



4. Huvepharma is a global biotech and pharmaceutical company that develops, manufactures, and commercializes human and animal health products, including enzymes for food and animal feed. One of Huvepharma's products that it successfully sells in the United States is OptiPhos®, which is an additive to feed for animals, including swine and poultry, and in particular an *Escherichia coli* (“*E. coli*”) derived 6-phytase, which is recombinantly produced in a heterologous yeast host *Pichia pastoris* (“*P. pastoris*”), in a submerged fermentation process. OptiPhos® is available in solid and liquid forms, at different concentrations.

5. Previously competing phytase products were less effective than OptiPhos® because, for example, they only operate effectively within a limited pH range and are less thermally tolerant during the feed manufacturing process when the phytase is combined with animal feed (pelleting process to increase palatability). These previous competing phytase products were also inferior to OptiPhos® because they degrade more readily when exposed to pepsin, which is a naturally present (endogenous) enzyme produced in the stomach of animals.

6. Huvepharma's OptiPhos® is more effective in animal diets for monogastric animals such as poultry and swine than these previously available phytases because, for example, it works effectively at a broad pH range (between pH 1 and 5), is more thermally tolerant during the manufacturing process when combined with animal feed, and is relatively insensitive to degradation by pepsin. OptiPhos® also operates catalytically faster than other previously-used phytase products in releasing phosphorus from indigestible phytate, a natural form in which most of the phosphorus is stored in grains and seeds, and thus enables the poultry and swine ingesting the product to grow faster and to receive other health benefits without the need for dietary phosphorous supplementation.

7. The method of manufacturing Huvepharma's OptiPhos® was invented and initially developed during or around 1996 by Dr. Xingen Lei, a researcher at Cornell University, and constituted a publicly recognized breakthrough in the field of phytase enzymes for integration into animal feed. Cornell Research Foundation, Inc. ("CRF") obtained the '300 Patent that discloses, claims, and otherwise protects Dr. Lei's inventive method of producing phytases such as OptiPhos®.

8. Ultimately, CRF entered into an exclusive license with Huvepharma in return for Huvepharma commercializing OptiPhos® in the United States. However, as explained below, Huvepharma's commercialization efforts have been negatively impacted, and the patent rights have been infringed, by the actions of Defendants, and in particular based on Defendants' manufacture, importation, sale, distribution, and commercialization in the United States of animal feed products that infringed claims of the '300 Patent, *i.e.*, the accused phytase animal feed products.

9. Upon information and belief, the accused Natuphos® E phytase animal feed products include products that were commercialized in the United States under various trade names, including at least Natuphos® E 5000, Natuphos® E 10000, Natuphos® E 5000L, Natuphos® E 10000L, Natuphos® E 5000G, Natuphos® E 10000G, Natuphos® E 50000, and Natuphos E® SD Powder as well as combination products containing Natuphos® E, such as Natuphos® E 5000 Combi L and Natuphos® E 5000 Combi G (hereinafter "Natuphos® E" or "accused phytase animal feed products"). These products have been manufactured outside of the United States and imported into and commercialized by Defendants in the United States. For example, Natuphos® E 50000 has been manufactured overseas, imported into the United States, and commercialized in the United States by Defendants.

10. BASF SE is a corporation organized under the laws of the Federal Republic of Germany, with its principal place of business at 67056 Ludwigshafen, Germany.

11. Defendant BASF Corporation (“BASF Corp.”) is a corporation organized under the laws of Delaware, with a principle place of business at 100 Park Avenue, Florham Park, NJ 07932. BASF Corp. may be served with process through its registered agent, The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware, 19801.

12. Upon information and belief, BASF Corporation is a wholly owned subsidiary of BASF SE or a common holding company or intermediate subsidiary, and is effectively controlled by BASF SE.

13. Upon information and belief, Natuphos® E phytase was developed in or around 2014 by BASF.

14. Upon information and belief, since in or around 2014, BASF SE, or its wholly-owned subsidiaries in Germany, has been engaged in the manufacture of *E. coli* derived phytase enzymes for use in animal feeds, including at least Natuphos® E phytase, and since in or around 2016 has been exporting Natuphos® E to the U.S.

