IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH HOLDINGS CORPORATION,
5 Giralda Farms
Madison, NJ 07940

and

WYETH,
Acting On Behalf of Its Fort Dodge Animal Health Division,
5 Giralda Farms
Madison, NJ 07940

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

and

U.S. FOOD AND DRUG ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857,

and

MICHAEL O. LEAVITT,
in His Official Capacity as Secretary of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201,

and

ANDREW C. VON ESCHENBACH, M.D.,
in His Official Capacity as Commissioner

Civil Action No.

of Food and Drugs, U.S. Food and Drug Administration,
5600 Fishers Lane
Rockville, MD 20857,

and

UNITED STATES PATENT AND TRADEMARK OFFICE,
Madison Building East, Room 10B20
600 Dulany Street
Alexandria, VA 22314,

and

JON W. DUDAS, *in His Official Capacity as Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office*,
Madison Building East, Room 10B20
600 Dulany Street
Alexandria, VA 22314,

Defendants.

COMPLAINT
FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Plaintiffs Wyeth Holdings Corporation, formerly known as American Cyanamid Corporation (collectively and individually referred to herein as "Wyeth Holdings Corporation") and Wyeth, acting on behalf of its Fort Dodge Animal Health Division ("Wyeth"), in their complaint against the U.S. Department of Health and Human Services, Michael O. Leavitt, in his official capacity as Secretary of the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration ("FDA" or the "Agency"), Andrew C. von Eschenbach, M.D., in his official capacity as Commissioner of FDA, the United States Patent and Trademark Office ("PTO"), and Jon W. Dudas, in his official capacity as Director of the PTO, allege as follows:

NATURE OF THE ACTION

1. This is an action to hold unlawful and set aside FDA's final determination of the regulatory review period for Plaintiffs' animal drug product CYDECTIN® (moxidectin) Pour-On ("Cydectin") from which the patent term extension for U.S. Patent No. 4,916,154 ("the '154 patent") is derived as erroneous, arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law.

2. Congress enacted the patent term extension legislation to restore patent term that is effectively lost during a drug product's ordinarily lengthy regulatory review period. The regulatory review period consists of two phases: the *testing* phase and the *approval* phase. Generally, the patent term extension comprises one-half of the time it takes to test the drug, as well as all of the time it takes for FDA to review and approve it. The statute specifically states that the FDA *approval* phase begins on the date the marketing application was "initially submitted." 35 U.S.C. § 156(g)(4)(B)(ii). Congress intentionally used the phrase "initially submitted" because Congress wanted the approval phase to begin when the agency begins its review, even though the application may *not* yet be complete. H.R. Rep. No. 98-857, pt. 1, at

44 (1984) (regarding similar patent term extension language for human drug products). According to Congress, "As long as the application was complete enough so that agency action could be commenced, it would be considered to be 'initially submitted.'" *Id.* Congress intended that the patent term restored during the approval phase be meaningful and correspond to the period of *actual substantive review* by FDA. Consistent with Congress's intent, FDA's regulations define "initially submitted" to mean the date the application "contains sufficient information to allow FDA to *commence review* of the application." 21 C.F.R. § 60.22(f) (emphasis added).

3. Plaintiffs submitted the information supporting the marketing application for Cydectin on a phased basis, as FDA allows, to speed the review of drugs. The initial submission was the first technical section on *August 8, 1995*. That initial submission was followed by the submission of five additional technical sections over approximately the next year. Even though FDA began to review the application on August 8, 1995, when the first technical section was submitted, FDA failed to use that date as the beginning of the approval phase for patent term extension purposes. Rather, FDA determined that the approval phase began only after FDA had *finished reviewing all* of the technical sections, and only after Wyeth had submitted an administrative document called an Administrative New Animal Drug Application ("Administrative NADA") on January 13, 1998. Despite statutory language and legislative history to the contrary, FDA determined that, for new animal drugs, "the approval phase begins when the marketing application is complete." 71 Fed. Reg. 54993, 54994 (Sept. 20, 2006). Under FDA's interpretation of the statute, FDA determined that the approval phase for the Cydectin application lasted a mere ***16 days***, while the testing phase lasted 2,841 days. This result is unreasonable, and deprives Wyeth Holdings Corporation of more than 10 months

of its rightful patent term, as it should have been extended. Plaintiffs' calculation is that the approval phase lasted ***904 days***, while the testing phase lasted 1,947 days.

