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and New Ace Research Company

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

BAYER HEALTHCARE LLC,  
UNIVERSITY OF KENTUCKY  
RESEARCH FOUNDATION, and  
NEW ACE RESEARCH COMPANY,

Plaintiffs,

v.

WEDGEWOOD VILLAGE PHARMACY,  
INC.

Defendant.

Civil No. \_\_\_\_\_

**COMPLAINT**

Plaintiffs Bayer HealthCare LLC (“Bayer”), University of Kentucky Research Foundation (“UKRF”), and New Ace Research Company (“New Ace”) (collectively “Plaintiffs”), for their Complaint against Defendant Wedgewood Village Pharmacy, Inc. (“Wedgewood”), allege as follows:

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code.

### **THE PARTIES**

2. Bayer is a limited liability company organized and existing under the laws of the State of Delaware and having a place of business located at 12707 Shawnee Mission Parkway, Shawnee Mission, Kansas 66216.

3. UKRF is a corporation organized and existing under the laws of the Commonwealth of Kentucky and having a place of business located at 311 Main Building, University of Kentucky, Lexington, Kentucky 40506.

4. New Ace is a corporation organized and existing under the laws of the Commonwealth of Kentucky and having a place of business located at P.O. Box 5, Paynes Depot Road, Versailles, Kentucky 40383.

5. Based upon information and belief, Wedgewood is a corporation organized and existing under the laws of the State of New Jersey and having a principal place of business located at 405 Heron Drive, Suite 200, Swedesboro, New Jersey 08085.

### **JURISDICTION AND VENUE**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1338(a) and 1331.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

### **THE PATENT**

8. On March 16, 1999, the United States Patent & Trademark Office duly and legally issued United States Patent No. 5,883,095, entitled “Formulations and Method to Treat and Prevent Equine Protozoal Myeloencephalitis” (“the 095 patent”). A true and correct copy of the 095 patent is attached hereto as Exhibit A.

9. UKRF is the owner of the 095 patent and has been since its issuance.

10. New Ace is the exclusive licensee of the 095 patent in a particular field of use, namely the use of triazine-based anti-coccidials to treat or prevent Equine Protozoan Myelencephalitis (“EPM”) in horses. Bayer holds an exclusive sub-licensee from New Ace under the 095 patent in that field of use.

11. Plaintiffs have all rights to enforce the 095 patent.

### **FACTUAL BACKGROUND**

12. Equine Protozoan Myelencephalitis (“EPM”) is the most commonly diagnosed neurological condition in horses in America. EPM is caused by infection by *Sarcocystis neurona*, a coccidial organism within the class of protozoan parasites.

13. Bayer sells a product for the treatment/prevention of EPM in horses under the trade name Marquis® Antiprotozoal Oral Paste, which contains ponazuril, a triazine-based anti-coccidial, as an active ingredient. The Bayer product is the first product approved by the Food and Drug Administration (“FDA”) for treatment of EPM in horses.

14. Based upon information and belief, Wedgewood is a compounding pharmacy that creates customized medications for doctors, including veterinarians, and their patients.

15. Based upon information and belief, Wedgewood makes, uses, offers for sale, and/or sells Toltrazuril, including Toltrazuril in an apple-flavored oral paste or suspension, for treatment and prevention of EPM in horses. Toltrazuril is a triazine-based anti-coccidial.

16. On or about July 16, 2008, Wedgewood issued a press release concerning its Toltrazuril product that states, "Toltrazuril is compounded by Wedgewood as an apple-flavored oral paste and suspension, package size and strength dependent upon dosage form. Research indicates that Toltrazuril is frequently prescribed by veterinarians as an anti-protozoal to treat equine protozoal myeloencephalitis." A true and correct copy of the Wedgewood Toltrazuril press release, available at <http://newsroom.wedgewoodpharmacy.com/guaifenesin-toltrazuril.html>, is attached hereto as Exhibit B.

17. Based upon information and belief, Wedgewood uses its Toltrazuril products to treat EPM in horses, and markets, distributes, sells, and offers for sale its Toltrazuril products for use by its customers to treat EPM in horses. Toltrazuril is a triazine-based compound having anti-coccidial properties.

18. Wedgewood's Toltrazuril-containing apple-flavored oral pastes and suspensions are especially made and adapted for oral administration to horses.

19. Claim 3 of the 095 patent covers a method to treat EPM in a horse in need of such treatment, comprising administering a pharmaceutically effective amount of a triazine-based anti-coccidial, wherein the triazine-based anti-coccidial is toltrazuril.

20. Wedgewood's Toltrazuril products compete with Bayer's Marquis® product.

21. In 2008, Bayer notified Wedgewood that Wedgewood is infringing the 095 patent.

22. Based upon information and belief, Wedgewood's Toltrazuril product is not approved by the FDA for treatment of EPM in horses.

**COUNT I – INFRINGEMENT OF CLAIM 3 OF U.S. PATENT NO. 5,883,095**

23. The allegations contained in paragraphs 1-22 above are incorporated herein by reference.

24. Under 35 U.S.C. § 271, Wedgewood has infringed and is infringing Claim 3 of the 095 patent by using its Toltrazuril products to treat or prevent EPM in horses, and by inducing and/or contributing to the infringement of Claim 3 of the 095 patent in the United States by its customers and others, by virtue of Wedgewood's distribution, offer for sale, and sale in the United States of its Toltrazuril products, including its Toltrazuril products in an apple-flavored oral paste and/or suspension.

25. Wedgewood has induced and is inducing infringement by its customers by, *inter alia*, selling its Toltrazuril products in association with labeling and/or advertising that promotes the use of the products for the treatment and/or prevention of EPM in horses. Wedgewood has contributed to, and is contributing to, infringement by its customers by, *inter alia*, selling its Toltrazuril products in the form of an apple-flavored oral paste, which is especially made and adapted for oral administration to horses and has no substantial use in horses other than in the treatment and/or prevention of EPM, which use infringes the 095 patent.

26. Based upon information and belief, Wedgewood has been aware of the 095 patent since at least August 19, 2008.

27. There was an objectively high likelihood that Wedgewood's actions constituted infringement of Claim 3 of the 095 patent. Although Wedgewood knew or should have known

of this risk, it has continued its acts of infringement even after becoming aware of the 095 patent. Thus, Wedgewood's infringement of Claim 3 of the 095 patent has been, and continues to be, willful and deliberate.

28. Plaintiffs, individually and collectively, have been, and are still being, damaged by Wedgewood's infringing activities.

29. Based upon information and belief, Wedgewood will continue its infringing activities unless enjoined by this Court.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment:


- (a) holding that Wedgewood has infringed Claim 3 of the 095 patent under 35 U.S.C. § 271;
- (b) awarding damages adequate to compensate Plaintiffs for the infringement of Claim 3 of the 095 patent by Wedgewood, with prejudgment and post-judgment interest and costs as fixed by the Court as provided by 35 U.S.C. § 284;
- (c) holding that Wedgewood's infringement of Claim 3 of the 095 patent has been willful and awarding treble damages pursuant to 35 U.S.C. § 284;
- (d) declaring that this is an exceptional case and awarding to Plaintiffs its reasonable attorney's fees incurred in prosecuting this action as provided by 35 U.S.C. § 285;
- (e) permanently enjoining Wedgewood, and Wedgewood's affiliates, and officers, agents, employees, attorneys, and all other persons in active concert or participation with them, from further infringement of Claim 3 of the 095 patent during its term as provided by 35 U.S.C. § 283; and

(f) awarding to Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: October 19, 2009

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BY: \_\_\_\_\_



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