15. Upon information and belief, BASF Corp. is importing, and has participated in the importation of, Natuphos® E into the United States. BASF Corp. then distributes, sells, or otherwise commercializes in the United States at least Natuphos® E through its business unit BASF Animal Nutrition, North America.<sup>1</sup>

16. Upon information and belief, BASF SE effectively controls and has effectively controlled the production and shipping overseas, and the importation, distribution, use, offers for sale, and sale of Natuphos® E in the Unites States by BASF Corp.

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<sup>1</sup> BASF Animal Nutrition is a business unit of BASF Nutrition and Care, one of twelve worldwide divisions of BASF SE.

17. Upon information and belief, BASF SE effectively controls its subsidiaries, including co-defendant BASF Corp., through central corporate controls, and has operated itself and its subsidiaries as one corporate organization having diversified business segments. (Ex. 2 at 18-21 and 132-140.) For example, BASF SE has referred to its subsidiaries, including the co-defendant in this suit, as the “BASF Group,” “our businesses,” and “its functional units.” (Ex. 2 at 19.) BASF SE stated regarding the Nutrition & Care segment (through which Natuphos E is commercialized) that “. . . we strive to expand our position as a leading provider of nutrition and care ingredients for consumer products. . . [c]ustomers include food and feed producers . . . [w]e aim to enhance and broaden our product and technology portfolio.” (*Id.*)

18. Upon information and belief, BASF SE’s subsidiaries’ activities, including those of BASF Corp., are centrally controlled by BASF SE’s “Corporate governance.” (Ex. 2 at 132-140.) For example, the BASF SE Board approves strategies and budgets of its subsidiaries as well as its individual business areas, determines the company’s internal organization and decides on the composition of management on levels below the Board. (Ex. 2 at 132.) The Board also “manages and monitors BASF Group business by planning and setting the corporate budget, allocating resources and management capacities, monitoring and making decisions on significant individual measures, and supervising operational management.” (*Id.*) Further, BASF SE embeds “. . . business critical parts of its functional units - such as engineering services, procurement and logistics - into the divisions to bring its employees closer to its customers and improve customer-specific agility.” (Ex. 2 at 19.)

19. Upon information and belief, BASF SE requires its subsidiaries, including co-defendant BASF Corp., to follow its “Group-wide Compliance Program,” where “[a]ll employees and managers are obligated to adhere to its guidelines, which describe our principles for proper

conduct to cover topics ranging from corruption and antitrust laws to human rights, labor, and social standards, conflicts of interest and trade control, and protection of data privacy.” (Ex. 2 at 140.)

20. Upon information and belief, BASF SE also centrally operates and controls its enzyme business worldwide. (Ex. 3 at 4.) BASF SE operates an “enzyme hub” which serves as “an holistic interface for our enzyme activities . . . by operating as a centralized back-end steering research, technology and manufacturing” hub. In this framework, BASF SE “will engage in directly commercializing enzymes to selected markets.” (*Id.*)

21. Upon information and belief, Defendants have imported, made, used, offered for sale, sold, and/or distributed accused phytase animal feed products within the United States. Defendants performed at least some of these activities in the United States under the trade names BASF and BASF Corporation Animal Nutrition.

### **JURISDICTION AND VENUE**

22. This action arises under the Patent Laws of the United States, Title 35, United States Code, §§ 1 *et seq.*, including 35 U.S.C. §§ 271 and 281.

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

24. This Court has personal jurisdiction over defendant BASF SE at least under Fed. R. Civ. P. 4(k)(2).

25. This Court has personal jurisdiction over defendant BASF Corp., at least because BASF Corp. has purposefully availed itself of the benefits and protections of Delaware state law by incorporating in Delaware.

26. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because BASF Corp. is a Delaware corporation, BASF SE is a foreign company, and Delaware is a convenient forum for resolution of the parties' disputes set forth herein.

