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

IN RE ALCON LABORATORIES, INC. PATENT NO. 3,691,279
September 1, 1989

Donald J. Quigg

Commissioner of Patents and Trademarks

Final Decision on Request for Patent Term Extension Under 35 U.S.C. § 156

***1** An application for patent term extension has been filed under 35 U.S.C. § 156. [FN1] The application raises a question of eligibility for patent term extension of a patent claiming one of two active ingredients in a drug product that was approved for commercial marketing and use by the Food and Drug Administration (FDA). Each of the active ingredients had been approved separately for commercial marketing and use in previous regulatory reviews by the FDA. For the reasons set forth below, the application is denied.

Facts

An application for patent term extension of U.S. Patent No. 3,691,279, granted September 12, 1972, was filed in the Patent and Trademark Office (PTO) on October 17, 1988. The basis for the application is stated to be 35 U.S.C. § 156. The application was filed by Alcon Laboratories, Inc. (Alcon) as agent [FN2] for the owner of record of the patent, Eli Lilly Industries, Inc., a wholly owned subsidiary of Eli Lilly and Company.

Tobradex is a drug product that was approved for commercial marketing or use by the FDA on August 18, 1988, [FN3] pursuant to § 507 of the Federal Food, Drug and Cosmetic Act (Act). [FN4] Tobradex was approved for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. [FN5] According to the application, the active ingredients in Tobradex are tobramycin and dexamethasone. [FN6] The application for patent term extension was filed within sixty (60) days of the date the new drug application (NDA) for Tobradex was approved by the FDA, and otherwise appears to comply with the requirements of § 156(d) and the provisions of 37 CFR § § 1.740 and 1.741.

The application states that Patent No. 3,691,279 claims one of the active ingredients (tobramycin) because the product claimed in claim 5 contains tobramycin. [FN7] No other claim in the patent covers tobramycin, and none of the claims are directed to dexamethasone nor to a combination of tobramycin and dexamethasone.

Letters from the FDA advised PTO that the active ingredients in Tobradex have been approved previously as single entities (i.e., drug

products having a single active ingredient) by the FDA. Thus, in a letter dated November 30, 1988, from Ronald L. Wilson, Director of the Health Assessment Policy Staff at FDA, PTO was advised as follows with respect to Tobradex:

A review of the Food and Drug Administration's official records confirms that Tobradex was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate, however, that FDA has previously approved drug products containing either tobramycin, dexamethasone, or related compounds.

***2** ....

The applicant correctly states that FDA has not previously approved a drug product containing both tobramycin and dexamethasone, and that the relevant provisions of law under which the above products were approved were sections 505 and/or 507 of the Federal Food, Drug, and Cosmetic Act. Tobradex's approval occurred under section 507 of the Act.

In a letter dated May 10, 1989, from Stuart Nightingale, M.D., Associate Commissioner for Health Affairs at FDA, PTO was advised as follows about FDA's prior approval of the active ingredients of Tobradex and approval of drug products containing a combination of active ingredients in general:

As noted in our prior letter to you of November 30, 1988, Tobradex is a combination of tobramycin and dexamethasone, whichFDA approved on August 18, 1988 under the provisions for approval of antibiotics in section 507 of the FD & C Act. Prior to approving Tobradex, FDA had approved a number of tobramycin and dexamethasone products as single entities. The tobramycin products were approved under § 507, as was Tobradex. The dexamethasone products, which are not antibiotics, were approved under FDA's new drug provisions found in section 505 of the FD & C Act.

....

FDA's policy for fixed-combination prescription drugs is in 21 CFR § 300.50. In general, the policy requires that each component contribute to the claimed effects of the product, e.g., an added component may enhance the safety or effectiveness of the principal active component. The policy is used in determining the type of evidence required for approval of fixed combination drugs and antibiotics under § § 505 and 507 of the Act. Products are not, however, "approved under" 21 CFR § 300.50. They are approved under § § 505 or 507.

On June 16, 1989, the PTO issued an order giving Alcon an opportunity to show cause why its application should not be denied. Alcon's response focused on the failure of the PTO to consider FDA's Fixed-Combination Policy (21 CFR § 300.50) directed to drug products containing more than one drug or active ingredient as a "provision of law" within the meaning of § 156(a)(5)(A). Alcon alleged that the PTO position suggests that FDA's Fixed-Combination Policy does not have the force and effect of law. [FN8]

Discussion of Eligibility Criteria For Patent Term Extension

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. 454, 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 to 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).

