IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERVET INC., d/b/a MERCK ANIMAL HEALTH and THE ARIZONA BOARD OF REGENTS, on behalf of The University of Arizona,	)	
Plaintiffs/Counterclaim Defendants,	)	C.A. No. 11-595-LPS
v.	)	**JURY TRIAL DEMANDED**
BOEHRINGER INGELHEIM VETMEDICA, INC.,	)	**PUBLIC VERSION**
Defendant/Counterclaim Plaintiff.	)	

VETMEDICA'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO AMEND ITS ANSWER AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

OF COUNSEL:

Mark Pals
Bryan Hales
Amanda Hollis
Hari Santhanam
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, Illinois 60654
Tel: (312) 862-2011

Richard L. Horwitz (#2246)
David E. Moore (#3983)
Bindu A. Palapura (#5370)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Defendant/Counterclaim Plaintiff Boehringer Ingelheim Vetmedica, Inc.

Dated: August 29, 2012
Public Version Dated: September 5, 2012
1072830/37150

TABLE OF CONTENTS

Page

I. Introduction 1

II. Nature and Stage of the Proceedings 1

III. Summary of the Argument 1

IV. Brief Statement of Facts 2

A. The '059 Patent 2

B. Stills 1991 and Its Materiality to the '059 Patent 3

C. Inventors' Knowledge And Copying Of Stills 1991 5

D. Joens 1997 7

E. The Inventors' Intentional and Deceptive Failure to Disclose Stills 1991, Joens 1997, or the Inventors' Use of Stills 1991 to the United States Patent and Trademark Office 8

V. Argument 9

A. Vetmedica Has Demonstrated Good Cause to Modify the Scheduling Order 9

B. Leave to Amend Should Be Freely Given as None of the *Foman* Factors Apply 12

1. Vetmedica Is Pleading Inequitable Conduct Without Undue Delay 12

2. Vetmedica Is Not Pleading Inequitable Conduct in Bad Faith 14

3. Vetmedica's Amended Pleading Will Not Prejudice Plaintiffs 14

4. Vetmedica's Amended Pleading Is Far From Futile 15

VI. Conclusion 20

TABLE OF AUTHORITIES

Page(s)

CASES

Adams v. Gould, Inc.
739 F.2d 858 (3d Cir. 1984) 9

Aerocrine AB v. Apieron Inc.
C.A. No. 08-787, 2010 WL 1225090 (D. Del. Mar. 30, 2010) 14

Arthur v. Maersk, Inc.
434 F.3d 196 (3d Cir. 2006) 14

BigBand Networks, Inc. v. Imagine Communications, Inc.,
C.A. No. 07-351 JJF, 2010 WL 2898286 (D. Del. Jul. 20, 2010) 12, 13

Cargill, Inc. v. Canbra Foods, Ltd.
476 F.3d 1359 (Fed. Cir. 2007) 18

Charpentier v. Godsil
937 F.2d 859 (3d Cir. 1991) 9

Cordance Corp. v. Amazon.com, Inc.
255 F.R.D. 366 (D. Del. 2009) 14

Delano Farms Co. v. California Table Grape Commission
655 F.3d 1337 (Fed. Cir. 2011) 18

Dole v. Arco Chemical Co.
921 F.2d 484 (3d Cir. 1990) 2, 9

Enzo Life Sciences., Inc. v. Digene Corporation,
270 F. Supp. 2d 484 (D. Del. 2003) 10, 13

Ethypharm S.A. France v. Abbott Laboratories
748 F. Supp. 2d 354 (D. Del. 2010) 10

Exergen Corporation v. Wal-Mart Stores, Inc.
575 F.3d 1312 (Fed. Cir. 2009) ..... passim

Foman v. Davis
371 U.S. 178 (1962) 2, 9, 12

TABLE OF AUTHORITIES (CONT'D)

Page(s)

Hill v. Equitable Bank, N.A.
109 F.R.D. 109 (D. Del. 1985) 12

ICU Medical., Inc. v. RyMed Technologies., Inc.
674 F. Supp. 2d 574 (D. Del. 2009) ..... passim

Leader Technologies, Inc. v. Facebook, Inc.
C.A. No. 08-862 LPS, 2010 WL 2545959 (D. Del. June 24, 2010) 9

Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.,
984 F.2d 1182 (Fed. Cir. 1993) 18

Roquette Freres v. SPI Pharma, Inc.,
C.A. No. 06-540 GMS, 2009 WL 1444835 (D. Del. May 21, 2009) ..... passim

Therasense, Inc. v. Becton, Dickinson & Co.
649 F.3d 1276 (Fed. Cir. 2011) 13, 16

Wyeth Holdings Corporation v. Sandoz, Inc.
C.A. No. 09-955-LPS, 2012 WL 600715 (D. Del. Feb. 3, 2012),
report and recommendation adopted, 2012 WL 749378 (D. Del. Mar. 1, 2012) 18

STATUTES

35 U.S.C. § 102(b) 3, 16

RULES

Fed. R. Civ. P. 9 ..... 10, 13, 15, 18

Fed. R. Civ. P. 15 ..... 1, 9, 12, 13

Fed. R. Civ. P. 16 ..... 1, 9, 12, 13

D. Del. LR 15.1 1

D. Del. LR 7.1.1 ..... 11, 12

I. Introduction

Pursuant to Federal Rule of Civil Procedure 15(a), 16(b), and Local Rule 15.1, Defendant Boehringer Ingelheim Vetmedica, Inc. ("Vetmedica") seeks leave to amend its Answer and Counterclaims to Intervet's Complaint for Patent Infringement to add an affirmative defense and counterclaim that U.S. Patent No. 5,610,059 ("'059 patent") is unenforceable due to inequitable conduct before the United States Patent and Trademark Office. Through its diligent discovery, Vetmedica recently has learned that both inventors named on the '059 patent violated their duty of candor by failing to tell the PTO about Stills 1991, a prior art publication disclosing exactly what the inventors claimed to have invented and that the inventors knowingly used to obtain their claimed invention, and Joens 1997, the inventors' own article confirming the relevance of Stills 1991 to the inventors' claimed invention. Attached as Exhibit 1[1] is Vetmedica's Proposed Amended Answer and Counterclaims to Intervet's Complaint for Patent Infringement adding inequitable conduct as the ninth affirmative defense and third counterclaim ("Amended Pleading").

II. Nature and Stage of the Proceedings

This case was filed on July 6, 2011. Plaintiffs Intervet, Inc. d/b/a Merck Animal Health ("Intervet") and the Arizona Board of Regents on Behalf of the University of Arizona ("The University of Arizona") (collectively "Plaintiffs") accuse Vetmedica of infringing the '059 patent. The deadline to amend pleadings was February 16, 2012. (D.I. 20). Fact discovery is ongoing and trial is scheduled to begin June 17, 2013.

III. Summary of the Argument

Vetmedica has demonstrated good cause to file its Amended Pleading because it pleads its inequitable conduct claim "based on [a] new set of facts obtained and confirmed during

[1] Exhibits 1 and 2 referenced herein are attached to the motion.

discovery which took place after the Scheduling Order's deadline for amended pleadings." *ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 577 (D. Del. 2009) (citing *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990)). Because Vetmedica has demonstrated good cause, Vetmedica is seeking leave to amend without undue delay or bad faith, and the amendment will not unduly prejudice Plaintiffs and is not futile, the Court should grant leave to amend. *See Foman v. Davis*, 371 U.S. 178, 182 (1962).

IV. Brief Statement of Facts

A. The '059 Patent

The application resulting in the '059 patent was filed on November 9, 1992 and issued on March 11, 1997. Lynn Joens and Robert Glock are the sole named inventors. Attorney Nicholas Seay of the law firm Quarles & Brady LLP prosecuted the '059 patent. The University of Arizona is the named assignee of the '059 patent and employs Dr. Joens and Dr. Glock.

The '059 patent "relates generally to bacterial gastroenteric diseases of pigs and in particular to a bacterial agent which causes porcine proliferative enteritis." Ex. 3,'059 Patent at 1:6-9. According to the patent, porcine proliferative enteritis ("PPE") is "characterized by crypt hyperplasia and by the presence of intracellular campylobacter-like organisms," and a thickening of intestinal walls. *Id.* at 1:15-16; 1:55. The "clinical response . . . includes intermittent diarrhea, anorexia, marked dullness and apathy, and a wasting syndrome." *Id.* at 1:23-25. The '059 patent describes the claimed invention as "[a]n intracellular organism isolated from experimentally infected enterocytes [that] produces a PPE-type condition in pigs upon oral inoculation." *Id.* at 2:38-40 ("Summary of the Invention"). Claim 1, the only independent claim, states as follows:

> 1. A biologically pure culture of a mammalian host cell infected by an obligate intracellular bacterium that causes porcine proliferative enteritis after inoculation

> into pigs having all of the identifying characteristics of ATCC Accession No. 55370.