## **BACKGROUND**

### **PHYTASE PRODUCTS FOR ANIMAL NUTRITION**

27. The ingestion by certain animals, such as poultry and swine, of phosphate ("P") helps to accelerate growth and provides other health benefits. Phytate (myo-inositol hexaphosphate), is the major storage form of P in legumes and cereals. Phytases, which are a group of enzymes classified as monoester phosphatases, initiate the release of P from the phytate and are often included in animal feed for this purpose, *i.e.*, to enable the animals to ingest P. (Ex. 1 at 1:31–47.)

28. Monogastric animals such as swine and poultry have little natural phytase in their gastrointestinal tracts. Thus, these animals naturally fail to effectively release P from the phytate in their food, and consequently fail to gain the benefits of that P. Under these circumstances, the phytate with bound P passes through the monogastric animals' gastrointestinal tracts intact and excretes as manure, which unfortunately pollutes the environment. Therefore, the diet of the swine and poultry needs to be supplemented with inorganic P, which is a non-renewable nutrient, such as in the form of a vitamin. Phytase is added to animal feed to enable the animals such as monogastric animals to initiate the release from the phytate the P that facilitates efficient protein synthesis in the animal. (*Id.*)

29. Two phytases, PhyA and PhyB, were used prior to the invention that is the subject of the patent-in-suit. PhyA and PhyB were extracted from *Aspergillus niger* NRRL3135 (*A. niger*), and cloned and sequenced. (Ex. 1 at 1:52-56.) As an example, a PhyA polynucleotide was

introduced into *A. niger*, *i.e.*, a homologous host, and this phytase was to a certain degree effective in releasing P from phytate in animal feed. In particular, supplemental microbial phytase of this source in the diets for swine and poultry was shown to be effective in allowing the animals to release P from the phytate in their feed. However, PhyA and PhyB were subject to problems. For example, PhyA and PhyB were expensive to produce commercially. In addition, certain properties of PhyA and PhyB made them difficult to manufacture and incorporate effectively as functional enzymes into animal feed. For example, the manufacturing process of feed pellets involves the application of a certain amount of heat (*i.e.*, increase in temperature), but unfortunately PhyA and PhyB are sensitive to heat and therefore denatured when exposed to this heat. In other words, the PhyA and PhyB phytases are not sufficiently thermotolerant for this manufacturing process to avoid degradation. (Ex. 1 at 2:42-49.)

30. To solve the shortcomings and problems of producing a viable, *i.e.*, catalytically functional, phytase enzyme for use in animal feed, Dr. Lei discovered the invention that is the subject of the '300 Patent while he was a professor in the Department of Animal Science and Department of Horticultural Sciences at Cornell University. The production methods Dr. Lei invented produced phytases that were at least as effective as, yet more thermostable than, the existing PhyA and PhyB phytases, and therefore were more effective in the animal feed industry.

31. The '300 Patent involves producing phytases that are encoded by polynucleotides isolated from bacterial cells, *i.e.*, from *E. coli*. These encoded polynucleotides are not expressed in their homologous bacterial cells, but instead are expressed in a fungal strain such as a yeast strain, *i.e.*, a heterologous host. Isolating the expressed product of encoded polynucleotides leads to an *E. coli* phytase that catalyzes the release of P from phytate. The heterologous host phytase

production methods advantageously create phytases, which along with other improved biochemical properties, are characterized by improved thermal stability.

32. Cornell Research Foundation, wishing to commercialize Dr. Lei's breakthrough discovery, collaborated with Phytex, LLC, which was a company formed to produce and commercialize Dr. Lei's new thermostable phytase. On September 1, 2001, CRF entered into an exclusive license agreement with Phytex in return for Phytex producing and commercializing the thermostable phytase. Phytex commercialized the phytase product under the trademarked name "OptiPhos®," which it began manufacturing and selling in the United States in 2006.

