UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GOVERNMENT ACCOUNTABILITY PROJECT,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
U.S. FOOD AND DRUG ADMINISTRATION,	)	
	)	**Civ. No. 1:12-cv-01954 (KBJ)**
Defendant,	)	
	)	
and	)	
	)	
ANIMAL HEALTH INSTITUTE,	)	
	)	
Intervenor-Defendant.	)	

PLAINTIFF'S RESPONSE TO INTERVENOR-DEFENDANT
ANIMAL HEALTH INSTITUTE'S STATEMENT OF MATERIAL FACTS

PROCEDURAL BACKGOUND

1. This dispute concerns a Freedom of Information Act ("FOIA") request submitted by Plaintiff Government Accountability Project ("GAP") for information from the Food and Drug Administration ("FDA"). GAP originally submitted its FOIA request on February 10, 2011, seeking:

> (1) printed copies of all educational and outreach materials that FDA has prepared in order to inform and assist antimicrobial drug sponsors in fulfilling their duty to report the amount of antimicrobial active ingredient in their drugs that have been sold or distributed for use in food-producing animals pursuant to Sec 105 of the Animal Drug User Fee Amendments of 2008; (2) FDA's data for use of antimicrobial drugs in food-producing animals in 2009 as broken down by container size, strength, and dosage form; and (3) FDA's data for use of anti-microbial drugs in food- producing animals in 2009 as broken down by class of animal.

Garcia-Malene Decl. ¶ 5 (D.E. 8-5).

PLAINTIFF'S RESPONSE: Admitted.

2. GAP filed this lawsuit on December 5, 2012 and alleged that the FDA violated FOIA by wrongfully withholding agency records responsive to parts two and three of GAP's FOIA request. Complaint (D.E. 1). GAP subsequently amended its FOIA request to seek aggregated data. Joint Status Report at 1 (D.E. 5).

PLAINTIFF'S RESPONSE: Admitted.

3. On April 8, 2013, FDA released two documents (Documents 1 and 2) partially responsive to GAP's modified FOIA request. *Id*. On September 12, 2014, FDA released a Revised Document 2. Revised Document 2 (D.E. 21-1) (attached to the accompanying Memorandum of Law as Exhibit A). FDA and GAP agree that the only remaining issue in this case is Revised Document 2. Joint Status Report at 1 (D.E. 22). FDA has argued that certain information on Revised Document 2 is exempt from disclosure under FOIA pursuant to FOIA Exemptions 3 and 4. (D.E. 21-1).

PLAINTIFF'S RESPONSE: Admitted.

REVISED DOCUMENT 2

4. Revised Document 2 contains data submitted to the FDA pursuant to the Federal Food, Drug, & Cosmetic Act, and, specifically, the Animal Drug and User Fee Amendments of 2008 ("ADUFA"), codified at 21 U.S.C. § 360b(l)(3). (D.E. 21-1). ADUFA requires sponsors of approved animal drugs containing antimicrobial active ingredients to submit data to the FDA on "the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals." 21 U.S.C. § 360b(l)(3)(A).

PLAINTIFF'S RESPONSE: Denied. This is a statement of the law, and is not a material fact.

5. Revised Document 2 presents calendar year 2009 data on the volume of "approved antimicrobial animal drugs sold and distributed for use in food-producing animals." (D.E. 21-1). The data is subdivided in three ways: (1) by domestic or export market, (2) by route of administration (injection, intramammary, feed, oral, topical, or water), and (3) by class of antimicrobial active ingredient. *Id*. The volumes are presented in kilograms. *Id.*

PLAINTIFF'S RESPONSE: Admitted.

6. For each volume amount shown, Revised Document 2 denotes the number of sponsors whose sales contribute to that figure — one, two, or three or more. *Id.*

PLAINTIFF'S RESPONSE: Admitted.