Id. at 8:23-27. "ATCC Accession No. 55370" refers to a biological deposit that the inventors were required to make publicly available as a condition of getting their patent. The '059 patent does not identify what "all the identifying characteristics" of that deposit are, and the deposit is not publicly available. *See* Ex. A to D.I. 51 at [ATCC00041], Ex. B to D.I. 51 at [ATCC00028-29], Ex. C to D.I. 51 at [ATCC00048]. The '059 patent does, however, identify some characteristics of the deposit. These include (1) the mammalian host cells are of the Henle 407 cell line; (2) the bacterium is 0.24-0.27 μm in width and 1.4-2.4 μm in length; (3) the bacterium has a curved shape; and (4) cytopathic effect (CPE) occurs in the recited cells 2-4 days after inoculation and is characterized by the elongation and subsequent rounding and sloughing of cells by day 7-10. Ex. 3,'059 Patent at 3:20-25, 3:57-61, 6:55-61, 8:4. Example 1 of the '059 patent describes the procedure used by the inventors to isolate their claimed invention. *Id.* at 6:37-55.

B. Stills 1991 and Its Materiality to the '059 Patent

In September 1991, more than one year before the '059 patent application was filed, an article by Harold F. Stills was published entitled *Isolation of an Intracellular Bacterium from Hamsters (Mesocricetus auratus) with Proliferative Ileitis and Reproduction of the Disease with a Pure Culture*. Ex. A to Ex. 1, Stills, H.F., Infection and Immunity, Vol. 59, No. 9, p. 3227-3236 (1991) ("Stills 1991"). Stills 1991 is highly material to the '059 patent. Stills 1991 is prior art to the '059 patent under 35 U.S.C. § 102(b) and, as shown by the chart attached as Exhibit 4, anticipates and/or renders obvious every '059 patent claim. Stills 1991 discloses a "pure culture" of a mammalian host cell infected by an "intracellular bacterium" which caused "proliferative enteritis" "after inoculation." The bacterium of Stills 1991 has the same size and "curved" shape

as that of the '059 patent ("[t]he bacteria . . . measured 1.4 to 1.7 μm in length by 0.26 to 0.34 μm"), Ex. A to Ex. 1, Stills 1991 at 3231, and, just like that of the '059 patent, is hosted in Henle 407 mammalian host cells. *Id.* at 3228, 3231.

Stills 1991 also contradicts arguments the applicants made to the PTO to obtain the '059 patent. To support their application for the '059 patent, the applicants told the PTO that theirs was "the first biological isolate able to induce PPE-like disease on inoculation" and distinguished prior art isolates on that basis. Ex. 3,'059 Patent at 4:3-4, 2:29-30. That statement is not true in light of Stills 1991, which published Dr. Stills' findings regarding his isolate several months before the inventors named on the '059 patent conducted the experiments that lead to the '059 patent. [redacted] Additionally, the PTO rejected the '059 patent application on several grounds, including because the claims were invalid over the prior art "Alderton" and "Lomax" references. Ex. 6, 04/07/1993 Office Action at 6–7 [IVET-00000146–47], Ex. 7, 03/10/1995 Office Action at 4 [IVET-00000198]. To overcome these prior art rejections, the applicants argued that their bacterium was distinguishable because it was intracellular and caused PPE, not just symptoms of PPE:

> The agent here, an obligatory **intracellular bacterium**, cannot be confused with the bacterium of Lomax, which can clearly be grown extrinsic to any host (see Lomax page 1623, second full paragraph).
>
> ***
>
> In addition, the applicants wish to stress that although Alderton demonstrated certain symptoms of PPE, namely gross pathological lesions, ileitis, etc., it is not apparent from Alderton that **proliferative porcine enteritis was induced.** There is no indication in Alderton that the organism used was responsible alone for true porcine proliferative enteritis. While an organism may cause certain symptoms of the disease, it may not be sufficient to cause the disease itself, as the Examiner has already noted. True PPE has been shown by the applicants and, subsequently, by others, to be caused by an **obligate intracellular bacterium** which is

