UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BAYER HEALTHCARE, LLC,	)	
	)	
Plaintiff,	)	No. 12 C 00630
	)	
v.	)	
	)	Judge Edmond E. Chang
ZOETIS INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

I. Introduction

This patent case between Bayer Healthcare, LLC and Pfizer, Inc.[1] is a fight about patent number 5,756,506 (the '506 patent), which is owned by Bayer. The '506 patent covers a process for treating bovine respiratory disease using "a pharmaceutically effective composition comprising a fluoroquinolone … in one high dose, single treatment."[2] In September 2012, the Court issued a claim-construction order after holding a *Markman* hearing. After discovery closed, Pfizer moved for reconsideration of the claim-construction order and for summary judgment on a number of invalidity defenses, including anticipation, obviousness, and lack of written description. Bayer responded with its own cross-motions against these invalidity claims; it also moved for summary judgment on infringement (to which

[1]As a formal matter, Pfizer spun-off a corporation, Zoetis Inc., which is now the named Defendant. See R. 418. For convenience's sake, because the exhibits and briefs refer to Pfizer, this Opinion will stick with that corporate name.

[2]The Court has subject matter jurisdiction over this case under 28 U.S.C. §§ 1331, 1338. Citations to the record are noted as "R." followed by the docket number and the page or paragraph number.

Pfizer cross-moved for non-infringement) and summary judgment against Pfizer's prior invention defense. After these motions were fully briefed, the parties reported that a settlement was likely and asked the Court to refrain from deciding on the pending motions. But settlement discussions were unsuccessful, so the Court now addresses these motions. For the reasons explained below, the Court decides as follows:

- Pfizer's motion to reconsider the claim-construction order, R. 355, is denied.
- Pfizer's motion for summary judgment for invalidity based on the lack of written description, R. 297, is denied. Bayer's cross-motion for summary judgment against Pfizer's written description defense, R. 349, is granted.
- Pfizer's motion for summary judgment for invalidity based on anticipation and obviousness, R. 302, is denied. Bayer's cross-motion for summary judgment against Pfizer's anticipation and obviousness defenses, R. 345, is granted.
- Bayer's motion for summary judgment against Pfizer's prior invention defense, R. 295, is denied.
- Bayer's motion for summary judgment on infringement, R. 270, is denied as to both direct infringement and inducement. Pfizer's cross-motion for summary judgment on non-infringement, R. 355, is granted as to direct and contributory infringement, but denied as to inducement.

II. Background

A. Fluoroquinolones

Bovine respiratory disease (BRD), which is also called "shipping fever," is a serious problem in the cattle industry that causes significant cattle deaths each year. DSOF (Anticipation/Obviousness) ¶¶ 29, 38; R. 300-17, Def.'s Exh. 17, Babish Report ¶ 51; R. 309-14, Def.'s Exh. 14, Clay Report ¶ 64.[3] It is primarily caused by

[3]The parties submitted four sets of Local Rule 56.1 statements of facts. They are abbreviated as follows:

- For Bayer's motion for summary judgment on infringement, R. 270, and Pfizer's cross-motion on non-infringement and motion to reconsider the claim-construction order, R. 355 (Pfizer briefed these two motions together):
    - "PSOF (Infringement)" (for Bayer's Statement of Facts) [R. 272]; "Def.'s Resp. PSOF (Infringement)" (for Pfizer's Response to Bayer's Statement of Facts) [R. 357 at 1]; "DSOF (Infringement)" (for Pfizer's Statement of Additional Facts) [R. 357 at 12]; "Pl.'s Resp. DSOF (Infringement)" (for Bayer's Response to Pfizer's Statement of Additional Facts) [R. 376].
- For Bayer's motion for summary judgment on Pfizer's prior invention defense, R. 295:
    - "PSOF (Prior Invention)" (for Bayer's Statement of Facts) [R. 298]; "Def.'s Resp. PSOF (Prior Invention)" (for Pfizer's Response to Bayer's Statement of Facts) [R. 354 at 1]; "DSOF (Prior Invention)" (for Pfizer's Statement of Additional Facts) [R. 354 at 24]; "Pl.'s Resp. DSOF (Prior Invention)" (for Bayer's Response to Pfizer's Statement of Additional Facts) [R. 379].
- For Pfizer's motion for summary judgment for invalidity based on lack of written description, R. 297, and Bayer's cross-motion against Pfizer's written description defense, R. 349:
    - "DSOF (Written Description)" (for Pfizer's Statement of Facts) [R. 300]; "Pl.'s Resp. DSOF (Written Description)" (for Bayer's Response to Pfizer's Statement of Facts) [R. 351 at 1]; "PSOF (Written Description)" (for Bayer's Statement of Additional Facts) [R. 351 at 29]; "Def.'s Resp. PSOF (Written Description)" (for Pfizer's Response to Bayer's Statement of Additional Facts) [R. 382].
- For Pfizer's motion for summary judgment for invalidity based on anticipation and obviousness, R. 302, and Bayer's cross-motion against Pfizer's anticipation and obviousness defenses, R. 345:
    - "DSOF (Anticipation/Obviousness)" (for Pfizer's Statement of Facts) [R. 309]; "Pl.'s Resp. DSOF (Anticipation/Obviousness)" (for Bayer's Response to Pfizer's Statement of Facts) [R. 347 at 1]; "PSOF (Anticipation/Obviousness)" (for Bayer's Statement of Additional Facts) [R. 347 at 27]; "Def.'s Resp. PSOF

the bacteria *pasturella haemolytica* and *pasturella multocida.* PSOF (Written Description) ¶ 380; Babish Report ¶ 52; R. 309-7, Def.'s Exh. 7, 1/17/13 Papich Dep. 236:5-9; R. 309-18, Def.'s Exh. 18, 1990 Veterinary Medicine Textbook at PFE_BAY0002969. Bayer and Pfizer are pharmaceutical companies that make animal health products; in the late 1980s and early 1990s, both companies sought to develop new treatments for BRD using fluoroquinolones. PSOF (Anticipation/Obviousness) ¶¶ 251, 259; R. 348-18, Pl.'s Exh. 97, 6/19/12 Copeland Dep. 41:9-44:20; R. 348-13, Pl.'s Exh. 92, 7/20/12 Boettner Dep. 68:15-22; R. 321, Pl.'s Exh. 60, Pfizer 93-052 Study. Fluoroquinolones are a class of antimicrobials[4] that were invented in the 1970s and 1980s and later used to combat diseases in food-producing animals. DSOF (Written Description) ¶ 7; Clay Report ¶ 27; R. 353-12, Pl.'s Exh. 131, Papich Report ¶ 13. All fluoroquinolones share the same basic chemical structure and kill bacteria by targeting two enzymes: DNA Gyrase and Topoisomerase IV. PSOF (Written Description) ¶ 374; Papich Report ¶¶ 14-15; Clay Report ¶ 28; Babish Report ¶ 41. In the late 1980s and early 1990s, various studies investigated the pharmacokinetics (how the body affects a drug's absorption, distribution, and metabolism) as well as the pharmacodynamics (how a drug affects the body) of fluoroquinolones. R. 309-22, Def.'s Exh. 22, 1993 Craig Article

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(Anticipation/Obviousness)" (for Pfizer's Response to Bayer's Statement of Additional Facts) [R. 384].

Where a fact is admitted, only the asserting party's statement of facts is cited; where an assertion is otherwise challenged, it is so noted. The Court cites to the sealed versions of the briefs and exhibits. As the Court later explains, the parties must explain why any facts and exhibits discussed in this Opinion should remain sealed.

[4]The parties refer to fluoroquinolones as both antimicrobials and antibiotics. Although these two types of drugs work differently in combating bacteria, Babish Report ¶ 45; Papich Report ¶ 13 n.1, the differences are not material for purposes of these motions.

("Pharmacodynamics of Antimicrobial Agents as a Basis for Determining Dosage Regimens"); R. 309-25, Def.'s Exh. 25, 1993 Sullivan Article (investigating pharmacokinetics and pharmacodynamics in article entitled "Evaluation of the Efficacy of Ciprofloxacin against *Streptococcus pneumoniae* by Using a Mouse Protection Model"); R. 309-21, Def.'s Exh. 21, 1995 Meinen Article ("Pharmacokinetics of enrofloxacin in clinically normal dogs and mice and drug pharmacodynamics in neutropenic mice with *Escherichia coli* and staphylococcal infections").

In the early to mid-1990s, a number of fluoroquinolones were believed to be effective at treating BRD, including danofloxacin, enrofloxacin, and ciprofloxacin, although the full range of fluoroquinolones was still unknown. PSOF (Written Description) ¶ 28; R. 348-27, Pl.'s Exh. 106, 1991 Giles and Grimshaw Article ("Efficacy of danofloxacin in the therapy of acute bacterial pneumonia in housed beef cattle"); R. 300-9, Def.'s Exh. 9, 1/24/13 Clay Dep. 209:14-18 (explaining that "there are any number of fluoroquinolones that could be effective"). The literature also began to reveal that fluoroquinolones were concentration-dependent drugs, meaning (as the name suggests) that the effectiveness of these drugs depends on whether the drug's concentration in the blood or tissue has reached a certain minimum inhibitory concentration (MIC) needed to kill the bacteria. DSOF (Anticipation/Obviousness) ¶¶ 51-53; 1993 Craig Article at PFE_BAY0002229 ("Since the aminoglycosides and quinolones[5] demonstrate concentration-dependent

[5]Fluoroquinolones are a subclass of quinolones. Pl.'s Resp. DSOF (Anticipation/Obviousness) ¶ 30; Babish Report ¶¶ 39-40 (explaining that "[q]uinolones are

killing, large doses should produce similar or superior bacterial killing than multiple small doses … . The major goal of a dosage regimen for these drugs would be to maximize concentration."); 1993 Sullivan Article at PFE_BAY0002234 ("[O]ptimal dosing of quinolones may involve the use of large single doses to attain the high levels in serum necessary to achieve a high ratio of maximum concentration in serum/MIC."); 1995 Meinen Article at BHC00036079 ("With concentration-dependent bactericidal activity, the rate and extent of killing increases as the concentration of the drug increases."); Babish Report ¶¶ 46-48. In contrast, the effectiveness of time-dependent drugs depends on maintaining the drug in the bloodstream at a concentration above the MIC for an extended period of time. DSOF (Anticipation/Obviousness) ¶¶ 51, 53; Babish Report ¶ 47; 1995 Meinen Article at BHC00036076 ("For antimicrobials that kill by time-dependent mechanisms, the pharmacokinetic value that correlates with efficacy is the time that serum concentration remains above the [MIC] or the pathogen."). Bayer, on the other hand, disagrees that a person having ordinary skill in the art would have appreciated the concentration-dependent nature of fluoroquinolones at the time.

In the United States, fluoroquinolones became commercially available to treat BRD in 1995. Pl.'s Resp. DSOF (Written Description) ¶ 23; R. 300-13, Def.'s Exh. 13, 5/15/13 Clay Dep. 12:17-19. Around this time, the conventional fluoroquinolone treatment for BRD involved several doses given over multiple days. PSOF (Anticipation/Obviousness) ¶ 241; R. 348-11, Def.'s Exh. 90, 6/13/12 Giles

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synthetic chemical compounds that were developed to combat bacterial infections," and that fluoroquinolones are a "modification of the basic quinolone structure through the addition of a fluorine atom at position 6 (F6)").

Dep. 55:17-23, 77:12-15, 205:8-21; 7/20/12 Boettner Dep. 48:3-11. For example, a typical regimen could be 1.25 mg/kg given once for three to five days. *Id.*; *see also* 6/13/12 Giles Dep. 63:23-64:17; 1991 Giles and Grimshaw Article at PFE_BAY0000654 (testing a 1.25 mg/kg dose of danofloxacin given once daily for three consecutive days, and two additional days if pneumonia was still present); R. 304-7, Pl.'s Exh. 47, 1987 Bauditz Article at PFE_BAY0000465[6] (recommending a 2.5 mg/kg dose over three days for calves). Even though it was known that fluoroquinolones were concentration-dependent rather than time-dependent, a multi-day dosage remained the conventional regimen, as there were still perceived benefits to maintaining the dosage in the bloodstream for an extended period of time, such as to prevent resistance and relapse. PSOF (Anticipation/Obviousness) ¶ 243; 1993 Craig Article at PFE_BAY0002229-30 (even though fluoroquinolone efficacy "was dependent on the amount of drug administered, not on how often it was administered … there might be other reasons for preferring certain dosage regimens," including to prevent "[t]he emergence of resistant organisms"); 1993 Sullivan Article at PFE_BAY0002235 (some bacterial diseases like pneumococcus "may present a special penetration problem for ciprofloxacin, i.e., slow rate of antimicrobial uptake that allows effective concentrations to be attained only after several days of multiple dosing"). As explained in more detail later in the Opinion, Pfizer disagrees with this point, arguing that the concentration-dependency quality of fluoroquinolones obviated the need for multi-day dosing regimens.

[6]The Bauditz article submitted by the parties does not have a date, but the parties agree that it was published in 1987. Pl.'s Resp. DSOF ¶ 12 (Anticipation/Obviousness).

The parties do agree that there was increasing motivation in the cattle and pharmaceutical industries to develop a single-dose treatment for BRD. DSOF (Anticipation/Obviousness) ¶¶ 38-44; Babish Report ¶ 51; Clay Report ¶ 64; R. 309-15, Exh. 15, 1/24/13 Clay Dep. 78:2-80:1; R. 309-17, Def.'s Exh. 17, 1990 Gorham Article at PFE_BAY0000658-59. A single-dose treatment would save money by reducing the time and resources needed to identify and treat sick animals, decreasing tissue damage caused by injections, and minimizing the stress on cattle from multiple treatments. *Id.* As a result, the pharmaceutical industry began moving towards a single-dose product that was long acting—that is, a drug that would be administered once, but that would stay in the bloodstream for an extended period of time, so that the overall length of treatment remained the same. PSOF (Anticipation/Obviousness) ¶¶ 245-48, 251; 6/19/12 Copeland Dep. 44:4-14, 45:23-46:6, 94:23-95:9, 259:7-24. Both Bayer and Pfizer's development efforts, as explained below, reflected that trend.

B. Bayer's Fluoroquinolone Development

1. Bayer's Research

In the 1980s, Bayer began developing a multi-day regimen using enrofloxacin, a type of fluoroquinolone, for the treatment of BRD. PSOF (Prior Invention) ¶ 126; R. 310, Pl.'s Exh. 46, 6/19/12 Copeland Dep. 41:9-42:2. The enrofloxacin showed broad antibacterial activity in low concentrations, efficacy against resistant strains, high absorption ability, and good tolerance in all species.

1987 Bauditz Article at PFE_BAY0000460. The recommended dose and length of treatment for calves was 2.5 mg/kg for three days. *Id.* at PFE_BAY0000465.

Because of the desire for a more convenient treatment regimen, Bayer began pursuing a long-acting (or sustained-release) formulation[7] of fluoroquinolone that could be given in a single dose—that is, a drug that was administered only once, but that maintained a certain blood MIC level for an extended period of time. PSOF (Prior Invention) ¶¶ 125, 127; 6/19/12 Copeland Dep. 44:4-14, 94:7-95:9, 259:7-24. But after the sustained-release formulas did not provide the desired results, Bayer changed course and began testing a single-shot treatment that was *not* long acting—that is, a high dose that did not maintain a MIC level for an extended period of time. *Id.*; PSOF (Prior Invention) ¶¶ 128-29; R. 311, Pl.'s Exh. 48, 8/4/10 Copeland Dep. 155:4-156:17.