4. Plaintiffs therefore seek a declaratory judgment against FDA declaring that the Agency's determination of the date on which the marketing application for Cydectin was initially submitted, and the Agency's corresponding determination of the regulatory review period for Cydectin, is erroneous, arbitrary, capricious, an abuse of discretion, and not in accordance with the law. Plaintiffs seek injunctive relief ordering FDA to recalculate the regulatory review period based on a proper determination of the date on which the marketing application for Cydectin was initially submitted.

5. Plaintiffs also seek injunctive relief ordering the PTO to refrain from issuing a final certificate of extension for the '154 patent until FDA has recalculated the regulatory review period in a manner consistent with the Food, Drug, and Cosmetic Act ("FDCA") and the Agency's implementing regulations.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1361 (mandamus).

7. The relief requested is authorized pursuant to 28 U.S.C. § 1651 (all writs act); 28 U.S.C. § 2201 (declaratory relief); and 28 U.S.C. § 2202 (further relief).

8. Plaintiffs have a right to bring this action pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 701-706, because FDA has engaged in final agency action presenting an actual controversy for which Plaintiffs are entitled to relief, and Plaintiffs have adequately exhausted all of its administrative remedies.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because this is a civil action in which one or more of the defendants is an officer of the United States residing in this judicial district, or an agency of the United States residing in this judicial district.

PARTIES

10. Plaintiff Wyeth Holdings Corporation is a Maine corporation, formerly known as American Cyanamid, which has its principal office at 5 Giralda Farms, Madison, NJ 07940.

11. Plaintiff Wyeth is a Delaware corporation, which has its principal office at 5 Giralda Farms, Madison, NJ 07940.

12. Defendant U.S. Department of Health and Human Services, which has its principal office at 200 Independence Avenue, S.W., Washington, D.C. 20201, is a federal agency headquartered in the District of Columbia that has authority over FDA.

13. Defendant Michael O. Leavitt is sued in his official capacity as Secretary of Health and Human Services. As Secretary, Mr. Leavitt has the ultimate responsibility for the activities of the Department of Health and Human Services, including those actions complained of herein. Mr. Leavitt maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

14. Defendant FDA, which has its principal office at 5600 Fishers Lane, Rockville, MD 20857, is a federal agency headquartered in Maryland. FDA reviews and approves new animal drug applications. FDA also makes determinations regarding the regulatory review period for new animal drug applications for the purposes of patent term restoration under authority delegated by Congress and the Secretary of the U.S. Department of Health and Human Services.

15. Defendant Andrew C. von Eschenbach, M.D. is sued in his official capacity as Commissioner of the FDA. As Commissioner, Dr. von Eschenbach has the ultimate

responsibility for the activities of the FDA, including those actions complained of herein. Dr. von Eschenbach maintains an office at 5600 Fishers Lane, Rockville, MD 20857.

16. Defendant PTO, which has its principal office at Madison Building East, Room 10B20, 600 Dulany Street, Alexandria, VA 22314, is a federal agency headquartered in Virginia. The PTO determines the eligibility of patents for which patent term extension is sought and issues a certificate of extension for eligible patents.

17. Defendant Jon W. Dudas is sued in his official capacity as Director of the PTO. As Director, Mr. Dudas has the ultimate responsibility for the activities of the PTO, including those actions complained of herein. Mr. Dudas maintains an office at Madison Building East, Room 10B20, 600 Dulany Street, Alexandria, VA 22314.

GENERAL ALLEGATIONS

I. Statutory And Regulatory Background

A. Patent Term Extensions Restore Patent Term Lost During Regulatory Review Of A Drug Product

18. The Generic Animal Drug and Patent Term Restoration Act of 1988 ("GAD/PTR Act") extends a patent term for an animal drug product for up to 5 years if, before marketing, the product was subject to regulatory review by FDA. 35 U.S.C. § 156(g)(4)(A).

