

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
DURHAM DIVISION
DOCKET NO. 1:11-cv-152**

AgSaver LLC,

Plaintiff,

vs.

Bayer CropScience LP,

Defendant.

**COMPLAINT
(JURY TRIAL DEMANDED)**

NOW COMES Plaintiff/Relator AgSaver LLC (“AgSaver” or “Plaintiff”), by and through its counsel, makes the following allegations against Defendant Bayer CropScience LP (“Bayer”):

NATURE OF THE ACTION

1. This is a *qui tam* action under the false patent marking provisions set forth in §292 of the Patent Act, as amended.

PARTIES

2. Plaintiff AgSaver is a limited liability corporation organized and existing under the laws of the State of Arkansas, having a principal place of business in McGehee, Arkansas. AgSaver is the holder of seven pesticide registrations with the United States Environmental Protection Agency (“EPA”) and has several additional pesticide registration applications pending with the EPA. Pesticides registered by AgSaver are distributed throughout the United States.

3. Defendant Bayer is a corporation organized and existing under the laws of the State of Delaware, that is registered to do business in North Carolina and has, on information and belief, a principal place of business at 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, North Carolina 27709, which is in Durham County, North Carolina. Defendant Bayer is the North American branch of the Bayer CropScience group of companies (collectively the “Bayer Group”) and an indirect subsidiary of Bayer CropScience AG (“Bayer AG”), a company organized and existing under the laws of Germany that acts as global headquarters for the Bayer Group.

4. The Bayer Group is a leading producer of agricultural pesticides. The Bayer Group holds approximately 1,842 patents and owns the EPA registrations for and produces over 250 agricultural pesticides. Defendant Bayer distributes the Bayer Group products throughout the United States. In 2009, Bayer AG was the second largest agricultural chemical company in the world, with sales in excess of \$8 billion. Upon information and belief, Bayer Environmental Science is a division of Bayer which operates under the Bayer corporate umbrella.

JURISDICTION

5. Subject matter jurisdiction in this case is proper under 28 U.S.C. §§ 1331 and 1338(a) in that this is a civil action arising under an Act of Congress relating to patents.

6. Venue is proper in this district under 28 U.S.C. § 1391(b). Defendant Bayer resides and may be found in this district and is subject to personal jurisdiction in this State and District.

GENERAL ALLEGATIONS

7. Defendant Bayer violated and continues to violate 28 U.S.C. § 292 by marking products it manufactured, distributed, marketed or sold as being covered by a patent when those products were not actually covered by a valid patent with the intent to deceive the public.

Bayer's Expired Patents

8. Bayer is the owner of United States Patent No. 4,240,819, issued on December 23, 1980, for "Method for the Inhibition of Plant Growth" (the "'819 Patent"). The process registered under the '819 Patent is applied to products sold by Bayer under variations of the names "PREP," "ETHREL," "PROXY," and "CERONE." A true and complete copy of the '819 Patent is attached hereto as **Exhibit A**.

9. The '819 Patent expired on December 23, 1997.

10. Bayer is the owner of United States Patent No. 4,130,413 issued on December 19, 1978, for "Heterocyclic Phenyl Ethers and Herbicides Containing Same," a pesticide (the "'413 Patent"). The pesticide registered under the '413 Patent is sold by Bayer under the name "WHIP® 360 Herbicide." A true and complete copy of the '413 Patent is attached hereto as **Exhibit B**.

11. The '413 Patent expired on September 8, 1997.

Pesticide Regulation and Labeling

12. The EPA strictly regulates the content and labels of pesticide products in the United States. The sale and distribution of pesticides is subject to one of the strictest regulatory regimens in the U.S., which in scientific rigor and regulatory breadth is on par with the regulation of drugs.

13. Under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), it is unlawful to sell or distribute a pesticide in the U.S. without a registration issued by the EPA. It is a violation of FIFRA for any person to use a pesticide in a manner inconsistent with its labeling. 7 U.S.C. §136j(a)(1)(G).

14. As part of the process of registering a pesticide product, the EPA reviews and approves the content and format of the label that must appear on the pesticide product and assigns a unique pesticide registration number to the product. A registrant may not sell or distribute a product with a label that is not approved by the EPA. 7 U.S.C. § 136a(c)(3)(5).