In October 1994, Bayer conducted a study (labeled the 94A-002 Study) that compared three different dosages of enrofloxacin on cattle suffering from BRD: (1) 0 mg/kg (a control); (2) 2.5 mg/kg given once daily for three days; (3) 7.5 mg/kg given once or 15 mg/kg given once. R. 312, Pl.'s Exh. 49, Bayer 94A-002 Study at BHC00036543. "The objective of this study was to determine if a single elevated dose of enrofloxacin was as effective as the established daily dose of 2.5 mg/kg given once daily for three days." *Id.* at BHC0003642. Evaluating outcomes of mortality rates, percentage of lung consolidation, and weight gain after the treatment

[7]A drug formulation describes the materials that are combined with the active drug to produce the final product; the formulation can affect the drug's response in the animal. *See* 5/15/12 Clay Dep. 34:17-35:2. For example, a fluoroquinolone can be delivered through a "sesame oil gelled carrier with an aluminum substance," 7/20/12 Boettner Dep. 48:19-22, or a "mesylate in water," Pfizer 93-052 Study at PFE_BAY0001305.

regimens, the study concluded that "[t]he three treatment groups were not significantly different from each other in any of the variables examined." *Id.* at BHC00036543. Further, "[t]hese data support[ed] the 7.5 mg/kg dose of enrofloxacin given once subcutaneously as an equivalent efficacious alternative to the 2.5 mg/kg dose of enrofloxacin given daily for three days. The 15.0 mg/kg dose given once was not more efficacious than the 7.5 mg/kg dose." *Id.*

2. The '506 Patent

The results of the 94A-002 Study led Bayer to file the '506 patent on May 27, 1997, as a continuation of an earlier application filed on June 27, 1995. Def.'s Resp. PSOF (Prior Invention) ¶ 131; '506 Patent at [22] (listing filing date of May 27, 1997), col. 1 ll. 4-5 (explaining that "[t]his application is a continuation of application Ser. No. 08/496,117, filed June. 27, 1995, now abandoned"). The patent was issued on May 26, 1998. *Id.* at [45]. The background of the '506 patent explains that although the established fluoroquinolone treatment at the time involved daily doses for three to five consecutive days, the prior "art has not taught use of a single elevated dose of a fluoroquinolone to treat the likes of bovine respiratory diseases," in part "due to the perceived need for a special formulation to prolong the blood levels." *Id.* col. 1 ll. 18-21, 27-27. But "[s]urprisingly, it has been found that a single, high dose of fluoroquinolones can be administered to effectively treat" BRD, and this dose "replace[d] repeated treatments without the need for special prolonged release formulations." *Id.* col. 2 ll. 14-18, col. 1 ll. 28-31. The patent then gives three example studies; the first compared three different enrofloxacin dosing regimens—

2.5 mg/kg for three days, 7.5 mg/kg once, and 15 mg/kg once (plus a control of no treatment)—and concluded that the three treatment groups were equally successful, as measured by mortality rates, lung consolidation, and weight gain. *Id.* col. 2 ll. 25-49. This first example reflected Bayer's 94A-002 experiment, as explained above. The second example in the patent compared three dosages of enrofloxacin—5.0 mg/kg once, 7.5 mg/kg once, and 2.5 mg/kg over three days (with a control of no treatment)—with a single injection of tilmicosin, which is a long-acting non-fluoroquinolone (with the brand name Micotil). *Id.* col. 2 l. 51 to col. 3 l. 11; Clay Report ¶ 21 ("Micotil, also known as tilmicosin, was a member of the macrolide class of drugs … Micotil was also a type of treatment known in the field as a 'long acting' drug."). The results concluded that the "7.5 mg/kg of enrofloxacin given as a single injection is as effective as 3 daily injections of 2.5 mg/kg enrofloxacin. It is also as effective as a single injection of the long acting tilmicosin." '506 Patent col. 3 ll. 8-11. The third example in the patent tested enrofloxacin on swine, and also concluded that the single 7.5 mg/kg and 10 mg/kg doses were as effective as three daily injections of 2.5 mg/kg. *Id.* col. 3 ll. 12-37.

After describing the studies, the '506 patent claimed, in relevant part:

> 1. A process for treating a bacterial infection in an animal in need thereof comprising administering to said animal a pharmaceutically effective composition comprising a fluoroquinolone, an ester, or a salt thereof in one high dose, single treatment.
>
> …
>
> 4. The process of claim 1, wherein the bacterial infection is bovine respiratory disease.

5. The process of claim 4, wherein the bovine respiratory disease is caused by Pasturella, haemolytica or Pasturella multocida.

Id. col. 4 ll. 10-28.

In the fall of 1998, after conducting the 94A-002 Study and filing the '506 patent application, Bayer launched a product called Baytril 100 (or Baytril for short), which Bayer characterizes as the "commercial embodiment of the '506 patent." PSOF (Prior Invention) ¶ 132. The label described Baytril as an "antimicrobial solution that contains enrofloxacin, a broad-spectrum fluoroquinolone antimicrobial agent" to treat BRD associated with *mannheimia haemolytica*, *pasteurella multocida* and *haemophilus somnus*. R. 304-12, Pl.'s Exh. 52, Baytril Label at BHC00023580. The drug could be administered as a single-dose therapy of 7.5 to 12.5 mg/kg, or as a multiple-day therapy of 2.5 to 5.0 mg/kg given once daily for three days, and up to five days for "animals which have shown clinical improvement but not total recovery." *Id.* The label also informed that "[s]election of the appropriate dose and duration of therapy should be based on an assessment of the severity of disease, pathogen susceptibility and clinical response." *Id.*

C. Pfizer's Fluoroquinolone Development

1. Pfizer's Research

Like Bayer, Pfizer was also working on various BRD treatments; in the 1980s, it released LA-200, which was a long-acting formulation of tetracycline (another type of antibiotic). Def.'s Resp. PSOF (Prior Invention) ¶ 141; Clay Report ¶ 22. Pfizer also began working on a fluoroquinolone product; in 1989, it began a several-year investigation of danofloxacin in a long-acting formulation. R. 354-31,

Def.'s Exh. 31, Pfizer Notebook 18531 at PBA_00292761-62 ("Long-Acting I.M.[8] Injectable Development"); R. 354-32, Def.'s Exh. 32, Pfizer Notebook 20730 at PBA_00176095-97 (listing several danofloxacin index entries with "LA" dosage, including "Preparation of Danofloxacin LA formulations for Testing in Cattle in Terre Haute"); R. 354-33, Def.'s Exh. 33, Pfizer Notebook 22960 at PBA_00176715-16 (listing several danofloxacin index entries with "LA" dosage); R. 354-34, Def.'s Exh. 34, Pfizer Notebook 24463 at PBA_00177022-23 (same); R. 354-35, Def.'s Exh. 35, Pfizer Notebook 24673 at PBA_00177345-51 (same). Although Pfizer argues that it was testing a single, high dose of danofloxacin, DSOF (Prior Invention) ¶¶ 201-02, all of the excerpts of the early laboratory records that were provided to the Court clearly state "long-acting" or "LA." *Id.*

At the same time, Pfizer was also conducting pharmacokinetic and injection site toleration tests on cattle for various danofloxacin formulations and dosages. DSOF (Prior Invention) ¶ 203; R. 354-39, Def.'s Exh. 39, Pfizer 91-017 Study at PBA_00178179 (noting a 2.5 mg/kg dose, but unclear as to the duration of therapy); R. 354-41, Def.'s Exh. 41, Pfizer 92-019 Study at PBA_00178168 (noting a 6 mg/kg dose in various oil vehicles, but unclear as to the duration of therapy), PBA_00178172 (listing experiment title as "Long-Acting Formulations of Danofloxacin-Pharmacokinetics"); R. 351-42, Def.'s Exh. 42, Pfizer 92-009-5 Study at PBA_00178194 (listing objective of "Discovery-Pharmacokinetics Screen and Injection Site Toleration (CP-133, 805-Danofloxacin Pro-drug)"). One of these tests did involve a single injection of 25 mg/ml in water, but the study was focused on

[8]"IM" stands for "intramuscularly." 7/20/12 Boettner Dep. 48:3-10.

observations of the injection site, rather than the drug's effect on BRD caused by *pasturella haemolytica* or *pasturella multocida.* DSOF (Prior Invention) ¶ 203; R. 354-40, Def.'s Exh. 40, Pfizer 91-009 Study at PBA_00178144 (listing objective of "Discovery Cattle Injection Site Toleration Screen"). Pfizer published the results of these studies in various articles. DSOF (Prior Invention) ¶ 204; R. 354-46, Def.'s Exh. 46, 1991 Giles and Magonigle Article ("Clinical pharmacokinetics of parenterally administered danofloxacin in cattle"); R. 354-45, Def.'s Exh. 45, 1992 Mann Article ("Pharmacokinetic study of danofloxacin in cattle and swine").

In 1993, Pfizer began "full-scale efficacy testing" of danofloxacin treatments for BRD, focusing on the long-acting formulation. DSOF (Prior Invention) ¶ 206. For example, experiment number 1831B-60-93-050 ("the 93-050 Study") compared a "conventional" multi-day regimen with two long-acting formulations. *Id.*; R. 320, Def.'s Exh. 59, Pfizer 93-050 Study at PFE_BAY0001277. Pfizer tested a saline control as well as three treatment groups, one of which was "CP 76, 136-27 (1.25 mg/kg, SIDX3, IM)," which scientist Wayne Boettner explained was the "conventional formulation" of 1.25 mg/kg dose given once daily for three days. Pfizer 93-050 Study at PFE_BAY0001278; 7/20/12 Boettner Dep. 48:3-11. This conventional dose was compared to two "gelled oil formulations" with doses of 6 mg/kg and 3.75 mg/kg. Pfizer 93-050 Study at PFE_BAY0001278. Pfizer hoped that these gelled oil formulations would produce a long-acting drug. 7/20/12 Boettner Dep. 48:12-49:15. [redacted]

[redacted]

After conducting the 93-050 Study, Pfizer conducted experiment number 1831B-60-93-052 ("the 93-052 Study"), which was entitled "Comparative evaluation of the therapeutic efficacy of conventional and single-shot formulations of danofloxacin (CP 76,136) against natural bovine respiratory disease." DSOF (Prior Invention) ¶¶ 206-208; Pfizer 93-052 Study. This time, the test materials included (1) a saline control; (2) 25 mg/ml danofloxacin in a formulation of "mesylate in water"; (3) 60 mg/ml danofloxacin in a formulation of "zwitterion in Terramycin-LA vehicle (peak-only profile)"; (4) 60 mg/ml danofloxacin in a formulation of "zwitterion in phosphate buffer with suspending agents (tail-only profile)"; (5) 60 mg/ml danofloxacin in a formulation of "mesylate in sesame oil gelled with 1.5% aluminum monostearate (peak and tail profile, positive control)"; and (6) 60 mg/ml danofloxacin in a formulation of "sulfate in Synergistin vehicle (peak and tail profile)." Pfizer 93-052 Study at PFE_BAY0001305-06. Test material number two, the 25 mg/ml danofloxacin, was the conventional dosage of 1.25 mg/kg administered over three days. *Id.* at PFE_BAY0001304; 7/20/12 Boettner Dep. 73:1-20. And according to Pfizer, "peak and tail" profiles—test items five and six—were long-acting formulations that sustain the drug concentration over a period of time, while the "peak only" formulation—test item three—had a high concentration that rapidly

trailed off. DSOF (Prior Invention) ¶ 211; R. 354-27, Def.'s Exh. 27, 6/7/12 Mann Dep. 39:2-40:16. The 93-052 Study ultimately concluded that "formulations which induced either peak-only or peak and tail plasma pharmacokinetic profiles provided efficacy similar to that observed with the conventional dose and regimen." Pfizer 93-052 Study at PFE_BAY0001304. Further, "presentations of danofloxacin which induce either a substantial peak plasma concentration or moderate peak concentrations in combination with a sustained release provide efficacy similar to or better than that observed with the conventional dose and regimen." *Id.* So Pfizer contends that this 93-052 Study revealed that the single high-dose treatment with a "peak only" profile, which was a non-long-acting formulation, was just as effective as a multi-day dose. DSOF (Prior Invention) ¶¶ 212-213. Pfizer also claims that the "peak only" formulation used in the 93-052 Study was the most successful and ultimately commercialized. *Id.* ¶ 214. Bayer, on the other hand, disputes that Pfizer had successfully created a non-long-acting, single-dose BRD treatment in the 93-052 Study. Pl.'s Resp. DSOF (Prior Invention) ¶¶ 212-214; *see also* R. 378, Pl.'s Reply (Prior Invention) at 11-12.

On December 2, 1994, Pfizer's danofloxacin formulation committee sent a memo to Dr. A. C. Goudie summarizing its conclusions about its danofloxacin development efforts. DSOF (Prior Invention) ¶ 217. The Goudie Memo stated that single-shot danofloxacin did not work well:

> In order to meet the future needs of this market, we initiated a research program in 1990 seeking a formulation of danofloxacin which delivered efficacy against BRD following a single injection that would be comparable or superior to the best available treatments. Many

> different pharmaceutical technologies were evaluated in pursuit of this ambitious objective. *Unfortunately, we were not able to identify a single-shot danofloxacin presentation, and we have since halted this research due to greatly diminished prospects for future success.*

R. 325, Pl.'s Exh. 64, Goudie Memo at PBA_00229315 (emphasis added). According to Bayer, the Goudie Memo shows that Pfizer abandoned its work on a single-shot BRD treatment and pursued a two-shot product instead. PSOF (Prior Invention) ¶ 147. But Pfizer asserts that it continued to work on a single-dose danofloxacin product from 1994 to 1997, despite the recommendations in the Goudie Memo. DSOF (Prior Invention) ¶¶ 217-220; R. 345-13, Def.'s Exh. 13, 95-206 Study (testing the plasma pharmacokinetics of single-dose 1.25 mg/kg, 6 mg/kg and 10 mg/kg treatments); R. 285, Pl.'s Exh. 20, Pfizer 96-249 Study (testing a single-dose 8 mg/kg treatment in an Idaho feedlot); R. 286, Pl.'s Exh. 21, Pfizer 96-250 Study (testing a single-dose 8 mg/kg treatment in a California feedlot); R. 287, Pl.'s Exh. 22, Pfizer 97-258 Study (testing a single-dose 8 mg/kg treatment in a Texas feedlot); R. 288, Pl.'s Exh. 23, Pfizer 97-261 Study (testing a single-dose 8 mg/kg treatment in a Nebraska feedlot).

2. A180

In 1996, Pfizer was preparing for the release of Advocin 180 (or A180 for short), a new single-dose danofloxacin treatment that could also be used as a two-shot treatment. DSOF (Prior Invention) ¶ 221. Bayer was aware of Pfizer's ongoing work during this time period; in May 1996, Bayer noted in its Baytril Market Launch Plan that "Advocin is a fluoroquinolone. Its stage of development and regulatory approval is most threatening to Baytril. We are uncertain where Pfizer is

in its development and registration of Advocin, however we know that they are pursuing development of danofloxacin as a single-dose product." DSOF (Prior Invention) ¶ 239; R. 354-74, Def.'s Exh. 74, Baytril Launch Plan at BHC00132747. In October 1996, Pfizer completed its Full Development Plan for danofloxacin, explaining that "[s]trategic administration of one to two high-dose injections of danofloxacin 18% injectable solution will provide effective therapy for Bovine Respiratory Disease and [redacted] while meeting the needs of customers who demand low frequency regimens for cattle." DSOF (Prior Invention) ¶ 221; R. 354-60, Def.'s Exh. 60, Pfizer Full Dev. Plan at PBA_00041166. The report discussed plans to release the product across the world. *Id.*

In 1998, after completing additional testing, Pfizer submitted an application to the Food and Drug Administration (FDA) to register A180 as both a single-shot and two-shot treatment. DSOF (Prior Invention) ¶ 222; R. 354-9, Def.'s Exh. 9, 4/29/98 Pfizer Letter to FDA at PBA_00003170-71 (requesting review of Advocin "at a single dose of 8 mg/kg body weight … or two injections of 6 mg/kg body weight … administered 48 hours apart."). But in 2002, the FDA expressed concerns with potential bacterial resistance and rejected the single-shot product in the human food safety portion of the approval process. DSOF (Prior Invention) ¶ 223; R. 354-11, Def.'s Exh. 11, 1/15/02 FDA Letter to Pfizer at PBA_00022249 ("[B]ecause of the results of the bacterial resistance study with respect to Treatment 3 (10 mg/kg, SID X 1), this [issuance of a human food safety technical section complete letter] is not possible. We recommend that you consider a similar request for the proposed

conditions of use in Treatment 2 (6 mg/kg, q48 x 2) alone."). Ultimately, for various business reasons, Pfizer decided not to pursue approval of the single-shot danofloxacin product in the United States, though Pfizer did move forward with its two-shot product. DSOF (Prior Invention) ¶¶ 224-225; R. 354-6, Def.'s Exh. 6, 6/13/12 Giles Dep. 242:20-245:13. In October 2002, Pfizer received FDA approval for its two-shot A180 product, DSOF (Prior Invention) ¶ 226; R. 354-65, Def.'s Exh. 65, 10/02/02 FDA Letter to Pfizer, with an approved dosage of two 6 mg/kg injections given 48 hours apart. PSOF (Infringement) ¶ 10; R. 279, Pl.'s Exh. 10, 5/16/12 Pollreisz Dep. 19:6-24.