7. Industry participants are well aware of which companies and specific animal drugs fall into each category. Ex. B, Elam Decl. ¶ 23; Ex. C, Uppal Decl. ¶ 7; Ex. G, Martin Decl. ¶ 12. Drug products for each class can also be identified using the FDA website or other publicly available information. Ex. B, Elam Decl. ¶ 23; Ex. C, Uppal Decl. ¶ 7.

PLAINTIFF'S RESPONSE: Denied. No information reported by the FDA pursuant to ADUFA identifies the particular locations where antimicrobial animal drugs are sold or used, or otherwise identifies the amounts sold or used in any particular location.

8. FDA redacted from Revised Document 2 all of the sales volume data for classes and routes of administration where there are one or two distinct sponsors of medications in that category. *See* Garcia-Malene Decl. ¶ 21 (D.E. 8-4). FDA also redacted aggregated sales data for classes and routes of administration with three or more distinct sponsors, if disclosure would reveal the aggregated sales data for other classes and routes of administration with one or two distinct sponsors. *See id*.

PLAINTIFF'S RESPONSE: Admitted.

9. At least five AHI members (Boehringer Ingelheim Vetmedica, Inc., Elanco Animal Health, Merck Animal Health, Phibro Animal Health Corporation, and Zoetis, Inc.) submitted data to FDA in 2009 that is included in the aggregated total set forth in Revised Document 2. Ex. B, Elam Decl. ¶ 11; Ex. C, Uppal Decl. ¶ 4; Ex. D, Mlodzik Decl. ¶ 8; Ex. E, Bormann Decl. ¶ 6; Ex. F, Harper Decl. ¶ 10; Ex. G, Martin Decl. ¶ 6.

PLAINTIFF'S RESPONSE: Admitted.

10. AHI members submit information to FDA with the understanding that it will be used for its statutorily mandated purpose and will not be publicly released. *See* Ex. C, Uppal Decl. ¶ 4; Ex. F, Harper Decl. ¶ 10; Ex. E, Bormann Decl. ¶ 1; Ex. D, Mlodzik Decl. ¶ 15.

PLAINTIFF'S RESPONSE: Admitted.

THE ANIMAL HEALTH INDUSTRY IS HIGHLY COMPETITVE

11. The industry for animal drug products is highly competitive. Ex. B, Elam Decl. ¶ 15; Ex. C, Uppal Decl. ¶ 18; Ex. D, Mlodzik Decl. ¶ 18; Ex. E, Bormann Decl. ¶ 12; Ex. F, Harper Decl. ¶ 15; Ex. G, Martin Decl. ¶ 11.

PLAINTIFF'S RESPONSE: Denied. In their declarations, many sponsors simply state that "the market for" these drugs "is highly competitive," "the data is highly competitive," "highly competitive business," and/or a "highly competitive field." *See* FDA Ex. C ¶ 15; Ex. F ¶ 12; Ex. G ¶ 7; Ex. H ¶ 16; Ex. J ¶ 10; and Ex. K ¶ 6. These statements are conclusory, and are insufficient to meet Defendant's burden. *See Niagara*

Mohawk Power Corp. v. United States DOE, 169 F.3d 16, 18 (D.C. Cir. 1999). In fact, Dr. Elam attests that "[i]n the last ten years there have been no significant new competitors entering the antibiotics area in the animal health industry, and there have been few novel new products introduced." FDA Ex. C ¶18.

12. In addition to the AHI members listed in paragraph 9, at least twenty other companies compete to sell antimicrobial medications in the U.S. for food-producing animals: Bimeda Animal Health; Ceva Animal Health; Vetoquinol; Merial; Huvepharma AD; Planalquimica Industrial Ltda.; Norbrook Laboratories Ltd.; Agri Laboratories, Ltd.; Bayer HealthCare LLC, Animal Health Division; G.C. Hanford Mfg. Co.; Dechra Ltd.; Cross Vetpharm Group Ltd.; Quo Vademus, LLC; Pennfield Oil Co.; ADM Alliance Nutrition, Inc.; First Priority, Inc.; Provimi North America, Inc.; Sparhawk Laboratories, Inc.; Yoder Feed; and Cross Vetpharm Group Ltd. Ex. B, Elam Decl. ¶ 15; *see also* Ex. D, Mlodzik Decl. ¶ 17 (listing certain competitors); Ex. E, Bormann Decl. ¶ 12 (listing certain competitors); Ex. G, Martin Decl. ¶ 11 (listing certain competitors).