19. Congress recognized that "animal drug innovators typically lose years of patent protection because of FDA's scientific testing requirements and regulatory review. While this FDA process is essential to confirming the safety and effectiveness of animal drugs, it can have the effect of reducing incentives to develop new animal drugs." H.R. Rep. No. 100-972, pt. 1, at 3 (1988).

20. Congress intended the GAD/PTR Act to stimulate research and development of animal drugs by restoring patent term lost during the lengthy *testing* and *review* period required

by FDA, thereby allowing developers of new animal drugs to recoup more of their research and development costs. *Id.*; *see also* 134 Cong. Rec. 30272 (1988) (statement of Sen. Hatch); 134 Cong. Rec. 30560 (1988) (statement of Rep. Waxman).

21. The GAD/PTR Act brought animal drugs and veterinary biologicals within the statutory framework Congress had previously established for human drugs in the Drug Price Competition and Patent Term Restoration Act of 1984 ("DPC/PTR Act", also known as the "Hatch-Waxman Act"). H.R. Rep. No. 100-972, pt. 1, at 2. The purpose of the GAD/PTR Act was "to create in the animal drug industry similar conditions for generic drugs and patent term restoration as Congress did in the human drug industry in 1984" with the DPC/PTR Act. *Id.*; *see also id.* at 8 (GAD/PTR Act "simply makes the additions to [the DPC/PTR Act] necessary to include animal drugs . . . .")

B. The Procedure For Obtaining A Patent Term Extension Involves A Determination Of The Regulatory Review Period By FDA

22. To obtain a patent term extension, the patent's owner must apply to the Director of the PTO within 60 days of receiving marketing approval for the drug product covered by the patent. 35 U.S.C. § 156(d)(1).

23. Within 60 days of receiving such a patent term extension application, the Director of the PTO must notify the Secretary of Health and Human Services of the application and send the Secretary a copy of such application. 35 U.S.C. § 156(d)(2)(A)(ii).

24. No later than 30 days after receiving the application from the Director of the PTO, the Secretary must determine the applicable "regulatory review period" for the drug product covered by the patent for which the term extension is sought and must publish a notice of such determination in the Federal Register. 35 U.S.C. § 156(d)(2)(A).

25. Subject to statutory limitations, the term of a patent that can be extended by the time it took for the approved animal drug product to be tested and approved. 35 U.S.C. § 156(c).

26. If the Director of the PTO determines that the patent term is eligible for an extension, the Director issues a certificate of extension, under seal, for the period corresponding to the regulatory review period. 35 U.S.C. § 156(e)(1).

C. The "Regulatory Review Period" For Animal Drug Products Is Comprised of Two Phases

27. The "regulatory review period" for purposes of patent term extension covers the time consumed by the investigational drug testing phase under an Investigational New Animal Drug ("INAD") exemption, as well as the FDA approval phase. 35 U.S.C. § 156(g)(4)(B); *see also* 21 C.F.R.§ 60.22(d); H.R. Rep. 98-157, part 1, at 40 ("[a]ll regulatory review periods are divided into a testing phase and an agency approval phase"); *see also* 44 ("in all cases [the regulatory review period] is considered to have a testing phase and an agency approval phase.").

28. The patent term may be extended by the sum of (i) one-half of the time an animal drug was in the testing phase; and (ii) as many days as the animal drug was under review by FDA before approval. 35 U.S.C. § 156(c).

29. The testing phase begins on the date "an [INAD] exemption under subsection (j) of section 512 [of the Food, Drug, and Cosmetic Act] became effective for the new animal drug product," and ends "on the date an application was *initially submitted* for such animal drug product under section 512." 35 U.S.C. § 156(g)(4)(B)(i) (emphasis added); *see also* 21 C.F.R. § 60.22(d)(1) ("The testing phase begins on the date . . . on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug

[*i.e.*, an investigational new animal drug (INAD) file] . . . and ends on the date a marketing application under section 512 of the Act is initially submitted to FDA.").

