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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,600,706

FINAL DECISION REGARDING PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156

This is in response to the application for extension of the patent term of U.S. Patent No. 4,600,706 (the '706 patent) filed under 35 U.S.C. § 156 in the United States Patent and Trademark Office (USPTO) on May 13, 2004, the request for reconsideration filed March 7, 2007, and the request for an interim extension of the '706 patent filed under 35 U.S.C. § 156(e)(2) on October 22, 2007. The application was filed by Arkion Life Sciences, Inc. (Applicant), the patent owner of record at the time application was filed. Extension was sought based upon the premarket review under § 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a food additive known by the tradename NSURE® which comprises natamycin. Because the Food and Drug Administration (FDA) and the PTO have determined that the approval of NSURE® (natamycin) does not constitute the first permitted marketing or use of natamycin under the provision of law under which the regulatory review period occurred, Applicant's requests for extension of the patent term of the '706 patent under 35 U.S.C. § 156(d)(1) and 35 U.S.C. § 156(e)(2) are **DENIED** and its request for reconsideration is **DENIED**. Additionally, the three interim extensions previously granted under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*.

A. Factual Background

In February of 1998, the FDA announced that Protein Technologies International filed a petition to amend the food additive regulations to provide for the safe use of a dry form of natamycin (pimaricin) as an antimycotic in food to inhibit mold spoilage. See Protein Technologies International; Filing of Food Additive Petition, 63 Fed. Reg. 6945 (Feb. 11, 1998). The FDA indicated that approval of a food additive occurs under section 409(b)(5) of the FFDCA (21 U.S.C. § 348(b)(5)). Id.

In December of 1998, the FDA amended the food additive regulation, 21 C.F.R. § 172.155, to provide for the safe use of a dry form of natamycin as an antimycotic on the surface of cuts and slices of cheese. See Food Additives Permitted for Direct Addition to Food for Human Consumption; Natamycin (Pimaricin), 63 Fed. Reg. 66014-15 (Dec. 1, 1998). Notably, the FDA acknowledged that natamycin was already used as an antimycotic agent for cheese when applied an aqueous solution by dipping or spraying. Id.

On April 13, 2004, the FDA approved the Food Additive Petition No. 2234 for NSURE® (natamycin) as an animal feed additive for use in broiler chicken feed to retard or inhibit the growth of *Aspergillus Parasiticus* fungi.

One month later, on May 13, 2004, Applicant filed an application to extend the term of the '706 patent (PTE Application) under 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f) with the USPTO.[1] In its PTE Application, Applicant alleges that the '706 patent claims a method for using the product NSURE® (natamycin). Applicant likewise alleged that NSURE® (natamycin) "is currently subject to review under Section 409(b)(1) of the [FFDCA] (the act) (21 U.S.C. § 348(a))."

On November 17, 2004, the USPTO sent a letter to the FDA requesting assistance in determining the eligibility of the '706 patent for extension under 35 U.S.C. § 156(d)(1) based on the premarket review of NSURE® (natamycin). The USPTO indicated that it initially determined that the '706 patent was eligible for extension.

In a letter dated July 24, 2006, the FDA indicated that NSURE® (natamycin) had been subject to regulatory review period under section 409 of the FFDCA before its commercial marketing or use, but that the approval did not represent the first permitted commercial marketing or use of the active ingredient of NSURE® (natamycin) under 21 U.S.C. § 348, the provision of law under which the regulatory review period occurred. The FDA stated: "NSURE does not represent the first permitted commercial marketing or use of the food additive natamycin under 21 U.S.C. § 348, the provisions of law under which the regulatory review period occurred."

On September 7, 2006, the USPTO mailed a notice of final determination to Applicant, dismissing the PTE Application on grounds that not all of the requirements of 35 U.S.C. § 156 were satisfied. Specifically, in light of the FDA's letter, the USPTO explained that NSURE® (natamycin) did not constitute the first permitted commercial marketing or use of the product under the provision of law under which the regulatory review period occurred as required by 35 U.S.C. § 156(a)(5)(A).

