NOT FOR PUBLICATION [Docket Nos. 111, 218, 220, 241, 333]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER CROPSCIENCE AG,

Plaintiff,

v.

DOW AGROSCIENCES LLC,

Defendant.

Civil No. 10-1045 RMB/JS

OPINION

Frederick L. Cottrell, III
Jeffrey L. Moyer
Anne Shea Gaza
Stephen M. Ferguson
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801

Robert J. Koch
Jay I. Alexander
Arie M. Michelsohn
Stephanie R. Amoroso
Edwards J. Mayle
Milbank, Tweed, Hadley & McCoy LLP
1850 K Street NW, Suite 1100
Washington, D.C. 20006

Attorneys for Plaintiff Bayer CropScience AG

Steven J. Balick
Lauren E. Maguire
Andrew C. Mayo
Ashby & Geddes, P.A.
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899

Peter A. Bicks
Alex V. Chachkes
Joseph A. Sherinsky
Orrick, Herrington & Sutcliffe LLP
51 West 52nd Street
New York, New York 10019

Elizabeth A. Howard
Orrick, Herrington & Sutcliffe LLP
1000 Marsh Road
Menlo Park, California 94025

Hardip B. Passananti
Orrick, Herrington & Sutcliffe LLP
4 Park Plaza, Suite 1600
Irvine, California 92614

Attorneys for Defendant Dow AgroSciences LLC

BUMB, United States District Judge
(sitting by designation):

The poet Ella Wheeler Wilcox once said that "a weed is but an unloved flower." Farmers and the parties to this litigation disagree.

Each party has sought patent protection for intellectual property that allows crops, primarily corn and soybeans, to resist a powerful weed herbicide known as 2,4-Dichlorophenoxyacetic acid ("2,4-D"). Use of the 2,4-D herbicide maximizes crop yields because the crops no longer have to compete with weeds for water, nutrients, and sun.

The Plaintiff, Bayer CropScience AG ("Bayer"), claims that the Defendant, Dow AgroSciences LLC ("Dow"), has infringed its patent, patent number 6,153,401 (the "401 Patent") through its "Enlist Weed

Control" product.[1] Bayer has moved for partial summary judgment on claims 1-3 and 8 of the 401 Patent. [Docket No. 111]. Dow has moved for summary judgment of non-infringement. [Docket No. 218]. Dow has also moved for summary judgment asserting that: (1) claims 4 and 5 of the 401 Patent are invalid [Docket No. 220]; and (2) the 401 Patent is invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112 [Docket No. 241].

For the reasons that follow, Bayer's motion for partial summary judgment is DENIED; Dow's motion for summary judgment of non-infringement is GRANTED; Dow's remaining motions are DENIED as moot.[2]

I. Background

A. Bayer's 401 Patent

In the mid-1980s, Bayer scientists sought to genetically engineer plants that would be resistant to 2,4-D, which ordinarily kills weeds and plants alike. At that time, it was known that several species of bacteria could grow on 2,4-D through a metabolic process that involved, as its first step, the degradation of 2,4-D into

[1] See U.S. Patent No. 7,838,733; International Patent Publication No. WO 2007/053482.

[2] Bayer also moved to strike portions of Dow's written description motion [Docket No. 333]. That motion is DENIED as moot because: (1) this Court grants Dow's motion for summary judgment of non-infringement; and (2) even if the motion were granted, it would not change this Court's conclusion, described below, that, if this Court accepted Bayer's construction of the 401 Patent, the patent would be invalid under the written description requirement.

2,4-dichlorophenol ("2,4-DCP"). [Docket No. 211, Declaration of Robert P. Hausinger ¶ 14)]("Hausinger Dec."). One of those species was called Alcaligenes eutrophus. Hausinger Dec. ¶ 13. It contains a gene, known as the *tfdA* gene, which provides genetic coding for the production of an enzyme, known as the TfdA enzyme, that catalyzes the reaction that converts 2,4-D into 2,4-DCP. Id.

Specifically, in the presence of (i) 2,4-D, (ii) two oxygen atoms, and (iii) a-ketoglutarate, the TfDA enzyme causes a reaction in which one oxygen atom combines with 2,4-D to form an unstable hyrodroxylated 2,4-D, one oxygen atom combines with aKG to form succinate, and carbon dioxide is produced. [Docket No. 217, Declaration of Joseph Martin Bollinger ¶ 29]("Bollinger Dec."). The unstable hydroxylated 2,4-D then splits apart to form 2,4-DCP and glyoxylate. Id. In the 401 patent, Bayer describes this process, through which the unstable hydroxylated 2,4-D splits apart, as the "cleavage of the side chain." 401 Patent, col. 2:25-27. Because the TfdA enzyme causes a reaction in which two oxygen atoms are incorporated into products other than water, it is classified as a dioxygenase. Bollinger Dec. ¶ 13. A dioxygenase is simply an enzyme that causes a reaction in which two oxygen atoms are incorporated into products other than water. Bollinger Dec. ¶ 8.