30. The approval phase covers the time it takes FDA to review and approve the application. It begins "on the date the application was *initially submitted* for the approved animal drug product under subsection (b) of section 512" and ends "on the date such application was approved under such section." 35 U.S.C. § 156(g)(4)(B)(ii) (emphasis added); *see also* 21 C.F.R.§ 60.22(d)(2) ("The approval phase begins on the date a marketing application under section 512 of the Act is initially submitted to FDA and ends on the date the application is approved.").

31. Pursuant to FDA's regulations, a marketing application "is *initially submitted* on the date it contains sufficient information to allow FDA to commence review of the application." 21 C.F.R. § 60.22(f) (emphasis in original).

32. The Agency's definition of the statutory term "initially submitted" is consistent with the definition in the House Report accompanying the DPC/PTR Act. Congress there explained that the approval phase begins on the date FDA has enough information to begin reviewing the application, rather than on the date that FDA considers the application to be complete, or "filed":

> [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 agency action could be commenced, it would be considered to be 'initially submitted'.*
>
> H.R. Rep. No. 98-857, pt. 1, at 44 (1984) (emphasis added).

33. Congress intended that the patent term restored during the "approval phase" be meaningful and correspond to the period of *actual substantive review* of the application by FDA -- not on the date all the application filing requirements have been completely met. The former more accurately reflects the time that the marketing application was under FDA review.

D. The Technical Sections That Make Up A New Animal Drug Application (NADA) May Be Submitted, And Are Substantively Reviewed By FDA, On A Rolling Or Phased Basis

34. An applicant for approval of a new animal drug product may submit the entire marketing application, or New Animal Drug Application ("NADA"), as a single submission. 21 U.S.C. § 514.1(b).

35. FDA also permits an applicant, on a voluntary basis, to file the various technical components of a NADA under FDA's "Phased Review Policy." *See* FDA, Center for Veterinary Medicine, The Administrative New Animal Drug Application Process: Draft Guidance #132 (Nov. 6, 2002) ["CVM Draft Guidance #132"], p. 3; *see also* FDA, Center for Veterinary Medicine, Document and Submission Information – An Update (April 1995) ["CVM Update"], p. 1.

36. Under phased review, an applicant may submit data or information in support of a NADA technical section, or may submit a complete technical section of the NADA, separately from (and normally ahead of) the other sections. FDA begins review of the submitted technical sections even if the other sections have not yet been submitted. FDA then notifies the applicant in writing of its conclusions regarding the data submitted. *See* CVM Update, p. 13; CVM Draft Guidance #132, p. 6.

37. FDA encourages sponsors to use phased review to streamline the drug review process. As explained by FDA, "The [FDA] Center for Veterinary Medicine (CVM) encourages sponsors to submit data for review at the most appropriate and productive times in the drug development process *rather than submitting all data at one time*." CVM Draft Guidance #132, p. 2 (emphasis added).

38. Procedurally, FDA requires that the technical submissions made under the Phased Review Policy be made to the INAD file for the new animal drug product. CVM Draft Guidance #132, p. 3.

39. FDA issues a technical section "complete letter" for each technical section submitted under phased review that FDA decides has fulfilled the requirements for approval of the new animal drug product. CVM Draft Guidance #132, p. 2.

40. This alternative, "phased" method for submitting a NADA culminates with the filing of an "Administrative NADA" by the applicant. CVM Draft Guidance #132, pp. 3, 6. Once an applicant has received technical section complete letters for each of the technical sections submitted to support approval of a new animal drug product, the applicant may then file an Administrative NADA.

41. The Administrative NADA includes a cover letter, a table of contents, a summary, a copy of each technical section "complete letter," and some other ministerial documents. *Id.*

42. The formal act of submitting an Administrative NADA occurs only *after* the Agency *has completed* its substantive review of the various technical sections. As FDA explained, "[i]f an application meets the definition of an Administrative NADA, the review should take fewer than 180 days because the *review of the individual sections of the*

application has already been completed." CVM Draft Guidance #132, at p. 7 (emphasis added).

43. Thus, FDA has the information to commence review of the technical sections of the NADA long before the submission of an Administrative NADA.