PLAINTIFF'S RESPONSE: Admitted that there are at least twenty other companies compete to sell antimicrobial medications in the U.S. for food-producing animals. All other allegations are denied.

13. Animal drug manufacturers compete across routes of administration and classes of antimicrobial active ingredients. Ex. B, Elam Decl. ¶ 16; Ex. D, Mlodzik Decl. ¶ 16; Ex. E, Bormann Decl. ¶ 12; Ex. C, Uppal Decl. ¶ 18; Ex. G, Martin Decl. ¶ 11. This competition across classes occurs because "[d]rugs of different classes may be marketed to treat similar or the same diseases in food-producing animals" and "[w]hile some drugs may be marketed for use in multiple diseases or multiple species, other drugs are species-specific or disease-specific within a species." Ex. B, Elam Decl. ¶ 16.

PLAINTIFF'S RESPONSE: Denied. Different species of food animals are produced for different markets and in different regions of the country with different disease ecologies, resulting in a high degree of variability in antimicrobial use among sponsors' clients. Pl's Ex. 1 ¶ 20.

14. Many of the antimicrobial animal drugs that have sales volume data included in the categories set forth in Revised Document 2 are generic medications, with limited or no intellectual property protections. Ex. B, Elam Decl. ¶ 17; Ex. E, Bormann Decl. ¶ 13; Ex. F, Harper Decl. ¶ 16.

PLAINTIFF'S RESPONSE: Admitted that many of the antimicrobial animal drugs that have sales volume data included in the categories set forth in Revised Document 2 are generic medications. All other allegations are denied.

15. Where a drug lacks patent protection and regulatory exclusivity, an animal drug manufacturer can introduce a competitor product by seeking FDA approval for a new generic version of that drug. Ex. B, Elam Decl. ¶ 17; Ex. E, Bormann Decl. ¶ 16; Ex. G, Martin Decl. ¶ Regulatory approval of generic animal drugs through an Abbreviated New Animal Drug Application is significantly less onerous than approval of pioneer drugs. Ex. B, Elam Decl. ¶ 30; Ex. E, Bormann Decl. ¶ 16; Ex. F, Harper Decl. ¶ 16; *see also* Ex. G, Martin Decl. ¶ 21.

PLAINTIFF'S RESPONSE: Admitted.

16. Some animal health companies have dormant drugs for which they hold approved applications but which they do not currently market and sell. Ex. B, Elam Decl. ¶ 31; Ex. E, Bormann Decl. ¶ 16.

PLAINTIFF'S RESPONSE: Admitted.

17. Because of the lack of patent protections for many animal drug products, the key factors driving their market are price and supply and demand. Ex. B, Elam Decl. ¶ 17; Ex. E, Bormann Decl. ¶ 13 ("[t]he market is highly price sensitive and Merck's success is driven by our ability to capture market share based on marketing and pricing"); Ex. F, Harper Decl. ¶ 15; Ex. G, Martin Decl. ¶ 21.

PLAINTIFF'S RESPONSE: Denied. Different species of food animals are produced for different markets and in different regions of the country with different disease ecologies, resulting in a high degree of variability in antimicrobial use among sponsors' clients. Pl's Ex. 1 ¶ 20.

18. The market for antimicrobial animal drugs, particularly in certain segments, is dominated by a relatively small number of large customers. Ex. B, Elam Decl. ¶ 19. The concentrated buying power of these major customers makes direct sales (rather than distributor sales) more attractive, as distributor sales are subject to regulations that restrict negotiating flexibility. *Id.*

Direct sales to large customers result in increased price competition. *Id.* Large customers will sometimes employ bidding or quasi-bidding processes to select their vendors. *Id.*; Ex. F, Harper Decl. ¶ 25.