15. The EPA’s regulations set forth in detail the information that must be included in a pesticide label. 40 C.F.R. Part 156. Each applicant for a pesticide registration must provide to the EPA the proposed label text for the pesticide product which conforms to the EPA’s requirements for label content and format. 40 C.F.R. § 152.50(e).

16. Upon issuance of a pesticide product registration, the EPA provides documentation of the approved registered label by date-stamping the approved label text and returning it to the applicant.

17. Revisions to EPA-approved pesticide labeling may be accomplished through various means depending on the nature of the change.

18. The majority of changes to a pesticide label require the submission to the EPA of a formal application for an amendment and an EPA review process of three months or more. 40 C.F.R. § 152.44(a).

19. Certain amendments, however, are considered minor changes by the EPA and may be accomplished through a “notification” process that involves a simplified filing with the EPA and an expedited, thirty (30) day review period. 40 C.F.R. § 152.46(a); EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998). An example of such a minor change would be the addition of a brand name.

20. Minor label revisions which do not involve text related to the regulated status of the product under FIFRA may be made without any notification to the EPA. 40 C.F.R. § 152.46; EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998). The marking of a pesticide product label with a patent claim is non-FIFRA text and thus may be amended without notification to the EPA.

21. Upon acceptance of a proposed amendment to a pesticide product label filed either as a formal amendment or as a notification, the EPA provides documentation of the approved amended label text by date-stamping the approved amended label text, returning a copy to the registrant and posting a copy on its website.

22. Prior to the sale or distribution of a pesticide product, the registrant is required to file with the EPA a copy of the final printed label that will appear on the product as distributed.

23. If a party amends the label for a pesticide product, it must within 18 months of EPA's approval of the amendment only sell or distribute the affected product with the amended label. It is a violation of FIFRA to distribute a product with an outdated label text after this 18 month grace period.

24. Given the nature of the regulation of pesticide product labels and the processes for amending those labels, Bayer, which holds over 250 EPA pesticide registrations, must devote significant resources to the management of its registrations and labels, and must pay exacting attention to the label text and the appropriate procedures for amending any label.

25. Despite this focus on the language of pesticide labels, Bayer continues to refer to the expired '819 and '413 Patents on the labels of certain of its products as if those patents were still in force and applicable to those products.

Bayer's Violation of 35 U.S.C. 292

26. Section 292 of the Patent Act (35 U.S.C. §292) provides that “[w]hoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article the word ‘patent’ or any word or number importing that the same is patented, for the purpose of deceiving the public...[s]hall be fined not more than \$500 for every such offense.”

27. The statute further provides that “[a]ny person may sue for the penalty, in which event one-half shall go to the person suing and the other half to the use of the United States.”

28. Subsequent to the expiration of the ‘819 and ‘413 Patents, Defendant Bayer has continued to mark, affix to and use in advertising, labels on its PREP, PROXY, ETHREL and CERONE lines of products (collectively, the “PPEC Line Products”) and on its “WHIP® 360 Herbicide” products which contain words or numbering indicating that such products are patented in violation of §292 of the Patent Act.

29. Bayer holds registrations from EPA for six (6) pesticide products which were at one time covered by the ‘819 Patent. Bayer uses some variation of the names “ETHREL,” “PREP,” “CERONE” or “PROXY” for these products:

- (a) ETHREL® brand Ethephon Plant Growth Regulator is registered to Bayer under EPA Registration number 264-257 and has been registered to Bayer or one of its predecessor entities since at least September 29, 1971. The label for ETHREL® brand Ethephon Plant Growth Regulator currently contains a false

mark for the '819 Patent, and has continuously contained such false mark since the expiration of the '819 Patent on December 23, 1997. Bayer has amended its ETHREL® brand Ethephon Plant Growth Regulator label twice since the expiration of the '819 Patent, yet has never removed the false patent marking from the label. Bayer most recently obtained EPA approval to amend its ETHREL® brand Ethephon Plant Growth Regulator label on November 18, 2002, approximately 5 years after the expiration of the '819 Patent. A true and complete copy of the falsely marked label, dated November 18, 2002, for ETHREL® brand Ethephon Plant Growth Regulator is attached hereto as **Exhibit C**.