While it was unknown at the time whether 2,4-DCP would itself be toxic to plants, Bayer scientists hypothesized that if the gene used in bacteria that allowed this metabolic process could be

introduced into a plant, it could confer 2,4-D resistance to the plant without otherwise harming the plant. [Docket No. 210, Declaration of Alan Jones ¶ 7]("Jones Dec."). This prediction was proven accurate when Bayer scientists were able to isolate the *tfdA* gene responsible for this process in the Alcaligenes bacteria and successfully introduce it into a plant, creating a 2,4-D resistant, but otherwise unchanged, plant. Jones Dec. ¶ 11.

These scientists did so by: (1) creating a mutant strain of Alcaligenes bacteria that lacked 2,4-D resistance; (2) transferring segments of DNA of the non-mutant, 2,4-D resistant Alcaligenes bacteria into the mutant; (3) testing whether the transfer resulted in 2,4-D resistance for the previously vulnerable mutant; and (4) introducing the gene that resulted in 2,4-D resistance in the mutant, the *tfdA* gene, into a plant. Markman Tr. 132:1 – 136:9; Jones Dec. ¶ 14. Bayer refers to the process by which it tested genes on the mutant as a "complementation assay" and discloses this procedure in the 401 Patent. [Docket No. 374, p. 3 ("The patent also describes an exemplary *tfdA* gene isolated from the *Alcaligenes eutrophus* bacteria using the complementation assay and provides its DNA sequence in Fig. 10.")].

With their efforts successful, Bayer deposited the mutant bacteria in a bacteria depository accessible to the public and sought

to patent their discovery. Markman Tr. 132:20- 133:8.[3] Bayer filed for the 401 Patent on March 10, 1989. Eleven years later, on November 28, 2000, the 401 Patent was issued.

B. Bayer Claims Infringement of 401 Patent

In this lawsuit Bayer claims that Dow has developed genetically modified soybean and corn crops that infringe the 401 Patent. Notably, Bayer does not dispute that Dow's products utilize a gene other than the *tfdA* gene and that Dow's genes – dubbed the *aad* genes - code for a different enzyme other than the TfdA enzyme. Despite utilizing different genes, however, Dow's products create 2,4-D resistant plants through the same mechanism as the TfdA enzyme, described above. The parties agree that Dow's enzymes, like Bayer's TfdA enzyme, are dioxygenases.

The fact that Dow's enzymes are dioxygenases is significant. At the time Bayer filed its 401 Patent in 1989, the TfdA enzyme was wrongly believed to be a monooxygenase, not a dioxygenase.[4]

[3] "Markman Tr." Refers to the transcript of the Markman hearing conducted by the Court on June 25-28, 2012.

[4] Four years later, in 1993, Dr. Robert P. Hausinger ("Dr. Hausinger"), Bayer's expert in this litigation, co-authored a paper that identified this error. Markman Tr. 82:20-25. The methods used by Dr. Hausinger to discover the error were, however, known in the scientific community at the time Bayer sought patent protection. Markman Tr. 188:15-22. In fact, one of the inventors disclosed on the 401 Patent, Dr. Wolfgang R. Streber, reported conducting similar experiments to Dr. Hausinger, prior to filing for the patent, which should have suggested to him that classification of the TfDA enzyme as a monooxygenase was erroneous. Markman Tr. 193:10-20, 272:11-277:19. In those experiments, Dr. Streber observed that NADH, which would be expected to stimulate conversion of 2,4-D into

Bollinger Dec. ¶ 14; Markman Tr. 77:25-78:7. Unlike a dioxygenase where the atoms of oxygen are incorporated into a product other than water, a monooxygenase is an enzyme that causes a reaction in which one atom of oxygen is converted into water and one is incorporated into another product other than water. Bollinger Dec. ¶ 8. In a 2,4-D monooxygenase enzyme, the enzyme - in the presence of (i) 2,4-D, (ii), two oxygen atoms, and (iii) NADH or NADPH – causes a reaction in which the products are an unstable hydroxylated 2,4-D that breaks down into 2,4-DCP and glyoxylate, water, and NAD plus or NADP plus. Bollinger Dec. ¶ 28; Markman Tr. 254:20-255:21. Consistent with that mistaken belief, the 401 Patent repeatedly describes the TfdA enzyme as a monooxygenase.

Claim 1 of the 401 Patent is no exception, as it expressly uses the term "monooxygenase." It claims:

> A recombinant gene, comprising a DNA sequence encoding a polypeptide having the biological activity of 2,4-D monooxygenase which is capable of being expressed in a plant, operably linked to a heterologous promoter capable of promoting the expression in a plant of a structural gene operably linked thereto.

401 Patent, Col. 32, 12-19.

C. The Markman Hearing

2,4-DCP in the presence of 2,4-D, the TfdA enzyme, and oxygen, did not. Id. That same finding led Dr. Hausinger to launch his investigation and discover that the TfDA enzyme was, in fact, a dioxygenase. Id. See also discussion infra.

