, 870 F.2d 627, 629 (Fed.Cir.1989).[5]

II.

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"When ... the terms of a statute [are] unambiguous, judicial inquiry is complete, except in rare and exceptional circumstances." United States v. James, 478 U.S. 597, 606, 106 S.Ct. 3116, 3121, 92 L.Ed.2d 483 (1986) (quoting Rubin v. United States, 449 U.S. 424, 430, 101 S.Ct. 698, 701, 66 L.Ed.2d 633 (1981) (internal quotation marks omitted)). Moreover, absent a "clearly expressed legislative intention to the contrary," a statute's plain meaning "must ordinarily be regarded as conclusive." Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102, 108, 100 S.Ct. 2051, 2056, 64 L.Ed.2d 766 (1980).

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We conclude that section 156(f)(2)'s terms, "active ingredient of a new drug ... including any salt or ester of the active ingredient," all have a plain meaning. We reach this conclusion because we must interpret statutory words as " 'taking their ordinary, contemporary, common meaning,'

" unless otherwise defined by Congress. Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426, 7 USPQ2d 1152, 1155 (Fed.Cir.1988) (quoting Perrin v. United States, 444 U.S. 37, 42, 100 S.Ct. 311, 314, 62 L.Ed.2d 199 (1979)). In particular, the terms "active ingredient," "salt," and "ester" had well-defined, ordinary, common meanings when Congress enacted the Act. See, e.g., 45 Fed.Reg. 72,582; 72,591 (1980); 44 Fed.Reg. 2932, 2937-38 (1979); Chemical Dictionary, supra note 3, at 418, 907. The Commissioner, however, suggests that Congress "inartfully" and "awkwardly" selected this combination of terms intending something other than their combined, common and ordinary meanings. Brief for Defendant-Appellant Quigg at 10, 24, Glaxo Operations UK Ltd. v. Quigg, No. 89-1407 (Fed.Cir. filed July 19, 1989) [hereinafter Commissioner's Brief]. This approach is unpersuasive because it simply overlooks the legal consequence that ordinarily attaches whenever statutory language has a clear and plain meaning. Instead, the Commissioner simply ignores the plain meaning of these terms and argues, as a totally unrelated question, that Congress intended a meaning contrary to the plain meaning.

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Nonetheless, even when the plain meaning of the statutory language in question would resolve the issue before the court, the legislative history should usually be examined at least "to determine whether there is a clearly expressed legislative intention contrary to the statutory language." Madison Galleries, 870 F.2d at 629 (emphasis added); see LSI Computer Sys. v. United States Int'l Trade Comm'n, 832 F.2d 588, 590, 4 USPQ2d 1705, 1707 (Fed.Cir.1987).[6] Consequently, although we conclude that the statutory language is unambiguous, we consider the legislative history of the Act, but only to determine whether a clear intent contrary to the plain meaning exists.

III.

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Although we should consider the legislative history to ascertain whether Congress' intent was contrary to section 156(f)(2)'s plain meaning, we do not analyze this history from a neutral viewpoint. Rather, given the plain meaning, the Commissioner must provide an "extraordinary showing of contrary intentions." Garcia v. United States, 469 U.S. 70, 75, 105 S.Ct. 479, 482, 83 L.Ed.2d 472 (1984) (emphasis added); Fisons PLC v. Quigg, 876 F.2d 99, 101, 10 USPQ2d 1869, 1870 (Fed.Cir.1989). We conclude that no such showing has been made.

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The Commissioner correctly notes that the Act has two general purposes: (1) to increase the availability of low-cost drugs by expanding a generic drug approval procedure; and (2) to further encourage new drug research by restoring some of the patent term lost while drug products undergo testing and await FDA pre-market approval. H.R.Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 14-15 [hereinafter House Report], reprinted in 1984 U.S.Code Cong. & Admin.News. 2647, 2647-48 [hereinafter USCCAN]. The Commissioner contends that applying the plain meaning of section 156 to patent term extension determinations will create absurd results contrary to these purposes. Although we agree that the Commissioner's interpretation of the meaning of section 156 is consistent with these general purposes, the plain meaning of section 156 is also consistent; the plain meaning can be said to provide exactly how the general objectives of the Act are to be sought. This is all the more so when, as here, the two objectives are divergent if not in outright opposition to one another. The terms Congress selected achieve a balance between the broader extensions some urged and the narrower extensions others sought and the Commissioner now advocates.

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The Commissioner merely argues, via his interpretation of section 156, that fewer patents should be eligible for extensions than the plain meaning of that section suggests, and that his interpretation attains a better balance between the competing purposes of the Act. Congress, however, may decide, and here clearly did decide, how to best accommodate the conflicting objectives. Moreover, Congress clearly had articulated policy reasons for making more types of patents eligible for extension, including to encourage research. As even the Commissioner acknowledges, his interpretation would reduce the profits of brand name manufacturers who would be entitled to more limited protection from generic drug competitors than they would receive under the plain meaning interpretation of section 156. Commissioner's Brief, supra, at 29-30.[7] Lesser profits might result in less research on new drugs.