PLAINTIFF'S RESPONSE: Denied. The statements relied upon are conclusory, not based upon personal knowledge, and/or are provided without a proper foundation. Fed.R.Civ.P., Rule 56(c)(4); *Niagara Mohawk,* 169 F.3d at 18.

19. Due to the competitive nature of the industry, animal health companies invest significant resources in market research and appoint senior personnel to handle marketing analysis. Ex. B, Elam Decl. ¶ 5; Ex. F, Harper Decl. ¶ 4. In particular, many companies use predictive analytics to engage in market forecasting. Ex. C, Uppal Decl. ¶ 13. Through predictive analytics and data mining, companies can use available data to identify trends and patterns and develop predictive models. *Id.* ¶ 14.

PLAINTIFF'S RESPONSE: Admitted.

20. The accurate 2009 sales data in Revised Document 2 are valuable for forecasting of current market conditions because the industry has not changed significantly in the intervening years. Ex. C, Uppal Decl. ¶ 15; Ex. B, Elam Decl. ¶ 20 ("[T]he overall nature of the market and the basis of competition between competitors, as described above, have not materially changed since 2009."). A review of the public FDA summary reports from 2009 - 2012 (the last year with available data) demonstrates that the market has not materially changed and "each class of antimicrobial ingredient has constituted the same share of the overall domestic market for antimicrobial drugs." Ex. B, Elam Decl. ¶ 41.

PLAINTIFF'S RESPONSE: Denied. The total amounts of antimicrobial animal drugs in each class in 2011 and 2012 differ substantially from the amounts sold in 2009. FDA Ex. 4. There is no way to develop a useful model or trend based solely on the 2009 sales data. P. Ex. 6 ¶ 7.

MARKET ANALYSIS IN THE ANIMAL HEALTH INDUSTRY

21. Any changes in the animal drug market since 2009 are well understood by companies in the industry and can be accounted for in market predictions. Ex. F, Harper Decl. ¶ 19; Ex. B, Elam Decl. ¶ 41; Ex. G, Martin Decl. ¶ 23. For example, industry players are well aware of major droughts in particular years that would impact the demand for certain products. Ex. B, Elam Decl. ¶ 41.

PLAINTIFF'S RESPONSE: Denied. The period during which the inferences are being made must be relatively stable. A number of major shocks have impacted the livestock and poultry

industries since 2009 to include the general economic crisis during the years since 2009, which affected consumer demand for livestock and poultry products as well as availability of farm credit, and increased uncertainty in all business decisions. P. Ex. 1 ¶ 8 and 9. The shocks mentioned are difficult to incorporate into a forecasting model and the 2009 sales data would not be useful in validating a model in 2015 and subsequent years. Changes in industry since 2009 have diminished sharply the value any possible accurate prediction from 2009 data. P. Ex. 6 ¶ 10.

22. Animal health companies closely guard sales volume data from 2009 and continue to keep it confidential years later. Ex. B, Elam Decl. ¶¶ 43-44; Ex. G, Martin Decl. ¶¶ 8-9, 23 ("The animal health industry does not release confidential information such as the Redacted Information to the public even if it is 5 or 10 years old, because it remains relevant and confidential business information."); Ex. C, Uppal Decl. ¶¶ 8-10; Ex. D, Mlodzik Decl. ¶¶ 11-12; Ex. E, Bormann Decl. ¶¶ 9-10; Ex. F, Harper Decl. ¶¶ 11-12. Even when this data is shared by companies with its own employees or business partners, non-disclosure agreements are used to ensure the information is protected from public release. Ex. C, Uppal Decl. ¶¶ 9-10; Ex. D, Mlodzik Decl. ¶ 12; Ex. E, Bormann Decl. ¶ 10; Ex. F, Harper Decl. ¶ 12; Ex. G, Martin Decl. ¶ 8.