Because the construction of Claim 1 and other claims in the 401 Patent was central to resolution of this dispute, the Court conducted a claim construction hearing pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) (the "Markman Hearing"). Importantly, at the Markman Hearing and in prior depositions, experts from both sides agreed that: (1) the meanings of the terms monooxygenase and dioxygenase, described above, have been fixed for decades prior to Bayer's filing of the 401 Patent and are unchanged today; and (2) the TfdA enzyme was a dioxygenase and describing it as a monooxygenase was scientifically incorrect.[5]

II. Legal Analysis

A. Construction of Claim 1

Dow makes three arguments regarding its construction of Claim 1:

(1) Claim 1 only covers genes coding for monooxygenase enzymes and Dow's products code for dioxygenase based enzymes;

(2) if the foregoing construction of Claim 1 is not accepted by the Court, the only alternative

[5] [Docket No. 291, Ex. A at 56:8-20 ("Q: And how long in your judgment has [the difference between monooxygenase and dioxygenase] been known? DR. HAUSINGER: Over 50 years.")]; Markman Tr. 249:4-8 (Dow's expert testifying that he had no "reason to contradict" Dr. Hausinger's testimony that the definitions of monooxygenase and dioxygenase had been fixed for over 50 years). Markman Tr. 143:21-144:9 ("Q: You said if somebody knows [that the TfdA enzyme is a dioxygenase] and they go ahead and call it a monooxygenase, you said that's scientifically invalid or misleading. Yes or no? DR. HAUSINGER: It's incorrect. Q: But you said it's scientifically invalid or misleading not just incorrect. A: It is . . . ."); Id. at 304:8-305:10 (Dow's expert testifying that calling the TfdA enzyme a monooxygenase was a mistake).

construction would be even more limited and would only cover the *tfdA* gene, which it is undisputed Dow's products do not utilizes;

(3) even if Bayer's construction of Claim 1 is accepted, Bayer's proposed construction would render the entire patent invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112.

While Bayer vigorously disputes Dow's claim constructions, it does not dispute that if either of Dow's first two claim construction arguments are accepted, Dow's motion for summary judgment of non-infringement should be granted. Nor does Bayer dispute that a failure to satisfy 35 U.S.C. § 112 would also warrant summary judgment in Dow's favor.

Specifically, as to Claim 1, the parties dispute the construction of three claim limitations:

(1) "a DNA sequence encoding a polypeptide;"

(2) the "biological activity of 2,4-D monooxygenase;" and

(3) "capable of being expressed in a plant."

As set forth below, only construction of the second claim limitation is necessary to resolve the present motions. As such, the Court does not address the first and third disputed claim limitations.

1. *Biological activity of 2, 4-D monooxygenase.*

Bayer claims that the term "biological activity of 2,4-D monooxygenase" should be interpreted to mean "the biochemical (enzymatic) conversion of 2,4-D into 2,4-DCP through the cleavage of the side chain of 2,4-D." In offering this construction, Bayer defines "2,4-D monooxygenase" as "a polypeptide having the biological

activity of bringing about the cleavage of the side chain of 2,4-D." Dow argues that the term should be interpreted to mean "the biochemical reactions that occur and the reaction products that form, in a biological system in the presence of a 2,4-D monooxygenase enzyme and 2,4-D." Dow further defines a 2,4-D monooxygenase enzyme as "an enzyme that reacts with the two atoms of molecular oxygen to add one to 2,4-D and reduces the other to water." The parties' respective positions on this claim limitation are shown as follows:

Claim Limitation	Bayer's Proposed Construction	Dow's Proposed Construction
2,4-D monooxygenase (Claim 1)	A polypeptide having the biological activity of Bringing about the cleavage of the side chain of 2,4-D	An enzyme that reacts with the two atoms of molecular oxygen to add one to 2,4-D and reduces the other to water
Biological activity of 2,4-D monooxygenase (claim1)	The biochemical (enzymatic) conversion of 2,4-D into 2,4-DCP through the cleavage of the side chain of 2,4-D	The biochemical reactions that occur, and the reaction products that form, in a biological system in the presence of a 2,4-D monooxygenase enzyme and 2,4-D

In construing a claim, courts must afford the words of a claim the "ordinary and customary meaning" they would "have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). In

determining the "ordinary and customary meaning" of claim terms, courts may consider extrinsic evidence, including, among other things, expert testimony and dictionary definitions.[6] Id. at 1317.

Both the expert testimony and dictionary definitions support Dow's construction. At the Markman Hearing, and elsewhere, the experts for both sides were generally in consensus as to the ordinary and customary meaning of each of the component terms of "biological activity of 2,4-D monooxygenase."[7] They agreed that:

(1) "biological activity," includes all enzymatic activity that occurs in a biological system[8]; and

[6] While Bayer repeatedly claimed that this Court could resolve the parties' claim construction disputes based solely on the intrinsic evidence in the patent itself, that claim was belied by Bayer's own heavy reliance on extrinsic expert opinion evidence throughout this litigation.