***3** Under 35 U.S.C. § 156(a), a patent must "claim," inter alia, a product in order to be eligible for patent term extension. In addition, the following conditions enumerated in § 156(a) must be satisfied for a patent to be eligible for patent term extension: [FN9]

(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

(2) the term of the patent has never been extended;

(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 subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or

(B) ... [pertains to a patent claiming a method of manufacturing a product which primarily uses recombinant DNA technology]....

The enumerated conditions in paragraphs (1) through (4) appear to be satisfied in the instant case, and the provisions of paragraph (5)(B) are not applicable.

The determination of eligibility of U.S. Patent 3,691,279 for patent term extension turns on the provisions in § 156(a)(5)(A). Thus, the statutory requirement that the product claimed in the patent has been subject to a regulatory review period before its commercial marketing or use (§ 156(a)(4)) is qualified in § 156(a)(5)(A) by the provision that the permission for the commercial marketing or use of the product after such regulatory review period [i.e., the period applicable to the product which forms the basis of the application for patent term extension] is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

The term product is defined in 35 U.S.C. § 156(f) as follows:

(f) For purposes of this section:

(1) The term "product" means:

(A) A human drug product.

(B) ...

(2) The term "human drug product" means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. [Emphasis supplied.]

Where, as in the present case, no salts or esters of active ingredients are involved, the definition of "product" provided in section 156(f) can be applied to the extension requirements of sections 156(a) and 156(a)(5)(A) as they would apply to a human drug product as follows:

§ 156(a) The term of a patent which claims [the active ingredient ..., as a single entity or in combination with another active ingredient] ... shall be extended ... if--

***4** (5)(A) ... the permission for the commercial marketing or use of [the active ingredient ..., as a single entity or in combination with another active ingredient] after such regulatory review period is the first permitted commercial marketing or use of [the active ingredient ..., as a single entity or in combination with another active ingredient] under the provision of law under which such regulatory review period occurred;

Thus, eligibility under § 156(a) requires that the patent claim the active ingredient of a new drug, as a single entity or in combination with another active ingredient. Section 156(a)(5)(A) permits patent term extension based on FDA approval of the active ingredient as a single entity or in combination with another active ingredient, provided it is the first FDA approval of the active ingredient, as a single entity or in combination with another active ingredient.

For a product which contains a plurality of active ingredients, as here, the statute must be analyzed with respect to each active ingredient. Active ingredient, as defined in § 156(f), is singular and the definition of "human drug product" explicitly recognizes that the "active ingredient" may be used "in combination with another active ingredient" to embrace a human drug product with a combination of active ingredients. If the term "active ingredient" was interpreted to include a plurality of active ingredients, the phrase "including any salt or ester of the active ingredient" would not make any sense because there is no such thing as a salt or ester of two ingredients. A statute should be construed, if possible, to avoid absurd results. United States v. Turkette, 452 U.S. 576 (1981).

The "provision of law under which such regulatory review period occurred" [§ 156(a)(5)(A)] refers to the applicable provision of law defined in the definitional section for regulatory review period, [FN10] which is further defined in § 156(f)(4) as being the corresponding section in the Act or the Public Health Service Act. For a human drug product, the applicable provision of law can be section 505 [FN11] of the Act for a new drug, section 507 of the Act for an antibiotic drug, or section 351 of the Public Health Service Act for a human biological product. Tobradex was approved under § 507.

Application of Eligibility Criteria to Patent 3,691,279 and Tobradex

Under § 156(a), Patent No. 3,691,279 may be considered eligible for patent term extension if a claim of the patent covers Tobradex. As tobramycin and dexamethasone are the active ingredients in Tobradex, a patent claim would cover Tobradex within the meaning of § 156(a) if it claimed:

1) tobramycin alone [single entity];
2) dexamethasone alone [single entity]; or
3) the mixture of tobramycin and dexamethasone [active ingredient ... in combination with another active ingredient]

Patent No. 3,691,279 satisfies § 156(a) because it is said to claim one of the active ingredients [tobramycin] in Tobradex "... as a single entity...." If the mixture of active ingredients [tobramycin and dexamethasone] in Tobradex was to be considered "the active ingredient" for the purposes of § 156, Patent No. 3,691,279 would not be eligible for patent term extension because the patent does not claim the mixture of active ingredients in Tobradex.