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The Commissioner simply makes an unsupported assumption that Congress wanted to give greater emphasis to the Act's purpose of increasing generic drug availability as opposed to providing greater economic incentive to development of new patentable drugs. Congress' intent might well have been exactly the opposite of what the Commissioner suggests. More likely, it could have been a compromise between the aggressively advocated and opposing interests of brand name manufacturers versus the generic drug manufacturers.

We are reminded by the Supreme Court that:

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all legislation is not simple nor its consequences obvious or to be controlled, even if obvious. Whether there should be any legislation at all and its extent and form may be matters of dispute. Its consequences may be viewed with favor or with alarm; some regretted but accepted as inevitable--accepted as the shadow side of the good. In such situation it is for the legislature to determine, and it is very certain that the judiciary should not refuse to execute that determination from its view of some consequence which ... may have been contemplated and appreciated when the act was passed, and considered as overbalanced by the particular advantages the act was calculated to produce.... "It would be dangerous in the extreme, to infer from extrinsic circumstances, that a case for which the words of an instrument expressly provide, shall be exempted from its operation."

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Pirie v. Chicago Title and Trust Co., 182 U.S. 438, 451-52, 21 S.Ct. 906, 911-12, 45 L.Ed. 1171 (1901) (quoting Sturgis v. Crowninshield, 17 U.S. (4 Wheat.) 122, 202, 4 L.Ed. 529 (1819)). We simply cannot say that the plain meaning of section 156 would provide unwanted results because Congress may very well have contemplated all the ramifications of its chosen definition in light of the political realities as seen played out in the legislative process, and we must assume it did.

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Further, we are hesitant to stray from the plain meaning of the statute because both the terms Congress used and the terms the Commissioner would have us substitute were all well-known and well-defined at the time the Act was passed.[8] Nevertheless, Congress chose particular terms--"active ingredient, ... including any salt or ester of an active ingredient...." Accordingly, we can infer that in so choosing, Congress may have deliberately rejected the very terms the Commissioner asserts were the intended meaning of section 156.

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Besides asserting that to accept the common meaning of section 156's terms compromises the general purposes of the Act, the Commissioner cites specific language in the House Report as evidencing Congress' contrary intent:

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The Committee's bill requires extensions to be based on the first approval of a product because the only evidence available to Congress showing that patent time has been lost is data on so-called class I, new chemical entity drugs. These drugs had been approved by the Food and Drug Administration (FDA) for the first time.

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House Report, supra, at 38 (emphasis added), reprinted in USCCAN, supra, at 2671. The Commissioner notes that this Report describes the House bill which, without amendment, became section 156, and that the House Report specifically refers to the FDA classification system by using the terms "class I, new chemical entity drugs." The Commissioner argues that this language shows Congress' intent that "product" was to mean "new chemical entities" as defined by FDA.[9] We are unpersuaded because although the Commissioner's construction may provide an equally admirable result, we see this House Report language as ambivalent as to Congress' intended meaning for "product." The House Report language, including the phrase "evidence available," can just as well be read as giving an historical description of how the problem addressed by the bill came to light, as opposed to exactly how the problem was to be resolved; we simply cannot find any clear statement that extensions are required based on first approval of "new chemical entities." In fact, if that were Congress' intent, one would expect it to use the same term--"new chemical entity"--in the bill as is used in the House Report. Instead, the bill employed other terms with an equally clear but quite different meaning.

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Additionally, the Commissioner quotes two floor statements by sponsors of the bill resulting in the Act as also evidencing Congress' intent that "product" mean "new chemical entities." See 130 Cong.Rec. 24,425 (1984) (Rep. Waxman); id. at 23,765 (Sen. Hatch). Although we acknowledge that the sponsors' remarks--which, like the House Report, refer to "new chemical entities"--should be afforded some weight as to the meaning of the bill, we are equally reminded by the Supreme Court that "[o]ral testimony of ... individual Congressmen, unless very precisely directed to the intended meaning of particular words in a statute, can seldom be expected to be as precise as the enacted language itself." Regan v. Wald, 468 U.S. 222, 237, 104 S.Ct. 3026, 3035, 82 L.Ed.2d 171 (1984) (emphasis added). These statements, however, were not precisely directed to the definition of "product." First, these statements could very well have been simply the sponsors' shorthand simplification for the technical language, "active ingredient ... including any ester or salt of the active ingredient...." Second, they were both directed toward a different title of the Act than the one at issue in this appeal. Consequently, we cannot say that these statements provide a clearly expressed contrary intent that section 156's terms not be afforded their ordinary meaning.

