UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH HOLDINGS CORP., et al., **Plaintiffs,** **v.** **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,** **Defendants.**	**Civil Action 08-00981 (HHK)**

MEMORANDUM OPINION

Wyeth Holdings Corporation and Wyeth ("Wyeth") bring this action against defendants U.S. Department of Health and Human Services, U.S. Food and Drug Administration, and others (together, "FDA") under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq*. ("APA") seeking a longer patent term extension for their animal drug product ("Cydectin") than that which the FDA has provided. Before the court are the FDA's motion to dismiss or alternatively for summary judgment [#22], and Wyeth's cross-motion for summary judgment [#32]. Upon consideration of the cross-motions, the oppositions thereto, and the record of this case, the court concludes that the FDA's motion to dismiss or alternatively for summary judgment must be granted and that Wyeth's motion for summary judgment must be denied.

I. BACKGROUND

Before a new animal drug may be marketed its sponsor must submit, and the FDA must approve, a New Animal Drug Application ("NADA"). The NADA process proceeds in two phases. First, the applicant must conduct testing and an investigation concerning the drug

("Testing Phase") with respect to seven "technical sections" and submit its findings to the FDA.[1] Second, the FDA must evaluate and approve the technical sections ("Approval Phase"), and thereby approve the drug. The sponsor may submit the technical sections together (triggering "Traditional Review") or in stages (triggering "Phased Review"). In Traditional Review, the Testing Phase ends and the Approval Phase begins when the sponsor completes its investigation and submits all of the technical sections as its final NADA. In Phased Review, the sponsor submits the technical sections on a rolling basis into an Investigational New Animal Drug file ("INAD File"). The FDA then evaluates the sections on a rolling basis, issuing a "Complete Letter" as to each one. Once the FDA has approved all the technical sections, the sponsor may submit the final NADA, known as the Administrative NADA.[2] In a Phased Review, it is less clear when the Testing Phase ends and the Approval Phase begins. It is this uncertainty that presents the question that underlies this action. It is a pivotal question because certain animal drug patents, such as the one in this case, are eligible for a patent term extension if patent life was lost while the drug was under regulatory review. The extension length is half of the Testing Phase, 35 U.S.C. §§ 156(c)(2) and (g)(4)(B)(i), plus all of the Approval Phase, not exceeding five years, *see* 35 U.S.C. § 156(g)(4)(B)(ii).

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[1] The seven technical sections are: Chemistry; Manufacturing and Controls; Effectiveness; Target Animal Safety; Human Food Safety; Environmental Impact; Labeling; Freedom of Information Summary; and All Other Information.

[2] "An 'Administrative NADA' is a new animal drug application that is submitted after all of the technical sections that fulfill the requirements for the approval of the new animal drug under 21 C.F.R. § 514.1 have been reviewed by the Center for Veterinary Medicine and the CVM has issued a technical section complete letter for each of those technical sections." U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (CVM), *The Administrative New Animal Drug Application Process: Guidance for Industry*, FDA000107-14, FDA000109 (Nov. 6, 2002) ("Guidance #132").

In March 1990, Wyeth asked the FDA to establish an INAD File for Cydectin, a drug designed to treat and control parasites in beef and dairy cattle. In April 1990, the FDA established the INAD File, which initiated the Administrative NADA process for Cydectin as a Phased Review. Wyeth submitted the first technical section (Chemistry) for Cydectin in August 1995. The FDA issued a Complete Letter for this section in December 1997. Thereafter, Wyeth submitted each technical section. For the duration of the Phased Review, there was no time when a technical section was not pending; thus, there was no lag in the submission of technical sections. (*See* Pl. Mot. for Summ. J. [#32], at 15.) In August 1996, Wyeth submitted the final technical section (Environmental Impact), and the FDA issued a Complete Letter for it in December 1997. At that time, however, at least one other section (Public Safety) was still pending, and the FDA requested supplemental information from Wyeth. By January 1998, Wyeth had submitted all the necessary technical information, and the FDA issued the final Complete Letter on January 13, 1998. Wyeth submitted the Administrative NADA for Cydectin that same day. On or about January 28, 1998, the FDA issued the marketing approval letter for Cydectin.