(b) PREP™ brand Ethephon Plant Regulator For Cotton is registered to Bayer under EPA Registration number 264-380 and has been registered to Bayer or one of its predecessor entities since at least December 16, 1982. The label for PREP™ brand Ethephon Plant Regulator For Cotton currently contains a false mark for the '819 Patent, and has continuously contained such false mark since the expiration of the '819 Patent on December 23, 1997. Bayer most recently obtained EPA approval to amend its PREP™ brand Ethephon Plant Regulator For Cotton label on November 27, 2002, approximately 5 years after the expiration of the '819 Patent. A true and complete copy of the falsely marked label, dated November 27, 2002, for PREP™ brand Ethephon Plant Regulator For Cotton is attached hereto as **Exhibit D**.

(c) PREP™ brand Ethephon For Cotton And Tobacco is registered to Bayer under EPA Registration number 264-418 and has been registered to Bayer or one of its predecessor entities since at least December 16, 1982. The label for PREP™ brand Ethephon For Cotton And Tobacco currently contains a false mark for the ‘819 Patent, and has continuously contained such false mark since the expiration of the ‘819 Patent on December 23, 1997. Bayer most recently obtained EPA approval to amend its PREP™ brand Ethephon For Cotton And Tobacco label on November 9, 2010, approximately 13 years after the expiration of the ‘819 Patent. A true and complete copy of the falsely marked label, dated November 9, 2010, for PREP™ brand Ethephon For Cotton And Tobacco is attached hereto as **Exhibit E.**

(d) ETHREL® brand Ethephon Plant Regulator is registered to Bayer under EPA Registration Number 264-267 and has been registered to Bayer or one of its predecessor entities since at least April 24, 1973. The label for ETHREL® brand Ethephon Plant Regulator currently contains a false mark for the ‘819 Patent, and has continuously contained such a false mark since the patent’s expiration on December 23, 1997. Bayer has amended its ETHREL® brand Ethephon Plant Regulator label no less than six times since the expiration of the ‘819 Patent, yet has never removed the false patent marking from the label. Bayer most recently obtained EPA approval to amend its ETHREL® brand Ethephon Plant Regulator label on March 6, 2001, more than 4 years after the expiration of the ‘819 Patent.

A true and complete copy of the falsely marked label, dated March 6, 2001, for ETHREL[®] brand Ethephon Plant Regulator is attached hereto as **Exhibit F**.

(e) CERONE[®] brand Ethephon Plant Regulator is registered to Bayer under EPA Registration Number 264-377 and has been registered to Bayer or one of its predecessor entities since at least March 29, 1985. The label for CERONE[®] brand Ethephon Plant Regulator currently contains a false mark for the '819 Patent, and has continuously contained such a false mark since the patent's expiration on December 23, 1997. Bayer has not amended its CERONE[®] brand Ethephon Plant Regulator label in the over 13 years since the '819 Patent's expiration to remove the false patent marking from its label. This label, approved on July 15, 1997, continues to be used by Bayer on its CERONE[®] brand Ethephon Plant Regulator products. A true and complete copy of the July 15, 1997 label for CERONE[®] brand Ethephon Plant Regulator is attached hereto as **Exhibit G**.

(f) PROXY[®] Growth Regulator is registered to Bayer Environmental Science, a division of Bayer, under EPA Registration Number 432-1230 and has been since at least January 4, 2001. The label for PROXY[®] Growth Regulator contained a false mark for the '819 Patent from the time of Bayer's or its predecessor entity's EPA registration of this label on January 4, 2001 until EPA's approval of Bayer's most recent amendment to the label on March 20, 2009 (over 9 years). The '819 Patent expired on December 23, 1997, over 3 years prior to Bayer's EPA registration of its PROXY[®] Growth Regulator product, so the PROXY[®] Growth

Regulator label contained a false mark for the '819 Patent since the label's inception. Bayer has amended its PROXY® Growth Regulator label no less than five times since the expiration of the '819 Patent, yet maintained the false patent marking on the label until the most recent March 20, 2009 amendment. A true and complete copy of the falsely marked label, dated April 26, 2005 for PROXY® Growth Regulator is attached hereto as **Exhibit H**.