PLAINTIFF'S RESPONSE: Admitted.

23. Information comparable in detail and accuracy to the 2009 sales data in Revised Document 2 is not publicly available. Ex. B, Elam Decl. ¶¶ 39-40 ("Sales volume data for competing products within that market segment would be extremely valuable in undertaking this analysis, as it would provide a direct indication of the market potential. However, I have not been able to locate such data because it is not publicly available."); Ex. C, Uppal Decl. ¶¶ 8-9; Ex. E, Bormann Decl. ¶ 8; Ex. F, Harper Decl. ¶¶ 13-14; Ex. G, Martin Decl. ¶ 9.

PLAINTIFF'S RESPONSE: Admitted.

24. Because animal health companies do not publicly disclose this data, market intelligence reports generated by third-party market analysts are based on estimates and therefore are often inaccurate. Ex. B, Elam Decl. ¶ 39; Ex. C, Uppal Decl. ¶ 25. While these third-party market analyses may have some value, they are viewed "as rough, and unreliable, estimates" and are used primarily to identify "very general trends on broad product categories and geographic sales patterns." Ex. B, Elam Decl. ¶ 39. These reports are not freely available and often cost many thousands of dollars. Ex. C, Uppal Decl. ¶ 26 ("Market intelligence regarding animal drug sales is extremely expensive, and reports can cost hundreds of thousands of dollars.").

PLAINTIFF'S RESPONSE: Admitted.

25. Competitors to AHI members could use the non-public 2009 sales data in Revised Document 2 to generate an accurate projection of current sales. Ex. C, Uppal Decl. ¶ 16; Ex. B, Elam Decl. ¶ 42; Ex. G, Martin Decl. ¶ 23.

PLAINTIFF'S RESPONSE: Denied. It is not possible to estimate coefficients of this sort using a single data point, and to develop a model of this sort that would have any degree of statistical reliability, you would need at least a dozen or more data points as economic trends tend to fluctuate year to year. Pl's Ex. 5 ¶ 11.

COMPETITIVE HARMS RESULTING FROM RELEASE OF INFORMATION

26. Armed with accurate projections of current market demand for certain medications, competitors would be able to determine which market segments offer opportunities for introducing new products that would capture market share from the sponsor of an existing product. Ex. B, Elam Decl. ¶ 26 ("Armed with this information, competitors would more aggressively compete in those market segments where potential demand is high, thereby capturing market share from, and causing financial harm to, companies that already sell products in those market segments, including AHI members."); Ex. C, Uppal Decl. ¶ 19 ("Competitors will be incentivized to bring new products to market to capture market share from Zoetis where the data reveals a relatively high volume of sales for a Zoetis product."); Ex. G, Martin Decl. ¶ 14; Ex. D, Mlodzik Decl. ¶¶ 20, 23; Ex. E, Bormann Decl. ¶¶ 15-16; Ex. F, Harper Decl. ¶ 10. In addition, competitors could activate dormant products for which they already have regulatory approval but have not been actively marketing, to capture market share from the sponsor of an existing product. Ex. B, Elam Decl. ¶ 31; Ex. D, Mlodzik Decl. ¶ 20; Ex. E, Bormann Decl. ¶ 16.

PLAINTIFF'S RESPONSE: Denied. As multiple data points are required to detect any trend, the accuracy of a model of this sort cannot be significantly improved by comparison of a single estimate with a single true value, whether the single true value was the result of a random occurrence, unlikely to reoccur in the future, or was a reflection of more normal market conditions. P. Ex. 5 ¶ 12.