II. Factual Allegations

A. The '154 Patent

44. The Fort Dodge Animal Health Division of Wyeth holds the approved NADA 141-099 for Cydectin (moxidectin). Cydectin is an animal drug product that is labeled for use in beef and dairy cattle for the treatment and control of internal and external parasites.

45. On April 10, 1990, the PTO issued the '154 patent, titled "23-Imino Derivatives of LL-F28249 Compounds." It named as inventors, Goro Asato and Donald J. France.

46. The '154 patent was duly and legally assigned to American Cyanamid Company of Stamford, CT.

47. By virtue of a name change in December 2002, American Cyanamid Company is now known as Wyeth Holdings Corporation.

48. Wyeth Holdings Corporation is the current assignee of the '154 patent, and owns all rights, title, and interests in and to the '154 patent.

49. Claims 1, 2, 3, 4, and 5 of the '154 patent cover the compound moxidectin.

50. Claims 7, 8, and 9 of the '154 patent claim a method of using the approved product.

51. Claim 15 of the '154 patent claims a composition which contains the approved product, and which is of use in the approved product.

52. The original expiration date of the '154 patent is April 10, 2007.

53. On March 9, 2007 and March 21, 2008, the PTO granted the '154 patent interim extensions under 35 U.S.C. § 156(e)(2). Under the interim extensions, the expiration date of the '154 patent is April 10, 2009.

B. FDA's Regulatory Review Of Cydectin

54. The marketing application for the use of Cydectin on a food-producing animal was approved by FDA on January 28, 1998.

55. On or about March 26, 1990, Wyeth Holdings Corporation formally asked the FDA to establish an Investigational New Animal Drug (INAD) file for the use of moxidectin in a food-producing animal.

56. On or about April 5, 1990, FDA notified Wyeth Holdings Corporation that the INAD file for moxidectin had been assigned INAD number 6736.

57. In 1995, Wyeth Holdings Corporation submitted the first technical section regarding Cydectin for phased review.

58. Specifically, on August 8, 1995, Wyeth Holdings Corporation submitted to FDA the Residue Chemistry technical section of the marketing application for Cydectin. This submission contained four sets of information, covering the subjects of total metabolism in target animal, comparative metabolism in rodents, tissue residue depletion studies, as well as analytical methods and method validations.

59. On March 26, 1996, FDA issued a letter stating that it had "proceeded with [its] review." FDA advised Wyeth Holdings Corporation that more information was needed in connection with the Residue Chemistry technical section.

60. On December 10, 1997, FDA issued a "complete letter" for the Residue Chemistry technical section.

61. Wyeth Holdings Corporation made its Target Animal Safety submission on December 15, 1995. FDA issued a "complete letter" for this component on June 22, 1996.

62. Wyeth Holdings Corporation made its submission relating to Manufacturing Chemistry on December 21, 1995. FDA issued a "complete letter" for this component on September 17, 1996.

63. Wyeth Holdings Corporation made its submission relating to Effectiveness on January 16, 1996. FDA issued a "complete letter" for this component on November 4, 1997.

64. Wyeth Holdings Corporation made a submission relating to Public Safety on June 7, 1996. FDA issued a "complete letter" for this component on January 13, 1998.

65. Wyeth Holdings Corporation made a submission relating to Environmental Safety on August 14, 1996.

66. Once Wyeth Holdings Corporation submitted the Environmental Safety technical section on August 14, 1996, all of the technical sections necessary for a complete NADA had been submitted to FDA.

67. FDA submitted a "complete letter" for the Environmental Safety technical submission on December 23, 1997.

68. On January 13, 1998, upon receipt of the "complete letter" for the final component of the application, Wyeth submitted its Administrative NADA for Cydectin. That complete letter cited all the "complete letters" FDA had previously issued for all of the components of the application.

69. On January 14, 1998, the agency issued an acknowledgement letter for the Administrative NADA.

70. On January 28, 1998, FDA issued the marketing approval letter for Cydectin.

C. Wyeth Holdings Corporation's Patent Term Extension Application For The Patent Covering Cydectin

71. On March 27, 1998, within the 60-day period for submission, Wyeth Holdings Corporation filed with the PTO a Request for Extension of Patent Term Under 35 U.S.C. § 156. *See* 37 C.F.R. 1.720(f).

