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12	Attorneys for Plaintiffs Bayer Healthcare, LLC, Bayer Animal Health GMBH, Bayer Intellectual Property GMBH		
13	UNITED STATES DISTRICT COURT DISTRICT OF NEVADA		
14	BAYER HEALTHCARE, LLC, BAYER	CASE NO.	
15	ANIMAL HEALTH GMBH, BAYER INTELLECTUAL PROPERTY GMBH,	CHSE IVE.	
16	,	COMPLAINT	
17	Plaintiffs, vs.	(Jury Trial Demanded)	
18	SHP CHEMICAL, INC.,		
19	Defendant.	/	
20	Plaintiffs Bayer HealthCare, LLC, Bayer Animal Health GmbH, Bayer Intellectual		
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22	Property GMBH (collectively "Bayer"), by its attorneys, hereby alleges as follows:		
23	NATURE OF THE ACTION		
24	This is an action for patent infringement under the patent laws of the United States, Title		
25	35, United States Code, and declaratory judgment under the Federal Declaratory Judgment Act,		
26	Title 28, United States Code, §§ 2201 and 2202, relating to SHP Chemical, Inc.'s ("SHP")		
27	application for registration with the Environmental Protection Agency of an imidacloprid		
28 FENNEMORE CRAIG, P.C. 300 E. SECOND ST. SUITE 1510 RENO, NEVADA 89501 (775) 788-2200			

to certain uses of imidacloprid in treatment of companion animals, as well as formulations of imidacloprid suitable for such treatment. The formulation or use of SHP's imidacloprid technical product as intended by SHP will infringe one or more of Bayer's patents, and SHP's offer for sale or sale of its imidacloprid technical product with a label for companion-animal uses will infringe one or more of Bayer's patents.

THE PARTIES

- 1. Plaintiff Bayer HealthCare, LLC is a limited liability corporation organized and existing under the laws of the State of Delaware, having its Animal Healthcare Division located at 12809 Shawnee Mission Parkway, Shawnee Mission, Kansas 66216.
- 2. Plaintiff Bayer Animal Health GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany (HRB 52145 Cologne), with a place of business at Kaiser-Wilhelm-Allee 10, 51373 Leverkusen, Germany.
- 3. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim, Germany.
- 4. On information and belief, defendant SHP is a corporation organized and existing under the laws of the State of Nevada, with a place of business at 311 West Third St., Suite #212-2808, Carson City, Nevada 89703.

JURISDICTION AND VENUE

- 5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 6. SHP is subject to personal jurisdiction in Nevada because, among other things, it is incorporated in Nevada, regularly transacts and/or solicits business in Nevada and has purposefully

availed itself of this forum such that it should reasonably anticipate being haled into court here.

7. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

PATENTS

- 8. On May 15, 2001, United States Patent No. 6,232,328 ("the '328 patent"), Ex. A, entitled "Non-Systemic Control of Parasites," was duly and legally issued and remains in force. The '328 patent teaches and covers, *inter alia*, a novel method of non-systemically controlling a parasitic insect on an animal, including fleas in companion-animals. The '328 patent covers, *inter alia*, use of Bayer's Advantage II for Cats and Dogs, Advantage Multi for Cats and Dogs, and K9 Advantix II for Dogs products.
- 9. Bayer is the assignee and current owner of the '328 patent, and the owner of all rights, title, and interest in and to the '328 patent, including all rights to enforce the '328 patent and to recover for any and all infringement thereof.
- 10. On December 14, 1999, United States Patent No. 6,001,858 ("the '858 patent"), Ex. B, entitled "Parasiticide Formulations Suitable For Dermal Application," was duly and legally issued and remains in force. The '858 patent teaches and covers, *inter alia*, a novel formulation containing imidacloprid and various solvents. The '858 patent covers at least Bayer's Advantage II for Cats and Dogs and Advantage Multi for Cats and Dogs products.
- 11. Bayer is the assignee and current owner of the '858 patent, and the owner of all rights, title, and interest in and to the '858 patent, including all rights to enforce the '858 patent and to recover for any and all infringement thereof.
- 12. On June 1, 2010, United States Patent No. 7,728,011 ("the '011 patent"), Ex. C, entitled "Dermally Applicable Liquid Formulations for Controlling Parasitic Insects on Animals," was duly and legally issued and remains in force. The '011 patent teaches and covers, *inter alia*, a novel formulation containing imidacloprid and permethrin. The '011 patent covers

at least Bayer's K9 Advantix II for Dogs products.

13. Bayer is the assignee and current owner of the '011 patent, and the owner of all rights, title, and interest in and to the '011 patent, including all rights to enforce the '011 patent and to recover for any and all infringement thereof.