> **demonstrably different from that of Alderton most notably in its intracellular nature.**

See Ex. 8, 10/12/1993 Applicant Resp. at 4-5 [IVET-00000154-55] (emphasis added), Ex. 9, 08/14/1995 Applicant Resp. at 6 [IVET-00000206]. In allowing the '059 patent, the PTO Examiner explicitly relied on these purported distinctions:

> The following is an examiners statement of reasons for allowance: **the closest prior art does not teach or suggest the isolation of a microorganism in a mammalian host cell line wherein the microorganism causes porcine proliferative enteritis (PPE).** The claimed PPE-causative agent is an obligate, intracellular microorganism. The microorganism taught by the closest prior art **causes only symptoms of PPE** and **is not an intracellular organism.**

Ex. 10, '059 patent file history, 08/28/1996 Notice of Allowance, at 2-3 [IVET-00000236-37] (emphasis added). The isolate of Stills 1991, however, is intracellular and causes, not just symptoms of proliferative enteritis, but "reproduction of proliferative ileitis" itself. Ex. A to Ex. 1, Stills 1991 at 3227. Stills 1991 also explicitly teaches that porcine proliferative enteritis could be caused by the same bacterium Stills 1991 isolated from hamsters. *See id.* ("Porcine proliferative enteropathy is a disease of pigs with similar lesions and possibly the same etiology as hamster proliferative ileitis."). Thus had Stills 1991 been disclosed to the Examiner, the applicants would not have been able to successfully make the arguments they did to overcome the prior art and the Examiner would not have allowed the '059 patent claims.

C. Inventors' Knowledge And Copying Of Stills 1991

Both Lynn Joens and Robert Glock knew about Stills 1991 and its materiality to the '059 patent while their application for the '059 patent was being prosecuted. [redacted]

[redacted]

[redacted]

Notably, the "Isolation" process the inventors used to obtain their claimed invention as described in Example 1 of the '059 patent traces the "Isolation" process disclosed in Stills 1991. *Compare* Ex. 1 at Ex. A, Stills 1991 at p. 3227-28 *with* Ex. 3, '059 Patent at 6:37-55. [redacted]

Dr. Glock similarly knew about Stills 1991 while the '059 patent was being prosecuted. [redacted]

[redacted] Thus, like Dr. Joens, Dr. Glock knew about Stills 1991 and understood its significant relevance to their patent.

D. Joens 1997

In or around September 1996, while the '059 patent was being prosecuted, an article co-authored by Lynn Joens and Robert Glock was submitted to the American Journal of Veterinary Research for publication. Ex. B to Ex. 1, L.A. Joens, et. al, *Induction of Gross and Microscopic Lesions of Porcine Proliferative Enteritis by Lawsonia Intracellularis*, AJVR, Vol. 58, No. 10, October 1997 ("Joens 1997"). In that article, the authors made numerous references to Stills 1991—confirming again that they knew about that reference—and confirmed their understanding of Stills 1991's relevance to their claimed invention. In particular, the inventors confirmed (a) that Dr. Stills had isolated a bacterium from the intestinal cells of hamsters with proliferative enteritis, propagated the organism in a Henle 407 cell line, and induced lesions in the small intestine of hamsters after oral inoculation with Henle 407 cells containing the intracellular bacterium; (b) that the organism isolated by Stills was a curved rod having dimensions 0.26 to

0.34μm wide by 1.4 to 1.7 μm long; (c) that the organism isolated by Stills was intracellular; (d) that Stills 1991 and Stills' work "provided researchers with a proven method for isolation of intracellular agents without risk of contamination by normal intestinal flora;" and (e) that they used the methods described in Stills 1991 to purportedly isolate *Lawsonia intracellularis* (the species of bacteria Plaintiffs contend is the subject of the '059 patent):