On March 7, 2007, Applicant requested reconsideration of the dismissal, arguing that the provision of law under which the food additive petition for NSURE® (natamycin) was filed (i.e., 21 C.F.R. § 573) is a different provision of law than the provision of law that the FDA referenced

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[1] The '706 patent expired by operation of law on November 17, 2003. However, Applicant filed a series of interim extension requests, which the USPTO granted, extending the term of the '706 patent on an interim basis pending completion of both FDA regulatory review process and the PTE application review. Specifically, Applicant filed its first interim extension request under 35 U.S.C. § 156(d)(5) on November 3, 2003, extending the '706 patent for one-year until November 17, 2004. It then filed three other interim extension requests, all under 35 U.S.C. § 156(e)(2), each extending the patent by one more year such that the patent will expire on November 17, 2007.

in its letter (i.e., 21 U.S.C. § 348).

On October 22, 2007, Applicant filed a fourth interim extension request under 35 U.S.C. § 156(e)(2) for the '706 patent.

B. U.S. Patent No. 4,600,706 Is Not Eligible for Patent Term Extension

Under 35 U.S.C. § 156(a), the term of a patent which claims a product shall be extended if six specific requirements are satisfied. Subparagraph (a)(5)(A) provides in pertinent part that "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." 35 U.S.C. § 156(a)(5)(A) (emphases added).

Here, Applicant's product, NSURE® (natamycin), fails to meet the requirement of 35 U.S.C. § 156(a)(5)(A) because NSURE® (natamycin) does not represent the first permitted marketing or use of natamycin under the provision of law under which the regulatory review period occurred (i.e., 21 U.S.C. § 348). Applicant states in its PTE Application at page 3 that its feed additive "was subject to review under Section 409(b)(1) of the [FFDCA] (the Act) (21 U.S.C. § 348(a))." The FDA also pointed to 21 U.S.C. § 348 as being the applicable "provision of law" for the regulatory review period of NSURE® (natamycin) in its response to the USPTO's request for input. The USPTO, however, uncovered that natamycin (pimaricin) had been previously approved as a food additive under Section 409 of the FFCDA (21 U.S.C. § 348) for use as an antimycotic agent in cheese sometime before 1998. See 63 Fed. Reg. 6945. As a result, NSURE® (natamycin) plainly is not the first permitted marketing or use of natamycin under 21 U.S.C. § 348.

In its request for reconsideration, Applicant argues that the '706 patent is entitled to an extension under 35 U.S.C. § 156 because NSURE® (natamycin) was approved under 21 C.F.R. § 573, which although obtaining authority from 21 U.S.C. § 348, is a different provision of law than 21 U.S.C. § 348. Applicant is mistaken in its reading of 35 U.S.C. § 156(a)(5)(A). The phrase "provision of law" as used in 35 U.S.C. § 156(a)(5)(A) refers to the statutory provision under which the regulatory review period occurs for a particular class of products that is eligible for patent term restoration. It does not refer to a particular provision of a regulation, as argued by Applicant.

Section 156(g) of Title 35 and its implementing regulations confirm the USPTO's reading of 35 U.S.C. § 156(a)(5)(A). That is, 35 U.S.C. § 156(g) and its implementing regulations identify the statutory authorities under which regulatory review occurs for food and color additives.[2]

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[2] Notably, for all other classes of products for which patent term restoration is available, § 156(g) reflects statutory provisions under which regulatory review occurs: (i) section 505 of the FFDCA for new drugs; (ii) section 505 of the FFDCA and section 351 of the Public Health Service Act for licensed biologics; (iii) section 515 of the FFDCA for medical devices;

35 U.S.C. § 156(g) refers in general to the FFDCA for food additives and not to a regulation such as 21 C.F.R. § 573. The implementing regulations for 35 U.S.C. § 156(g), in turn, are more specific and refer to section 409 of the FFDCA. See 21 C.F.R. § 60.3(b)(9) (indicating that the provision of law for food additives is section 409 of the FFDCA).