IV.

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In construing this Act, we must consider whether deference is due the Commissioner's interpretation of the intended meaning of section 156. The Commissioner asserts a number of reasons why this court should defer.

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First, the Commissioner argues, broadly, that this court must defer to his statutory interpretation provided it is "reasonable," and not clearly contrary to Congress' intent, citing, inter alia, Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43, 104 S.Ct. 2778, 2781-82, 81 L.Ed.2d 694 (1984), and Chemical Manufacturers Association v. Natural Resources Defense Council, Inc., 470 U.S. 116, 126, 105 S.Ct. 1102, 1108, 84 L.Ed.2d 90 (1985). The Commissioner's position is untenable, however, because he has mistaken the applicability of those cases to the instant case. The rule of deference enunciated in those cases is limited to when the statutory language has "left a gap" or is ambiguous. See Chevron, 467 U.S. at 842-44, 104 S.Ct. at 2781-83; Chemical Manufacturers, 470 U.S. at 126, 105 S.Ct. at 1108. Here, as we have already stated, section 156(f)(2)'s operative terms, individually and as combined in the full definition, have a common and unambiguous meaning, which leaves no gap to be filled in by the administering agency. Accordingly, we need not defer to any reasonable interpretation of the Commissioner.

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Additionally, the Commissioner asserts that deference is due a contemporaneous construction of the agency charged by Congress with implementing the new statute. Often cited by the Supreme Court as well as this court, see, e.g., Chevron, 467 U.S. at 844 n. 14, 104 S.Ct. at 2782 n. 14; Chula Vista, 824 F.2d at 1580, this doctrine has been applied when the statutory language is "doubtful and ambiguous" and the agency's construction is soon after the statute's enactment when the circumstances surrounding its enactment were well known. See Edwards' Lessee v. Darby, 25 U.S. (12 Wheat.) 206, 210-11, 6 L.Ed. 603 (1827); Smith-Corona Group v. United States, 713 F.2d 1568, 1576 & n. 24, 1 Fed.Cir. (T) 130, 138 & n. 24 (1983). Here, the situation is quite different. First, section 156(f)(2) is unambiguous on its face. Second, whether the Commissioner's construction was contemporaneous is questionable; his interpretation was neither applied nor publicly announced until nearly four years after the date of enactment of the Act, September 24, 1984. Compare Illinois Commerce Comm'n v. Interstate Commerce Comm'n, 749 F.2d 875, 881 (D.C.Cir.1984) (final agency interpretation of statute two years after being passed not considered contemporaneous), cert. denied, 474 U.S. 820, 106 S.Ct. 70, 88 L.Ed.2d 57 (1985), with Zenith Radio Corp. v. United States, 437 U.S. 443, 450, 98 S.Ct. 2441, 2445, 57 L.Ed.2d 337 (1978) (deference accorded agency interpretation formed within one year of statute's enactment).

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Finally, the Commissioner asserts that his interpretation must be accorded deference because this case involves "highly technical, scientific questions within the agency's special expertise." Commissioner's Brief, supra, at 15. Once again the Commissioner describes a rule of jurisprudence which is inapposite to this case. Significant deference is due to an agency's technical expertise when Congress has explicitly or implicitly delegated to the agency the making of scientific determinations. See, e.g., Industrial Union Dep't, AFL-CIO v. American Petroleum

Inst., 448 U.S. 607, 642, 656, 100 S.Ct. 2844, 2864, 2871, 65 L.Ed.2d 1010 (1980). But when "the interpretation rests not on policy considerations but on a narrow dissection of statutory language, the courts are equally skilled in making such an interpretation, and reduced deference is owed." Illinois Commerce Comm'n, 749 F.2d at 882 n. 10.

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In the instant case, Congress qualified its express authorization to the Commissioner to determine whether patents are eligible for extension, see 35 U.S.C. Sec. 156(e)(1) (Supp. V 1987), by providing an explicit and precise definition of "product" in section 156(f)(2), using well-established scientific terms. Although the definition does involve technical subject matter, Congress specifically selected terms with narrow meanings that it chose from among many alternatives.[10] Congress could have, but did not, select broad terms with a range of possible meanings. If it had, Congress could be said to have implicitly delegated discretion to the Commissioner to use his scientific expertise to determine what further definition would best carry out the purposes of the Act.[11] Here, all Congress left to the Commissioner's technical expertise was determining whether any patented chemical compound named in a patent term extension application fell within the statutory definition of "product," but not what "product" was to mean. Consequently, we will give great deference to the Commissioner's determinations as to which patented chemical compounds fall within Congress' definition of "products," but little or no deference to the Commissioner's surmise of Congress' intent in framing its definition.