27. In addition to understanding current market demand for specific drugs, competitors could also use sales volume data to accurately estimate a company's revenues because drug prices can often be derived through market intelligence. Ex. B, Elam Decl. ¶ 28 ("[A]s is frequently the case, a competitor can obtain animal drug product prices from common customers, distributors' publicly available pricing lists, or other market intelligence."); Ex. D, Mlodzik Decl. ¶ 21 ("Information about BIVI's product prices is publicly available to customers and information about BIVI's net revenues may be obtainable from other third-party sources.");

Ex. F, Harper Decl. ¶ 17. Understanding the total revenue generated by a particular drug or class of drugs would give competitors an even larger competitive advantage in determining which market segments to enter or avoid. Ex. B, Elam Decl. ¶ 28. Competitors may also be able to accurately estimate a company's profit margins, because production costs in the animal health industry tend to be well understood by industry participants. Ex. B, Elam Decl. ¶ 29. This is in part because "[m]any of the antimicrobial active ingredients currently marketed have been marketed for decades and the process by which the drugs are made is not proprietary." *Id*; *see also* Ex. E, Bormann Decl. ¶ 18.

PLAINTIFF'S RESPONSE: Denied. As it is not possible to use a single data point to estimate coefficients to develop a prediction model with any degree of statistical reliability, because multiple data points are needed to detect any trend, learning the aggregate sales volume for a particular drug in 2009 won't enable a competitor to discern how that drug performs under varying market conditions, or how the drug's sales respond to particular events. P. Ex. 5 ¶ 11-13.

28. For overseas competitors with lower production costs, identifying U.S. market segments with high demand and revenue potential would provide them with important information on which market segments to target for competition. Ex. B, Elam Decl. ¶ 33; Ex. E, Bormann Decl. ¶ 18; Ex. F, Harper Decl. ¶ 20.

PLAINTIFF'S RESPONSE: Denied. Defendant AHI's declarants' statements are conclusory, not based upon personal knowledge, and/or are provided without a proper foundation. Fed.R.Civ.P., Rule 56(c)(4); *Niagara Mohawk,* 169 F.3d at 18.

29. Competitors that sell products that already compete with a sponsor's product could utilize sales volume data for the sponsor's product to adjust their marketing and pricing strategies. Ex. C, Uppal Decl. ¶ 20; Ex. F, Harper Decl. ¶ 21; Ex. G, Martin Decl. ¶ 19. For example, if a competitor learned that an AHI member company had high sales for a particular product, the competitor may reduce their prices to substantially increase their sales by cutting into the AHI member company's large customer base. Ex. C, Uppal Decl. ¶ 20. The risk of competitive harm from pricing adjustments resulting from release of this information is heightened by the use of competitive bidding and "bundled" pricing in the animal drug industry. Ex. B, Elam Decl. ¶ 34; Ex. C, Uppal Decl. ¶ 21; Ex. F, Harper Decl. ¶ 24.

PLAINTIFF'S RESPONSE: Denied. Even where constructed using a robust set of accurate data points, the predictive accuracy of any model diminishes rapidly as the forecast moves

further into the future beyond the last known value. The information about 2009 sales would not enable any of these companies to produce an estimate of current sales that would be any more reliable or useful than an intuitive estimate based on in-house data and years of experience working in the industry. P. Ex. 5 ¶ 16.

30. Due to the specialized nature of the animal drug industry, in many cases there is a single supplier of raw materials needed to product various animal medications. Ex. B, Elam Decl. ¶ 37 ("[I]t is often the case that there is only one supplier of an active ingredient, due to the specialized nature of animal medications."). The supply chains of animal drug manufacturers are therefore vulnerable to attack by aggressive competitors who may attempt to "corner the market" for specific ingredients. Ex. B, Elam Decl. ¶ 36; Ex. F, Harper Decl. ¶ 25; Ex. E, Bormann Decl. ¶ 19; Ex. G, Martin Decl. ¶ 17. In addition, the raw material suppliers themselves could take advantage of this information in negotiations with manufacturers. Ex. B, Elam Decl. ¶ 37.

PLAINTIFF'S RESPONSE: Defendant AHI's declarants' statements are conclusory, not based upon personal knowledge, and/or are provided without a proper foundation. Fed.R.Civ.P., Rule 56(c)(4); *Niagara Mohawk,* 169 F.3d at 18.

Dated: April 2, 2015

Respectfully submitted,

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