[7] To the extent that Bayer's experts offered contrary constructions of these terms (see, e.g., Hausinger Dec. ¶ 5 (opining that "one of ordinary skill in the art reading the '401 patent would conclude that the recital in the claims of the phrase 'the biological activity of 2,4-D monooxygenase' means 'the biochemical (enzymatic) conversion of 2,4-D into 2,4-DCP through the cleavage of the side chain of 2,4-D.'")), this Court does not credit them because they were conclusory and at odds with the plain language of the claim itself. Phillips, 415 F.3d at 1318.

[8] Markman Tr. 163:8-14 (Dr. Hausinger testifying that "[t]he biological activity is the larger activity that within it there is some enzyme activity but you don't always know what that enzyme activity is"); Id. at 166:22-167:1 ("When [enzymatic activity is] occurring inside of the cell then it is a component of the biological activity, but you may not always know what the enzymatic activity is"); Id. at 167:7-9 ("THE COURT: "Enzymatic activity is part of the biological activity. And you seem to be saying – DR. HAUSINGER: Yes."); Id. at 167:18-23 ("THE COURT: Right. So the enzymatic activity is one or the other, dioxygenase or monooxygenase? DR. HAUSINGER: Right. THE COURT: Monooxygenase. But either one is part of the biological activity? Yes or no?" DR. HAUSINGER: When it's inside the cell, yes."); Id. at 165:20-24 (Dr. Hausinger testifying

(2) a "2,4-D monooxygenase" is an enzyme that causes a reaction with 2,4-D, and two atoms of oxygen, where one atom of oxygen is added to 2,4-D and the other ultimately forms water.[9]

---

that, in a peer-reviewed article, he defined activity as "the overall activity of the enzyme"); Id. at 141:25-142:19 (Dr. Hausinger testifying that, to capture the type of broad functional claiming Bayer proposes, you would need language like "biological activity of 2,4-D decomposition or degradation"); Id. at 260:11-260:16, 261:23-25 (Dow's expert testifying that the biological activity of an enzyme is the reaction that the enzyme catalyzes in a biological system); Id. at 263:16-24 (Dow's expert testifying that he would "go a little farther" than saying that enzymatic activity is a part of biological activity and that enzymatic activity is the "basis" for biological activity); Id. at 284:22-285:14 (Dow's expert testifying that biological activity "is the enzyme reaction occurring in a biological system"); Id. at 288:12-289:8 (Dow's expert agreeing that the term "biological activity" encompasses "every part of the enzyme, biological activity" and that he "lumped them all together as part of the biological activity").

[9] Markman Tr. 196:8-15 (Dr. Hausinger distinguishing between a 2,4-D monooxygenase and a 2,4-D dioxygenase and testifying that "the 2,4-D monooxygenase is where one atom of oxygen goes to water. That was as in ***tftA***, it's not as if ***tfdA***. So in ***tfdA*** you get both atoms of oxygen, they get incorporated); Id. at 83:22-84:3 (Dr. Hausinger agreeing with the Court that "it was well known in the science that there is a class of enzymes dioxygenase and monooxygenase")); Id. at 82:23-83:3 (Dr. Hausinger testifying that his experiment showed that the TfDA enzyme is "not a 2,4-D monooxygenase but rather it's a ferrous iron dependent and alpha-ketoglutarate dependent dioxygenase"); Id. at 143:20-144:9 (Dr. Hausinger agreeing that calling the TfdA enzyme a 2,4-D monooxygenase would be "misleading," "incorrect," and "scientifically invalid" because it is in fact a dioxygenase); Id. at 198:5-19 (Dr. Hausinger testifying that he would not have used the term "monooxygenase" to describe the enzymatic activity at issue because the exact nature of that activity was unknown and would instead have used the term "hydroxylase . . . [t]o be more inclusive."); [Docket No. 291, Ex. A at 15 (deposition testimony of Dr. Hausinger distinguishing between monooxgyenases and dioxygenases)]; Markman Tr. 248:19-249:14, 250:25-251:3 (Dow's expert testifying as to the definitions of a monooxygenase and a dioxygenase and that they have been fixed for over 50 years); Id. at 254:20-257:11 (Dow's expert testifying as to the distinction between a 2,4-D monooxygenase and a 2,4-D dioxygenase); Id. at 283:25-284:21)(Dow's expert testifying that 2,4-D monooxygenase has a distinct scientific meaning that is

And those definitions are consistent with dictionary definitions of these terms offered by Dow – dictionary definitions Bayer does not dispute. [Docket No. 227, Dow's Opening Claim Construction Brief at 8-9 (offering dictionary definitions of "biological," "activity," and "monooxygenase")].

Therefore, looking at these two series of claim terms together, and considering (i) the expert opinions, (ii) the dictionary definitions offered, and (iii) that the TfdA enzyme was erroneously believed at the time of filing to be a monooxygenase, these terms' plain and ordinary meaning is the enzymatic activity of an enzyme, in a biological system, that causes a reaction with 2,4-D, and two molecules of oxygen, where one molecule of oxygen is added to 2,4-D and the other ultimately forms water. That definition comports with the definition offered by Dow, which this Court adopts.

