3-22-94

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

In re Morflex, Inc.	:	DECISION DENYING
U.S. Patent No. 4,710,532	:	REQUEST FOR PATENT
	:	TERM EXTENSION
	:	

An application for extension of the term of U.S. Patent No. 4,710,532 granted December 1, 1987, was filed under 35 USC § 156[1] in the Patent and Trademark Office (PTO) on February 26, 1992, by the patent owner Morflex, Inc. (Morflex). The application raises a question of eligibility for extension of the patent term because the active ingredient in the drug product that was approved for commercial marketing and use by the Food and Drug Administration (FDA) had been previously approved under the same provision of law for commercial marketing and use in a prior regulatory review by the FDA. For the reasons set forth below, the application is denied.

Facts

The product which received approval from the FDA is the Adsol Red Cell Preservation Solution System in PL 2209 Plastic. The approved product is a combination product which includes an Adsol Red Cell Preservation Solution (Adsol) in a PL 2209 type plastic container. The Adsol solution includes dextrose, sodium chloride, mannitol and adenine. The PL 2209 plastic contains a plasticizing amount of n-butyryl-tri-n-hexyl citrate (BTHC), polyvinyl chloride, a stabilizer, a lubricant and a stabilizing plasticizer. The patent claims a polyvinyl chloride composition and a medical article comprising a blood bag formed from a polyvinyl chloride composition.

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1. All (156+) subsections relate to Title 35, United States Code. All (500+) subsections relate to the Federal Food, Drug and Cosmetic Act (FFDCA).

The product (Adsol in a PL 2209 plastic container) was approved for commercial marketing and use by the FDA as a drug product on December 27, 1991, pursuant to § 505 of the Federal Food, Drug and Cosmetic Act (FFDCA). Adsol in a PL 146 plastic container had previously been approved by the FDA under § 505.

The application for patent term extension contains alternative grounds on which Morflex asserts that the patent is eligible for extension under 35 USC § 156. Morflex's first ground is that even though the "product" (the combination of an Adsol solution and a PL 2209 plastic container) was reviewed and approved by the FDA as a new drug under § 505, the "product" can be considered to be a medical device approved for containing and using the Adsol solution. Alternatively, Morflex argues that since the FDA considered the combination of the Adsol solution and a PL 2209 plastic container to be a drug product to be approved under § 505, the "active ingredient" of the product is either the PL 2209 plastic or the BTHC ingredient of the plastic. Morflex contends that under the above alternative grounds, the "product" for purposes of § 156(f) is the PL 2209 plastic (or its BTHC ingredient) of the approved combination which is either a "medical device" or, alternatively, the "active ingredient" of a drug product.

Discussion of Eligibility Criteria For Patent Term Extension

The Commissioner of Patents and Trademarks may grant an extension of the term of the patent to the extent authorized by the statute. The starting point for statutory interpretation is the plain language of the statute. Unless it is ambiguous, the language Congress chose is conclusive of its meaning absent a clearly stated contrary intention. Burlington Northern R.R. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461 (1987). See also Glaxo Operations UK Ltd. v. Quigg, 13 USPQ2d 1628, 1630 (Fed. Cir. 1990) (absent a "clearly expressed legislative intention to the contrary," a statute's plain meaning "must ordinarily be regarded as conclusive").

Section 156(a) sets forth the requirements for a patent to be eligible for patent term extension. Under § 156(a):

> (a) The term of a patent which claims a product ... shall be extended in accordance with this section ... if- ...
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> (4) the product has been subject to a regulatory review period before its commercial marketing or use;
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> (5)(A) ... the permission for the commercial marketing or use of the product ... is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; .... . [Emphasis added.]

The determination of eligibility of the subject patent turns on the provisions in § 156(a) that: (1) the patent claims the approved product, (2) the product was subject to a regulatory review period within the meaning of the statute, and (3) the permission for commercial marketing or use is the first such permission for the product within the meaning of the statute.

For purposes of the statute, the term "regulatory review period" is defined in § 156(g). For a medical device, § 156(g)(3) provides:

> (3) (A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) .... .
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> (B) The regulatory review period for a medical device is the sum of --
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> (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
>
> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

Under the statute, the term "product" is defined in § 156(f) as follows:

> (f) For purposes of this section:
>
> (1) The term product means:
>
> (A) A drug product.
>
> (B) Any medical device ... under the Federal, Food, Drug and Cosmetic Act.
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> (2) The term "drug product" means the active ingredient of -
>
> (A) a new drug ... (as those terms are used in the Federal Food, Drug and Cosmetic Act) .... . [Emphasis added.]