The dispute in this case arises in connection with Wyeth's application for a patent term extension based on the regulatory review process for Cydectin. The FDA determined that the Testing Phase began on April 5, 1990, (the date the FDA established the INAD file), and that the Approval Phase began on January 13, 1998, (the date Wyeth submitted the Administrative NADA). The FDA thus determined the Testing Phase was 2,841 days, and the Approval Phase was 16 days. Based on these determinations, the U.S. Patent and Trademark Office ("PTO") extended the Cydectin patent from April 10, 2007, to March 14, 2011 — an extension of nearly

four years. Wyeth disputed the FDA's determinations and thus the length of its patent term extension. Accordingly, Wyeth filed a Request for Revision of the Regulatory Review Period with the FDA. Specifically, Wyeth contended that the Approval Phase began upon submission of the first technical section in August 1995, and that the Cydectin patent should be extended from April 10, 2007, until January 28, 2012 — approximately ten months longer than Wyeth's current extension. Alternatively, Wyeth contended that the Approval Phase began no later than upon submission of its final technical section in August 1996, which would extend the patent until November 26, 2011 — approximately eight months longer than Wyeth's current extension. The FDA denied Wyeth's request. Wyeth now seeks a court order that would set aside the FDA's final determination of the regulatory review period for Cydectin.

II. ANALYSIS

The sole question before the court is the following question of law: whether the FDA rightly decided that the Approval Phase began upon submission of the Administrative NADA for Cydectin. Because the court must review this question under the APA, the court only will set aside the FDA's decision if it finds that decision to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). Applying this standard, the court turns to the following statutory provisions, which establish when the Approval Phase for Cydectin began, and thus determine the appropriate length of the patent term extension for Cydectin:

> (g) For the purposes of this section, the term regulatory review period has the following meanings:
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> (4)(A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation in paragraph (6) applies:
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> (B) The regulatory review period for a new animal drug product is the sum of –
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> > (i) [Testing Phase] the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and
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> > (ii) [Approval Phase] the period beginning on the date the *application was initially submitted* for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

35 U.S.C. § 156(g)(4) (emphasis added).[3]

The parties and the court agree that in reviewing this question of statutory interpretation, the court must follow the two-step inquiry set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). Under *Chevron*, the court first inquires as

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[3] As discussed in Section I, *supra*, any patent term extension would include all of the Approval Phase but only half of the Testing Phase:

> (c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that--
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> (2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g); . . .

35 U.S.C. § 156(c)(2).

to "whether Congress has directly spoken to the precise question at issue." *Id*. at 842. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id*. at 842-43. Second, "[if] the court determines [that] Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute . . . ." *Id*. at 843. "Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the [FDA's interpretation] is based on a permissible construction of the statute." *Id*. If the FDA's interpretation "fills a gap or defines a term in a way that is reasonable in light of the legislature's revealed design, [the court gives] the FDA's judgment 'controlling weight.'" *NationsBank of N.C. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 257 (1995) (quoting *Chevron,* 467 U.S. at 844).

A. *Chevron* Step One

The FDA determined that the Approval Phase for Cydectin began on January 13, 1998, the date on which Wyeth submitted the Administrative NADA. The FDA contends that this interpretation follows from the unambiguous language of 35 U.S.C. § 156(g)(4)(B)(ii). Specifically, the FDA emphasizes that the Approval Phase does not commence until "the *application* [i]s initially submitted . . . for the approved animal drug product under subsection (b) of section 512 [of the Food, Drug, and Cosmetic Act ("FDCA")." *Id.* (emphasis added). According to the FDA, an application does not constitute an "application" within the meaning of section 512 of the FDCA, 21 U.S.C. § 360b(b), unless it contains all of the information, samples,

and specimens that are required for FDA approval.[4] *See* 21 U.S.C. § 360b(b); *see also* 21 C.F.R. § 514.1(b) (describing application as consisting of all required technical sections). Accordingly, the FDA contends that an "application" is not "initially submitted" under the Phased Review process until the FDA confirms all technical sections are complete and the applicant submits an Administrative NADA.

Wyeth counters that the Approval Phase corresponds to the entire period of time that the FDA actually spends performing its substantive review of an application, not just the amount of time required to review an Administrative NADA. According to Wyeth, this interpretation follows from the unambiguous language of 35 U.S.C. § 156(g)(4)(B)(ii). Specifically, Wyeth

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[4] Section 512(b) of the FDCA provides:

> (1) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; (G) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (H) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe . . . .

21 U.S.C. § 360b(b).

emphasizes that the Approval Phase does not commence until "the application [i]s *initially submitted* . . . for the approved animal drug product under subsection (b) of section 512 [of the FDCA]." 35 U.S.C. § 156(g)(4)(B)(ii) (emphasis added). According to Wyeth, Congress has explained that an application is *initially submitted* when an applicant submits sufficient information to allow the FDA to *commence* its substantive review:

> [The term "initially submitted"] is used instead of the term "filed" because an application is often not considered to be filed, even though agency review has begun, until the agency has determined that no other information is needed and a decision on the application can be made. For purposes of determining the regulatory review period and its components periods, an application for agency review is considered to be "initially submitted" if the applicant has made a deliberate effort to submit an application containing all information necessary for agency review to begin. The Committee recognizes that the agency receiving the application might decide it needs additional information or other changes in the application. As long as the application was complete enough so that the agency action could be commenced, it would be considered to be "initially submitted."