Bayer offers six arguments against this plain construction, each of which this Court addresses. First, Bayer argues that this construction is improper because it would exclude the *tfdA* gene disclosed in the 401 Patent from coverage because that gene encodes for a dioxygenase enzyme. Bayer contends that this Court should instead construe the claim terms in a manner that does not exclude the preferred embodiment of the patent – the *tfdA* gene. While Bayer

---

inconsistent with Bayer's proposed construction); Id. at 295:15-20 (Dow's expert testifying that, where there is uncertainty as to whether an enzyme is a monooxygenase or a dioxygenase, it would be proper to call it a hydroxylase).

is correct that courts "normally do not interpret claims in a way that excludes embodiments disclosed in the specification," the Court's construction of this claim is warranted in this case. Oatey Co. v. IPS Corp., 514 F.3d 1271, 1277 (Fed. Cir. 2008). Courts may only "construe claims to sustain their validity when the claims are amenable to more than one reasonable construction; when the claims are susceptible to only one reasonable constructions, [courts must] construe the claims as the patentee drafted them." Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200, 1215 (Fed. Cir. 2008)(citations omitted). Here, the claim language is unambiguous, susceptible to only one construction. As the testimony at the Markman Hearing unequivocally demonstrated, the terms were plain and unambiguous. Thus, although it turned out that the TfdA enzyme specified in the 401 Patent was a dioxygenase, this Court "may not redraft [the claim] to cure a drafting error made by [Bayer]." Lucent, 525 F.3d at 1215-16; Elektra Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, (Fed. Cir. 2000)("Moreover, having concluded that the amended claim is susceptible of only one reasonable construction, we cannot construe the claim differently from its plain meaning in order to preserve its validity (upon which we do not opine)."); Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc., 322 F.3d 1335, 1356 (Fed. Cir. 2003)("As a general rule, claim interpretations, which operate to exclude the preferred embodiment, are rarely, if ever, correct and require highly persuasive evidentiary support.

However, we have found that such a conclusion can be mandated by clear intrinsic evidence, such as unambiguous claim language.")(quotation and citation omitted)(in dissent).

Second, Bayer argues that this Court can ignore the claim limitation's plain meaning because it acted as its own lexicographer to give the term "biological activity of 2-4,D monooxygenase" the functional definition it proposes above. In support, Bayer cites to a portion of the patent that describes the enzyme at issue as "having the biological activity of bringing about the cleavage of the side chain of 2,4-D." 401 Patent at col. 2:25-27 ("The tfDA gene codes for 2,4-D [monooxygenase], a polypeptide having the biological activity of bringing about the cleave of the side chain of 2,4-D."). While courts may ignore the plain meaning of plain language in favor of a special definition offered by the patentee (Interdigital Comms, LLC v. Int'l Trade Comm'n, No. 2010-1093, 2012 WL 3104597, at *5 (Fed. Cir. Aug. 1, 2012)), they may only do so where the patentee "communicates a deliberate and clear preference for this alternate definition." Kumar v. Ovonic Battery Co., Inc., 351 F.3d 1364, 1368 (Fed. Cir. 2003); Helmsderfer v. Bobrick Washroom Equipment, Inc., 527 F.3d 1379, 1381 (Fed. Cir. 2008); Renishaw PLC v. Marposs Societa' per Azioni, 157 F.3d 1243, 1249 (Fed. Cir. 1998). Here, however, Bayer failed to communicate a deliberate and clear preference for this alternate definition in the 401 Patent. Its cited language does not signal in any way that it is communicating a non-standard definition

of 2,4-D monooxygenase. Rather, it merely describes the key function of the enzyme at issue. Moreover, Bayer's proposed construction would result in this claim covering all genes having the specific activity of cleaving the side chain - - whether a monooxygenase, dioxygenase gene, or other gene.

Third, Bayer argues that its proposed construction is, in fact, consistent with the ordinary and customary meaning of "2,4-D monooxygenase" because, at the time of the invention, the TfdA enzyme was, erroneously, believed to be a monooxygenase. Bayer is, of course, correct that claims must be construed from the viewpoint of a person of ordinary skill in the art at the time of the invention. Phillips, 415 F.3d at 1312-13. But Bayer's argument conflates the relevant analysis. It is immaterial that persons of ordinary skill in the art at the time of the invention erroneously understood the claim terms "2,4-D monooxygenase" to include the TfdA enzyme. That misimpression was not based on a misunderstanding of what it meant to be a 2,4-D monooxygenase, but rather on the mistaken belief that the TfdA enzyme qualified as a 2,4-D monooxygenase. What is material is that 2,4-D monooxygenase had a specific meaning to persons of ordinary skill in the art at the time (just as did dioxygenase and hydroxylase): that meaning would not capture the TfdA enzyme, as the parties agree TfdA is a dioxygenase. Indeed, as the testimony at the Markman Hearing demonstrated, the inventors had a choice of words. They could have written monooxygenase, dioxygenase or even

"hydroxylase" to cover both 2,4-D monooxygenase and 2,4-D dioxygenase enzymes. Bayer's own expert, Dr. Hausinger, testified that the distinction between "monooxygenase" and "dioxygenase" enzymes was well known in the art:

> The Court: So at the time it was well known in the art that there are these different classes of enzymes.
>
> A: Yes
>
> The Court: Specifically though you were focusing on TfdA, but it was well known in the science that there is a class of enzymes dioxygenase and monooxygenase?
>
> A: Yes

Markman Tr. 83:22-84-3; see also Dr. Bollinger's testimony at 254:13-257:11 (distinguishing monooxygenases from dioxygenases).