3. Advocin

In January 2012, around ten years after A180 was released, the FDA approved an additional dosage regimen for A180 "for the treatment of bovine respiratory disease in beef cattle … associated with *Mannheimia haemolytica*, and *Pasteurella multocida* in beef cattle." PSOF (Infringement) ¶ 20; R. 273-15, Pl.'s Exh. 15, 77 Fed. Reg. 4226 (January 27, 2012). A180 could now be used as a single-dose 8 mg/kg treatment. *Id.* at 4227.

Pfizer began rebranding A180, which could now be used as a single or double-dose treatment, as Advocin. Def.'s Resp. PSOF (Infringement) ¶¶ 9-19, 22, 38-49; R. 273-13, Pl.'s Exh. 13, 1/27/12 Pfizer Webinar 33:19-34:1 ("And the third equally fundamental attribute, it has to work in a single-dose regimen. Products that do not work in a single-dose regimen are not really practical in today's environment. So [we] wanted to make the awareness of a single-dose regimen [] more prominent with

a new brand and a chance to introduce this."). Pfizer also began comparing Advocin to Baytril; in an internal presentation called the "Advocin Launch Plan," Pfizer explained that there were "only two existing FQ [fluoroquinolone] BRD treatment drugs at present: Baytril (enrofloxacin) [and] A-180 (danofloxacin)." R. 280, Pl.'s Exh. 11, Advocin Launch Plan at PBA_00056448. The launch plan also stated that "Baytril holds 94% MS [market share] of the FQ [fluoroquinolone] market" and "is the second largest BRD treatment product in feedlot/stocker markets" with sales of $64 million, as compared to A180's $4 million. *Id.* In comparison to Baytril, A180 also had "poor product adoption" because the "[t]wo-shot FQ [was] less convenient versus one-shot Baytril." *Id.* at PBA_00056445. Recognizing that Bayer's '506 patent was expiring in 2015, [redacted] *Id.* at PBA_00056458. [redacted] *Id.* Pfizer's other marketing materials similarly highlighted Advocin's single-dose characteristic and drew direct comparisons to Baytril. *E.g.*, R. 283, Pl.'s Exh. 16, Advocin Ad (stating "battle of the BRD antimicrobials" and "Advocin vs. Baytril" underneath a photo of the two products); R. 273-17, Pl.'s Exh. 17, 1/26/12 Pfizer Webinar 27:10-13 ("You now have a second option with a single injection or a single-day regimen fluoroquinolone. Our plan is to make it a cost-effective alternative to Baytril."); R. 292, Pl.'s Exh. 28, Advocin Presentation at PFE_BAY0000037 (explaining that the "3 key messages"

were "single shot FQ, cost-effective alternative to Baytril, [and] 4 day withdrawal time"); R. 293, Pl.'s Exh. 29, 2012 Priority Update Letter at PBA_00294438 ("Pfizer Animal Health is excited to announce that you have a new single dose fluoroquinolone to treat cattle with bovine respiratory disease (BRD) … ADVOCIN is an injectable antimicrobial with the following key benefit[]: Cost-effective alternative to Baytril® (enrofloxacin) … ."). And J.P. Pollreisz, Pfizer's technical services veterinarian, remembers speaking to ten to fifteen individual customers about using Advocin as a single-dose regimen and was aware of three customers who actually did. PSOF (Infringement) ¶¶ 47-49; 5/16/12 Pollreisz Dep. 157:9-158:24.

D. Present Litigation

On January 30, 2012, Bayer brought this lawsuit against Pfizer for direct and induced infringement of the '506 patent. R. 1, Compl. In its Answer, Pfizer asserted various defenses and counterclaims, including non-infringement and invalidity "for failure to satisfy … 35 U.S.C. §§ 101, 102, 103, 112 and/or for being in violation" of any other section of Title 35. R. 67, Answer at 13-15. The Court held a *Markman* hearing about the meaning of "one high dose, single treatment" in Claim 1 of the '506 patent, R. 224, which Pfizer argued was indefinite. But the Court held that this claim was valid, and that the disputed terms "mean[t] the effective single dose that prevents death and cures the disease to the equivalent degree of lower, multiple doses." R. 226, 9/18/12 Order at 7. After discovery closed, both parties filed various summary judgment motions. First, Bayer moved for summary judgment on direct

and induced infringement. R. 270. Pfizer then cross-moved for non-infringement on direct, contributory, and induced infringement, R. 355, and also moved to reconsider the claim construction order of "one high dose, single treatment," *id.* Pfizer also moved for summary judgment on invalidity for lack of a written description, R. 297, anticipation, R. 302, and obviousness, *id.,* against all of which Bayer cross-moved, R. 349 (written description), R. 345 (anticipation), *id.* (obviousness). Finally, Bayer also moved for summary judgment against Pfizer's prior-invention defense, R. 295, to which Pfizer did not cross-move. The parties attempted to settle the case but ultimately were unsuccessful. R. 427.

III. Legal Standards

A. Summary Judgment Standard

Summary judgment must be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine issue of material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In evaluating summary judgment motions, courts must view the facts and draw reasonable inferences in the light most favorable to the non-moving party. *Scott v. Harris*, 550 U.S. 372, 378 (2007). When both parties move for summary judgment, the Court must draw reasonable inferences in Bayer's favor on Pfizer's motion, and vice-versa on Bayer's motion. The Court may not weigh conflicting evidence or make credibility determinations, *Omnicare, Inc. v. UnitedHealth Grp., Inc.*, 629 F.3d 697,

704 (7th Cir. 2011), and must consider only evidence that can "be presented in a form that would be admissible in evidence." Fed. R. Civ. P. 56(c)(2). The party seeking summary judgment has the initial burden of showing that there is no genuine dispute and that she is entitled to judgment as a matter of law. *Carmichael v. Vill. of Palatine*, 605 F.3d 451, 460 (7th Cir. 2010); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Wheeler v. Lawson*, 539 F.3d 629, 634 (7th Cir. 2008). If this burden is met, the adverse party must then "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 256.

B. Motion for Reconsideration Standard

Pfizer also moves to reconsider the Court's prior claim construction Order. R. 355. A court may reconsider an interlocutory ruling "at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Fed R. Civ. P. 54(b). Motions for reconsideration serve the narrow purpose of correcting manifest errors of law or fact or presenting newly discovered evidence. *Rothwell Cotton Co. v. Rosenthal & Co.*, 827 F.2d 246, 251 (7th Cir. 1987) (citation omitted). Thus, a motion to reconsider is proper when "the Court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension." *Bank of Waunakee v. Rochester Cheese Sales, Inc.*, 906 F.2d 1185, 1191 (7th Cir. 1990) (citation omitted). But a motion for reconsideration "does not provide a vehicle for a party to undo its own procedural failures, and it certainly does not allow a party to introduce new evidence or advance arguments that could

and should have been presented to the district court prior to the judgment." *Bordelon v. Chi. Sch. Reform Bd. of Trs.*, 233 F.3d 524, 529 (7th Cir. 2000) (citation and quotations omitted); *see also Caisse Nationale de Credit Agricole v. CBI Indus., Inc.*, 90 F.3d 1264, 1270 (7th Cir. 1996) ("[R]econsideration is not for rehashing previously rejected arguments.").

In the context of claim construction, a motion for reconsideration may be raised at any stage of the case. *E.g.*, *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) (after preliminary injunction ruling); *Bone Care Int'l LLC v. Pentech Pharm., Inc.*, 2010 WL 3023423, at *1 (N.D. Ill. July 30, 2010) (after *Markman* hearing). Indeed, the Federal Circuit has noted that "[d]istrict courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." *Jack Guttman*, 302 F.3d at 1361 (citation omitted). Still, there must be some reason, whether factual or legal, to reconsider a construction. *Id.*

IV. Analysis

A. Claim Construction

1. "High Dose, Single Treatment"

Before diving into invalidity and infringement, the Court will first address Pfizer's motion to reconsider the September 2012 claim-construction Order. To review, the parties' primary dispute during claim construction was the definition of "one high dose, single treatment." 9/18/12 Order. Remember that Claim 1 of the '506 patent covers "[a] process for treating a bacterial infection in an animal in need

thereof comprising administering to said animal a pharmaceutically effective composition comprising a fluoroquinolone, an ester, or a salt thereof in one high dose, single treatment." '506 Patent col. 4 ll. 11-15. And Claims 4 and 5 apply this treatment to BRD caused by the *pasturella haemolytica* and *pasturella multocida* bacteria. *Id.* col. 4 ll. 24-29.

Pfizer previously argued that the term "high" was indefinite because it is a term of degree. 9/18/12 Order at 2-4. But the Court concluded that when viewing the claim language and specification as an ordinary-skilled artisan, "a single, 'high' dose means a single fluoroquinolone dose that is as effective in treating bovine respiratory disease (caused by the specified bacteria) in cattle as multiple doses administered over multiple days." *Id.* at 3. The Court explained that "[t]he invention's improvement on the prior art 'compris[es] a high dose equivalent to the total dose normally administered daily for several days.'" *Id.* (quoting '506 Patent col. 1 ll. 37-39). "Before the invention, there was a 'perceived need for a special formulation to prolong the blood levels' of the active ingredient (the fluoroquinolone). … The patent reports that, '[s]urprisingly, it has been found that a single, high dose of fluoroquinolones can be administered to effectively treat disease such as bovine respiratory disease.'" *Id.* at 3 (quoting '506 Patent col. 1 l. 26, col. 2 ll. 14-16). So "high" was not indefinite because it referred to the single dose that was as effective as a multi-day dose in treating BRD. *Id.* at 4.

Pfizer now moves to reconsider this prior construction of "high dose," arguing that evidence developed after the original *Markman* briefing has since revealed that

the term actually means a precise mathematical sum, namely, "the sum of the total dose amount for an established multi-dose regimen, as opposed to any dose amount that provides equivalent efficacy to a multi-dose therapy." R. 356, Def.'s Resp. (Infringement) at 7. In other words, if an effective drug regimen is 1.25 mg/kg given once daily for three days, Pfizer believes that the infringing single dose would be 3.75 mg/kg, which is the exact sum of three 1.25 mg/kg doses. As a result, a different single dose—say 4 mg/kg or 5 mg/kg or 7.5 mg/kg—would *not* be infringing, even if it was just as effective as the multi-day treatment.

For support of this sum-based interpretation, Pfizer points to the testimony of Bayer inventors Terry Wollen and Dennis Copeland, Bayer prosecuting attorney Godfried Akorli, and Bayer expert Mark Papich. *Id.* As an initial matter, Bayer argues that all of this testimony is "irrelevant" extrinsic evidence that may not be considered because the intrinsic evidence—the claims and specifications within the four corners of the '506 patent—is clear. R. 375, Pl.'s Reply (Infringement) at 3-4. But there is no absolute ban on this type of evidence. It is true that the starting points of claim construction are the specification and claims themselves, which should be afforded the "ordinary and customary meaning … that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention" and considered in the context of the entire patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). But the Federal Circuit has also recognized that "[b]ecause the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent," courts may look to other "sources

available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Id.* at 1314 (citation and quotations omitted). Extrinsic evidence that supplies "relevant scientific principles, the meaning of technical terms, and the state of the art" is helpful, and can include dictionaries, treatises, expert testimony, and inventor testimony. *Id.* at 1314, 1317-18. To be sure, extrinsic evidence can be less reliable than intrinsic evidence, so courts should be wary of evidence "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id.* at 1318 (citation and quotations omitted). But given the overarching interpretive principle—what the claim term means to an ordinary-skilled artisan—it should come as no surprise that explanations of how an expert would interpret a claim are sometimes worth considering.

Although the testimony from Wollen, Copeland, Akorli, and Papich is relevant, none of it, when considered in context, shows that the term "high dose" means the *literal* sum of the daily dose amount in an effective multi-dose regimen. For example, Pfizer points out that Copeland testified to the following: "Q. Okay. And that statement, the high dose equivalent to the total dose normally administered daily for several days, that is what we're talking about here, taking the dosages in the multiple day regimen, adding them up, and that is the high dose equivalent? … A. I – I agree with your – with what you just said, yes." R. 357-12, Def.'s Exh. 12, 6/19/12 Copeland Dep. 182:16-183:3. But a few minutes earlier,

Copeland was asked a more open-ended question, "Do you have the general recollection that the studies you did in the single dose area in the 1994 time frame were driven more by volume considerations as opposed to scientifically determining what might lead to the appropriate serum levels?", to which he replied "I would have the exact opposite view. Our concern was determining *if it was effective and at what dose – not volume*." R. 377-1, Pl.'s Exh. 160, 6/19/12 Copeland Dep. 180:8-17 (emphasis added). This shows that Copeland's experiments focused on which dosages were *effective* at curing disease. *Id.* Copeland then explained that in Bayer's 1994 experiments, "we picked 7.5 and 15 as a speculation that that would be the best dose to try because it would be the same total dose as if you gave a daily injection for three days. The 15 milligram would be the same – the same story for the high end recommendation of 5 milligrams per kilogram for three days." *Id.* 180:19-181:5. Here, Copeland was suggesting that he determined the starting points for his experiments by taking the dosages in the multiple-day regimen and then adding them up, *id.* 182:16-183:3, so these dosages were *a few possible* pharmaceutically effective compositions. All in all, his testimony—which must be considered in light of the intrinsic evidence, *see* 9/18/12 Order—suggests that the focus was on what single dose would prove *effective*, not just a rote summing of individual daily dosages.

The same is true of the other evidence cited by Pfizer; put simply, context matters. Pfizer also points to testimony by Bayer inventor Wollen, who was asked: "When [the specification] says, 'The total dose normally administered daily for

several days,' is the – is a fair reading of that, that that would be adding up whatever the daily dose would be, for example, 2.5, and, if it was given for three days, adding up 2.5 plus 2.5 plus 2.5 to come to the total dose?" R. 357-11, Def.'s Exh. 11, 5/24/12 Wollen Dep. 149:2-7. Wollen responded "You could assume that." *Id.* 149:10. But the problem here is that this question was not asked in the context of a discussion about whether "high dose" meant the literal sum of daily doses or a single dose that was as pharmaceutically effective as the multi-day treatment (at least not in the five-page excerpt supplied by Pfizer). Wollen was not asked, and did not testify, that "high dose" always means the sum of the individual doses, as opposed to the pharmaceutically effective equivalent. The question posed was what could be "a fair reading" of the patent language, and Wollen seems only to concede that the sum of the three doses—7.5 mg/kg—could possibly fall within the definition of "high dose." The context of the discussion and the broad answer do not show that "high dose" always means the literal sum of the individual doses, especially in light of the clear language of the '506 patent and Copeland's testimony to the contrary, 6/19/12 Copeland Dep. 180:8-17. The other testimony to which Pfizer points has similar defects—context suggests that the summed dosages could *possibly* fall into the definition of "high dose," but not that "high dose" *necessarily* means summed doses. R. 357-13, Def.'s Exh. 13, 6/22/12 Akorli Dep. 35:11-20 ("Q. And this reference to the high dose equivalent to the total dose normally administered daily for several days, what this is referring to is essentially taking what was normally given over multiple days and dosages, adding that up and giving it all at once as a single dose,

is that fair? A. That's fair."); R. 357-14, Def.'s Exh. 14, 1/17/13 Papich Dep. 170:17-171:1 ("Q. Okay. And all I'm asking you as a person of skill in the art, your technical understanding of – of what this means, the question is when it's referring to the high-dose equivalent to the total dose normally administered daily for several days, the high-dose equivalent is adding up the total doses that were normally administered for several days and giving those all at once. Is that correct? A. That's my understanding of what the sentence says.").