BACKGROUND

- 14. Bayer HealthCare's Animal Health division has been a world leader in researching and developing products for animal health and pest control since 1919, including for both food-producing and companion animals. Among the products it has developed for companion animals are imidacloprid-based topical solutions used for the prevention and treatment of fleas and other parasites for cats and dogs. These products include the Advantage line, including Advantage II for Cats and Dogs, Advantage Multi for Cats and Dogs, and K9 Advantix II for Dogs.
 - 15. SHP holds conditional EPA registration No. 90057-1, for imidacloprid technical.
- 16. On information and belief, as set forth below, SHP has taken significant, concrete steps and has made meaningful preparations, either alone or in concert with third-parties, to offer to sell, sell, and/or use imidacloprid technical material labeled for use in companion animals. The offer for sale, sale, or use such material will constitute infringement of the '328, '858, and/or '011 patents.
- 17. In a letter dated October 4, 2013, SHP informed Bayer that SHP was applying for a new product registration for a product with the proposed name "Imidacloprid Technical." Ex. D.
- 18. SHP's October 4, 2013 letter stated that the "sole labeled use" of the Imidacloprid Technical product "is for formulation into insecticide products for use on companion animals." Ex. D.

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- 19. In response to SHP's letter, Bayer has repeatedly, but unsuccessfully, sought assurances from SHP that SHP would not infringe Bayer's patents.
- 20. On October 15, 2013, counsel for Bayer wrote a letter to the Director of J&T Associates, LLC, SHP's listed agent for its imidacloprid registration, specifically identifying the '328, '858, and '011 patents, and requesting that SHP identify any basis it has to believe that it is not infringing, inducing infringement, or contributing to infringement of these patents. Ex. E.
- 21. On October 22, 2013, the Director of J&T Associates, on behalf of SHP, responded to Bayer's October 15, 2013 letter. SHP's response did not identify any basis to support a belief by SHP that it was not infringing, inducing infringement, or contributing to infringement of Bayer's identified patents. Instead, the response stated that "[SHP] are not willing to reveal in writing any basis for the belief that they are not infringing, inducing infringement or contributing to the infringement of any Bayer patent." Ex. F.
- 22. On October 31, 2013, counsel for Bayer wrote to the Director of J&T Associates, again requesting that SHP state the basis for its belief that it is not, and will not be, infringing, inducing infringement, or contributing to infringement of Bayer's patents. Ex. G. Bayer has received no response.
- 23. On August 28, 2014, SHP received conditional registration for its imidacloprid product. The conditional approval is tied to a label that states:

Only for formulation into an insecticide for the following uses:

- (1) Residential Indoor: Companion Animal
- (2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with U.S. EPA requirements.

Ex. H.

- 24. The only EPA-approved use of imidacloprid in companion animals involves the non-systemic control of parasitic insects by topical application, a use covered by the '328 patent.
- 25. Based on the foregoing, Bayer has formed a reasonable belief that SHP is infringing, or will soon be infringing, Bayer's intellectual property rights.
- 26. On information and belief, SHP, either alone or in concert with third parties, has offered for sale, sold, or used and/or will offer for sale, sell, or use throughout the United States its imidacloprid technical product, knowing and intending that its customers or the end-users of its customers will use these imidacloprid-based products in accordance with the methods covered by the '328 patent.
- On information and belief, SHP, either alone or in concert with third parties, has offered for sale, sold, or used and/or will offer for sale, sell, or use throughout the United States its imidacloprid technical product, knowing and intending that its customers or the end-users of its customers will formulate imidacloprid into a product covered by, or the use of which is covered by, the claims of the '858 or '011 patents.
- 28. Bayer has made substantial investments in its imidacloprid-companion-animal business, including acquiring intellectual property, improving products through research and development, marketing its products and establishing a strong brand, and developing strong customer relationships.
- 29. To help protect its substantial investments, Bayer has obtained patents, including the '328, '858, and '011 patents that grant Bayer the legal right to exclude others from using its inventions. If SHP is permitted to use, sell, and/or offer for sale its imidacloprid technical material for use in companion animals, Bayer will suffer irreparable harm—unrecoverable by money damages, and incalculable.