***5** Under § 156(a)(5)(A), as it pertains to the active ingredient claimed in the patent [tobramycin], the patent would be eligible for patent term extension if:

> ... the permission for the commercial marketing or use of [the active ingredient ..., as a single entity (tobramycin) or in combination with another active ingredient] after such regulatory review period [Tobradex] is the first permitted commercial marketing or use of [the active ingredient ..., as a single entity (tobramycin) or in combination with another active ingredient] under the provision of law [§ 507 of the Act] under which such regulatory review period occurred.

Here, the patent is not eligible because the active ingredient claimed in the patent [tobramycin] previously was permitted to be commercially marketed and used under the same provision of law [§ 507 of the Act] under which the regulatory review for Tobradex occurred. The approval of Tobradex did not represent the first permitted commercial marketing or use of tobramycin under § 507 of the Act. The fact that the other active ingredient [dexamethasone] in Tobradex had not been previously permitted to be commercially marketed or used under § 507 of the Act does not give rise to eligibility, because dexamethasone is not claimed in the patent.

Alcon has argued that FDA's rule (21 CFR § 300.50) stating its policy on approval of combination drug products should be considered a provision of law within the meaning of § 156(a)(5)(A) because it is a substantive rule and has the force and effect of law. Assuming, arguendo, that § 300.50 is a substantive rule and has the force and effect of law, that rule is not "the provision of law" within the meaning of § 156(a)(5)(A). Quite the contrary, FDA has specifically noted [FN12] that § 300.50 "is used in determining the type of evidence required for approval of fixed combination drugs and antibiotics under § § 505 and 507 of the Act." Further, if § 300.50 is considered to be "the provision of law" under which the regulatory review period for Tobradex occurred, the subject patent and Tobradex would not be eligible for patent term extension under § 156 because (1) § 156(g) does not refer to § 300.50 and (2) therefore, there would have been no "regulatory review period" within the meaning of § 156(g).

The Legislative History Supports the PTO Position

The PTO's position is that the patent is not eligible for patent term extension. The permission for commercial marketing of Tobradex was not the first permitted commercial marketing or use of the active ingredient claimed in the patent within the meaning of § 156(a)(5)(A). This position is consistent with the statute itself, including the statutory definition of the term "product" in § 156(f), and the legislative history supports the PTO position.

From the beginning of the congressional debate that led to enactment of § 156, attention focused on the decline of effective patent life for new chemical entity (NCE) drugs. [FN13] Although acknowledging that pharmaceutical innovation was not limited to the introduction of NCEs, the reason for focusing on the introduction of NCEs was explained in a report by the Congressional Office of Technology Assessment to the 97th Congress as follows: [FN14]

***6** Although important pharmaceutical innovations may result from new therapeutic applications of existing chemicals, new processes for making chemicals, or new combinations or formulations of existing chemicals, this study concentrates primarily on innovations resulting from the discovery or synthesis of NCEs. This approach is used for several reasons. Many of the pharmaceutical breakthroughs that have occurred have resulted from NCE research and the development of NCEs generally has required more time and money than other types of innovation and has involved greater risks. Moreover, because FDA testing requirements generally have been more time- consuming for NCEs than for other types of innovation, they have had their greatest impact on the effective patent terms of NCEs. By focusing on NCEs, the most extreme reductions in effective patent terms can be determined, but these effects are not representative of the average effects for all new pharmaceuticals.

Congress adopted the focus on NCEs when it proscribed patent term extension [§ 156(a)(5)(A)] if the active ingredient had received permission for commercial marketing or use in a regulatory review period that was concluded prior to a subsequent regulatory review period upon which the application for patent term extension is based. If the active ingredient had already received permission for commercial marketing from FDA under the same provision of law, it would not be considered to be an NCE in a subsequent regulatory review period-- whether the active ingredient was used alone or in combination with another active ingredient or approved for a different indication. According to a report by the House Committee on Energy and Commerce accompanying H.R. 3605, 98th Cong., 2d Sess. (1983): [FN15]

Paragraphs (6) and (7 [FN16] describe two conditions which must be met by the product which is claimed in the product patent to be extended, or the use or manufacture of which is claimed in the use or process patent to be extended. First, the product must have been subjected to a regulatory review period under an applicable federal law, and approved, before the product was allowed to be commercially marketed. (The product which can be the subject of a patent extension is hereafter referred to as the "approved product.") Second, with one exception, the approved product must have been approved for commercial marketing for the first time. The exception involves an approved

product made under a patented process which primarily uses recombinant DNA technology. Such an approved product could have received its second approval for commercial marketing, but it must be the first time a product made by the claimed process has been approved.