For the foregoing reasons, the term of the '706 patent is not eligible for extension under 35 U.S.C. § 156 based upon the regulatory review period and approval of the product NSURE® (natamycin) as a feed additive.

C. Applicant's Pending Fourth Interim Extension Request Is Denied

Applicant filed a fourth interim extension application to extend the term of the '706 patent for another year because the '706 patent is due to expire on November 17, 2007. Section 156(e)(2) of Title 35 provides for an interim patent term extension while an applicant's PTE application is pending before the Office:

> If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

35 U.S.C. § 156(e)(2) (emphases added).

The express language of § 156(e)(2) sets forth at least two conditions that must be satisfied in order for the Director to issue an interim extension: (i) the patent at issue "would expire before a certificate of extension is issued or denied," and (ii) the Director must determine "that the patent is eligible for extension." The Federal Circuit recently confirmed that § 156(e)(2) contains these two requirements for an interim extension. See Somerset Pharms., Inc. v. Dudas, 500 F.3d 1344, 1346 (Fed. Cir. 2007). Here, neither requirement is met.

The first requirement is not met because the '706 patent will not expire before a certificate of extension is issued or denied since the Director has denied Applicants' PTE application under 35 U.S.C. § 156(d)(1) herein as explained above. The second requirement is not met because the Director issued a negative eligibility determination, thus divesting him of authority to grant an interim extension. See Somerset, 500 F.3d at 1346 ("[T]he Director has denied Somerset's application for extension. Therefore, the Director has no statutory authority to issue the interim extension Somerset seeks."); see also In re Alcon Labs. Inc., 13 USPQ2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (denying an interim extension application because the underlying patent term extension application was denied and because the patent was not eligible for

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and (iv) section 512 of the FFDCA for new animal drugs. Section 156(g) never mentions any regulations.

extension). Accordingly, because Applicant's PTE is denied herein and because the '706 patent is not eligible for patent term extension, the Office must deny Applicant's pending fourth interim extension request.

D. The Previously Granted Interim Extensions of the '706 Patent Are Vacated

During the pendency of Applicant's PTE Application before the USPTO, Applicant filed three previous interim extension requests under 35 U.S.C. § 156(e)(2). The USPTO granted each of the requests, extending the '706 patent for a total of three years while the USPTO determined whether the '706 patent was eligible for patent term extension. Because the USPTO has concluded herein that the '706 patent is not eligible for a patent term extension, the interim extensions previously granted under section 156(e)(2) are vacated *ab initio*. See In re Alcon, 13 USPQ 2d 1115, 1123 (Comm'r Pat. & Trademarks 1989) (stating that "an interim extension can be granted only in those circumstances, unlike the present case, where the Commissioner has determined that the patent is eligible for extension); see also In re Reckitt, 230 USPQ 369 (Comm'r of Pat. & Trademarks 1986) (recognizing that if a patent is ineligible for a patent term extension, then any interim extension granted to maintain a patent during the eligibility review process would be invalid); U.S. Pat. & Trademark Off., Manual of Patent Examining § 2755.01 (8th ed. 2001, rev. Oct. 2005) ("Where a determination is made that the patent is not eligible for patent term extension, an interim extension of the patent term is not warranted under § 156(e)(2). . . . Where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension may be vacated *ab initio* as ineligible under § 156(e)(2).").

E. Conclusion

In sum, Applicant's requests for extension of the patent term of the '706 patent are **DENIED**; Applicant's request for reconsideration is **DENIED**; and the three interim extensions previously granted to Applicant under 35 U.S.C. § 156(e)(2) are **VACATED** *ab initio*.

THIS DECISION MAY BE VIEWED AS A FINAL AGENCY ACTION.

Any correspondence with respect to this matter should be addressed as follows:

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Attention: Beverly Friedman

Re: NSURE® (natamycin)
FDA Docket No. 2005E-0250