30. Bayer holds one registration from EPA which was at one time covered by the '413 patent. WHIP® 360 Herbicide was registered to Agrevo USA Co. since at least February 22, 2000 (EPA Registration number 45639-181) and was transferred to Bayer or one of its predecessor entities under EPA Registration number 264-647 on February 22, 2000. The label for WHIP® 360 Herbicide currently contains a false mark for the '413 Patent, and has continuously contained such a false mark from the time Bayer or its predecessor entity acquired an EPA registration for this label on February 22, 2000. The '413 Patent expired on September 8, 1997, over 2 years prior to Bayer's or its predecessor entity's acquisition of an EPA registration for its WHIP® 360 Herbicide product, so the WHIP® 360 Herbicide label contained a false mark for the '413 Patent since the label's inception. Bayer has amended its WHIP® 360 Herbicide label no less than 4 times since the expiration of the '413 Patent, yet has never removed the false patent marking from the label. Bayer most recently obtained EPA approval to amend its WHIP® 360 Herbicide label on August 8, 2008, more than 11 years after the expiration

of the '413 Patent. A true and complete copy of the falsely marked label, dated August 8, 2008, for WHIP® 360 Herbicide is attached hereto as **Exhibit I**.

31. Bayer has marked, affixed to, or used in advertising the word “patent” or other words or numbers implying patents in connection with the unpatented PPEC Line Products and its WHIP® 360 Herbicide product.

32. Upon information and belief, Defendant Bayer marks or has marked its PPEC Line Products and WHIP® 360 Herbicide with words or numbering indicating that such products are patented with the intent to deceive the public thereby. Among other things, Defendant Bayer’s conduct deters existing and potential competing registrants from seeking generic registration of products containing the same active ingredients. Bayer has made the process of entering the market for potential competitors producing generic brands more costly by creating a need to conduct expensive investigations to determine the validity of the patents prominently marked on its products.

33. The Bayer Group is a group of sophisticated pesticide manufacturing companies that has collectively been assigned approximately 1,842 patents or publications and over 250 EPA registrations. The Bayer Group has decades of experience obtaining and/or licensing patents. Bayer itself holds a number of patents directly and has been expressly granted the full and complete right to enforce certain patents held by other companies within the Bayer Group.

34. On information and belief, Bayer received and reviewed copies of the '819 and '413 Patents and was aware of the expiration dates of those patents. Further

demonstrating its active management of and knowledge about its patent portfolio, Bayer was required to pay, and, on information and belief, did pay, periodic maintenance fees for the '819 and '413 Patents that were due 3½, 7½ and 11½ years after each patent was originally issued. Thus, Bayer knows, or at least should know, that '819 and '413 Patents have expired.

35. Bayer has removed expired patent markings from its pesticide product labels in the past, albeit belatedly. Bayer is the owner of United States Patent No. 3,879,188 for "Growth Regulation Process," which expired on April 22, 1992 (the "'188 Patent"). A true and complete copy of the '188 Patent is attached hereto as **Exhibit J**. Bayer's ETHREL® brand Ethephon Plant Growth, PREP™ brand Ethephon Plant Regulator for Cotton, and PREP™ brand Ethephon Plant Regulator for Cotton and Tobacco products were covered at one time by the '188 Patent, and Bayer's labels for these products contained a marking for the '188 Patent. The labels for these products no longer contain a patent marking for the '188 Patent. See **Exhibits C, D, and E**. Although the '188 Patent markings have been removed from these labels, Bayer continued to use the '188 Patent marking on these labels for a number of years after the expiration of the '188 Patent.