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. An exception was allowed for products made through recombinant DNA because this innovative, new technique is being employed to improve already approved drugs. [Emphasis supplied.]

***7** The legislative history shows Congress intended that the condition expressed in § 156(a)(5)(A) should apply to the product [active ingredient] claimed in the patent [§ 156(a)], and that patent term extension should be available only to active ingredients that are NCEs--approved by the FDA for the first time. The only evidence available to Congress showing that patent time had been lost in the regulatory review process before the FDA related to NCE drugs.

Thus, the legislative history of § 156 shows that Congress intended to grant patent term extensions only to those products [active ingredients] classified by FDA as new chemical [or new molecular] entities under FDA's long- standing drug classification system. [FN17] According to this classification system, Type I drugs are new molecular entities--i.e., the active moiety [FN18] is not yet marketed in the United States by any drug manufacturer either as a single entity or as part of a combination product. Type I drugs are contrasted to other types under the classification system which are directed to new salts, esters or derivatives of active moieties marketed in the U.S. (Type 2), new formulations (Type 3), new combinations of drugs not previously marketed together (Type 4), and already marketed drug products (Types 5 and 6). These Types are not mutually exclusive, but where the drug product falls into more than one category, all appropriate categories are reflected in the overall classification for the drug.

Congress found no evidence relating to new combinations of old active ingredients, old active ingredients administered in a new dosage form and no evidence relating to an old active ingredient approved for a new indication (use) that would justify patent term extension based on products of these types. As noted in Fisons plc v. Quigg, 876 F.2d 99, 10 USPQ2d 1869 (Fed.Cir.1989), there is strong support in the legislative history of § 156 for the interpretation of § 156(a)(5)(A) adopted by the PTO in the Fisons plc applications that patent term extension is available only to drug products that are NCEs--i.e., active ingredients that had been approved for the first time by the FDA.

Each of the active ingredients in the approved product Tobradex was a well- known therapeutic agent that individually had been approved for commercial marketing and use prior to FDA approval of Tobradex. Since both active ingredients had been previously approved and were marketed in the United States, neither tobramycin nor dexamethasone was a new chemical/molecular entity at the time of FDA approval of Tobradex. Accordingly, it is consistent with the legislative history of § 156 that a patent claiming an active ingredient [tobramycin] which has enjoyed commercial marketing and use for its anti-bacterial activity

since the mid-1970s and as an ophthalmic product since 1981 be denied patent term extension based on the 1988 approval of a drug product containing that active ingredient.

***8** There is a direct parallel between the facts in the instant case and those considered by the Federal Circuit in the Fisons cases. In each case, the active ingredient had been previously approved for commercial marketing and use and the application for patent term extension was based on a subsequent approval of the same active ingredient for a new indication [use] that did not fall within the scope of the previous approval (here, the use of tobramycin with dexamethasone). For the reasons endorsed by the Federal Circuit in Fisons in interpreting § 156(a)(5)(A), FDA approval of new uses for an old and well-known active ingredient does not form a proper basis for patent term extension under § 156.

In addition to the clear meaning of the statute as a whole, and achieving a result which comports with the Congressional intent to make patent term extension available only to new active ingredients (pioneer chemical entities), the legislative history also reflects that Congress intended to refer to the laws specified in § 156(g)(1) when it referred to a provision of law under which a regulatory review period occurred. According to a report by the House Committee on the Judiciary accompanying H.R. 3605, 98th Cong., 2d Sess. (1983): [FN19]

> Under section 156(g)(1) the regulatory review period for drug products is the sum of the periods: (1) beginning when an exemption under 505(i) or 507(d) was granted and ending when the initial submission of an application for approval under section 351 of the Public Health Service Act, 505, 507, of the Federal Food, Drug, and Cosmetic Act; and (2) beginning when an application for approval was initially submitted under the mentioned laws and ending when the application was approved. [Emphasis supplied.]