The experts were also in agreement that these definitions may have been settled for as long as 50 years:

> Q: And how did you come up with these definitions?
>
> A: Well, these definitions are well known in the field, have been since at least the nineteen-seventies. I think Dr. Hausinger said for over 50 years, and I don't have any reason to contradict that.

Markman Tr. 249:4-8 (testimony of Dow's expert).[10] And Bayer's expert, Dr. Hausinger, agreed:

> The Court: But if you wanted to cover all enzymatic

[10] The hearing testimony was consistent with the documentary evidence. The differences between monooxygenases and dioxygenases were described in textbooks at the time the application for the '401 patent was filed. See Ex. 95 (Walsh textbook); Ex. 96 (Stryer textbook); Ex. 36 at ¶¶ 8, 11, 13, 17 (Bollinger Decl.). Dr. Hausinger published multiple peer reviewed papers exploring and explaining the significant differences between monooxygenases and dioxygenases. See Exs. 90-93; Ex. 36 at ¶ 15.

> activity, you would claim monooxygenase and dioxygenase enzymatic activity, or you would just say enzymatic activity, you wouldn't limit it to monooxygenase.
>
> A: I would have probably used the terminology that was applied at the time which everyone was calling that activity, assuming it was a 2,4-D monooxygenase, but perhaps if I were one of the authors, the inventors of the patent, I would have said 2,4-D hydroxylase, for example, just to be more general because --
>
> The Court: To be more inclusive.
>
> A: To be more inclusive, because nobody had specifically done the enzyme mechanism types of studies to discern whether it was a true 2,4-D monooxygenase as was assumed versus some other type of chemistry.

Markman Tr. 198:5-19. Dow's expert also agreed that the appropriate term to capture both monooxygenases and dioxygenases would have been "hydroxylase":

> The Court: And do you agree with Dr. Hausinger that - - and is it hydroxamine or hydroxylase?
>
> A: Hydroxylase, hydroxylase is the catchall term for a monooxygenase or a dioxygenase.
>
> The Court: Okay, It would include both?
>
> A: Yes.

Markman Tr. 295:15-20. Or, as Dr. Bollinger suggested, the inventors could have claimed "either/or":

> Q: So, wasn't it prudent for the inventors to call it a 2,4-D monooxygenase when they wrote their patent?
>
> A: No, it was not only not prudent, it was in my view sloppy. They had another term hydroxylase which they clearly could have used. And they could, I believe, although I'm not a patent lawyer, it seems they could have used monooxygenase or dioxygenase so –
>
> The Court: You mean those two terms together, not one together?

> A: Either/or. If you don't know what it is, you can say it's this or that.
>
> Markman Tr. 319:13-23.

Moreover, it is notable that Bayer's expert testified that the inventors had the means to determine whether TfdA was, in fact, a monooxygenase at the time of the patent's filing. As Dr. Hausinger testified:

> Q: It has been known in the literature that there are tests available for somebody to try to figure out if an enzyme is a monooxygenase or a dioxygenase, right?
>
> A: If you have a purified enzyme then there is clear ways to distinguish whether it is a monooxygenase or a dioxygenase, yes.

Markman Tr. 188:9-14; see also Ex. 209 (indicating that inventor had purified TfdA prior to filing an application fort what would become the '401 patent). Dr. Bollinger also confirmed that the inventor could have tested to see whether TfdA was truly a monooxygenase. See also note 3 supra. In the final analysis, even though the inventors erroneously believed that TfdA was a monooxygenase, this Court should construe the claim "as written, not as the patentee[] wish[ed] [it] had written it." Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004).

Fourth, Bayer contends that Dow's construction would inappropriately render Claim 4 of the 401 Patent meaningless. Claim 4 depends on Claim 1 and refers to a figure displaying the DNA sequence for the *tfdA* gene, which Dow's construction of Claim 1 would exclude

from coverage. While courts generally "strive[] to reach a claim construction that does not render claim language in dependent claims meaningless," that interpretation is unavoidable here because "the only possible interpretation of the claim" terms at issue is the one that this Court has reached. Ortho-McNeil Pharma., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1362 (Fed. Cir. 2008)(contrasting the result there, where this "nonsensical result" could be avoided with the result in Chef Am. Inc. v. Lamb Weston, Inc., 358 F.3d 1371 (Fed. Cir. 2004) where such a result was unavoidable). Any other interpretation would simply be inconsistent with the plain language of the patent. As discussed above, the inventors deliberately chose the term monooxygenase. There is no dispute between the parties that the inventors had both a choice of words (monooxygenase, dioxygenase, hydroxylase) and the means to distinguish TfdA. The inventors chose monooxygenase because scientists believed, erroneously, that TfdA was just that. Because this Court cannot redraft Claim 1 to reflect the construction Bayer attempts to give it today, Claim 4 necessarily must fall.