33. In 2013, Huvepharma acquired all of Phytex's rights in the thermostable phytase, *i.e.*, OptiPhos®. In particular, Huvepharma acquired Phytex's exclusive license agreement with Cornell, which gave Huvepharma the exclusive rights to produce and commercialize OptiPhos®, and an exclusive license to Cornell's '300 Patent. Huvepharma has been manufacturing and commercializing OptiPhos®, which is recognized as the most efficient and stable phytase available in the market with a track record of proven effectiveness. Huvepharma has continually produced and sold OptiPhos® in the United States since acquiring the rights discussed above.

34. Upon information and belief, beginning in or around 2014, BASF SE began manufacturing Natuphos® E at its enzyme production facility in Ludwigshafen, Germany. In or around 2015, BASF SE obtained regulatory approval to commercialize Natuphos® E in the United States. Further, beginning in or around 2016, the Defendants began importing, selling, offering to sell, distributing, and otherwise commercializing Natuphos® E in the United States. At least Natuphos® E has been manufactured outside of the United States, and then imported into and commercialized in the United States by Defendants, and used, offered for sale, distributed, and/or sold by Defendants in the United States.

35. Upon information and belief, the accused phytase animal feed products are produced using the same methods in the context of and as claimed in the '300 Patent. Thus, the evidence and descriptions below describing the method of producing Natuphos® E 5000 G and Natuphos® E 10000 G, and Natuphos® E 5000 L and Natuphos® E 10000L, are applicable to any one or more of the other accused phytase animal feed products.

36. Upon information and belief, beginning in or around 2014, BASF SE began operating an enzyme production plant in Germany to produce the accused phytase animal feed products for export, sale, and distribution to customers around the world.

37. Additionally, upon information and belief, beginning in or around 2016, wholly-owned BASF SE subsidiary BASF Corp. has imported accused phytase animal feed products that were manufactured by BASF SE in Germany.

38. Upon information and belief, after importation the accused phytase animal feed products including at least Natuphos® E 5000, Natuphos® E 10000, Natuphos® E 5000L, Natuphos® E 10000L, Natuphos® E 5000G, Natuphos® E 10000G, Natuphos® E 25000L, Natuphos® E 50000, Natuphos® E 5000 Combi L, Natuphos® E 5000 Combi G, and Natuphos E® SD Powder were transferred to at least BASF Corp. which then used, offered for sale, distributed, and/or sold those products in the United States under the company trade names BASF and/or BASF Animal Products.

39. Upon information and belief, the accused phytase animal feed products were produced in fungal cells. (Ex. 4 at 1, 7; Ex. Ex. 5 at 1, 5; Ex. 6 at 2; Ex. 8 at 6.)

40. Upon information and belief, the accused phytase animal feed products were produced by providing a polynucleotide encoding a phytase derived from *E. coli*. (Ex. 10 at 4.)

Laboratory proteomics testing confirmed the presence of *E. coli* AppA proteins in a sample of Natuphos E. 50000 phytase. (Ex. 8; Ex. 11 at 1)

41. For example, upon information and belief, the phytase contained in the accused phytase animal feed products advertised and sold by BASF was expressed in the fungal host *Aspergillus niger* (“*A. niger*”). (Ex. 4 at 7; Ex. 5 at 5; Ex. 6 at 2.) In an example, the packaging of a bag of Natuphos® E 50000 acquired in the United States by Huvepharma indicates that Natuphos® E 50000 phytase was manufactured by BASF SE in Germany. (Ex. 8 at 1-7.) Although a BASF document states that Natuphos® E is produced from a synthetic hybrid donor gene sourced from *Hafnia sp.*, *Yersinia mollaretii* and *Buttiauxella gaviniae*, (Ex. 9 at 3), analytical test results confirmed the presence of an AppA phytase from *E. coli* in the product, indicating that the accused phytase animal feed products were made using an AppA encoding polynucleotide sequence from *E. coli* (Ex. 10 at 4; Ex. 11 at 1.)

42. Upon information and belief, the accused phytase animal feed products were produced by expressing the protein or polypeptide in fungal cells.