In sum, the claim-construction order previously explained that the language and context of the '506 patent revealed to an ordinary artisan that "there is really no other meaning that 'high' dose can bear—it must mean a dose that is effective in treating the disease." 9/18/12 Order at 4. Pfizer's post-*Markman* extrinsic evidence—four snippets of relatively inconclusive testimony—do not contradict this interpretation or establish that "high dose" actually means the literal sum of the dosages in a multiple-day regimen. Thus, Pfizer's motion to reconsider this construction is denied.

2. Long-Acting Formulations

The parties also dispute whether the '506 patent excludes single-dose, long-acting formulations—that is, a dose that is administered only once but that maintains a blood MIC level (remember, that means minimum inhibitory concentration) for an extended period of time, in contrast to a high dosage that achieves, but does not sustain a MIC level. Although the prior claim-construction Order did not separately address this issue (because the parties did not raise it), the

Court's construction of "high dose," viewing the whole patent as an ordinary artisan, implied the *exclusion* of long-acting formulations. 9/18/12 Order.

As explained above, the '506 patent covers "one high dose, single treatment." '506 Patent col 4. ll. 14-15. The claims do not explicitly say anything about the type of formulation covered by the patent. But the patent specification explains that before this invention, the only single-dose treatments disclosed in the art were "based on specific formulations which prolong the release of active ingredient and extend the blood and tissue levels of animals treated therewith." *Id.* col. 1 ll. 22-25. Example two in the patent also distinguished two single high-dose treatments (of 5.0 mg/kg and 7.5 mg/kg) from tilmicosin, a long-acting non-fluoroquinolone, *id.* col. 3 l. 11 (describing tilmicosin as long acting); Clay Report ¶ 21 ("Micotil, also known as tilmicosin … was also a type of treatment known in the field as a 'long acting' drug."). The experiment revealed that "7.5 mg/kg of enrofloxacin given as a single injection … is also as effective as a single injection of long acting tilmicosin." '506 Patent col. 3 ll. 8-11. So "[b]y the present invention, there is provided a single high dose treatment of fluoroquinolone to replace repeated treatments *without the need for special prolonged release formulations*." *Id.* col. 1 ll. 28-31 (emphasis added).

The specification thus shows that the single doses covered by the '506 patent were being *distinguished* from, and thus did *not* include, long-acting formulations. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002) (explaining that "claims must be read in view of the specification" (citation omitted)). The Court incorporated this context into its prior claim-construction

Order, explaining that the '506 patent, in addition to disclosing that a single, high dose of fluoroquinolone was as "pharmaceutically effective" in treating bovine respiratory disease as lower doses administered over multiple days, also challenged the prior belief that a single, high dose had to be long acting. 9/18/12 Order at 3. Thus, because the parties now raise the issue, the Court clarifies that a "high dose, single treatment" does *not* include sustained-release or long-acting drugs that prolong drug levels in the blood.

B. Invalidity

With claim construction reaffirmed and clarified, it is time to address Pfizer's invalidity arguments. Pfizer argues that the '506 patent was anticipated, is obvious, and lacks an adequate written description. Bayer cross-moves against each one of these defenses, and also moves for summary judgment against Pfizer's prior invention defense. The Court addresses each one of these invalidity arguments below, concluding that the '506 patent is not invalid for anticipation, obviousness, or lack of written description, but that there is a fact dispute on whether Pfizer was the prior inventor.

1. Written Description

Pfizer first argues that the '506 patent lacks an adequate written description. Every patent must include

> 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 or joint inventor of carrying out the invention.

35 U.S.C. § 112(a). From § 112(a), courts have derived three separate requirements: written description, enablement, and best mode. *See Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 921 (Fed. Cir. 2004). The written-description element of § 112(a)—which requires "full, clear, concise, and exact terms"—means that the patent "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (quotations omitted) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). "In other words, the test for sufficiency is whether the disclosure … reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)). The Federal Circuit acknowledges that the term "possession" is not self-defining; at baseline, however, it means the written description describes a complete invention. *Id.* When a chemical or scientific property is involved, the written description should "show[] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics … *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (quotations and emphases omitted) (quoting Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099 at 1106). And when a patent

involves a category of chemicals (the chemical "genus"), there must be "a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1363 (Fed. Cir. 2011) (quotations omitted) (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)). Whether the written description is adequate depends on context, including "the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad*, 598 F.3d at 1351 (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005)).

In this case, a reasonable factfinder could only find that the written description requirement is met because the '506 patent identifies the use of a class of chemical compounds—fluoroquinolones—that was undisputedly known and identifiable by chemical structure at the time of the patent's issuance. Fluoroquinolones are antimicrobials that were developed in the 1970s and 1980s. DSOF (Written Description) ¶ 7; Clay Report ¶ 27. Although there were different types (enrofloxacin, danofloxacin, and the like), all fluoroquinolones share the same basic chemical structure and kill bacteria by targeting the enzymes DNA Gyrase and Topoisomerase IV; this common structure and bacteria-killing mechanism was well documented in the literature and understood by ordinary artisans. PSOF (Written Description) ¶¶ 374-78; 1991 Giles and Magonigle Article at PFE_BAY0002211 ("The fluoroquinolones are bactericidal and act principally by the inhibition of bacterial DNA-gyrase which is necessary for supercoiling of DNA … .");

R. 353-10, Def.'s Exh. 129, 1989 Vancutsem Article at 173-75 (explaining that fluoroquinolones are chemically "based on the 4-quinolone ring" and "all act on the same bacterial target: the bacterial DNA gyrase (type II topoisomerase …)"); R. 300-5, Def.'s Exh. 5, 1992 McGuirk Article at PFE_BAY0000792 (explaining that fluoroquinolones "were examined for in vitro and in vivo antibacterial activity as well as inhibition of DNA gyrase, the enzyme responsible for DNA supercoiling … ."); Papich Report ¶¶ 14-15 (explaining that fluoroquinolones "all share the same basic chemical structure and operate as antimicrobials through the same general mechanism of action"); Clay Report ¶ 28 (explaining that "[f]luoroquinolones all operate through a common mechanism of action" and "inhibit enzymes that are necessary for DNA coiling, and, therefore, DNA replication"); Babish Report ¶ 41 ("The molecular basis for the bactericidal activity of fluoroquinolones is their ability to arrest DNA synthesis through the targeting of two essential bacterial enzymes, DNA gyrase and DNA topoisomerase IV."); R. 353-8, Pl.'s Exh. 127, 1/18/13 Babish Dep. 308:16-309:3 (explaining that fluoroquinolone is a description of a class of compounds, meaning that a "person of ordinary skill in the art … could visualize the pharmacophore that is used … ."); R. 353-9, Pl.'s Exh. 128, 1/15/13 Grooms Dep. 350:18-351:15 (explaining that fluoroquinolones "work[] on a specific enzyme that prevents DNA from unraveling and thereby DNA replication … ."). Pfizer has provided no evidence disputing fluoroquinolones' mechanism of action or their common chemical structure. Consequently, because fluoroquinolones describe a concrete class of chemical compounds that were known, identifiable, and understood

by an ordinary artisan to have a common bactericidal mechanism at the time of the '506 patent's issuance, Bayer has satisfied the written-description requirement, whose "hallmark … is disclosure." *Ariad*, 598 F.3d at 1351; *see also Bos. Sci.*, 647 F.3d at 1363 (written description is adequate when it supplies "a precise definition … structure, formula, [or] chemical name" that is "sufficient to distinguish [the claimed material] from other materials." (citation and quotations omitted)).

Pfizer nevertheless argues that the '506 patent lacks an adequate written description because it claims *all* fluoroquinolones, even though Bayer "at most, possessed and described use of a single formulation of a single fluoroquinolone—enrofloxacin—as of the filing date." R. 299, Def.'s Br. (Written Description) at 13. Similarly, Pfizer argues that Bayer's patent is far too broad because different types of fluoroquinolones have different traits, MIC values, and levels of efficacy. *Id.* at 17-18. But even if these facts are true, the written-description requirement is not designed to police this problem, which is more suited to an enablement challenge.[9]

[9]Pfizer has not moved for summary judgment on enablement grounds, and Bayer's cross-motion—to the extent that it presents an enablement argument—is inadequate (as explained later in this footnote), so the Court need not address this defense. Although the enablement and written description requirements are set out in the same paragraph of § 112(a), they require separate analyses. *Ariad*, 598 F.3d at 1345 ("[W]e also read Supreme Court precedent as recognizing a written description requirement separate from an enablement requirement … ."). The two requirements have different purposes; while written description focuses on disclosure, enablement requires "a patent [to] teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009) (citations and quotations omitted). In other words, enablement "ensures that the full extent of claims asserted by an applicant have utility, such that the public can make and use the invention recited therein." *Ariad*, 598 F.3d at 1368 (Linn, J., dissenting in part and concurring in part) (citation omitted).

Here, Pfizer filed no summary judgment motion on enablement. It is true that Bayer then "cross-moved" against Pfizer's enablement defense, R. 349, but it presented underdeveloped arguments without legal authority. R. 350, Pl.'s Resp. (Written

Instead, the written description requirement demands only full disclosure—that the patent fully describes the relevant characteristics that would allow the public to understand what has been claimed. *See Enzo Biochem,* 323 F.3d at 964. That requirement is met here, because the '506 patent disclosed fluoroquinolones, which could be distinctly identified by an ordinary artisan and understood to be effective in treating bacterial diseases. No more is required.

For additional support, Pfizer cites the Federal Circuit discussion in *Boston Scientific*, 647 F.3d 1353, but that case is distinguishable. There, the patent claimed a "drug eluting stent" that used "rapamycin, or a macrocyclic lactone analog thereof." *Id.* at 1363 (citation and quotations omitted). The Federal Circuit held that a "macrocyclic lactone analog" of rapamycin was improperly disclosed, because the analog was not identifiable. *Id.* at 1364. The patent's single reference to the analog "[gave] no guidance on how to properly determine whether a compound is a macrocyclic lactone analog of rapamycin besides vaguely indicating they must be 'structural[ly] similar' to rapamycin." *Id.* The court went on to explain that "[g]iven the structural complexity of rapamycin[,] … the universe of potential compounds that are structurally similar to rapamycin and classifiable as macrocyclic lactones is

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Description) at 20-21. Bayer states only that there is no enablement problem because the examples provided in the '506 patent "do not require change to formulation, route of administration, or any other aspect of treatment other than dose regimen." *Id.* at 21. Bayer also concludes, without explanation or citation, that "it is undisputed that moving from a multi-dose treatment to a single high dose treatment would not require undue experimentation." *Id.* at 21. Bayer's discussion of enablement is conclusory and incomplete. Thus, to the extent that Bayer is really moving for summary judgment on Pfizer's enablement defense, that motion is denied. Neither side sufficiently put enablement at issue at this summary judgment stage.

potentially limitless." *Id. Boston Scientific* is distinguishable because that patent attempted to claim all macrocyclic lactone *analogs* that were "structurally similar" to rapamycin; but because the patent gave no guidance on how to determine this structural similarity and provided few examples of analogs, the written description was too vague. *Id.* Even though some types of macrocyclic lactone analogs had been disclosed, the prior art was not "so well known as to excuse including a more detailed disclosure of the macrocyclic lactone analogs genus in the specification." *Id.* at 1364. In contrast, Bayer's reference to fluoroquinolones is enough, because fluoroquinolones were already well-known in the art; no further description of their chemical structure or mechanism of action was necessary for an ordinary artisan to understand the category of compounds covered by the '506 patent. Even if it was true that new fluoroquinolones were being developed in the mid-1990s, Def.'s Br. (Written Description) at 4-6, there was no doubt as to whether a compound was a fluoroquinolone. Further, even if there was variation in the effectiveness of various fluoroquinolones, *id.*, Bayer is claiming only those compositions that are pharmaceutically effective, '506 Patent col. 4 ll. 11-15. Thus, the claims in the '506 patent are adequately described, so Pfizer's summary judgment motion for lack of a written description is denied. Even with all inferences in Pfizer's favor, a reasonable factfinder must conclude that the written description was sufficient, so Bayer's cross-motion for summary judgment against that defense is granted.

2. Obviousness

Next, Pfizer argues that the '506 patent is invalid because it is obvious. "A patent for a claimed invention may not be obtained … if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Obviousness is a question of law but depends on resolution of factual findings about (1) the level of ordinary skill in the art; (2) the scope and content of the prior art; (3) the differences between the claims and the prior art; and (4) secondary considerations, such as commercial success, long felt but unsolved needs, and past failed attempts. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). The party challenging the patent for obviousness must "show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007).

As explained below, the Court holds that even when Pfizer gets the benefit of all reasonable factual inferences, the '506 patent is not invalid for obviousness. At the time of the '506 patent's filing, the standard fluoroquinolone treatment was a *multi*-day dosing regimen. Although the art revealed that fluoroquinolones were concentration dependent and that there was motivation to create a single-dose treatment, the movement towards a single-dose treatment was limited to long-

acting formulations, because there were still perceived benefits to maintaining prolonged drug levels. Thus, a skilled artisan did not have a "reasonable expectation of success" in achieving a single, high-dose treatment that was not long acting.

i. Level of Ordinary Skill in the Art

The parties disagree about the level of ordinary skill in the art, but they agree that this dispute is immaterial for purposes of the obviousness analysis. R. 303, Def.'s Br. (Anticipation/Obviousness) at 15 n.11; R. 346, Pl.'s Resp. (Anticipation/Obviousness) at 13 n.13. Pfizer defines the ordinary artisan as having a graduate-level degree in pharmacology, animal science, or similar field, plus at least one year of post-graduate work. DSOF (Anticipation/Obviousness) ¶ 30. Bayer defines the ordinary artisan as having a Doctorate in Veterinary Medicine with three to five years of experience treating cattle. Clay Report ¶ 48. In any event, because the parties agree that these differences are immaterial, they will not affect the obviousness analysis.

ii. Prior Art and '506 Patent

The Court will examine the next two *Graham* factors together, because they are related: the scope and content of the prior art, and the differences between the prior art and the claims in the '506 patent.

The prior art did disclose that fluoroquinolones were effective: the undisputed evidence shows that, at the time of the '506 patent's filing, fluoroquinolones were a known antimicrobial and many types were believed to be effective against BRD caused by *pasturella multocida* and *pasturella haemolytica*. *E.g.*, 1987 Bauditz

Article at PFE_BAY0000461 (explaining that Baytril (enrofloxacin) was "highly effective" in a study of calves with BRD from *pasturella multocida* and *pasturella haemolytica*); *id.* at PFE_BAY0000460 ("The superiority of Baytril over conventional substances justifies a wide range of uses in meat-producing livestock as the therapeutic agent of choice in almost all economically important infections requiring antibacterial therapy."); 1991 Giles and Grimshaw Article at PFE_BAY0000653 (concluding that danofloxacin was effective at treating respiratory diseases and pneumonia caused by *pasteurella* bacteria in cattle); R. 309-9, Def.'s Exh. 19, '853 Patent at [57] (describing "[a] method of treating livestock infected with, or protecting livestock against infection from, bacteria which comprises administering to such livestock an antibacterially effective amount of a quinolonecarboxylic acid or derivative of the formula").