Thus, if the product is a medical device, the statute must be analyzed with respect to a regulatory review period conducted under § 515. If the product is a new drug product, the statute must be analyzed with respect to the active ingredient of the drug. In either case, the patent must claim the approved product. The product approved by the FDA (Adsol in a PL 2209 Plastic container) is a combination of an old solution in a new plastic bag. Had the product been approved as a medical device after review under § 515, it appears that the subject patent would be eligible for patent term extension. However, the product was not approved by the FDA under § 515, it was approved by the FDA under § 505 as a drug product. The patent claims the new plastic bag and/or the composition of the plastic.

Under § 156 a patent is eligible for patent term extension if it claims a product (§ 156(a)) that has been subject to a regulatory review period (§ 156(a)(4)) so long as the FDA approval of the product "is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;" (§ 156(a)(5)(A)). Since the product approved by the FDA was a drug product, application of the statute (§ 156(f)) requires the PTO to identify the "active ingredient" of the drug product. The term "active ingredient" of a new drug is generally understood, in the context of eligibility for patent term extension, as the ingredient in a drug product that becomes therapeutically active when administered to a patient. Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 393; 13 USPQ2d 1628, 1629 (Fed. Cir. 1990) (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). Neither the PL 2209 Plastic nor the BTHC plasticizer are alleged to be therapeutically active, and neither is intended to be administered to a patient as part of the Adsol or anticoagulant solutions. If there is an active ingredient in the approved drug product, the active ingredient is a part of the Adsol or anticoagulant solution.

Morflex's First Ground of Eligibility

In support of its first ground (the product is a medical device approved for containing a solution), Morflex states (Appl., p. 15) that apparently the FDA reviewed the combination under § 505 because of the presence of the Adsol solution as determining the primary mode of action of the combination product. Morflex argues that the fact that the review of the combination product took place under § 505, rather than § 515, does not change the characterization of the PL 2209 plastic

as a medical device for purposes of § 156(f). Morflex further argues (Appl., p. 18) that regardless of the product's characterization as a drug product or a medical device, the product was subject to a regulatory review period before its commercial marketing or use and accordingly, the eligibility requirement of § 156(a)(4) is met. Morflex states at pages 18-19 of the application:

> For the purposes of [§ 156(a)(4)], it is irrelevant whether, under [§ 156(f)], the product is defined to be a medical device rather than a drug product. In other words, just because the product is defined to be a medical device under § 156(f), the fact that it was subject to regulatory review under § 505 of the FFDCA, rather than § 515, does not render the patent ineligible under [§ 156(a)(4)].
>
> Nor does § 156(g) of the patent statute affect the eligibility of the patent at issue under § 156(a)(4). Specifically, § 156(g) merely sets forth some definitions of regulatory review periods which are used to determine the length of various patent extensions, not the eligibility for an extension. Thus, if the product covered by the claims is considered to be a medical device, the fact that regulatory review occurred under the FFDCA drug section, § 505, rather than the medical device section, § 515, may be relevant to the calculation of the length of the extension, but not to the eligibility of the patent for extension under [§ 156(a)(4)].
>
> In sum, § 156(a)(4) does not require the product to have undergone a specific §156(g) regulatory review period based on the characterization of the product under § 156(f). Consequently, it is not necessary for eligibility purposes for a product which is a medical device to have been subject to a regulatory review period under § 515 of the FFDCA.

Morflex's assertions under its first ground are untenable. Contrary to Morflex's argument, § 156(a)(4) does require the product to have undergone a specific § 156(g) regulatory review period based on the characterization of the product under § 156(f). Under the terms of §§156(a)(4) and 156(g)(3)(B), the regulatory review of a medical device is limited to a regulatory review which was conducted under § 515 of the FFDCA to the exclusion of any regulatory review conducted under § 505. While the definition under § 156(g)(3)(B) is, as Morflex notes, relevant to the calculation of the length of the review period for purposes of § 156(c), it is also relevant to other sections of the statute as well. For example, the definition is relevant to § 156(a)(5)(A) [the permission for the use of the product is the first permitted use under the provision of law under which the regulatory review period occurred]; and to § 156(d)(1) [the application may only be submitted within the sixty-day period after the product was approved under the provision of law under which the applicable regulatory review period occurred]. Both of these subsections refer to the specific regulatory review period which occurred and not to the length of the review period.

In like fashion, the eligibility requirement of § 156(a)(4) refers to a regulatory review period which occurred as defined in § 156(g). If the approved product is a medical device, the regulatory review period must have occurred under § 515 of the FFDCA as prescribed in § 156(g)(3). Therefore, the "medical device" product was not subject to a regulatory review period within the meaning of § 156(a)(4). In addition, any regulatory review period determined for the approved product as a medical device would be zero, such that any extension granted under § 156(c) would be zero.