72. The Request for Extension of Patent Term indicated that the testing exemption under subsection (j) of section 512 (of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360b(j)) became effective for the new animal drug product on August 9, 1990, the date FDA assigned the INAD file number for moxidectin.

73. The Request for Extension of Patent Term indicated that the approval phase began when the marketing application was "initially submitted" on *August 8, 1995*. *August 8, 1995*, is the date on which the Residue Chemistry technical section was first submitted to FDA, allowing FDA to begin its review.

74. The Request for Extension of Patent Term indicated that the date the application was approved was January 28, 1998.

75. Based on Wyeth Holdings Corporation's calculation of one-half of the "testing phase" (after the grant of the patent) from April 10, 1990 to *August 8, 1995* (973.5 days); and a calculation of all the time corresponding to the "approval phase" from *August 8, 1995* to January 28, 1998 (904 days), Wyeth Holdings Corporation determined that the regulatory review period for the approved product is 1877.5 days.

76. Given that under 35 U.S.C. § 156(c)(3) and 156(g)(6)(A), the period of extension cannot exceed 5 years, and the period remaining in the term of the patent after the date of approval when added to the review period cannot exceed 14 years, Wyeth Holdings

Corporation determined that the '154 patent is eligible for an extension of a period of 1,754 days.

77. Thus, the new expiration date of the '154 patent based on an approval phase that began on *August 8, 1995*, the date when substantive review of the application could (and did) begin, would be *January 28, 2012*.

78. Because Wyeth Holdings Corporation was aware that this was, to its knowledge, the first patent term extension request for a phased animal health submission, the Request for Extension of Patent Term indicated, as an alternative, that the approval phase began when all the component technical sections of the marketing application were "initially submitted." August 14, 1996 is the date Wyeth Holdings Corporation initially submitted to FDA the final technical section of the marketing application -- the Environmental Safety technical section.

79. Based on Wyeth Holdings Corporation's calculation of one-half of the "testing phase" (after the grant of the patent) from April 10, 1990 to August 14, 1996 (1159 days), and a calculation of all the time corresponding to the "approval phase" from August 14, 1996 to January 28, 1998 (532 days), under this alternative, Wyeth Holdings Corporation determined that the appropriate regulatory review period for the approved product would be 1,691 days.

80. Under this alternative, the new expiration date of the '154 patent based on an approval phase that began on August 14, 1996, would be November 26, 2011.

D. FDA's Determination Of The Regulatory Review Period For Cydectin Unlawfully Relied On The Date The Administrative NADA Was Submitted Instead Of The Date Information Was Initially Submitted For FDA Review

81. On September 20, 2006, FDA published its determination of the regulatory review period for purposes of patent term extension for Cydectin in the Federal Register.

82. FDA determined that the applicable regulatory review period for Cydectin is 2,857 days. Of this time, FDA determined that *2,841* days occurred during the testing phase, while only *16* days occurred during the approval phase.

83. These periods of time were derived from a determination that April 5, 1990, is the effective date for the INAD, which began the testing phase.

84. The approval phase was based on FDA's determination that the Cydectin marketing application was initially submitted on January 13, 1998, the date on which the Administrative NADA for Cydectin was submitted.

85. FDA's reasoning for this determination was that "the approval phase begins when the marketing application *is complete*." 71 Fed. Reg. 54993, 54994 (Sept. 20, 2006). According to FDA, a review of FDA records revealed that the date of FDA's official acknowledgement letter assigning a number to the marketing application (*i.e.*, NADA 141-099) was January 13, 1998.

86. In addition, FDA's reasoning was based on the fact that the submissions for the Cydectin marketing application were technically submitted for FDA review in the INAD file.

87. FDA also determined that the date the marketing application was approved was January 28, 1998.

88. Based on FDA's determination of the regulatory review period for Cydectin, the PTO issued a notice of final determination on June 13, 2007 indicating that the period of patent term extension had been determined to be 1,434 days.

89. Thus, the PTO notice of final determination erroneously indicates that the new expiration date of the '154 patent, based on an approval phase that began on January 13, 1998, would be *March 14, 2011*.