It was also understood that the standard antimicrobial BRD treatment—including for fluoroquinolones—was a *multi*-day regimen. *See* 1987 Bauditz Article at PFE_BAY0000461 (explaining that enrofloxacin was effective at doses of 2.5 mg/kg administered three to five times or at doses of 1.0 to 7.5 mg/kg administered on five to eight days); 1989 Vancutsem Article at 183 ("Clinical studies in calves have been performed with doses from 1.25 mg/kg to 7.5 mg/kg and administration periods from 3 to 5 days."); R. 348-17, Pl.'s Exh. 96, 1991 Merck Veterinary Manual at BHCPF10011140 ("[u]nless long-acting drugs are used, treatment should be repeated for at least 3-4 days" for cattle respiratory diseases); 1991 Giles and Grimshaw Article at PFE_BAY0000657 ("In practice, cattle with acute pneumonia

are usually treated with antibiotics for a minimum of three days, but they may be treated for five days or longer depending on their clinical response."); R. 300-6, Def.'s Exh. 6, 1992 Kagota Presentation at BHCPFI0011198, BHCPFI0011200 (field trial of AT-4526, "a new quinolone derivative," tested doses of 1.25 mg/kg over three to five days, 2.5 mg/kg over two to five days, and 5.0 mg/kg over two to five days); 6/13/12 Giles Dep. 55:17-23 ("Q. So, at the time of this article, the standard practice for treating cattle with bovine respiratory disease with antibiotics was a course of treatment lasting three to give days, is that correct? A. At the time of this article, yes, that was the standard practice."); *id.* 64:8-17 (explaining that in 1993, there was a multi-day enrofloxacin product on the European market); *id.* 77:12-15 ("The conventional wisdom was short-acting products needed three to five days of treatment … ."); 205:18-21 ("Q. By conventional daily dosing, does that mean three to five daily doses of a fluoroquinolone? A. Yes."); 7/20/12 Boettner Dep. 48:7-11 ("Q. So as of March of 1993, what you were calling the conventional formulation of Advocin, that was a 1.25 milligram per kilogram dose given over three days intramuscularly? A. Yes, that would be how we referred to it."). Pfizer does not really dispute that the standard fluoroquinolone treatment was a multi-day one at the time of the '506 patent's filing; and although it argues that the terms "conventional" and "first half of the 1990s" are vague and overbroad, Def.'s Resp. PSOF (Anticipation/Obviousness) ¶ 241; Def.'s Resp. PSOF (Prior Invention) ¶ 135, the sources cited above show that this is not the case.

At the same time, the literature began to reveal that fluoroquinolones were concentration-dependent drugs, which kill bacteria by reaching a certain MIC level in the body. DSOF (Anticipation/Obviousness) ¶¶ 48-49. In other words, "large doses should produce similar or superior bacterial killing than multiple small doses … . The major goal of a dosage regimen for these drugs would be to maximize concentration." 1993 Craig Article at PFE_BAY0002229; *see also* 1993 Sullivan Article at PFE_BAY0002234 ("[O]ptimal dosing of quinolones may involve the use of large single doses to attain the high levels in serum necessary to achieve a high ratio of maximum concentration in serum/MIC."); 1995 Meinen Article at BHC00036079 ("With concentration-dependent bactericidal activity, the rate and extent of killing increases as the concentration of the drug increases."); Babish Report ¶¶ 46-48. In contrast, the effectiveness of time-dependent drugs depends on the amount of time that the drug is at a concentration above the MIC. DSOF (Anticipation/Obviousness) ¶¶ 51-53; Babish Report ¶ 47. Although Bayer contends that an ordinary artisan would not have known about the concentration-dependent nature of fluoroquinolones at the time, Pl.'s Resp. DSOF (Anticipation/Obviousness) ¶ 48, Bayer has not cited to any studies that would lead an ordinary artisan to doubt the concentration-dependent quality of fluoroquinolones.

At the time of the '506 patent's filing, it is also undisputed that there was motivation in the cattle and pharmaceutical industries to develop a single-dose treatment for BRD. Babish Report ¶ 51; Clay Report ¶ 64; 1/24/13 Clay Dep. 78:2-80:1; 1990 Gorham Article at PFE_BAY0000658 (Multi-day treatments "[are] labor

intensive because of the daily handling, and stressful to the cattle due to the restraint involved. An antibacterial treatment which could be administered as a single injection would offer numerous advantages."). Single-dose treatments would reduce the time and resources needed to identify and treat sick animals, decrease tissue damage caused by injections, and minimize the stress on cattle from multiple treatments. *Id.*

Pfizer argues that these factors—the concentration-dependent nature of fluoroquinolones and the industry's motivation to develop a single-dose drug—combine to make the '506 patent obvious. But this is not so for two reasons. For one, despite the concentration-dependent quality of fluoroquinolones, the industry was concerned that other factors weighed in favor of multi-dose regimens, such as the need to overcome bacterial resistance. One study explained that, even though the pharmacodynamics of fluoroquinolones revealed concentration-dependency, "there may be other reasons for preferring certain dosage regimens. The emergence of resistant organisms to aminoglycosides and quinolones can be prevented by peak levels greater than 8 to 10 times the MIC[]." 1993 Craig Article at PFE_BAY0002230. Thus, "one would expect that optimal dosage regimens would provide relatively continuous exposure of the organisms to the active drug levels." *Id.; see also* R. 309-15, 1/24/13 Clay Dep. 80:17-23 ("[T]here had been single-dose products available, but the bulk of those suffered from problems, whether they be injection site issues or resistance or some of them had viscosity issues. All of those played into the choice of a product."). In fact, Pfizer's own experiences showed that

it had practical difficulties implementing a single-shot treatment. Its single-shot option of A180 was originally "rejected due to [] microbial safety concerns (higher *E. coli* resistance versus two dose)." Advocin Launch Plan at PBA_00056446; *see also* 1/15/02 FDA Letter to Pfizer at PBA_00022249 (FDA explaining its resistance concerns with Pfizer's single-dose, but not the two-dose fluoroquinolone product). So in September 2002, "[Pfizer] chose to launch with [the] 6-0-6 regimen (6 mg/kg on days 1 and 3) as the single day regimen of 8 mg/kg was not an option … due to some [fluoroquinolone] resistant coliform isolates in feces of 8 mg/kg treatment group post-treatment … ." R. 282, Pl.'s Exh. 14, 2008 Pfizer Emails at PBA_00045190. Thus, it was not obvious that the concentration-dependent quality revealed in pharmacokinetics and pharmacodynamics studies would translate into a practically feasible single-shot formulation that worked in the field, because there were many other factors to consider. *See* 1995 Meinen Article at BHC00036076 (studying the pharmacodynamics of enrofloxacin but explaining that because "studies of the in vivo bactericidal activity of enrofloxacin have not been done … extrapolation between agents and for treatment of different bacteria must be done cautiously"); R. 309-27, Def.'s Exh. 27, 1995 Papich Article at 319 (explaining that various factors must be considered in treating bacterial infections, such as the location of the infection and barriers to drug penetration like infected tissues that may render a fluoroquinolone less effective).

What's more, although the industry did move towards a single-dose treatment, that movement was limited to *long-acting* formulations, because, as

explained above, it was still believed that there were benefits to maintaining the drug in the bloodstream for an extended period of time. A 1990 study, for example, evaluated single injection dosages of tilmicosin, which is a non-fluoroquinolone antibiotic; the study explained that "[t]he rationale for use of a single injection rather than several daily injections was … [that] one injection resulted in prolonged serum and tissue levels." 1990 Gorham Article at PFE_BAY0000659. There emerged other single-dose options, such as long-acting oxytetracycline (also a non-fluoroquinolone). *See id.* at PFE_BAY0000661 ("tilmicosin and long-acting oxytetracycline as single injections were compared to multi-day" treatments); 1989 Veterinary Medicine at PFE_BAY0002971 (one treatment for bovine pneumonic pasteurellosis was "longacting [oxytetracycline] at 20 mg/kg body weight, intramuscularly"); 1991 Merck Veterinary Manual at BHCPF10011140 (cattle respiratory diseases "must be treated early for best results … . Unless long-acting drugs are used, treatment should be repeated for at least 3-4 days."). Consistent with the state of the art, Bayer and Pfizer both investigated a long-acting formulation. *E.g.*, 6/19/12 Copeland Dep. 44:4-14 ("Q. And when do you recall that testing [of long-acting enrofloxacin formulations] occurring? A. Well, it would have been prior to the study that was the basis for [the '506] patent. So the work that we did prior to that was focused on long-acting formulations."), 46:8-21 (explaining that Bayer conducted serum level studies on long-acting formulations), 94:23-95:9 ("We certainly had a clear objective of trying to come up with a product that only had to be administered once. And our assumption at the time that … it had to be long-

acting. It had to be a special formulation."), 259:7-24 ("[W]e had tried a number of formulations … to hopefully provide a long—long-acting, sustain the serum levels of enrofloxacin over a longer period of time, and we were unsuccessful in developing or having developed for us a formulation that looked like it would work); Pfizer Notebook 18531 at PBA_00292761-62 ("Long-Acting I.M. Injectable Development"); Pfizer Notebook 20730 at PBA_00176095-97 (listing several index danofloxacin entries with "LA" dosage, including "Preparation of Danofloxacin LA formulations for Testing in Cattle in Terre Haute"); Pfizer Notebook 22960 at PBA_00176715-16 (listing several index danofloxacin entries with "LA" dosage); Pfizer Notebook 24463 at PBA_00177022-23 (same); Pfizer Notebook 24673 at PBA_00177345-51 (same). Thus, despite the pharmacokinetic and pharmacodynamics studies revealing the concentration-dependent quality of fluoroquinolones, the standard treatment at the time of the '506 patent's filing remained a *multi*-day treatment or a *long*-acting single dose treatment. Because it was still believed that it was beneficial to maintain concentration levels for a period of time, the single, high dose that was claimed in the '506 patent was not obvious.

To support its obviousness argument, Pfizer cites to certain studies on human bacterial infections, but the studies are irrelevant. To qualify as prior art for an obviousness analysis, a reference must be "analogous art," meaning that it is in "the same field of endeavor" or is "reasonably pertinent to the particular problem with which the inventor is involved." *K-TEC, Inc. v. Vita-Mix Corp.*, 696 F.3d 1364, 1375 (Fed. Cir. 2012) (citation omitted). "A reference is reasonably pertinent if it, as a

result of its subject matter, logically would have commended itself to an inventor's attention in considering his problem." *Id.* (citation and quotations omitted). In this case, Pfizer points to a study involving treatment of human urinary tract infections, R. 309-16, Def.'s Exh. 16, 1989 Backhouse Article ("Single-Dose Enoxacin Compared with 3-Day Treatment for Urinary Tract Infection"), and another involving gonorrhea patients, R. 309-26, Def.'s Exh. 26, 1987 Kaplowitz Article ("Norfloxacin in the Treatment of Uncomplicated Gonococcal Infections"). But there is nothing in the record showing that an ordinary artisan (as defined by either Bayer or Pfizer) would consider studies on humans involving different bacteria and different diseases to be relevant prior art. Although Pfizer argues that "[t]he practice of persons of skill in 1995 was to look to treatments that had been successfully used in humans to inform them [as to] what treatments might be successful in animals," Def.'s Br. (Anticipation/Obviousness) at 7 (citing DSOF (Anticipation/Obviousness) ¶ 67), the references cited—an article by Papich and his deposition transcript—do not support this proposition. Papich's 1995 article, entitled "Clinical Pharmacology and Selection of Antimicrobial Drugs," explains that various factors must be considered in treating bacterial infections, such as the location of the infection and barriers to drug penetration. 1995 Papich Article at 319. The only potentially relevant portion to this analysis is one statement that "[s]election of antimicrobials is based primarily on empiricism, their activity in vitro, or on the basis of what is effective *for a similar infection in people*," *id.* (emphasis added), but this, without more, does not establish that treatment of human urinary tract infections or

gonorrhea is applicable to *different* infections, such respiratory disease, in cattle. Nor does the article focus on dosage regimens or fluoroquinolones. *Id.* When asked in his deposition whether veterinary treatments were based on treatments for similar infections in humans, Papich hedged. He stated "I think I would need you to be more specific when you say 'bacterial infections,'" 1/17/13 Papich Dep. 115:21-116:5, followed by "I would … simply emphasize that I have stated different levels of factors that go into the decision, which, as it states, based on empiricism, activity in vitro, or on the basis what is effective for – so there are – I'm not putting more weight on one of those item than another," *id.* 117:3-8. Papich's hedging is consistent with the prior art, which warns that "fluoroquinolones have different properties and extrapolation between agents and for treatment of different bacteria must be done cautiously." 1995 Meinen Article at BHC00036076. Thus, Pfizer's human-medicine references cannot be considered analogous art.

Pfizer also argues that the '853 patent renders the '506 patent obvious because the '853 patent discloses a range of dosing regimens that included a single, high dose regimen. Def.'s Br. (Anticipation/Obviousness) at 16-17. This argument is also rejected; as the Court will explain in more detail in the anticipation section below, *see infra* Section IV.B.3, the '853 patent claims "[a] method of treating mycoplasmotic and bacterial infections in fowl which comprises administering drinking water to said fowl, and said drinking water containing an antimycoplasmotically or antibacterially effective amount of a quinolonecarboxylic acid and/or derivative of a compound of the formula." '853 Patent col. 14 ll. 27-32. To

demonstrate that "[t]he active compounds are used to combat bacterial diseases in livestock," *id.* col. 8 ll. 34-35, the specification lists a variety of diseases, treatments, and animals, including for "diseases of ruminants": "formulations for injection for parenteral administration, in doses of 1 to 20, preferably 1 to 5, mg/kg of body weight, once to twice a day, for 1 to 15, preferably 1 to 5, days, where appropriate repeated," *id.* col. 9 ll. 24-33. But the '853 patent, which is not concerned with dosing regimens or BRD, provides no additional context or discussion about this broad range. It does not explain why one dosing regimen would be preferable over another. So considered in combination with the rest of the known art, as described above, the '853 patent's listing of this dosing range, without more, does not make a single, high dose treatment obvious.

iii. Secondary Considerations

The final factor in an obviousness analysis—the catch-all of secondary considerations—also supports the non-obviousness of the '506 patent. "Secondary considerations of non-obviousness include the commercial success of the invention at issue and its satisfaction of a long-felt need." *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009) (citation omitted). Despite the label "secondary," this evidence must be considered alongside the other *Graham* factors in the obviousness analysis. *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1339 (Fed. Cir. 2016) (citations omitted).

Commercial success and long-felt need weigh heavily in favor of non-obviousness in this case. For commercial success, there must be a nexus between

that success and the feature of the invention that is disclosed and claimed in the patent. *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310-11 (Fed. Cir. 2010). That is, "[t]he commercial success of a product is relevant to the non-obviousness of a claim only insofar as the success of the product is due to the claimed invention." *Geo. M. Martin Co. v. All. Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2010) (citation omitted). If the patentee makes this showing, the challenger can rebut the existence of a nexus. *Crocs*, 598 F.3d at 1294. Here, Bayer has shown that Baytril, the product that was based on the '506 patent, was commercially successful because of its single-dose feature. From 2003 to 2011, the only fluoroquinolones on the market were Baytril, which had a single-shot dosage option, and Pfizer's A180, which was a multiple-dose regimen. *See* Advocin Launch Plan at PBA_00056448 (explaining that there were "only two existing FQ [fluoroquinolone] BRD treatment drugs at present: Baytril (enrofloxacin) [and] A-180 (danofloxacin)."). During these years, Bayer claimed $47 to $85 million in annual sales, dwarfing Pfizer's sales, which ranged from $3 to $15 million. R. 348-24, Pl.'s Exh. 103, Fluoroquinolone Sales at Tab 5a. Pfizer itself admitted that a major reason for Baytril's success, as compared to A180's faltering sales, was Baytril's single-dose option. The Advocin launch plan explained that "Baytril holds 94% MS [market share] of the FQ market" and "is the second largest BRD treatment product in feedlot/stocker markets." Advocin Launch Plan at PBA_00056448. In contrast, one reason for A180's "poor product adoption" was that "[t]wo-shot FQ [fluoroquinolone] [was] less convenient versus one-shot Baytril." *Id.* at PBA_00056445. This key difference

motivated Pfizer's development and marketing of Advocin. During a marketing webinar, Pfizer explained that a "fundamental attribute" allowing Advocin to compete with Baytril was the single-dose regimen. 1/27/12 Pfizer Webinar 33:19-34:1. "Products that do not work in a single-dose regimen are not really practical in today's environment. So [Pfizer] wanted to make the awareness of a single-dose regimen [] more prominent with a new brand and a chance to introduce this." *Id.*; s*ee also* Advocin Presentation at PFE_BAY0000037 (Advocin's "3 key messages" were "single shot FQ, cost-effective alternative to Baytril, [and] 4 day withdrawal time"). And this commercial success is consistent with the long-felt need and motivation to develop a single-dose product, as the Court has previously explained. *See supra* Section IV.B.2.ii. So Bayer has presented sufficient evidence connecting its commercial success to the single-dose quality of the '506 patent, while Pfizer has not pointed to any specific evidence to the contrary. R. 383, Def.'s Reply (Anticipation/Obviousness) at 16-17. Pfizer only makes the conclusory statement that "Bayer's commercial success arguments are un-tethered to the actual invention" without explaining that statement. *Id.* at 16. Thus, Baytril's commercial success, plus the industry's long-felt need to develop a convenient single-dose product, point strongly towards non-obviousness.