In addition to the clear and unambiguous language of the statute, the legislative history supports the PTO's view that Congress intended to specifically refer to § 156(g)(3)(B) when if referred to a regulatory review period for a medical device. A House Report, when addressing proposed § 156(g)(3) states:

> Under section 156(g)(3) the regulatory review period for a medical device is the sum of the periods: (1) beginning when human clinical investigations were commenced and ending when an application for approval was initially submitted; and (2) beginning when an application for approval was initially submitted and ending when the application was approved, or beginning when a notice of completion of a product development protocol was initially submitted and ending when the protocol was declared completed.

H.R. Rep. No. 98-857, Part II, 98th Cong., 2d Sess. 26 (1984), reprinted in U.S. Code Cong. & Admin. News 2686, 2710. Thus, Congress clearly intended that a medical device be approved for marketing and use under § 515 to be eligible for patent term extension. Therefore, if, as Morflex asserts, the approved product is a medical device, the patent would not be eligible for patent term extension under § 156(a)(4) because the medical device did not undergo a regulatory review period as defined in § 156(g)(3)(B).

Morflex's Second Ground of Eligibility

Under its alternative ground for eligibility, Morflex asserts the approved product is a human drug product which was approved under § 505, and that the"active ingredient" of the approved product is either the PL 2209 plastic or the BTHC ingredient of the plastic. Morflex asserts at pages 16-17 of the application:

> Due to the chemical interaction of the plastic containers and the [Adsol] solution therein, the FDA could well have deemed the PL 2209 Plastic to be an "active ingredient" for the purpose of review. ....

> In particular, the FDA approval letter (Appendix B) shows that the FDA was specifically concerned with the leaching or migration of the BTHC plasticizer into the contents of the PL 2209 Plastic containers. In fact, the marketing applicant made a commitment to the FDA to monitor the levels of the BTHC plasticizer in several blood components.
>
> Thus, due to the migration or leaching of the BTHC into the [Adsol] solution, the FDA may well have considered the BTHC to be an active ingredient of the drug product subject to regulatory review.

Morflex's conjecture that the FDA considered the PL 2209 Plastic or BTHC to be the active ingredient because of its possible migration or leaching into the solution in the bag is not supported by the record. The FDA's letter of December 27, 1991, (Appendix B) merely shows that the FDA was concerned about the stability of the plastic and its possible contamination of the solution. The record is silent on a new active ingredient being created by any migration or leaching of the plastic or its components into the solution. In this regard, in a letter dated March 3, 1993, pursuant to an inquiry from the PTO as to the identity of the "active ingredient" in the approved drug product, the FDA stated:

> According to FDA records, BTHC is not the active ingredient of the ADSOL Red Cell System. Instead, the active ingredients are sodium citrate, citric acid, dextrose, monobasic sodium phosphate, mannitol, and adenine. These active ingredients had been marketed in PVC containers, other than the new PL 2209 containers used in ADSOL Red Cell System, since May 10, 1983.

Accordingly, it is held that the product was approved as a human drug product and the active ingredients are sodium citrate, citric acid, dextrose, monobasic sodium phosphate, mannitol, and adenine (in the Adsol solution).

Under § 156(f)(2), the term "drug product" means the "active ingredient" of the new drug product and not the product as a whole (plastic bag and solution). Fisons plc v. Quigg, 876 F.2d 99, 10 USPQ2d 1869 (Fed. Cir.). Under § 156(a)(5)(A), the permission for the use of the approved product (the active ingredient) must be the first permitted use under the provision of law under which the regulatory review period occurred. Accordingly, under Morflex's alternative ground wherein the approved product is a human drug, the patent would not be eligible for patent term extension because the active ingredient had been previously approved under § 505.

Section 156(a) requires the subject patent to claim the approved product. As noted above, the approved product is a drug product and the active ingredients are sodium citrate, citric acid, dextrose, monobasic sodium phosphate, mannitol, and adenine (in the Adsol solution). Therefore, the patent is further ineligible for patent term extension because the patent does not claim the product (the active ingredient) as required by § 156(a). Claims 1-3 of the patent are drawn to a polyvinyl chloride composition comprising a number of listed components. Claims 4-7 of the patent are drawn to a medical article comprising a blood bag (claim 5) formed from a polyvinyl chloride composition comprising a number of listed components. While the claims may not exclude other medical devices which could contain a solution, or other components in the composition, none of the patent claims are drawn to the combination of a medical device and a solution (e.g., Adsol solution).

For all of the above reasons, the application for patent term extension is denied.

Date: 22 March 1994

C. E. Van Horn

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RE: Adsol Red Cell System

FDA Docket No.: 92E - 0154

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