43. For example, Defendants’ phytase enzyme was produced in the filamentous fungus *Aspergillus niger*. (Ex. 4 at 7; Ex. 5 at 5.) Filamentous fungi are within the Kingdom Fungi, *i.e.*, fungal cells. Natuphos® E is produced at BASF SE headquarters in Germany using BASF SE’s *Aspergillus niger* technology. (Ex. 6 at 2.)

44. Upon information and belief, the accused phytase animal feed products were produced by isolating the expressed protein or polypeptide.

45. For example, the Natuphos® E enzyme is isolated by solid/liquid separation, concentrated (Ultra-Filtration). (Ex 12 at 3.) In another example, BASF SE operates biorefineries that isolate expressed proteins or polypeptides. In the production process for Natuphos® E, after

removal of the biomass the broth containing the enzymes is further clarified and sanitized. Water and low molecular weight impurities are removed from the enzyme solution to further clarify and concentrate it by a factor of up to 30 - thus reducing the volume of the enzyme solution. (Ex. 7 at 7.) The production process for Natuphos® E includes obtaining the phytase by submerged aerobic fermentation of the production strain followed by a recovery and downstream processing. The resulting product is a liquid concentrate. (Ex. 4 at 8.)

46. Upon information and belief, the accused phytase animal feed products were produced by a method wherein said protein or polypeptide catalyzes the release of phosphate from phytate.

47. For example, the accused phytase animal feed products catalyze the release of phosphate from phytate. (*See, e.g.*, Ex. 9 at 26-33 (noting the impact of phytase digesting phytate in animal feed for broilers, layers, and turkeys).) As a further example, the accused phytase animal feed products catalyze the release of phosphate from phytate. (*See, e.g.*, Ex. 4 at 17-32 (noting the impact of phytase digesting phytate in animal feed for chickens for fattening, laying hens, turkeys for fattening, weaned piglets, and sows).) In another example, the accused phytase animal feed products have been specifically designed to break down phytate and its complexes present in plant-based ingredients in pig and poultry diets at the required location in the gastrointestinal tract. Natuphos® E ensures a very fast and efficient release of phytate-bound phosphorous, which is of considerable value to the global feed economy. (Ex. 6 at 2.)

#### **DEFENDANTS' WILLFUL INFRINGEMENT**

48. Upon information and belief, Defendants had actual knowledge during the period of infringement of the '300 Patent. Upon information and belief, Defendants would have been

aware of the '300 Patent based on being the successor-in-interest of Verenium Corp., which was the successor-in-interest of Diversa Corp.<sup>2</sup>

49. First, according to Diversa's Form 10-K filing for 2006, Diversa launched the *E. coli* phytase Phyzyme XP (one of the alleged infringing products in the case *Huvepharma EOOD, et al. v. E. I Du Pont De Nemours and Co., et al.*, C.A. No 1:18-cv-914 (RGA) (June 20, 2018)) in 2003 with "our partner Danisco Animal Nutrition." According to a 2003 press release, Diversa developed Phyzyme XP phytase enzyme in collaboration with Danisco Animal Nutrition.

50. Upon information and belief, in the same time frame, Diversa filed and prosecuted patent applications directed to thermotolerant phytase. For example, in 2001, Diversa filed a provisional patent application disclosing microbially-expressed thermotolerant phytase for animal feed. Diversa received at least two granted patents claiming priority to the 2001 provisional patent application: U.S. Patent No. 7,135,323 (the "'323 Patent") and U.S. Patent No. 7,138,260 (the "'260 Patent," which is a divisional of the '323 Patent).

51. During prosecution of Diversa's '323 Patent, Diversa cited and submitted as relevant prior art (via an Information Disclosure Statement) CRF's U.S. Patent No. 6,451,572 (the "'572 Patent") to Dr. Xingen Lei, which is the parent patent of the presently asserted '300 Patent. Because Diversa's '260 Patent was a divisional of its '323 Patent, CRF's '572 Patent is also of record to Diversa's '260 Patent. In fact, in the sole Office Action issued during USPTO examination of Diversa's '323 Patent, the Examiner discussed in the context of both rejections CRF's '572 Patent. Thus, Diversa was clearly aware of the CRF's '572 Patent and its descendants.