Pfizer also argues that its own simultaneous invention of the single, high dose product, as embodied in its 93-052 experiment, shows that the '506 patent is obvious. It is true that, as detailed later in the Opinion (when discussing Pfizer's prior-invention argument), there is a genuine and material dispute on whether

Pfizer reduced to practice the single, high dose claim of the '506 patent in its 93-052 Study dated January 1994. *See infra* Section IV.B.4. Pfizer completed the 93-052 Study before Bayer's August 1994 94A-002 Study that formed the basis of the '506 patent, and before Bayer filed the '506 patent application in May 1997. *Id.* But despite the possibility of a near-simultaneous invention, this is still not enough to create a reasonable dispute about obviousness given all of the other facts demonstrating non-obviousness discussed above. *Cf. Geo. M. Martin Co.*, 618 F.3d at 1306 ("[I]n light of the strong evidence of obviousness … , the [plaintiff's] objective evidence of non-obviousness, even if fully credited by a jury, would fail to make a difference in this case."). The Court has already explained that the standard dose at the time of the '506 patent was a multi-day dose with some movement towards a single-dose in a long-acting formulation. So given the differences between the single, high dose in the '506 patent and the state of the art at the time of its filing, the balance of the evidence—even considering this one instance of near-simultaneous invention—still proves non-obviousness, and no factfinder could reasonably conclude otherwise. *See Pfizer, Inc.*, 480 F.3d at 1372 ("Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion." (citation omitted)).

Finally, Pfizer points to patent number 6,024,979 (the '979 patent) as another example of simultaneous invention. R. 309-29, Def.'s Exh. 29, '979 Patent. This patent was filed on June 6, 1995 and issued on February 15, 2000. *Id.* at [22], [45]. But the '979 patent does not disclose a single, high dose treatment; rather, its

purpose was to develop "an oral veterinary composition, containing the fluoroquinolone antimicrobial agent difloxacin" that "provides (1) ready and extensive absorption from the rumen into the circulating blood and (2) an unexpectedly extended duration of therapeutic antimicrobial blood level." *Id.* col. 1 ll. 12-21. That is, the '979 patent is focused on a formulation that would sustain the drug in the bloodstream for a long period of time, which is akin to a long-acting formulation. The patent aims to address the absorption problem of oral antimicrobials in ruminant animals (like cattle); the digestive process in those animals biodegrade the drugs in the animals' rumen (one of the four compartments of the animal's stomach). *Id.* col. 1 ll. 24-32. In contrast, drugs administered parenterally—that is, through means other than digestive tract—do not have absorption problems. *Id.* Although the '979 patent does state that "it is preferred that the present method consist[s] of orally administering an effective amount of the composition in a single dosage," it goes on to explain that the proper dosage is the amount "needed to maintain an effective blood level in the ruminant for a length of time sufficient to treat the microbial infection." *Id.* col. 4 ll. 39-47. Consequently, the '979 patent does not show simultaneous invention but rather affirms that an ordinary artisan would have believed that it was necessary to maintain therapeutic blood levels for an extended period of time.

In sum, it is undisputed that when the '506 patent was issued, it was known that fluoroquinolones were concentration dependent and that there was motivation to create a single-dose treatment. Nevertheless, a single, high dose was not obvious

because the standard fluoroquinolone treatment remained a multi-day one, and the movement towards single-dose treatments was limited to long-acting formulations. As a result, the skilled artisan did not have a "reasonable expectation of success" in achieving the critical element of the '506 patent: a single, high-dose treatment that was not long acting and that did not stay in the body for an extended period of time. *Pfizer, Inc.*, 480 F.3d at 1361 (citations omitted). Pfizer's summary judgment motion for obviousness is denied, and Bayer's corresponding cross-motion is granted.

3. Anticipation

Pfizer also argues that the '506 patent is invalid because it is anticipated. A patent is invalid for anticipation if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. § 102(a)(1). Similarly, if the claimed invention was previously described in a prior patent, the patent at issue is anticipated and invalid. 35 U.S.C. § 102(a)(2). Said another way, a patent is anticipated when "the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1356 (Fed. Cir. 2010) (citation and quotations omitted). To determine whether a patent is anticipated, a court must construe the claims of the patent at issue and compare them to the prior art. *See Key Pharm. v. Hercon Labs. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998).

Pfizer's brief focuses on one prior art reference for purposes of anticipation: patent number 5,145,853 (the '853 patent). Def.'s Br. (Anticipation/Obviousness) at 10-14. The '853 patent, which was filed in January 1991 and issued in September 1992, "relates to bactericidal formulations which contain quinolonecarboxylic acids[10] and their derivatives, for use in the area of veterinary medicine." '853 Patent col. 1 ll. 7-9. It claims "[a] method of treating mycoplasmotic and bacterial infections in fowl which comprises administering drinking water to said fowl, and said drinking water containing an antimycoplasmotically or antibacterially effective amount of a quinolonecarboxylic acid and/or derivative of a compound of the formula." *Id.* col. 14 ll. 27-32. The broad specification lists numerous quinolonecarboxylic compounds, derivatives of such compounds, and formulations. *Id.* cols. 2-7. The specification also lists seventeen families of "active microorganisms pathogenic to livestock"; number seven is "[v]ibrionaceae (for example, Vibrio such as Vibrio cholera, Pasturella such as *Pasturella multocida*, Aeromonas, Actinobacillus and Streptobacillus)." *Id.* col. 8 ll. 1-3. It then names a wide swath of animals, including "mammals, such as, for example, cattle, horses, pigs, sheep, goats, dogs, cats, rabbits, camels, fur-bearing animals such as mink and chinchilla, and animals in zoos and laboratories, such as, for example, mice, and rats; reptiles, such as, for example, crocodiles and snakes." *Id.* col. 8 ll. 37-41. It also lists dozens of bacterial diseases affecting these animals, including "for example (cattle, sheep and goats) coli diarrhoea and septicaemia, bronchopneumonia, salmonellosis, shipping fever, pasteurellosis, mycoplasmosis,

[10]It is undisputed that quinolonecarboxylic acid refers to quinolones, of which fluoroquinolones are a subclass. Pl.'s Resp. DSOF ¶ 30 (Anticipation/Obviousness).

puerperal and postpuerperal genital infection, and mastitis." *Id.* col. 8 ll. 49-52. Finally, as relevant to the anticipation analysis, in another section describing "diseases of ruminants (cattle, sheep, and goats)," the '853 patent states: "formulations for injection for parenteral administration, in doses of 1 to 20, preferably 1 to 5, mg/kg of body weight, once to twice a day, for 1 to 15, preferably 1 to 5, days, where appropriate repeated." *Id.* col. 9 ll. 24-33.

It is true that the '853 patent mentions—albeit briefly and embedded in long, long lists—many elements of Claims 1, 4, and 5 of the '506 patent. First, the '853 patent mentions using a fluoroquinolone to treat a bacterial infection in an animal: the patent's abstract discloses "[a] method of treating livestock infected with … bacteria which comprises administering to such livestock an antibacterially effective amount of a quinolonecarboxylic acid or derivative of the formula." '853 Patent at [57]. And Claim 1 of the '853 patent covers a method of treating bacterial infections in birds by putting quinolonecarboxylic acid in their drinking water. *Id.* 14:17-32. The '853 patent also mentions BRD, listing "shipping fever" as a cattle disease. '853 Patent col. 8 ll. 49-53, col. 9 ll. 25-26. And it also lists the *pasturella multocida* bacteria in the list of "microorganisms pathogenic to livestock." *Id.* col. 8 ll. 1-3.

The flaw in Pfizer's anticipation argument, however, is that the '853 patent does not disclose a "pharmaceutically effective" single dose in the same way that this dose is defined by the '506 patent—that is, one that works just as effectively as a multi-day fluoroquinolone treatment. Pfizer points to the dosage range outlined in

the ’853 patent, which includes “doses of 1 to 20, preferably 1 to 5, mg/kg of body weight, once to twice a day, for 1 to 15, preferably 1 to 5, days, where appropriate repeated.” Def.’s Br. (Anticipation/Obviousness) at 4, 12 (quoting ’853 Patent col. 9 ll. 29-33). This range, according to Pfizer, “explicitly describes a one dose single treatment, *i.e.*, one administration for 1 day.” *Id.* at 4. True, it is *possible* to pluck a single dose of up to 20 kg/mg from this broad description and range, at least if all context is ignored. But there is no anticipation just because an element of a claim “necessarily falls within” a previously disclosed range “as a matter of fact.” *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012). “[Even if] true, the inquiry does not end there. How one of ordinary skill in the art would understand the scope of the disclosure or, stated differently, how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance.” *Id.* In *OSRAM*, for example, the Federal Circuit rejected a similar anticipation argument where the challenged ’905 patent claimed a buffer gas pressure of less than 0.5 torr (a torr is a unit of measure for pressure) and the allegedly anticipatory patent disclosed a range of “approximately 1 torr or less.” *Id.* at 701. The Federal Circuit explained “that the limitation of less than 0.5 torr is central to the invention claimed in the ’905 patent,” which asserted that prior lamps, including those disclosed in the prior art reference, “[were] inefficient and impractical … precisely because they use pressure well above that claimed in the ’905 patent.” *Id.* at 705-06. The ’905 patent also explained that lamps worked differently at the different points disclosed in the

allegedly anticipatory patent. *Id.* Thus, because the '905 patent emphasized the unique benefits of operating at less than 0.5 torr, the Federal Circuit could not definitively conclude that this claim was anticipated just because it happened to fit within the range of the prior art reference. *Id. See also, e.g.*, *Atofina v. Great Lakes Chem. Corp.,* 441 F.3d 991, 1000 (Fed. Cir. 2006) (prior art reference that disclosed a temperature range of 100-500°C did not anticipate the challenged patent, which claimed a method of synthesizing difluoromethane at a temperature between 330-450°C, just because there was "slight overlap" between the two ranges).

Similarly, in this case, even if the broad dosage ranges in the '853 patent technically encompass the dosages in the '506 patent, there is no anticipation because the '853 patent is not concerned with the unique properties of the single high dose. The '853 patent simply lists a broad dosage range in passing with no additional context or explanation. In contrast, the distinctive quality of the '506 patent was that a single high dose (that was not long-acting) was just as effective at treating BRD than the traditional multi-day regimen, and this single dose was critical to the inventiveness of the patent. Given the context (or, indeed, the *lack* of context) of the '853 patent, as well as the prior art, "no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim." *Atofina*, 441 F.3d at 993. Thus, Pfizer's motion for summary judgment on anticipation is denied, and Bayer's corresponding cross-motion against the defense is granted.

4. Prior Invention

The last invalidity defense is prior invention, against which Bayer moves for summary judgment. Because there is a material dispute as to whether Pfizer first reduced to practice the single, high dose disclosed in the '506 patent, Bayer's motion is denied.

Prior invention is based on the former § 102(g), which was amended in 2011 by the Leahy-Smith America Invents Act (AIA) when the patent laws moved from a "first to invent" to a "first to file" system. *See* Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 § 3 (2011); *Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 1000 n.1 (Fed. Cir. 2014). But the parties agree that the former version of the statute applies, because the AIA amendments do not apply to patents filed before March 16, 2013. *See* 125 Stat. at 293.

The former § 102(g) provided that "[a] person shall be entitled to a patent unless … before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2) (2006). In other words, "[a] patent is invalid under that section if the claimed invention was made in this country by another inventor before the patent's priority date." *Solvay*, 742 F.3d at 1000 (citation omitted). Section 102(g) "ensure[d] that a patent [was] awarded only to the 'first' inventor in law." *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001). A party is a prior inventor if "(1) [she] reduced [her] invention to practice first … or (2) [] was the first party to conceive of the invention and then exercised reasonable diligence

in reducing that invention to practice." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001) (citation omitted). The first way to be a prior inventor—reduction to practice—requires that the prior inventor "(1) constructed an embodiment or performed a process that met all the claim limitations, and (2) determined that the invention would work for its intended purpose." *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharms. LP & IPR Pharms., Inc.*, 661 F.3d 1378, 1383 (Fed. Cir. 2011) (citation omitted). Reduction to practice also requires testing or demonstration of the device in operation. *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186, 1195 (Fed. Cir. 2011). An inventor can also show prior invention in a second way: by conceiving of the invention, meaning that she "form[ed] in [her] mind … a definite and permanent idea of a complete and operative invention," *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (citation and quotations omitted), and then exercising reasonable diligence in reducing it to practice, *Mycogen*, 243 F.3d at 1332. Either way, in order to retain her status as a prior inventor, an inventor must not have abandoned, suppressed, or concealed the invention. *Id.* at 1331.

For purposes of this motion, both parties agree that Bayer reduced its single, high-dose BRD treatment to practice on June 27, 1995. R. 296, Pl.'s Br. (Prior Invention) at 14 n.5. Bayer argues that Pfizer did not conceive of or reduce to practice the single, high dose claimed in the '506 patent before this date because Pfizer's early development work focused on long-acting formulations. *Id.* at 11-13. In response, Pfizer points to two possible studies to show reduction to practice: the

93-050 study conducted in March 1993, and the 93-052 study conducted in November 1993. R. 352, Def.'s Resp. (Prior Invention) at 12. Each study is discussed in turn.

i. 93-050 Study

The Court agrees with Bayer that Pfizer's 93-050 Study does not constitute reduction to practice because the study only tested single-dose treatments using long-acting formulations that were intended to prolong the blood levels of fluoroquinolone. Pl.'s Br. (Prior Invention) at 10-11. And the Court has already construed the "high dose, single treatment" claim in the '506 patent to *exclude* long-acting or sustained-release formulations. *See supra* Section IV.A.2.

The objective of the 93-050 Study was to compare conventional (that is, multi-day) regimens with long-acting formulations of danofloxacin in cattle with BRD. Pfizer 93-050 Study at PFE_BAY0001277. Pfizer tested a saline control and three treatment groups, one of which was "CP 76, 136-27 (1.25 mg/kg, SIDX3, IM)" which Pfizer scientist Wayne Boettner explained was the "conventional formulation" of danofloxacin consisting of a 1.25 mg/kg dose given over three days. *Id.* at PFE_BAY0001278; 7/20/12 Boettner Dep. 48:3-11. This conventional formula was compared to two "gelled oil formulations" with single doses of 6 mg/kg and 3.75 mg/kg. Pfizer 93-050 Study at PFE_BAY0001278. The goal of the 93-050 Study was to develop a sustained-release formulation using an oil-gelled carrier to deliver the drug. 7/20/12 Boettner Dep. 48:12-49:15 ("It was a formulation which we hoped would be long-acting. We were probably not dead certain at that point."). The study

concluded that [redacted] The important point is that nowhere does the 93-050 Study suggest that it was testing any single-dose formulation that was *not* long-acting. So because Pfizer's 93-050 Study involved treatments that did not meet all the claim limitations of the '506 patent, *Teva Pharm.*, 661 F.3d at 1383, this study does not show reduction to practice. For the same reasons, Pfizer did not conceive of the single, high dose at the time it conducted this study, so the 93-050 Study does not show that Pfizer was a prior inventor. *Id.* ("Conception occurs when the inventor has a specific, settled idea, a particular solution to the problem at hand … ." (citations and quotations omitted)).

ii. 93-052 Study

Pfizer's argument that it reduced the single, high dose to practice in the 95-052 Study, on the other hand, holds more water—at least enough to raise a genuine issue of material fact that prevents Bayer from winning summary judgment.[11]

[11]Bayer argues that the 93-052 Study cannot be considered in the prior invention analysis because Pfizer did not disclose it in its final invalidity contentions. Pl.'s Reply (Prior Invention) at 7. Those invalidity contentions stated: "As shown in Exhibit 1 attached hereto, claim 1, 4 and 5 of U.S. Patent No. 5,756,506 are invalid under 35 U.S.C. § 102, including § 102(a) or § 102(g), and/or § 103 in view of Pfizer's prior work in the area, clinical knowledge, and use … , as described therein." R. 331, Pl.'s Exh. 70, Def.'s Final Invalidity

Unlike the 93-050 Study, which only tested the efficacy of single-dose treatments in long-acting formulations, there is evidence that Pfizer's 93-052 Study sought to develop a formulation of a single, high dose treatment that was not long acting. The study was entitled "Comparative evaluation of the therapeutic efficacy of conventional and single-shot formulations of danofloxacin (CP 76,136) against natural bovine respiratory disease." Pfizer 93-052 Study at PFE_BAY0001304. This time, the test materials included (1) a saline control; (2) 25 mg/ml[12] danofloxacin in a formulation of "mesylate in water"; (3) 60 mg/ml danofloxacin in a formulation of "zwitterion in Terramycin-LA vehicle (peak-only profile)"; (4) 60 mg/ml danofloxacin in a formulation of "zwitterion in phosphate buffer with suspending agents (tail-only profile)"; (5) 60 mg/ml danofloxacin in a formulation of "mesylate in sesame oil gelled with 1.5% aluminum monostearate (peak and tail profile, positive control"); and (6) 60 mg/ml danofloxacin in a formulation of "sulfate in Synergistin vehicle (peak and tail profile)." Pfizer 93-052 Study at PFE_BAY0001305-06.