As it applies to the drug product Tobradex, the applicable provision of law under which the regulatory review period occurred is § 507 of the Act.

It is further noted that the application indicates [FN20] that an application for patent was filed on March 9, 1988, directed to the topical ophthalmic use of tobramycin and dexamethasone combinations. It is further stated that the approved product, Tobradex, is covered by this patent application. Whatever the ultimate disposition of this application for patent, it is clear that none of the normal seventeen (17) year term of any patent which may be granted on this application for patent would have been eroded by the time elapsed in the regulatory review process of Tobradex at the FDA.

Application of Eligibility Criteria to Drug Products Containing Two Active Ingredients

The PTO has completed review of several applications for patent term extension based on drug products containing two active ingredients. These applications have presented a variety of fact patterns that have led to different conclusions regarding eligibility for patent term extension under § 156. Representative of these different fact patterns

are the following:

1. U.S. Patent No. 3,957,982 was denied eligibility for patent term extension. The application was based on FDA approval under § 505 of the Act of the drug product known as Triphasil-21 which contained two active ingredients: (A) ethinyl estradiol and (B) levonorgestrel. The patent claimed the combination of A + B. FDA previously had approved, under § 505 of the Act, drug products which contained A + B. Eligibility was denied on the basis of § 156(a)(5)(A) since each of the active ingredients in the approved product that was claimed in the patent (A and B) previously received permission for commercial marketing or use by the FDA under the same provision of law [§ 505 of the Act] in combination with another active ingredient (A with B and B with A). There was no NCE contained in the approved product which formed the basis of the application.

***9** 2. U.S. Patent No. 4,194,047 was granted an extension of the patent term under § 156. The application was based on FDA approval under § 505 of the Act of the drug product known as Primaxin which contained two active ingredients: (A) cilastatin sodium and (B) imipenem. The patent claimed B. FDA had not approved previously either active ingredient in any form (acid, salt or ester). Eligibility was not precluded under § 156(a)(5)(A) because the active ingredient claimed in the patent (B) had not received permission previously for commercial marketing or use under § 505 of the Act either singly or in combination with another active ingredient. The active ingredient (B) was an NCE contained in the approved product upon which the application was based.

3. U.S. Patent No. 4,217,347 was denied eligibility for patent term extension. The application was based on FDA approval under § 505 of the Act of a drug product known as Capozide which contained two active ingredients: (A) captopril and (B) hydrochlorothiazide. The patent claimed the combination A + B. FDA had approved previously, under § 505 of the Act, each of A and B separately and the combination A+C [C being an active ingredient different from A or B]. Eligibility was denied on the basis of § 156(a)(5)(A) because each of the active ingredients in the approved product claimed in the patent (A and B) previously received permission for commercial marketing or use by the FDA under the same provision of law [§ 505 of the Act] singly (i.e., A and B separately) and in one case (A+C) in combination with another active ingredient. There was no NCE contained in the approved product which formed the basis of the application.

4. U.S. Patent No. 4,234,579 was granted an extension of patent term under § 156. The application was based on FDA approval under § 505 of the Act of a drug product known as Unasyn which contains two active ingredients: (A) sulbactum sodium and (B) ampicillin sodium. The patent claimed both (A) alone and the combination (A+B). FDA had approved previously (B) alone, but had not previously approved (A) in any form. Eligibility was not precluded by § 156(a)(5)(A) because the active ingredient (A) claimed in the patent did not receive permission previously for commercial marketing or use under the same provision of law [§ 505 of the Act] either singly or in combination with another active ingredient. The active ingredient (A) was an NCE contained in the approved product upon which the application was based.

In each case, the PTO acted consistently with the terms of the statute in achieving the intent of the legislation to grant patent term extension to an NCE drug that is claimed in the patent, the term of which is to be extended. So long as the patent for which an extension of term is sought claims an active ingredient of an approved drug product which is an NCE, the letter and intent of § 156 are served in granting patent term extension. In each case where the patent either does not claim an NCE, or where the active ingredients in the new drug product are not NCEs, the letter and intent of § 156 are served by denying eligibility for patent term extension.