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- 30. SHP's infringement will cause Bayer to suffer lost market share, price erosion, damage to goodwill and reputation that Bayer has spent years to establish, and the loss of research and development resources and opportunities associated with future drug products.
- 31. There is a substantial and continuing justiciable controversy between Bayer on the one hand and SHP on the other hand relating to the infringement of Bayer's '328, '858, and '011 patents, at least on the basis of SHP's meaningful preparations to conduct infringing activities and the concrete steps it has taken toward that end. SHP's actions have created a reasonable apprehension in Bayer of imminent and irreparable harm and loss.
- 32. In light of SHP's concrete steps and meaningful preparations to sell, use, and offer for sale imidacloprid technical material for use in companion animals in the United States, and the fact that SHP's infringing activity may have already begun; its refusal to change course in the face of its knowledge of the '328, '858, and '011 patents; its approved EPA registration for companion animal uses for its imidacloprid technical material for commercial sale; its failure to provide assurances of non-infringement to Bayer, there is a real and immediate controversy concerning SHP's infringement of the '328, '858, and '011 patents.

COUNT I

- 33. Bayer incorporates by reference all preceding paragraphs as if set forth in their entirety.
- 34. SHP has infringed, is infringing, will continue to infringe, and/or will imminently infringe, literally or under the doctrine of equivalents, one or more claims of the '328 patent, by contributory infringement and/or by actively inducing infringement.
 - 35. SHP's infringement of the '328 patent was, is, and will continue to be willful.
- 36. As a consequence of SHP's infringement of the '328 patent, Bayer suffered, is suffering, and will continue to suffer irreparable harm for which there is no adequate remedy at

law. These injuries will continue unless and until SHP's infringing activities are preliminarily and permanently enjoined by this Court.

37. As a consequence of SHP's infringement of the '328 patent, Bayer suffered, is suffering, and will continue to suffer damages in an amount not yet determined.

COUNT II

- 38. Bayer incorporates by reference all preceding paragraphs as if set forth in their entirety.
- 39. SHP has infringed, is infringing, will continue to infringe, and/or will imminently infringe, literally or under the doctrine of equivalents, one or more claims of the '858 patent directly, or indirectly by contributory infringement and/or by actively inducing infringement.
 - 40. SHP's infringement of the '858 patent was, is, and will continue to be willful.
- 41. As a consequence of SHP's infringement of the '858 patent, Bayer suffered, is suffering, and will continue to suffer irreparable harm for which there is no adequate remedy at law. These injuries will continue unless and until SHP's infringing activities are preliminarily and permanently enjoined by this Court.
- 42. As a consequence of SHP's infringement of the '858 patent, Bayer suffered, is suffering, and will continue to suffer damages in an amount not yet determined.

COUNT III

- 43. Bayer incorporates by reference all preceding paragraphs as if set forth in their entirety.
- 44. SHP has infringed, is infringing, will continue to infringe, and/or will imminently infringe, literally or under the doctrine of equivalents, one or more claims of the '011 patent, directly, or indirectly by contributory infringement and/or by actively inducing infringement.

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- 45. SHP's infringement of the '011 patent was, is, and will continue to be willful.
- 46. As a consequence of SHP's infringement of the '011 patent, Bayer suffered, is suffering, and will continue to suffer irreparable harm for which there is no adequate remedy at law. These injuries will continue unless and until SHP's infringing activities are preliminarily and permanently enjoined by this Court.
- 47. As a consequence of SHP's infringement of the '011 patent, Bayer suffered, is suffering, and will continue to suffer damages in an amount not yet determined.

WHEREFORE, Bayer requests the following relief:

- (a) A declaration that the sale, use, and offer for sale of SHP imidacloprid technical product for use in companion animals will infringe one or more claims of the '328, '858, or '011 patents, either directly and/or by contributory infringement, and/or by actively inducing infringement;
- (b) Preliminarily and permanently enjoining SHP and its officers, agents, servants, employees, parents, subsidiaries, affiliates, successors, assignees, licensees, and attorneys, and all persons acting in concert or participation with it, from infringing the '328, '858, or '011 patents, directly, or by contributory infringement, and/or by actively inducing infringement;
- (c) In the event that SHP's product is commercialized, damages in an amount adequate to compensate Bayer for harm caused by SHP's plans to engage in activities that constitute infringement, and any infringement after the filing of this action, of the '328, '858, or '011 patents, that may be Bayer's lost profits, but in no event less than a reasonable royalty;
- (d) If necessary at some future date, awarding Bayer pre-judgment and post-judgment interest on the damages caused to it by reason of SHP's past and ongoing infringement of the '328, '858, or '011 patents;

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1	(e)	A declaration that this is an exceptional case and an award of attorneys'	
2	fees pursuant to 35 U	J.S.C. § 285;	
3	(f)	An award of Plaintiffs' costs and expenses in this action; and	
4	(g)	Such further and other relief as this Court may deem just and proper.	
5	DATED: Th	DATED: This 6 th day of February, 2015.	
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7		FENNEMORE CRAIG, P.C.	
9		By: /s/ Leslie Bryan Hart Leslie Bryan Hart (SBN 4932) Courtney Miller O'Mara, Esq. (SBN 10683)	
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