Pfizer argues that the 93-052 Study compared three dosage formulations: a conventional (multi-day treatment); a single, high, long-acting dose; and a single,

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Contentions at 8. Pfizer then listed dozens of examples of its prior development work, including studies 93-050 *and 93-052*. *Id.* at 9-10. And Exhibit 1 detailed the studies, including 93-050 *and 93-052*, that purported to overlap with claim 1 of the '506 patent. R. 354-28, Def.'s Exh. 28, Def.'s Exh. 1 to Final Invalidity Contentions at 1-2.

Based on those disclosures, the Court will consider the 93-052 Study as part of the prior invention defense. To be sure, the disclosures were far from perfect. Pfizer simply listed a number of studies potentially showing invalidity "under 35 U.S.C. § 102, including § 102 (a) or § 102(g), and/or § 103," without explaining which study goes to which defense and why. Def.'s Final Invalidity Contentions at 8. Nevertheless, because Bayer admits that it was on notice of the 93-050 Study, Pl.'s Reply (Prior Invention) at 7, then it must also have been on notice of the 93-052 Study, which was disclosed alongside the 93-050 Study.

[12]These are "potency" values, which are measured in mg/ml units, and not "dosage" amounts measured in mg/kg units. Pfizer 93-052 Study at PFE_BAY0001305-06.

high, dose that was not long acting. Test material number two, the 25 mg/ml danofloxacin, was the conventional dosage of 1.25 mg/kg administered over three days. 7/20/12 Boettner Dep. 73:1-20; Pfizer 93-052 Study at PFE_BAY0001304. The "peak and tail" profiles—test items five and six—were long-acting formulations that sustained the drug concentration over a period of time, while the "peak only" formulation—test item three—involved a high concentration that rapidly trailed off.[13] 6/7/12 Mann Dep. 39:2-44:17. Compared with the conventional formula, the single, high dose (peak-only profile) performed equally well or better in mortality rates, lung lesions, and positive responders, relapses, although slightly worse in weight gain. *Id.* at PFE_BAY0001312. The 93-052 Study ultimately concluded that the single-dose long-acting and non-long-acting formulations were as or more effective than the multi-dose regimen: "presentations of danofloxacin which induce either a substantial peak plasma concentration or moderate peak concentrations in combination with a sustained release provide efficacy similar to or better than that observed with the conventional dose and regimen." *Id.* at PFE_BAY0001304. Although Bayer argues that the 93-052 Study was just another attempt to create a long-acting formulation, Pl.'s Reply (Prior Invention) at 11-12, there is sufficient

[13]Notably, test material number three—the alleged single dose, non-long-acting formulation—is 60 mg/ml danofloxacin in a formulation of "zwitterion in Terramycin-LA vehicle (peak-only profile)." Pfizer 93-052 Study at PFE_BAY0001305. Despite the possibility that "LA" stands for "long-acting," there is still sufficient evidence to raise a fact dispute that this was *not* actually a long-acting formulation. For example, Mann's testimony suggests that the peak profile was a single, high dose, while the peak-and-tail profile was a long-acting formulation. *See* 6/7/12 Mann Dep. 39:2-44:17. In addition, Pfizer argues that this peak-only profile was later commercialized into A180, and then Advocin. 6/7/12 Mann. Dep. 40:2-16. And as explained below, there is no evidence that Advocin is a long-acting formulation. *See infra* Section IV.C.1.

evidence for a jury to find that Pfizer did test a high-dose, single treatment in the 93-052 Study that met all the claim limitations of the '506 patent.

Bayer also contends that the 93-052 Study did not constitute reduction to practice because Pfizer did not appreciate what it had made at the time. Pl.'s Reply (Prior Invention) at 6. But the 93-052 Study clearly revealed that the "peak only" formulation of zwitterion in Terramycin-LA performed as well as or better than the conventional formula in most of the outcome categories (mortality, lung lesion, relapse) and also yielded the highest proportion of positive responders. Pfizer 93-052 Study at PFE_BAY0001312. And as explained above, the study ultimately concluded that the single, non-long-acting formulation was as or more effective than the multi-dose regimen. *Id.* at PFE_BAY0001304. Moreover, Pfizer scientist Douglass Mann testified that the formulation with a "high peak and a modest tail" was the most successful formulation in the 93-052 Study. 6/7/12 Mann Dep. 40:2-16. It does not matter that another Pfizer scientist, Colin Giles, testified that he could only appreciate the results of the 93-052 Study with the benefit of hindsight. R. 315, Pl.'s Exh. 53, 6/13/12 Giles Dep. 338:1-24. At a different point of his deposition, Giles also stated the opposite—that as of December 1994, he believed that the 93-052 Study *had* shown that a single, high dose of danofloxacin was effective in treating BRD. R. 354-6, Pl.'s Exh. 53, 6/13/12 Giles Dep. 163:8-165:2. Viewed in the light most favorable to Pfizer, the 93-052 Study and Mann's testimony are enough to allow a jury to reasonably find that Pfizer timely interpreted the 93-052 Study results and understood them to show that the single, high dose formulation was as

effective at treating BRD as the conventional, multi-day dose. The jury, of course, might find otherwise, but the question remains one for the jury to decide.

In response, Bayer argues that even if the 93-052 Study can be considered a reduction to practice, the evidence shows that Pfizer later abandoned its invention. *Apotex*, 254 F.3d at 1036. Bayer points to the memo from Pfizer's danofloxacin formulation committee to Dr. Goudie in December 1994 informing Pfizer's management team that efforts to identify a single-shot danofloxacin product had been "halted … due to greatly diminished prospects for future success." Goudie Memo at PBA_0229315. The memo also recommended that Pfizer pursue the two-shot danofloxacin product instead. *Id.* at PBA_0227314 ("We recommend that Danofloxacin 2-Shot be progressed into full development for the treatment of bovine respiratory disease."); 6/13/12 Giles Dep. 150:9-14. According to Bayer, Pfizer did not resume its development efforts on a single-dose product until after it learned of Bayer's single high-dose BRD treatment in July 1996. PSOF (Prior Invention) ¶¶ 151-52. Taken together, these facts do support an argument that Pfizer abandoned the invention (if Pfizer even appreciated what it had).

But Pfizer has also pointed to evidence showing the opposite—that despite the Goudie Memo's recommendation, Pfizer continued to work on a single-dose danofloxacin product. Mann testified that Pfizer was always moving forward on developing a single-shot danofloxacin product. 6/7/12 Mann Dep. 191:8-193:6. And Bayer was aware of Pfizer's ongoing work: Baytril's May 1996 launch plan explained, under a section called "Future Fluoroquinolone Antibacterial Drugs,"

that "Advocin is a fluoroquinolone. Its stage of development and regulatory approval is most threatening to Baytril. We are uncertain where Pfizer is in its development and registration of Advocin, however *we know that they are pursuing development of danofloxacin as a single-dose product*." Baytril Launch Plan at 60 (emphasis added). Indeed, by 1996 and 1997, Pfizer's development efforts had advanced as far as conducting four FDA studies comparing danofloxacin BRD treatments in an 8 mg/kg single-dose regimen and a two-day 6 mg/kg regimen. 96-249 Study; 96-250 Study; 97-258 Study; 97-261 Study. Taken together and viewed in the light most favorable to Pfizer, this evidence supports a conclusion that Pfizer did not abandon its invention from 1994 through 1996, but in fact worked diligently to bring its single-dose product to market. Thus, there is a factual dispute as to whether Pfizer reduced to practice the claims in the '506 patent and then did not abandon these development efforts. So Bayer's motion for summary judgment against Pfizer's prior invention defense is denied. [14] [15]

[14]The Court notes that Pfizer did not cross-move for summary judgment on the prior invention defense.

[15]Bayer also contends that Pfizer's prior invention defense must fail because Pfizer has not identified an actual inventor. Pl.'s Reply (Prior Invention) at 1, 5. It is true that "[t]he term 'inventor' means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention." 35 U.S.C. § 100(f). But Pfizer stated in its invalidity contentions that "myriad individuals" were involved in the development and commercialization of the prior art, and that Drs. Boettner, Mann, and Giles in particular had knowledge of the development process. R. 331, Pl.'s Exh. 70, Def.'s Final Invalidity Contentions at 10. Although Pfizer could have been more explicit, this disclosure sufficiently put Bayer on notice of which witnesses would have discoverable information, and conformed with Local Patent Rule 2.3(b)(1) (requiring a party asserting invalidity under § 102(g) to disclose "the identities of the person(s) or entities involved in and the circumstances surrounding the making of the invention before the patent applicant.").

C. Infringement

The parties' final set of motions involve infringement. Bayer moved for summary judgment on direct and induced infringement, while Pfizer cross-moved for summary judgment on non-infringement on direct, contributory, and induced infringement. For the reasons explained below, the Court denies Bayer's motion as to both direct infringement and inducement. It also denies Pfizer's motion as to direct infringement and inducement, but grants it as to contributory infringement.

1. Direct Infringement

The patent laws provide that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). "[D]irect infringement of a method claim requires a showing that every step of the claimed method has been practiced." *Meyer Intellectual Properties Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1366 (citation omitted). This means that "for a party to be liable for direct patent infringement … that party must commit all the acts necessary to infringe the patent, either personally or vicariously." *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1362 (Fed. Cir. 2013) (citations and quotations omitted). A party may prove direct infringement with circumstantial evidence, as long as the evidence "show[s] that at least one person directly infringed an asserted claim during the relevant time period." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1364 (Fed. Cir. 2012) (citation omitted).

Bayer first argues that generally, the use of Advocin as a single-dose BRD treatment would infringe the patent. R. 271, Pl.'s Br. (Infringement) at 5-7. This is true—but as explained below, it is not enough for direct infringement. Advocin, which contains danofloxacin, is a fluoroquinolone approved "[f]or subcutaneous use in cattle for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica* and *Pasteurella multocida*." Advocin Label at PBA_00055017. So this overlaps with Claims 1, 4, and 5 of the '506 patent, which similarly cover "[a] process for treating a bacterial infection in an animal" with a fluoroquinolone to combat BRD caused by *pasturella haemolytica* or *pasturella multocida*. '506 Patent col. 4 ll. 10-29. Further, using Advocin as an 8 mg/kg single-dose treatment, as recommended on its label, would overlap with Claim 1's use of "high dose, single treatment." *Id.* col. 4 ll. 10-15; Advocin Label at PBA_00055017. And if the use of this single, high dose treatment proved to be "pharmaceutically effective," *id.* col. 4 l. 12—that is, as effective at treating BRD as a multi-day regimen, *see supra* Section IV.A.1—there would be direct infringement of the '506 patent.[16]

[16]Pfizer argues that the use of Advocin cannot be infringing because Advocin is a long-acting product. Def.'s Resp. (Infringement) at 1-2. This argument must be rejected because there is no record evidence of this asserted fact. It is true that at one point, Advocin was called "Terramycin LA," which could have stood for Terramycin Long-Acting. DSOF (Infringement) ¶ 32; Def.'s Resp. (Infringement) at 14. But the "LA" label by itself does not create a fact dispute. In fact, Giles, Pfizer's Rule 30(b)(6) witness, testified that Advocin is *not* long acting. R. 377-3, Pl.'s Exh. 162, 6/13/12 Giles Dep. 154:10-17 ("Q. During the discovery work, Pfizer worked on a danofloxacin mesylate in Terramycin-LA vehicle, is that correct? A. That's correct. Q. And sitting here today you don't consider that formulation to be a long-acting formulation, is that correct? A. It's not long acting."). And nothing in any of Pfizer's experiments, advertisements, marketing materials, or other records suggest that Advocin was a long-acting formulation.

The problem for Bayer, however, is that it has not shown *any specific instance* when Pfizer actually used Advocin as a single dose, pharmaceutically effective composition, in order to establish direct infringement. From a common sense perspective, it might seem that a pharmaceutical company like Pfizer must have used Advocin in an infringing manner at some point while marketing and distributing the drug. But without any direct or circumstantial evidence of that use, the Court cannot jump to this conclusion, because "a patentee must prove infringement by a preponderance of the evidence." *Meyer Intellectual Properties,* 690 F.3d at 1370 (citation omitted) (district court improperly found direct infringement by assuming that an established company like Bodum must have tested its products before putting them on the market without any actual evidence that this happened).

So Bayer does need to rely on some evidence, not just an assumption, in order to stave off summary judgment. But the evidence that Bayer cites is not enough to create a genuine factual dispute. Bayer first argues that it "has presented undisputed evidence that Pfizer submitted numerous studies and other documents to the FDA attesting to ADVOCIN's effectiveness and its equivalence to Pfizer's

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Pfizer responds that Bayer's expert Clay "agreed that some people consider Advocin to include a long-acting formulation." DSOF (Infringement) ¶ 38. But this characterization is inaccurate and taken out of context. In response to the question "Do you agree that some persons of ordinary skill in the art may consider Advocin to be a sustained release formulation?", Clay responded: "Well, that's vague. Some persons—there could be any number of people who have a different opinion of a variety of things. If we're going to be that vague, I'll have to say well, there could be somebody." R. 357-17, Def.'s Exh. 17, 1/24/13 Clay Dep. 64:5-12. When asked again: "Would it be fair for a person of ordinary skill in the art to conclude that Advocin was a sustained-release formulation?", Clay responds "No, I don't think so." *Id.* 64:17-21. And earlier, Clay testified that "my recollection is [that Advocin] was hoped to have been a sustained-release formulation but it was not." R. 384-9, Def.'s Exh. 38, 1/24/13 Clay Dep. 64:1-4. Clay's testimony does not come close to showing that that Advocin was long-acting.

multi-dose product." Pl.'s Reply (Infringement) at 8. Those four studies include the 96-249, 96-250, 97-258, and 97-261 clinical trials from 1996 and 1997, when Pfizer tested Advocin by comparing single and multi-dose treatments in various feedlots across the country. PSOF (Infringement) ¶ 30. But Pfizer responds that "these activities occurred before FDA approval and cannot support a finding of infringement" under 35 U.S.C. § 271(e)(1). Def.'s Resp. (Infringement) at 14-15 n.7. That section establishes a safe harbor, in which

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States … a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1). Here, the safe harbor applies to Pfizer's uses that are "reasonably related to the development and submission of information" to the FDA. *Id.* To be sure, there is an exception to the safe harbor, but Advocin is not "a new animal drug or veterinary biological product" that is "primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques," *id.*, so the exception to the safe harbor is not triggered. And it is undisputed that the 96-249, 96-250, 97-258, and 97-261 studies were done for FDA approval. PSOF (Infringement) ¶¶ 29-30; R. 284, Pl.'s Exh. 19, FDA FOIA Summary at PBA_00280347 (listing 96-249, 96-250, 97-258, and 97-261 as studies conducted "[t]o confirm the effectiveness of

danofloxacin 18% injectable solution against naturally-occurring bovine respiratory disease (BRD) under commercial conditions when administered subcutaneously at 8 mg danofloxacin/kg body weight as a single treatment."). Because Bayer's reply did not address why these studies do not qualify for the safe harbor when they were "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products," 35 U.S.C. § 271(e)(1), Bayer has forfeited this argument and the four studies cannot be considered as acts of infringement.