Fifth, Bayer argues that Dow's construction would inappropriately impose the requirement, on Bayer, that the inventor understand the scientific principles on which the invention rests. In support of its argument, Bayer cites to the maxim that "an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests." Fromson v. Advance Offset

Plate, Inc., 720 F.2d 1565, 1570 (Fed. Cir. 1983). But that principle does not support Bayer's argument. Under that principle, a court will not limit a claim based on an inventor's erroneous belief as to the science behind the invention if there is "no basis" to read that belief as a claim limitation. Id. ("There is no basis or warrant for incorporating that belief as a limitation in the claims.") (emphasis added) Here, there is a firm basis to do so. The plain language of Claim 1 expressly refers to a monooxygenase. Moreover, as discussed, the inventors comprehended the scientific principles at issue: they were aware at the time of the filing of the 401 Patent of the distinction between monooxygenases and dioxygenases and how to test for them.

Sixth, Bayer contends that, in this context, the term "biological activity" should be read as limited to the portion of enzymatic activity responsible for cleaving the side chain. Bayer argues that this construction is justified because that was the only part of the activity of TfdA that was fully understood by scientists at the time of the invention and that would be detected by the complementation assay disclosed in the patent. That interpretation is flatly contradicted, however, by Bayer's own expert who explained that biological activity includes all enzymatic activity, whether it was known or unknown at the time. See generally Markman Tr. 166-169.

> The Court: But I want to focus on the use of the words "biological activity." Can that consume the enzymatic activity? Or are they so distinct that there is no - - you know when you look at a Venn diagram, it's overlapping?

A: Yes.

The Court: Does the term "biological activity" include "enzymatic activity?"

A: Let me try to explain—

The Court: No, no. You can't answer that yes or not?

A: The biological activity is the larger activity that within it there is some enzyme activity, but you don't always know what that enzyme activity is.

The Court: Okay. Thank you.

Markman Tr. 163:3-14.

The Court: Right. So the enzymatic activity is one or the other, dioxygenase or monooxygenase?

A: Right.

The Court: Monooxygenase. But either one is part of the biological activity? Yes or no?

A: When it's inside the cell, yes.

The Court: Okay.

Q: And when we're talking about actually the way TfdA works, that enzyme, right, in real life, we're talking about in a cell, right?

A: That is correct.

Markman Tr. 167:18-168:4.

B. Summary Judgment as to Non-Infringement

Because this Court has adopted Dow's construction of Claim 1 and because Bayer does not dispute that Dow's dioxygenase-based products would not infringe the 401 Patent under such construction, summary judgment as to Dow's non-infringement claim is warranted. See, e.g., Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1578

(Fed. Cir. 1996)("the question of literal infringement collapses to one of claim construction and is thus amendable to summary judgment."). The Court therefore need not address Dow's second argument set forth above or the construction of the remaining claims of the patent.

C. Summary Judgment as to Bayer's Proposed Construction for Failure to Provide Written Description

Alternatively, Dow argues that even if this Court accepted Bayer's broad functional-based claim construction ("cleavage of the side chain"), summary judgment in favor of Dow would still be warranted. Dow contends that Bayer's proposed claim construction would invalidate the patent for failure to satisfy the written description requirement of 35 U.S.C. § 112. This Court agrees.

Section 112 provides, in relevant part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112.

As discussed above, Bayer's proposed claim construction of Claim 1 is functional. It claims any DNA sequence encoding a polypeptide that has the function of converting 2,4-D into 2,4-DCP through the cleavage of the side chain 2,4-D and which is capable of being expressed in a plant. To satisfy the written description requirement where the patentee claims a broad class of genes, as proposed by Bayer

here, the patentee must demonstrate that it has possession "of sufficient species to show that he or she invented and disclosed the totality of the genus." Carnegie Mellon Univ. v. Hoffman-La Roche, Inc., 541 F.3d 1115, 1126 (Fed. Cir. 2008). This requirement may be satisfied (i) by disclosure of structural features common to members of the genus, (ii) by disclosure of a representative number of genes, (iii) where the proposed claim is functional, as here, "by functional characteristics coupled with [disclosure of a] known or disclosed correlation between function and structure," or (iv) by a combination of the above "sufficient to show the applicant was in possession of the claimed genus." Id. at 1124; Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010)(en banc); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002). Importantly, the written description requirement may not be satisfied by the disclosure of "a mere wish or plan for obtaining the claimed invention." Carnegie, 541 F.3d at 1122.

In this case, despite claiming a broad genus of genes based on function, Bayer has not disclosed structural features common to members of its claimed genus. Nor has it disclosed a representative number of genes; it has instead only disclosed a single gene – the *tfdA* gene. Bayer disputes none of this. Bayer instead contends that its written description is adequate on two other grounds.