36. Bayer has shown its ability to actively manage its intellectual property, including its patents. For example, Bayer has brought at least four actions in the last five years alone against competitors of Bayer's alleging that the competitors infringed Bayer's patents, two of which actions were brought in this Court. *Bayer CropScience LP v.*

Tessenderlo Kerley, Inc. et al., C.A. No. 1:09-cv-833 (MDNC, filed on 10/28/2009); *Bayer CropScience Aktiengesellschaft and Bayer CropScience LP v. Control Solutions, Inc. et al.*, C.A. No. 5:08-cv-00051-F (EDNC, filed on 2/08/2008); *Bayer CropScience Aktiengesellschaft and Bayer CropScience LP v. Nufarm Americas, Inc. et al.*, Ca. No. 1:07-cv-0057-CMH-TCB (ED Va., filed on 6/13/2007); *Bayer CropScience LP v. Makhteshim Agan of North America, Inc.*, Ca. No. 1:06-cv-00921-JAB-WWD (MDNC, filed on 10/20/2006).

37. Upon information and belief, Bayer knew or should have known that it needed to modify the labels, marketing and advertising for its PPEC Line Products and its WHIP® 360 Herbicide products to remove any indicia that such products are patented after the '819 and '413 Patents expired.

38. Defendant Bayer had multiple opportunities to remove the offending statements on the labels at no cost when it was already revising the labels on its PPEC Line Products and its WHIP® 360 Herbicide products, but it did not do so.

39. Bayer could have taken the initiative at any point to remove the offending references on the labels without any EPA review required, but it did not do so.

FIRST CAUSE OF ACTION
(FALSE PATENT MARKING CLAIM FOR '819 PATENT)

40. Plaintiff incorporates paragraphs 1-39 above as if fully set forth herein.

41. Under 35 U.S.C. § 292, any product marked with a patent number must be covered by that patent.

42. Bayer marked, affixed and/or advertised the PPEC Line Products as being covered by the '819 Patent.

43. The PPEC Line Products ceased being covered by the '819 Patent.

44. Bayer knew or should have known that the PPEC Line Products ceased being covered by the '819 Patent.

45. Upon information and belief, Bayer intended to deceive the public by marking, affixing, or advertising the PPEC Line Products as being covered by the '819 Patent.

46. Defendant Bayer has violated 35 U.S.C. § 292 by falsely marking, affixing and/or advertising its PPEC Line Products as being subject to the '819 Patent with intent to deceive the public when those products are unpatented.

47. Plaintiff is a "person" within the meaning of 35 U.S.C. § 292 and is entitled to bring suit pursuant to that statute.

SECOND CAUSE OF ACTION
(FALSE PATENT MARKING CLAIM FOR '413 PATENT)

48. Plaintiff incorporates paragraphs 1-47 above as if fully set forth herein.

49. Under 35 U.S.C. § 292, any product marked with a patent number must be covered by that patent.

50. Bayer marked, affixed and/or advertised the WHIP® 360 Herbicide products as being covered by the '413 Patent.

51. The WHIP® 360 Herbicide products have ceased being covered by the ‘413 Patent.

52. Bayer knew or should have known that its WHIP® 360 Herbicide products has ceased being covered by the ‘413 Patent.

53. Upon information and belief, Bayer intended to deceive the public by marking, affixing, or advertising its WHIP® 360 Herbicide product as being covered by the ‘413 Patent.

54. Defendant Bayer has violated 35 U.S.C. § 292 by falsely marking, affixing and/or advertising its WHIP® 360 Herbicide products as being subject to the ‘413 Patent with intent to deceive the public when the products are unpatented.

55. Plaintiff is a “person” within the meaning of 35 U.S.C. § 292 and is entitled to bring suit pursuant to that statute.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against the Defendant Bayer and respectfully requests that the Court:

- (a) enter a judgment in favor of Plaintiff that Defendant Bayer falsely marked items in violation of 35 U.S.C. § 292;
- (b) order that Defendant Bayer pay a fine of \$500 for each instance of false marking;
- (c) order that one-half of the fine or penalty is paid to Plaintiff and that one-half is paid to the United States;

- (d) award Plaintiff its reasonable attorneys' fees;
- (e) award pre-judgment and post-judgment interest; and
- (f) grant such other and further relief as the Court deems appropriate and just.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on any issues so triable.

Respectfully submitted this 25th day of February, 2011.

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