Next, Bayer argues that Pfizer directly infringed the '506 patent when Pfizer conducted a "post-approval clinical trial comparing a single dose treatment of ADVOCIN with Baytril 100." Pl.'s Br. (Infringement) at 3. There are two problems with this argument. For one, Bayer has not explained what a "post-approval clinical trial" means and why this would also be precluded from the safe harbor exception in § 271(e)(1). The only evidence Bayer offers about this study is the deposition testimony of Dimitri Popov, Pfizer's marketing manager, who answered "yes" to the question: "Is Pfizer currently conducting a Phase IV trial comparing Advocin to Baytril 100?" R. 274, Pl.'s Exh. 1, 5/17/12 Popov Dep. 129:1-3. Later, he was asked: "Does the Phase IV trial that Pfizer is conducting compare Advocin at the 8 milligram per kilogram dose to the – to any of the indicated high doses in the Baytril 100 label?", to which Popov responded "Advocin as approved on the label is being compared as Baytril as approved on its label, yes." *Id.* 129:14-23. But there is no additional evidence explaining what a "Phase IV" trial entails. Does it refer to

any internal study that is conducted after FDA approval? Or is it a study that must be submitted to the FDA to monitor the drug on the market? FDA regulations, fortunately, provide some guidance:

> Concurrent with marketing approval, FDA may seek agreement from the sponsor to conduct certain postmarketing (phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time.

21 C.F.R. § 312.85. Under this definition, a Phase IV study is required by the FDA. So Pfizer's Phase IV study would *also* be "reasonably related to the development and submission of information under a Federal law" under § 271(e)(1), because the safe harbor applies to information submitted to the FDA at any point, not just during the pre-approval process. 35 U.S.C. § 271(e)(1); *see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) ("There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.").

Second, even assuming that the Phase IV trial does *not* fall into the safe harbor, Popov's testimony about the study is too vague to create a factual dispute. He explains only that Pfizer evaluated "Advocin as approved on the label" compared to "Baytril as approved on the label." 5/17/12 Popov Dep. 129:21-23. Bayer did not provide the Court with more context or other relevant testimony. Because both Baytril and Advocin have two uses on its label—a multi-dose regimen and a single-

dose regimen, a jury would not be allowed to simply guess from these few lines of testimony that the Phase IV study involved single, high-dose treatment. Accordingly, Bayer's motion for summary judgment on direct infringement is denied, and Pfizer's corresponding cross-motion is granted.

2. Contributory Infringement

Although Bayer has not moved for summary judgment on contributory infringement, Pfizer addressed this argument (albeit briefly) in its cross-motion on non-infringement, so the Court will address it. Contributory infringement is defined by § 271(c):

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c). The party asserting contributory infringement must show "1) that there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) that the component has no substantial noninfringing uses, and 4) that the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010) (citation omitted).

Pfizer's summary judgment motion on contributory infringement is granted because the third element of contributory infringement is not met; it is undisputed that Advocin has a substantial non-infringing use through its *multi*-day dosage option of 6 mg/kg given 48 hours apart. There is no contributory infringement when

"non-infringing uses … are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009) (citations omitted). To determine whether a use is substantial, courts may consider "the use's frequency … the use's practicality, the invention's intended purpose, and the intended market." *Toshiba Corp.*, 681 F.3d at 1362 (citation and quotations omitted).

In this case, it is undisputed that Advocin could be used as a multi-day regimen in addition to the one-shot option. Its label explains that "Advocin is administered subcutaneously at either 8 mg/kg of body weight … as a one time injection, or at 6 mg/kg of body weight … with this treatment repeated once approximately 48 hours following the first injection." Advocin Label at PBA_00055017. Immediately under these instructions is a chart outlining treatment schedules for various cattle weights for both the two 6 mg/kg doses and the single 8 mg/kg dose. *Id.* It is true, as this Opinion later explains, that Advocin's marketing materials promoted its use as a single-shot treatment. *See infra* Section IV.C.3.i. But "[r]ecommending one use over another does not mean the non-recommended use is not substantial," *Toshiba Corp.*, 681 F.3d at 1363, and even when granting all inferences in Bayer's favor, no reasonable jury could conclude that using Advocin as a multi-day regimen was "unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327 (holding no contributory infringement as a matter of law because "the accused devices are indisputably capable of non-infringing use" and the patent owner could

not show the use was insubstantial); *Toshiba Corp.*, 681 F.3d at 1363 (because the use of unfinalized DVDs did not infringe, and "Toshiba presented no survey, expert, or other evidence showing how frequently users choose not to finalize DVDs," summary judgment of no contributory infringement was proper). Thus, because there is undoubtedly a substantial non-infringing use of Advocin—the multi-day dose—there is no contributory infringement as a matter of law, and summary judgment for Pfizer is granted.

3. Inducement

The remaining issue is inducement, on which both parties move for summary judgment. Because there is a material dispute as to inducement, and in particular, whether there has been direct infringement by consumers, both parties' motions are denied.

Under § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "To prove inducement, the patentee must show direct infringement, and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010) (citation and quotations omitted); *see also Limelight Networks, Inc. v. Akamai Tech., Inc.*, 134 S. Ct. 2111, 2117-18 (2014). Unlike contributory infringement, inducement does not turn on whether there are any substantial non-infringing uses. *Toshiba Corp.*, 681 F.3d at 1364.

i. Active and Knowing Action

As for the intent element, the undisputed evidence shows that Pfizer has "actively and knowingly aid[ed] and abett[ed] another's direct infringement." *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (citations, quotations, and emphasis omitted). This element requires more than "mere knowledge of possible infringement by others," but rather "specific intent and action to induce infringement." *Id.* (citation and quotations omitted). Here, Pfizer's marketing efforts show that it had the specific intent to encourage customers to use Advocin as a single-dose regimen; a driving motivation behind Advocin's development was to compete with Baytril's single-dose option and capture Bayer's market share. In 2008, a senior marketing manager explained that [redacted] A few years later in 2011, while marketing Advocin, Pfizer explained that there were "only two existing FQ [fluoroquinolone] BRD treatment drugs at present: Baytril (enrofloxacin) [and] A-180 (danofloxacin)." Advocin Launch Plan at PBA_00056448. The launch plan stated that "Baytril holds 94% MS [market share] of the FQ market" and "is the second largest BRD treatment product in feedlot/stocker markets," with sales of $64 million, as compared to A180's $4 million. *Id.* In comparison to Baytril, A180 had "poor product adoption" because the "[t]wo-shot FQ [fluoroquinolone] [was] less convenient versus one-shot Baytril." *Id.* at PBA_00056445. Recognizing that Bayer's '506 patent would soon expire, [redacted]

[redacted] Pfizer concluded that [redacted] *Id.* at PBA_00056458. [redacted] *Id.*

Consistent with its desire to compete with Bayer, Pfizer took clear, affirmative steps to foster infringement by encouraging the use of Advocin as a single-dose regimen. Its marketing materials, webinars, and advertisements all touted Advocin as a single-shot formula that was as effective as a multi-day regimen, while providing direct comparisons to Baytril's single-dose option. During a webinar, Pfizer explained that one of Advocin's "fundamental attributes" was that it "work[ed] in a single-dose regimen. Products that do not work in a single-dose regimen are not really practical in today's environment. So we wanted to make the awareness of a single-dose regimen [] more prominent with a new brand and a chance to introduce this." 1/27/12 Pfizer Webinar 33:19-34:1. In another webinar, Pfizer explained that "[y]ou now have a second option with a single injection or a single-day regimen fluoroquinolone. Our plan is to make it a cost-effective alternative to Baytril." 1/26/12 Pfizer Webinar 27:10-13. And Pfizer's Advocin advertisement included a photo of Advocin and Baytril pitted against each other, with the statements "battle of the BRD antimicrobials" and "introducing Advocin … the single dose, cost-effective alternative to Baytril … ." Advocin Ad. *See also* Advocin Presentation at PFE_BAY0000037 (explaining that the "3 key messages"

were "single shot FQ, cost-effective alternative to Baytril, [and] 4 day withdrawal time"). Similarly, a "priority update" letter announcing Advocin's release told customers that "Pfizer Animal Health is excited to announce that you have a new single dose fluoroquinolone to treat cattle with bovine respiratory disease (BRD) … ADVOCIN is an injectable antimicrobial with the following key benefits: Cost-effective alternative to Baytril® … [and] [a] 4-day withdrawal period." Priority Update Letter at PBA_00294438. Pfizer's marketing department sent this letter to three or four hundred veterinarians. R. 277, Pl.'s Exh. 4, 11/15/12 Popov Dep. 241:16-242:8.

The undisputed evidence therefore shows that Pfizer "offer[ed] a product with the object of promoting its use to infringe," so it is "liable for the resulting acts of infringement by third parties." *DSU Med. Corp.*, 471 F.3d at 1305-06; *see also Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1223 (Fed. Cir. 2006) (intent was established when infringer provided its foreign customers with an engineering manual that was "replete with examples that are similar to the [the patentee's] designs. This constitutes circumstantial evidence that [the infringer] intended for its subsequent buyers, including foreign buyers, to install systems that infringe the claims of the [disputed] patent."). The only question, then, is whether there were actually any acts of infringement by non-parties.

ii. Direct Infringement by Consumers

Pfizer argues that Bayer cannot prove that any customers actually committed acts of direct infringement. Def.'s Resp. (Infringement) at 14-17. "To satisfy the

direct infringement requirement, the patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *Toshiba Corp.*, 681 F.3d at 1364 (citation and quotations omitted).

Summary judgment is denied for both parties' motions on inducement because there is a genuine and material dispute as to whether any customers directly infringed the '506 patent. It is rather strange that Bayer did not gather (or if it did, did not cite to) more evidence that specific Pfizer customers infringed; perhaps there are business reasons for the gap. Whatever the reason, the best Bayer can do is point to the testimony of J. P. Pollreisz, Pfizer's Technical Services Veterinarian, to show specific instances of direct infringement. Pl.'s Br. (Infringement) at 8. Pollreisz testified that he suggested, during three marketing webinars to veterinarians, that customers use the single-administration regimen of Advocin. 5/16/12 Pollreisz Dep. 157:9-21. Outside the webinar context, he also remembers speaking to ten or fifteen individual customers about Advocin; out of these individuals, he spoke with only three customers—Steve Baar, Jeff Platter, and Larry Moczygemba—about using the single-dose option. *Id.* 157:14-158:11. Moczygemba, however, told Pollreisz: "I've tried it both ways [the multi-dose and single-dose regimens] and I can't make it work either way." *Id.* 158:15-17. Although this evidence does not establish direct infringement so that summary judgment for Bayer is warranted, *see Meyer Intellectual Properties,* 690 F.3d at 1370, it is just enough to preclude summary judgment in Pfizer's favor. When viewing this

evidence in the light most favorable to Bayer on Pfizer's cross-motion, Pollreisz's testimony leaves open the possibility that at least two of Pfizer's customers—Platter and Baar—successfully used Advocin as a single dose regimen and thus infringed the '506 patent. (Moczygemba's use, however, does not infringe because he was not able to get Advocin to work at all, meaning that the "pharmaceutically effective" element of Claim 1 of the '506 patent, which is incorporated in Claims 4 and 5, was not practiced.)

In addition, Pfizer's marketing and advertising materials, which stress the use of the single-dosage regimen, also provide circumstantial evidence of direct infringement. The Federal Circuit has explained that "where an alleged infringer designs a product for use in an infringing way and instructs users to use the product in an infringing way, there is sufficient evidence for a jury to find direct infringement." *Toshiba Corp.*, 681 F.3d at 1365. In *Toshiba Corporation*, there were two possible uses of DVDs: as finalized discs (in which "[t]he test pattern and lead-out area" were written), and as unfinalized discs (which did not contain the test pattern or lead-out area). *Id.* at 1358. The use of finalized discs was infringing, while use of unfinalized discs was not. *Id.* The Federal Circuit explained that because the defendants' instruction book encouraged customers to use finalized, and not unfinalized discs, this evidence was enough to create a factual dispute as to whether there was any direct infringement in an inducement claim. *Id.* at 1365. The opinion further explained that "[a]lthough some users may use multisession mode and choose not to finalize, such use is contrary to Appellees' instructions"

encouraging users to finalize discs, because finalization provided better compatibility for disc drives. *Id.* So there was circumstantial evidence of direct infringement "[i]n light of all of the evidence in the record regarding why someone would finalize" the disc.[17] *Id.*; *see also Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1318 (Fed. Cir. 2009) (circumstantial evidence of direct infringement included "the extensive sales of Microsoft products and the dissemination of instruction manuals for the Microsoft products," which showed that Microsoft designed its products to be infringing and encouraged infringing use). Similarly, in this case, in light of all the evidence urging customers to use Advocin as a single-dose administration—Pfizer's encouragement, the convenience, plus the reduced time and reduced consumption of resources for treating BRD—combined with Pollreisz's testimony about two specific single-dose uses by customers Baar and Platter (perhaps Bayer has more evidence to offer at trial on liability and damages for inducement), there is enough evidence to create a fact dispute as to direct infringement on the inducement claim. Accordingly, both parties' summary judgment motions on inducement are denied.

[17]Notably, *Toshiba Corporation* came to this conclusion even though it had previously granted summary judgment to defendants for no contributory infringement because the plaintiff had not shown an insubstantial non-infringing use. *Toshiba Corp.*, 681 F.3d at 1363. So even though the instruction manual encouraging the infringing use of finalized DVDs provided circumstantial evidence of direct infringement for the inducement analysis, this was not enough to show that the non-infringing use of unfinalized DVDs was insubstantial for purposes of contributory infringement. *Id.* The same is true of Pfizer's marketing materials in this case.

V. Conclusion

As the Opinion explains, the Court decides as follows:

- Pfizer's motion to reconsider the claim-construction order, R. 355, is denied.
- Pfizer's motion for summary judgment for invalidity based on the lack of written description, R. 297, is denied. Bayer's cross-motion for summary judgment against Pfizer's written description defense, R. 349, is granted.
- Pfizer's motion for summary judgment for invalidity based on anticipation and obviousness, R. 302, is denied. Bayer's cross-motion for summary judgment against Pfizer's anticipation and obviousness defenses, R. 345, is granted.
- Bayer's motion for summary judgment against Pfizer's prior invention defense, R. 295, is denied.
- Bayer's motion for summary judgment on infringement, R. 270, is denied as to both direct infringement and inducement. Pfizer's cross-motion for summary judgment on non-infringement, R. 355, is granted in part as to direct and contributory infringement and denied in part as to inducement.

The remaining jury questions (at least the ones that arise from the summary-judgment motions) include (1) whether there was direct infringement by consumers for the inducement claim (and if so, what are the damages); and (2) whether Pfizer's 93-052 Study reduced the '506 patent to practice to establish a prior-invention defense. A status hearing is set for July 21, 2016, at 9:45 a.m. to discuss the next

step of the litigation. The Court encourages the parties to engage in settlement negotiations again.

Finally, the parties must review this Opinion to determine what, if any, statements in it should remain under seal. Each side shall identify the specific statements each party proposes to keep under seal and specifically explain why the particular statement should remain sealed. After reviewing the proposals, the Court will issue a publicly available, redacted version. The proposed Position Paper on Sealing is due from each side by July 18, 2016. For now, the Court will file the Conclusion section on the public docket.

ENTERED:

s/Edmond E. Chang
Honorable Edmond E. Chang
United States District Judge

DATE: July 6, 2016