90. FDA's determination of the approval phase and the regulatory review period based on the date the marketing application was "completed" is not in accordance with the FDCA and the Agency's implementing regulations, which state that the approval phase begins when the application is initially submitted and FDA may commence its review. FDA's actions also effectively punish Plaintiffs for doing exactly what the Agency encourages companies to do as a policy matter, *i.e.*, utilize the phased review pathway of drug review.

E. FDA's Method Of Calculating The Regulatory Review Period For Cydectin Is Contrary To The Method Used For Human Drug Products

91. Despite Congress's attempts to afford new animal drugs the same intellectual property protections as new drugs for humans, FDA's treatment of Wyeth Holdings Corporation's request for a patent term extension for Cydectin stands in stark contrast with its policy for calculating patent term extensions for human drugs. Indeed, on the same day FDA published its determination of the regulatory review period for Cydectin, FDA also published its determination of the regulatory review period for the purposes of patent term extension for a human drug product marketed by Roche. FDA used a different method to calculate the regulatory review period for the human drug product than FDA used for Cydectin, with the result being far more favorable to human drugs than to new animal drugs. Whether FDA's method of calculation for human drugs is correct or not, its disparate treatment of human drugs and new animal drugs, with little or no explanation and with no sound policy rationale, highlights the arbitrary and capricious nature of FDA's decision concerning Cydectin.

92. The marketing application, or New Drug Application ("NDA"), for the human drug FUZEON® ("Fuzeon"), was submitted in several units as part of a rolling NDA submission procedure authorized by statute for drugs intended to treat serious or life-threatening conditions, or address unmet medical needs. *See* 21 U.S.C. § 356.

93. In contrast to Cydectin, FDA determined that the NDA for Fuzeon was initially submitted on the day the "final module of the marketing application was submitted" to FDA. 71 Fed. Reg. 54993, 54997 (Sept. 20, 2006).

94. FDA provided no rational basis for treating the final submission in the Fuzeon marketing application as the date on which the marketing application was "initially submitted," but not treating the final submission for Cydectin as the date on which the marketing application was "initially submitted."

95. FDA's disparate treatment of human drug products and animal drug products in the calculation of the regulatory review period for the purposes of patent term extension has no rational basis and is arbitrary and capricious. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20 (D.D.C. 1997) (holding that the disparate treatment of similarly situated products is arbitrary and capricious). This is particularly the case given Congress's determination that the GAD/PTR covering new animal drugs should achieve the same objectives as the DPC/PTR covering human drugs. *See* H.R. Rep. No. 100-972, pt. 1, at 2 (stating that the purpose of the GAD/PTR Act was "to create in the animal drug industry similar conditions for generic drugs and patent term restoration as Congress did in the human drug industry in 1984").

F. Wyeth Holdings Corporation's Request For Revision Of Regulatory Review Period

96. Wyeth Holdings Corporation timely filed a Request for Revision of Regulatory Review Period with the FDA on November 20, 2006. It asked that the "date the application was initially submitted with respect to the animal drug product under section 512(b) of the act" be corrected from January 13, 1998, the date in the Federal Register notice, to *August 8, 1995*, the date Wyeth Holdings Corporation submitted to FDA the first technical section of the NADA application.

97. Wyeth Holdings Corporation also requested that the Agency recalculate the "regulatory review period" accordingly.

98. On May 7, 2008, FDA denied Wyeth Holdings Corporation's November 20, 2006 Request for Revision of Regulatory Review Period.

99. FDA's May 7, 2008 response constitutes the Agency's final action on the regulatory review period determination for purposes of the patent term extension for the '154 patent. *See* 21 C.F.R. § 60.26(b)(2).

100. In light of the above, Plaintiffs have exhausted all of their available administrative remedies.

CLAIMS FOR RELIEF

Count I

(Violation of 5 U.S.C. § 706(2)(A) and 5 U.S.C. § 706(2)(C))

101. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 9 of the Complaint, as set forth fully herein.

102. Wyeth Holdings Corporation "initially submitted" the marketing application for Cydectin on *August 8, 1995*, the date on which the Residue Chemistry technical section was submitted to FDA for review.