> **Stills isolated a bacterium from the enterocytes of hamsters with proliferative enteritis** and propagated the organism in a continuous epithelial cell line. The organism was described as a **curved** rod, with a trilaminar membrane, **having dimensions 0.26 to 0.34 μm wide by 1.4 to 1.7 μm long. Stills induced lesions** in the small intestine of hamsters **after oral inoculation** with **Henle 407 cells** containing the **intracellular agent.** A bacterium having the same measurements has also been cultured in a rat enterocyte cell line under an atmosphere of O2:CO2:N2 (8:8:84%).[14] **The bacterium was isolated from intestinal homogenates of a pig with proliferative ileitis, using methods similar to that of Stills [1991].**
>
> * * *
>
> Numerous research workers have attempted to isolate the PPE organism from the intestinal contents of pigs. **Stills' work with hamsters with ileitis provided researchers with a proven method for isolation of intracellular agents without risk of contamination by normal intestinal flora.** These methods were adapted for isolation of a bacterial agent from necrotic intestinal lesions typical of proliferative ileitis in the pigs of this study. The original isolation and growth of the organism was accomplished, using an atmosphere of 02:C02:H2:N2 (6:7:7:80%), as originally described by Stills [1991].

Id. at 1125, 1130 (emphasis added).

E. The Inventors' Intentional and Deceptive Failure to Disclose Stills 1991, Joens 1997, or the Inventors' Use of Stills 1991 to the United States Patent and Trademark Office

Dr. Joens and Dr. Glock both signed a declaration in which they acknowledged their duties to disclose information material to their patent application to the PTO. Ex. 16 at [IVET-00000040]. Yet, during the entire 4.5 year period the '059 patent was being prosecuted, neither Dr. Joens nor Dr. Glock disclosed any of the material information they had about Stills 1991, including Stills 1991 itself, Joens 1997, [redacted]

[redacted] There is no credible explanation for the inventors' failures except that they intended to deceive the PTO.

V. Argument

A schedule may be modified "for good cause and with the judge's consent." Fed. R. Civ. P. 16 (b)(4). "'Good cause' exists when the ordered schedule cannot reasonably be met despite the diligence of the moving party seeking the extension." *Leader Techs., Inc. v. Facebook, Inc.*, C.A. No. 08-862-LPS, 2010 WL 2545959, at *3 (D. Del. June 24, 2010) (citing Fed. R. Civ. P. 16(b)(4) Advisory Committee's Notes (1983 Amendments)).

Amendments of pleadings are governed by Fed. R. Civ. P. 15(a) which provides that "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). "The Third Circuit has adopted a liberal policy favoring the amendment of pleadings to ensure that claims are decided on the merits rather than on technicalities." *ICU Med.*, 674 F. Supp. 2d at 577 (citing *Dole*, 921 F.2d at 487); *see also Charpentier v. Godsil*, 937 F.2d 859, 864 (3d Cir. 1991) ("Unless the opposing party will be prejudiced, leave to amend should generally be allowed."). Leave to amend should be granted in the absence of (A) undue delay; (B) bad faith or dilatory motive on the part of the movant; (C) undue prejudice to the opposing party by virtue of allowance of the amendment; or (D) futility of the amendment. *Foman*, 371 U.S. at 182; *see also Adams v. Gould, Inc.* 739 F.2d 858, 868 (3d Cir. 1984).

A. Vetmedica Has Demonstrated Good Cause to Modify the Scheduling Order

Vetmedica has shown good cause because it pleads its inequitable conduct claim "based on [a] new set of facts obtained and confirmed during discovery which took place after the Scheduling Order's deadline for amended pleadings." *ICU Med.*, 674 F. Supp. 2d at 578. Despite

Vetmedica's diligence, it could not have pleaded the set of facts supporting its inequitable conduct claim by the Scheduling Order's deadline of February 16, 2012 or sooner than it did.

Inequitable conduct claims and defenses fall within the scope of Fed. R. Civ. P. 9(b), and therefore, must be pled with particularity. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-27 (Fed. Cir. 2009); *Ethypharm S.A. France v. Abbott Labs.*, 748 F. Supp. 2d 354, 359 (D. Del. 2010). Delay in moving to add inequitable conduct allegations in order to confirm those allegations through discovery is permissible, and "possibly required" to satisfy Rule 9(b). *Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 489 (D. Del. 2003); *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540 GMS, 2009 WL 1444835, at *5 (D. Del. May 21, 2009) (defendant "needed the depositions of the inventors and was justified in taking certain discovery before filing the motion").