First, it claims that its reference to, and deposit of, the mutant bacteria in a publically accessible depository and disclosure

of the complementation assay satisfies the written description requirement because together they provide a tool to identify other members of the class. This Court disagrees. Bayer's reference to the mutant in the patent is sufficient to describe the mutant itself. Enzo, 323 F.3d at 965 ("[W]e hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1."). But even if, as Bayer contends, the complementation assay, in conjunction with the mutant, allows persons of ordinary skill to "routinely identify and obtain" members of the claimed genus, it does not describe the members of the claimed genus, as required to demonstrate Bayer's possession of the claimed subject matter. It is instead an insufficient "plan for obtaining the claimed invention." Carnegie, 541 F.3d at 1122; Regents of the Univ. of Cal. V. Eli Lilly & Co., 119 F.3d 1559, 1566-67 (Fed. Cir. 1997)("Accordingly, an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.")(quotation omitted).[11] Indeed,

[11] In making its complementation assay argument, Bayer principally relies on Enzo Biochem, Inc. v. Gen-Probe Inc. 323 F.3d 956. Bayer claims that Enzo supports the notion that disclosure of a test, and material to utilize in that test to identify genes with common function, may be sufficient to satisfy the written description requirement. That

even Bayer's own witnesses testified that Bayer's proposed interpretation would render the 401 Patent overly broad.

> Q: Could you go anywhere in the world and find 2,4-D degrading microorganisms in soil samples?
>
> A: The answer is yes.
>
> Q: And give us a ballpark, like how many 2,4-D degrading microorganisms do you think you would see?
>
> A: I don't know how to answer that question, because one gram of soil can have a million types of microorganisms in it. We don't know how many would degrade 2,4-D. But you can isolate 2,4-D degrading microorganisms from almost any environment.
>
> Q: So in theory, just in theory, there could be billions that could degrade 2,4-D?
>
> A: Yes

Markman Tr. 186:12-24 (Dr. Hausinger).

> Q: Let me ask you this question. There are multiple sources, biological sources from which one could find a gene that encodes an enzyme that cleaves the side chain of 2,4-D; is that correct?

---

is not a correct reading of Enzo and that interpretation would run contrary to the Federal Circuit's repeated admonition that a plan for obtaining an invention is not enough to satisfy the written description requirement. Carnegie, 541 F.3d at 1122. Rather, in Enzo, the Federal Circuit merely recognized that, in claims for a broad class of genes that will hybridize with another substance under highly stringent conditions, disclosure of a limited number of genes may be capable of satisfying the written description requirement. Enzo, 323 F.3d at 967-68. The Federal Circuit reasoned that, for these claims, correlation between function and structure could potentially be established based on the recognized intrinsic relationship between the claimed function - hybridization at high stringency - and structure. Id. Therefore, Enzo did not disturb the rule that patent holders must sufficiently describe the structure of the claimed genus and not merely a plan to find its members. And, here, as discussed above, disclosure of the assay only discloses that Bayer had the ability to find genes with similar function to the claimed function. It does not establish any correlation between function and structure, as in Enzo.

A: That is correct.

Q: You can get it from animals, correct?

A: Yes.

Q: You can get it from plants, correct?

A: Yes.

Q: You can get those kind of genes from fungi, correct?

A: Yes.

Q: And you can get those kind of genes from soil bacterial, correct?

A: That's absolutely correct.

Markman Tr. 443:8-21 (Dr. Jones).

And, as discussed earlier, Dr. Hausinger testified that even sludge from sewage could cleave the side chain. Markman Tr. 185:2-16. These genes, however, are not described in the 401 Patent.

Second, Bayer argues that there is a known correlation between the claimed function and DNA structure and that this correlation may satisfy the written description requirement. While Bayer has presented scientific evidence in support of this argument, they have pointed to no portion of the patent itself that discloses such a correlation, as required. Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 925 (Fed. Cir. 2004)("In Enzo, we explained that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are coupled with a known or disclosed correlation

between function and structure, or some combination of such characteristics.")(quotation omitted); Enzo, 323 F.3d at 964 (Fed. Cir. 2002)("Thus, under the Guidelines, the written description requirement would be met for all of the claims of the '659 patent if the functional characteristic of preferential binding to N. gonorrhea over N. meningitides were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement.")(emphasis added).

In sum, even if this Court accepted Bayer's proposed construction, which it does not, Bayer's claim would fail as a matter of law. The claim would not provide an adequate written description and summary judgment in favor of Dow would be warranted on this ground also. Carnegie, 541 F.3d at 1127 (granting summary judgment based on written description where patent holder seeking protection of entire genus had only disclosed single gene and failed to demonstrate issue of fact that they had disclosed entire claimed genus).

III. Conclusion

For all these reasons, Bayer's motion for partial summary judgment is DENIED, Dow's motion for summary judgment of non-infringement is GRANTED, and Dow's remaining motions are DENIED as moot.

s/Renée Marie Bumb
RENÉE MARIE BUMB
United States District Judge

Dated: September 27, 2012