H.R. Rep. No. 98-857, pt. 1, at 44 (1984). Wyeth also points out that the review of an Administrative NADA does not require the FDA to perform a substantive review at all because an applicant only may submit an Administrative NADA after the FDA already has approved all the technical sections. Thus, according to Wyeth, the FDA's interpretation effectively would read the word "initially" out of the statutory text thereby instituting a "filing" requirement rather than an "initially submitted" requirement, which Wyeth contends is contrary to Congress's intent.

Pointing to the same Report, the FDA argues that the legislative history supports its reading that an application is not an "application" unless all technical sections are complete:

> For purposes of determining the regulatory review period and its component periods, an application for agency review is considered to be "initially submitted" if the applicant has made a deliberate effort to submit an application *containing all information necessary* for agency review to begin.

H.R. Rep. No. 98-857, pt. 1, at 44 (1984) (emphasis added). The FDA asks the court to interpret this section as evidencing Congress's intent that the submission of partial information to an INAD File, such as one technical section, could not begin the Approval Phase because the Approval Phase cannot begin until an "application contain[s] all information necessary for agency review to begin." *Id*. This argument notwithstanding, the FDA also contends that Wyeth's reliance on H.R. Rep. No. 98-857 is misplaced because the House Report was issued in 1984 and pertains only to Traditional Review considering that Phased Review was not instituted until five years later in 1989.

Although the parties agree that the Approval Phase commences when "the application [i]s initially submitted for the approved animal drug product under [21 U.S.C. § 360b(b)]," 35 U.S.C. § 156(g)(4)(B)(ii), they disagree as to the proper interpretation of this statutory provision and emphasize different text therein in support of their positions: the FDA contends that there was no "application" until Wyeth submitted its Administrative NADA; and Wyeth contends that the application was "initially submitted" upon its submission of the first technical section.[5] Because the court finds that both parties have advanced plausible readings of the statute at issue, the court holds that the statute is ambiguous.

The court begins by looking to the plain text of the provision at issue — 35 U.S.C. § 156(g)(4)(B)(ii). *See U.S. Dep't of Treasury v. Fabe*, 508 U.S. 491, 500 (1993); *Stewart v. Nat'l Shopmen Pension Fund*, 730 F.2d 1552, 1561 (D.C. Cir. 1984). There, the court finds no clear

[5] Wyeth seeks to allay any concerns that, under its interpretation, nearly any filing would trigger the approval process by noting that the FDA may reject a deficient technical section, (see FDA000004; FDA000019), and that only those periods during which an applicant is acting with reasonable diligence are included in a patent term extension, *see* 35 U.S.C. § 156(c)(1).

indication of congressional intent because the statute defines neither "application" nor "initially submitted." Looking to 21 U.S.C. § 360b(b), the court acknowledges the FDA's position that this section sets forth the required "part[s] of the application," but this section does not define "application" nor does it speak to the issue of when an "application" is "initially submitted." Indeed, the words "initially submitted" suggest that something less than a complete or final application may be sufficient to trigger the Approval Phase. Yet, the statute does not plainly state that it must be so.

Because the court cannot discern the meaning of the provision at issue from its plain text, the court must look beyond the text to "examine the meaning of certain words or phrases in context and also 'exhaust the traditional tools of statutory construction, including examining the statute's legislative history to shed new light on congressional intent'[.]" *Sierra Club v. E.P.A.*, 551 F.3d 1019, 1027 (D.C. Cir. 2008) (quoting *Am. Bankers Ass'n v. Nat'l Credit Union Admin.,* 271 F.3d 262, 267 (D.C. Cir. 2001)). Considering the context and legislative history of the statutory provision at issue, however, provides little clarity. As the parties have shown, the court may read H.R. Rep. No. 98-857, pt. 1, at 44 (1984) to support either of their interpretations. Accordingly, the court holds that 35 U.S.C. § 156(g)(4)(B)(ii) is ambiguous based on its text, context, and legislative history.[6]

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[6] Wyeth also relies on certain regulations in support of its contentions with respect to *Chevron* step one. (Pl. Mot. Summ. J. [#32], at 23-29 (citing 21 C.F.R. §§ 60.22(f) and 514.1(a).) Wyeth does not explain, however, how FDA regulations that were promulgated after the enactment of 35 U.S.C. § 156(g)(4)(B)(ii) should bear on the court's interpretation of that statute under *Chevron* step one. Nevertheless, the court has examined these regulatory provisions and determined that they, like the statutory provisions at issue, are sufficiently ambiguous to allow the FDA's interpretation that the Approval Phase commences upon submission of an Administrative NADA. The court reaches this conclusion having given due consideration to the significant deference that courts must afford to an agency's interpretation of