103. On December 10, 1997, FDA had completed its review of the Residue Chemistry technical section and issued a "complete letter" for this technical section, evidencing that "substantive review" had occurred.

104. Following the Residue Chemistry submission, submissions relating to Target Animal Safety, Manufacturing Chemistry, Effectiveness, Public Safety, and Environmental

Safety were made by Wyeth Holdings Corporation on December 15, 1995, December 21, 1995, January 16, 1996, June 7, 1996, and August 14, 1996, respectively.

105. FDA undertook review of these technical sections and issued "complete letters" for each section on July 22, 1996, September 17, 1996, November 4, 1997, January 13, 1998, and December 23, 1997, respectively. *See* Table 1 of Exhibit 4 of Wyeth Holdings Corporation's Request for Extension of Patent Term Under 35 U.S.C. § 156 (March 27, 1998).

106. Upon receipt of the January 13, 1998 complete letter, Wyeth Holdings Corporation immediately filed its Administrative NADA.

107. Thus, by the time the Administrative NADA was filed for Cydectin, FDA had reviewed *all* the technical sections that form the basis of the NADA for Cydectin. In addition, FDA had issued "complete letters" for all the technical sections that form the basis of the NADA for Cydectin.

108. The marketing application for Cydectin was initially submitted on *August 8, 1995*, the date the Residue Chemistry technical section was submitted to FDA because, at this time, the Agency had "sufficient information to allow FDA to commence review of the application." 21 C.F.R. § 60.22(f).

109. FDA's finding that the marketing application for Cydectin was initially submitted on January 13, 1998, the date on which the Administrative NADA was formally filed, and not on *August 8, 1995*, the date on which the first technical section of the marketing application for Cydectin was submitted, is contrary to law.

110. The Agency's determination of the regulatory review period in response to Wyeth Holdings Corporation's Request for Revision of Regulatory Review Period constitutes a final agency action that is reviewable by the district court. 5 U.S.C. § 704.

111. As set forth above, FDA's determination of the regulatory review period for Cydectin was erroneous, arbitrary, capricious, and not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A), in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C), and in violation of the FDCA and FDA's implementing regulations.

112. Plaintiffs have no adequate remedy at law and will suffer irreparable injury if FDA is not directed to recalculate the regulatory review period for Cydectin.

113. An order directing FDA to recalculate the regulatory review period would not substantially injure other interested parties, and the public interest will be furthered by a calculation of the regulatory review period that is not contrary to law.

114. An order directing PTO to refrain from issuing a certificate of extension for the '154 patent would not substantially injure other interested parties, and the public interest will be furthered by a certificate of extension that reflects a calculation of the regulatory review period that is not contrary to law.

WHEREFORE, Plaintiffs pray that this Court enter:

A. A declaratory judgment pursuant to 28 U.S.C. § 2201(a) in favor of Plaintiffs and against Defendants, by:

(i) declaring that FDA's determination of the regulatory review period for Cydectin was erroneous, arbitrary, capricious, and abuse of discretion, and in violation of the FDCA and the Agency's implementing regulations; and

(ii) declaring that FDA's finding that the marketing application for Cydectin was initially submitted on January 13, 1998 was erroneous, arbitrary, capricious, and abuse of discretion, and in violation of the FDCA and the Agency's implementing regulations.

B. An Order granting Plaintiffs injunctive relief that:

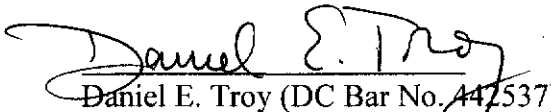
(i) directs FDA to recalculate the regulatory review period for Cydectin based on the date the marketing application for Cydectin was "initially submitted" pursuant to 35 U.S.C. § 156(g)(4)(B).

C. An Order granting Plaintiffs injunctive relief that:

(i) directs the PTO to refrain from issuing a final certificate of extension for the '154 patent until FDA has recalculated the regulatory review period for Cydectin in a manner consistent with the FDCA and the Agency's implementing regulations.

D. Order such other and further relief as the Court deems just and appropriate.

Respectfully submitted,



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