Vetmedica should be permitted to amend its answer now because it has sought leave to amend "soon after it was able to satisfy the pleading requirements" for inequitable conduct. *Enzo*, 270 F. Supp. 2d at 490. Vetmedica only discovered the set of facts supporting its inequitable conduct claim after the Court's deadline for amending pleadings had passed. Although Vetmedica served sixty-five requests for production of documents and things in October 2011, Plaintiffs produced only nine documents prior to the February 16, 2012 amendment deadline, none of which made apparent the inventors' knowledge of Stills 1991. Plaintiffs did not produce [redacted] or Joens 1997 until May 4, 2012. Plaintiffs did not produce Dr. Glock for his deposition, [redacted]

[redacted] And Plaintiffs did not produce Mr. Seay for his deposition until August 1, 2012. As the prosecuting attorney, it was important for Vetmedica to depose Mr. Seay to investigate whether he could offer some legitimate explanation for the inventors' failure to cite all of the relevant information they possessed relating to Stills 1991. He could not. He testified that he submitted a declaration by the inventors in which they acknowledged their duty of disclosure to the PTO, that he had no reason to doubt that the inventors understood their duty, and that he had no reason to believe he failed to inform them of it. Ex. 17, 08/01/2012 Seay Dep. 164:11-165:25.

On August 7, 2012, shortly after Mr. Seay's deposition, and in accordance with Local Rule 7.1.1, Vetmedica attempted to meet and confer with Plaintiffs about its proposal to add inequitable conduct to its defenses and counterclaims. *See* Ex. 18, 08/07/2012 email from A. Hollis to G. Bonifield. Plaintiffs requested a copy of Vetmedica's proposed pleading, which Vetmedica provided on August 14, 2012. *Id. at* 08/07/2012 email from M. Graham to A. Hollis, Ex. 19, 08/14/2012 email from A. Hollis to G. Bonifield and M. Graham. On August 21, 2012, Plaintiffs informed Vetmedica they would oppose Vetmedica's proposed amendment. *Id. at* 08/21/2012 email from G. Bonifield to A. Hollis. Vetmedica asked Plaintiffs for their reasons why they would oppose. *Id. at* 08/21/2012 email from A. Hollis to G. Bonifield and M. Graham. Plaintiffs responded on August 22, 2012, stating only: "Vetmedica's proposed amendment is tardy and Vetmedica has not provided support as to how it would establish the right to amend in consideration of the pertinent factors for amending, often stated as undue delay, bad faith, dilatory motive, prejudice, and futility." *Id. at* 08/22/2012 email from G. Bonifield to A. Hollis and M. Graham. Vetmedica prepared and filed this motion promptly after the meet and confer process concluded.

Inequitable conduct allegations should not be made lightly and Vetmedica should not be penalized for acting diligently to gather, analyze, and confirm evidence of inequitable conduct before pleading it or for the time it took to comply with Local Rule 7.1.1.

B. Leave to Amend Should Be Freely Given as None of the *Foman* Factors Apply

None of the *Foman* factors preclude Vetmedica's proposed amendment. *Foman*, 371 U.S. at 182.

1. Vetmedica Is Pleading Inequitable Conduct Without Undue Delay

Vetmedica did not unduly delay in seeking to amend its pleading. As discussed above, Vetmedica only recently discovered the set of facts supporting its inequitable conduct defense. Vetmedica was required by this Court's Local Rules to meet and confer with Plaintiffs prior to filing the instant motion. Vetmedica began that process on August 7, 2012, less than one week after deposing Mr. Seay and prepared and filed the instant motion only 7 days after the parties concluded their meet and confer. *See* Ex. 18, 08/07/2012 email from A. Hollis to G. Bonifield, Ex. 19, 08/22/2012 email from G. Bonifield to A. Hollis and M. Graham. Moreover, a "party's delay in moving to amend a pleading generally is an insufficient ground to deny an amendment, unless that delay unduly prejudices an opposing party." *Hill v. Equitable Bank, N.A.*, 109 F.R.D. 109, 112 (D. Del. 1985); *see also BigBand Networks, Inc. v. Imagine Commc'ns, Inc.*, C.A. No. 07-351 JJF, 2010 WL 2898286, at *1 (D. Del. Jul. 20, 2010) ("Delay alone is generally an insufficient reason to deny leave to amend"); *Roquette Freres,* 2009 WL 1444835, at *3. As discussed in Section V(B)(3) below, Plaintiffs will not be unduly prejudiced by Vetmedica's proposed amendment.