Decision

***10** The PTO concludes that U.S. Patent No. 3,691,279, which is said to claim one of the active ingredients [tobramycin] in the approved product Tobradex, is not eligible for patent term extension under 35 U.S.C. § 156. Accordingly, the application for extension of the term of Patent No. 3,691,279 is denied because the permission for commercial marketing or use of tobramycin in Tobradex was not the first permitted commercial marketing or use of tobramycin under the provision of law [§ 507 of the Act] under which regulatory review of Tobradex occurred. 35 U.S.C. § 156(a)(5)(A).

FN1. 35 U.S.C. § 156 codifies Title II, § 201 of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. 98-417, 98 Stat. 1585 (1984), as amended by the Generic Animal Drug and Patent Term Restoration Act, Pub.L. 100-670, 102 Stat. 3971 (1988).

FN2. Exhibit A of the application is an authorization signed by the Executive Vice President of Lilly authorizing Alcon to act as Lilly's agent solely for the purposes of applying for and securing patent term extension of U.S. Patent No. 3,691,279.

FN3. Letter from FDA to Alcon dated August 18, 1988, indicating that Tobradex is safe and effective for use as recommended, and that the New Drug Application (NDA 50-592) was approved. Exhibit D of the application.

FN4. 21 U.S.C. § 357.

FN5. Package insert and product monograph for Tobradex. Exhibits B and C of the application.

FN6. As explained in the product monograph for Tobradex, Exhibit C of the application, tobramycin and dexamethasone are individually well known therapeutic agents. Tobramycin is the antibiotic component of Tobradex which has been in medical use for its anti-bacterial activity since the mid-1970s and as an ophthalmic product since 1981. Dexamethasone is an ocular steroid that has been in use since the late

1950s and has proved to be an effective agent for the treatment of ocular inflammation.

FN7. 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. 35 U.S.C. § 156(e)(1).

FN8. Alcon response filed August 11, 1989, page 12.

FN9. Although some of the provisions of § 156 were amended by the enactment of the Generic Animal Drug and Patent Term Restoration Act, supra, n. 1, the application in issue was filed (October 17, 1988) one month before the date of enactment (November 16, 1988). Since this decision would not be affected by any change made to the statutory language, the wording of the statute at the time the application for patent term extension was filed, i.e., the language of the statute prior to the 1988 amendments, is referenced in this decision.

FN10. § 156(g), and particularly paragraph (g)(1) related to human drug products.

FN11. 21 U.S.C. § 355.

FN12. FDA letter to PTO dated May 10, 1989, footnote 1.

FN13. In a study reported by Martin M. Eisman and William M. Wardell in "The Decline in Effective Patent Life of New Drugs," Research Management 18-21 (Jan. 1981), reprinted in Innovation and Patent Law Reform: Hearings Before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary, Part 2, 98th Cong., 2d Sess. 1211, 1214 (1984), the term new chemical entities (NCEs) was defined as compounds of molecular structure not previously marketed in the U.S., excluding new salts or esters, vaccines, antigens, antisera, immunoglobins, surgical products, and diagnostic agents.

FN14. Patent-Term Extension and The Pharmaceutical Industry, Congress of the United States, Office of Technology Assessment 12 (1981), reprinted in Patent Term Restoration Act of 1981: Hearings on H.R. 1937, H.R. 6444, and S. 255 Before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary, 97th Cong., 1st Sess. 99, 112 (1982).

FN15. H.R.Rep. No. 98-857, Part I, 98th Cong., 2d Sess. 37-38 (1984), reprinted in 1984 U.S.Code Cong. & Admin.News 2647, 2670-2671.

FN16. Now paragraphs (a)(4) and (a)(5).

FN17. Copy of FDA Staff Manual Guide No. BD 4820.3, dated February 19, 1982, describing the IND/NDA Classification System is attached to this decision.

FN18. The active moiety of a drug is that part of the chemical compound that is responsible for the drug's therapeutic effect.

FN19. H.R.Rep. No. 98-857, Part II, 98th Cong., 2d Sess. 25 (1984), reprinted in 1984 U.S.Code Cong. & Admin.News 2686, 2709.

20. Page 12 of the application for patent term extension makes reference to pending U.S. Patent Application No. 165,950 (Cagle), filed March 9, 1988. Inspection of the copy of the patent application (Exhibit G of the application for patent term extension) reveals that claims to both a product containing a combination of tobramycin and dexamethasone and a method of using that product were presented for examination.

13 U.S.P.Q.2d 1115

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