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<sup>2</sup> In 2013, BASF Corporation acquired Verenium Corporation ("Verenium") which is now BASF Enzymes LLC, the enzyme R&D unit of BASF. Verenium's predecessor-in-interest is Diversa Corporation ("Diversa").

52. Upon information and belief, due to the partnership and development collaboration between Diversa/Verenium and BASF, Defendants were privy to Diversa's phytase efforts, and in particular privy to the same body of information as Diversa with regard to Diversa's efforts to patent aspects of its phytase products. Importantly, Defendants would have had knowledge of Diversa's patent applications and granted patents citing CRF's parent '572 Patent, and therefore would also have had knowledge of the CRF's patents during the period of infringement.

53. Despite having knowledge of the CRF patents from sources identified above, and despite the fact that infringement was readily determinable by Defendants, Defendants continued to sell their accused phytase animal feed products even after the '300 Patent issued in 2015, as a direct descendant of the other CRF patents, and would have come to Defendants' attention in the normal course of business. Nevertheless, Defendants did not cease selling infringing products, nor did Defendants enter into good-faith licensing negotiations with Huvepharma.

54. Therefore, Defendants knowingly infringed the '300 Patent. Accordingly, Defendants' infringement of Huvepharma's '300 Patent has been willful.

**COUNT I**  
**(Infringement of U.S. Patent No. 8,993,300)**

55. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint as if stated in their entirety, and incorporate them herein by reference.

56. On March 31, 2015, the United States Patent and Trademark Office duly and legally issued the '300 Patent, entitled "Overexpression of Phytase Genes in Yeast Systems," to inventor Xingen Lei. The '300 Patent was assigned at issuance to Cornell Research Foundation, Inc., Ithaca, New York. Cornell Research Foundation, Inc. is the owner of the '300 Patent by virtue of that assignment, which was duly recorded at the United States Patent and Trademark Office at Reel 009457 and Frame 0350, and continues to be the owner of the '300 Patent. Huvepharma holds an exclusive license to the '300 Patent, with the right to sue for infringement thereof.

57. Upon information and belief, Defendants have infringed at least claims 1-9 of the '300 Patent pursuant to 35 U.S.C. § 271(a) and/or (g), literally or under the doctrine of equivalents, at least by importing into the United States, making, offering to sell, selling, and/or using without authority accused phytase animal feed products.

58. Upon information and belief, each of the accused phytase animal feed products have been produced using the same methods in the context of the '300 Patent claims. Thus, the evidence and descriptions herein describing the method of producing any of the accused products is applicable to any one or more of the other accused phytase animal feed products.

59. As examples, Exhibit 10 is a preliminary and exemplary claim chart detailing Defendants' infringement of claims 1-9 of the '300 Patent. This chart is not intended to limit Huvepharma's right to modify the chart or allege that other products and/or activities of Defendants infringed the above identified claims or any other claims of the '300 Patent or any other patent. Exhibit 10 is hereby incorporated by reference in its entirety. Each claim element in

Exhibit 10 that is mapped to the accused products, shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

60. Defendants' infringement of the '300 Patent has injured Plaintiffs in their business and property rights. Plaintiffs are entitled to recover monetary damages based on the injuries arising from Defendants' infringement pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for relief as follows:

- A. Judgment that Defendants have infringed one or more claims of the '300 Patent;
- B. An award of damages pursuant to 35 U.S.C. § 284;
- C. Judgment that Defendants' acts were willful;
- D. A determination that this case is exceptional pursuant to 35 U.S.C. § 285 and an award to Plaintiffs of reasonable attorney fees.
- E. An award to Plaintiffs of their costs and reasonable expenses to the fullest extent permitted by law; and
- F. An award of such other and further relief as the Court may deem just and proper.

### **DEMAND FOR JURY TRIAL**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury on all issues so triable.

April 15, 2020

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