B. *Chevron* Step Two

The FDA contends that even if the court were to find that 35 U.S.C. § 156(g)(4)(B)(ii) is ambiguous, the court should defer to the FDA's reasonable interpretation of the statute. In addition to reiterating its arguments with respect to *Chevron* Step One, the FDA advances numerous policy arguments,[7] and it contends that its interpretation reflects long-standing practice and precedent.[8] Wyeth argues that even if the court finds that § 156(g)(4)(B)(ii) is ambiguous, the court must find the FDA's interpretation to be unreasonable and thus unworthy of deference. In addition to reiterating its arguments with respect to *Chevron* Step One, Wyeth argues that it is

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its own regulation. *Capital Network Sys., Inc. v. FCC*, 28 F.3d 201, 206 (D.C. Cir. 1994) (observing that the deference afforded to an agency's interpretation of its own regulation may be greater than the deference afforded to an agency's interpretation of a statute it is entrusted to administer).

[7] Specifically, the FDA contends that its interpretation is entitled to deference because the FDA reasonably balanced the complex policy considerations of patent term restoration and Phased Review. The FDA contends that the purpose of Phased Review is to create greater efficiencies in the approval process for new drugs thereby allowing them to enter the market faster. The trade-off, according to the FDA, is that drugs which in the Phased Review process generally receive a shorter patent term extension because the Approval Phase for an Administrative NADA is far shorter than the Approval Phase for a traditional NADA. The FDA argues that accepting Wyeth's interpretation would frustrate the policy balance by allowing Phased Review applicants not only to bring their drugs to market faster but also to increase their patent term extension by a disproportionally-long Approval Period. Wyeth discounts these policy objectives and accuses the FDA of supporting its interpretation with non-existent distinctions between the Traditional and Phased Review processes. The court cannot sustain Wyeth's efforts to undercut the FDA's policy arguments because it finds that the FDA's construction of 35 U.S.C. § 156(g)(4)(B)(ii) does not "frustrate the policy that Congress sought to implement." *Shays v. Fed. Election Comm'n*, 528 F.3d 914, 919 (D.C. Cir. 2008) (quoting *Cont'l Air Lines, Inc. v. Dep't of Transp.*, 843 F.2d 1444, 1453 (D.C. Cir. 1988)).

[8] The FDA points out that it has consistently determined that the Approval Phase begins upon submission of the Administrative NADA, and that such determinations have produced similarly short Approval Phases: Neutersol (34 days); Anipryl (54 days); Ivomec (17 days). (Defs.' Mot. to Dismiss [#22], at 8.)

inconsistent for the FDA to admit it is engaging in substantive review by issuing a Complete Letter while maintaining that the Approval Phase has not yet begun. Such an interpretation, according to Wyeth, effectively carves out the entire period of substantive review from the Approval Phase and runs contrary to congressional intent to credit the entire substantive review period toward patent term restoration.[9] The FDA rejoins that Wyeth's interpretation conflates the Approval Phase with the Testing Phase. In particular, the FDA points out that Wyeth cannot deny that while it submitted a technical section as early as 1995, Wyeth continued its investigation and testing with respect to other sections through 1998. Thus, according to the FDA, Wyeth's interpretation would have the court declare that the Testing Phase ended at a time when the bulk of the requisite testing still remained to be done.

Under *Chevron* step two, Wyeth bears the burden of showing that the FDA's interpretation is unreasonable. *See Sweet Home Chapter of Communities for a Great Oregon v. Babbitt*, 17 F.3d 1463, 1473 (D.C. Cir. 1994), *rev'd on other grounds*, 515 U.S. 687 (1995). Wyeth has not met its burden here because the court finds the FDA's arguments to be more persuasive than those made by Wyeth. Indeed, the FDA's construction runs true to the text and defines "initially submitted" in a manner "that is reasonable in light of the legislature's revealed design." *NationsBank*, 513 U.S. at 257. Accordingly, the court cannot say that the FDA's interpretation is based on an impermissible construction of the statute, nor can the court find that the FDA's interpretation violates the APA. *See Chevron,* 467 U.S. at 843; 5 U.S.C. § 706(2)(A).

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[9] Wyeth also contends that the FDA's treatment of animal drugs is inconsistent with its treatment of human drugs, which is contrary to Congressional intent that they be treated similarly. The FDA counters that there is no merit to this allegation because Phased Review is not available for human drugs. The court agrees with the FDA.

III. CONCLUSION

For the foregoing reasons, FDA's motion to dismiss or alternatively for summary judgment [#22] is GRANTED and Wyeth's cross-motion for summary judgment [#32] is DENIED.

An appropriate order accompanies this Memorandum Opinion.

Henry H. Kennedy, Jr.
United States District Judge