Conclusion

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We cannot say whether the meaning the Commissioner ascribes to section 156(f)(2) would provide a better balanced policy for patent term extensions. Nevertheless, that is not the issue before this court. Striking balances in legislative language is Congress' job. Here Congress utilized its constitutional powers vigorously, providing precise statutory definitions. We may only decide whether Congress has clearly expressed elsewhere an intent contrary to the plain meaning of the statutory terms. That, we are unable to do. Accordingly, the plain meaning of the statutory language must stand as Congress' intent and be honored by both the courts and the Patent and Trademark Office. The judgment of the district court is therefore

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AFFIRMED.

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CEFTIN, as well as ZINACEF and KEFUROX, infra, are federally registered trademarks, Registration Nos. 1,332,796; 1,133,466; and 1,445,894, respectively

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An ester is a compound derived from an acid by the exchange of a replaceable hydrogen of the latter for an organic radical, usually using an alcohol or other organic compound rich in OH groups. See The Condensed Chemical Dictionary 418 (G. Hawley rev. 10th ed. 1981) [hereinafter Chemical Dictionary]

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A salt is a compound formed when the hydrogen of an acid is replaced by a metal or its equivalent. See id. at 907

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The APA applies to district court review of such Commissioner's decisions. See Heinemann v. United States, 796 F.2d 451, 454-55, 230 USPQ 430, 433 (Fed.Cir.1986), cert. denied, 480 U.S. 930, 107 S.Ct. 1565, 94 L.Ed.2d 758 (1987); Smith v. Mossinghoff, 671 F.2d 533, 538, 213 USPQ 977, 982 (D.C.Cir.1982)

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The standard of review is not affected by deference to agency interpretation in the instant case. See Section IV, infra
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See also United States v. American Trucking Ass'ns, 310 U.S. 534, 544, 60 S.Ct. 1059, 1064, 84 L.Ed. 1345 (1940) ("[T]here certainly can be no 'rule of law' which forbids [the use of legislative history], however clear the words may appear on 'superficial examination.' ") (footnotes omitted); National Wildlife Fed. v. Gorsuch, 693 F.2d 156, 170 (D.C.Cir.1982) ("In virtually every case, ... it does not end [with the statutory language] but continues with a review of the legislative history.")
Often caution requires that the legislative history be considered at least to the extent necessary to ascertain whether a contrary intent exists even when the statutory language is clear. Nonetheless, this rule of caution does not preclude, in a particular case in which the statutory language is so clear as to Congress' intent, the decision that it would be unnecessary to look further into the legislative history. See, e.g., Brookside Veneers, Ltd. v. United States, 847 F.2d 786, 788 (Fed.Cir.), cert. denied, --- U.S. ----, 109 S.Ct. 369, 102 L.Ed.2d 358 (1988); see Norwegian Nitrogen Prods. Co. v. United States, 288 U.S. 294, 315, 53 S.Ct. 350, 358, 77 L.Ed. 796 (1933).
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Normally, utility patent terms last seventeen years. 35 U.S.C. Sec. 154 (1982). Under the Commissioner's interpretation, any part of the term lost to FDA review would not be restored for certain patents, thereby shortening the effective patent life
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See, e.g., 45 Fed.Reg. 72,582; 72,591 (1980); 44 Fed.Reg. 2932; 2937-38 (1979); Chemical Dictionary, supra note 3, at 418, 907; FDA, Bureau of Drugs, Staff Manual Guide BD 4820.3, at 1-2 (Feb. 19, 1982)
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FDA classifies drugs into six chemical types. One such type is defined:
Type 1 --New molecular entity--i.e., the active moiety is not yet marketed in the United States by any drug manufacturer either as a single entity or as part of a combination product.
FDA, Bureau of Drugs, Staff Manual Guide BD 4820.3, at 1-2 (Feb. 19, 1982). The Commissioner's interpretation is further questionable because the House Report refers to "Class I" and "new chemical entity" rather than the FDA's term "Type 1" and "new molecular entity."
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For example: "new molecular entity," "active moiety," or "new chemical entity."
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The FDA also has administrative duties under the Act. However, as opposed to title II of the Act, that applies to the Patent and Trademark Office, title I applies to the FDA. Title I includes language similar to the section 156 language in dispute in this appeal. See 21 U.S.C. Secs. 355(j)(4)(D)(i) & (v) (Supp. V 1987). The Commissioner attempts to bootstrap his claim of deference by emphasizing that the FDA has interpreted the nearly identical language of title I in a similar manner. He stresses that the FDA similarly has technical expertise. We are unpersuaded. First, the FDA's interpretation, like the Patent and Trademark Office's, may be based on its own judgment of what is better policy. Second, the FDA's interpretation of plain statutory terms is as unlikely to require technical expertise and technical judgment as is the Commissioner's