Numerous courts have allowed leave to amend in situations similar to that presented here. *See, e.g.*, *ICU Med.,* 674 F. Supp. 2d at 578-79 (holding both Rule 16(b) and 15(a) were satisfied when motion to amend to add inequitable conduct claim was filed after discovery had already closed, because defendant had diligently pursued discovery relating to its claim); *BigBand*, 2010 WL 2898286, at *2 (holding defendant satisfied both Rule 16(b) and 15(a) when it filed a motion to amend after amendment deadline because it filed motion within weeks of learning the required information from depositions conducted after the amendment deadline); *Roquette Freres,* 2009 WL 1444835, at *5-6 (holding that defendant satisfied both Rule 16(b) and 15(a) when it moved to amend seven months after deadline, because even though public documents were available

earlier, it was proper to wait until inventor depositions); *Enzo*, 270 F. Supp. 2d at 489-90 (holding that defendant satisfied both Rule 16(b) and 15(a) when it filed a motion to amend seven months after the deadline because even though information was available from prosecution history, defendant was prudent to confirm factual allegations through discovery to satisfy the pleading requirements of Rule 9(b)).

2. Vetmedica Is Not Pleading Inequitable Conduct in Bad Faith

Vetmedica's Amended Pleading is not brought for any improper purpose and is entirely consistent with the law of inequitable conduct. Vetmedica's good faith in seeking leave to amend is demonstrated by the fact that it waited to obtain evidence, such that it could plead inequitable conduct with particularity, rather than making hasty and unfounded allegations. Were the Court to deny Vetmedica's leave to amend now that evidence supporting an inequitable conduct claim has come to light, it would encourage the widespread pleading of premature or unsubstantiated inequitable conduct claims, as recently admonished by the Federal circuit, *see Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011), or preclude meritorious inequitable conduct pleadings.

3. Vetmedica's Amended Pleading Will Not Prejudice Plaintiffs

The Third Circuit has recognized that prejudice to the non-moving party is the touchstone for denying a leave to amend. *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006). In the Third Circuit, the non-moving party has the burden of proving that actual prejudice will result from the amendment. *Aerocrine AB v. Apieron Inc.*, C.A. No. 08-787 LPS, 2010 WL 1225090, at *7 (D. Del. Mar. 30, 2010). To show prejudice, Plaintiffs must show that they will be unfairly disadvantaged or deprived of an opportunity to present facts or evidence which they could have offered. *ICU Med.*, 674 F. Supp. 2d at 578. Where a defendant brings new allegations that are

directed to inequitable conduct, prejudice is unlikely because "the availability of the information regarding inequitable conduct is primarily within the control of [the non-moving party]." *See Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 373 (D. Del. 2009); *see also Roquette Freres*, 2009 WL 1444835, at *5 (finding no prejudice because "[i]nformation regarding the inventors' knowledge and what they did or did not . . . [represent] to the PTO would primarily be within the control of [plaintiff]").

Here, all of the facts supporting Vetmedica's inequitable conduct claims were within Plaintiffs' control. Dr. Joens and Dr. Glock both work for University of Arizona and all of their documents, [redacted], are within Plaintiffs' custody and control. Likewise, Plaintiffs controlled the production of documents from Quarles & Brady LLP and Mr. Seay for his deposition. If the Court were to hold that Plaintiffs would be prejudiced by the timing of Vetmedica's amendment, based entirely on Plaintiffs' information, litigants would be incentivized to delay production of incriminating documents as a tactic to escape meritorious new pleadings.

Furthermore, there is plenty of time left in the schedule for Plaintiffs to address Vetmedica's proposed amendment. Over four weeks of fact discovery still remain. Vetmedica shared a copy of its proposed pleading with Plaintiffs on August 14th, before they had taken a single deposition in this case. Plaintiffs have not even substantially completed their document production yet. Nothing prevents Plaintiffs from conducting their own discovery to refute any claims of inequitable conduct. Therefore, no unfair prejudice will befall Plaintiffs by Vetmedica's proposed amendment.

4. Vetmedica's Amended Pleading Is Far From Futile

Vetmedica's Amended Pleading is not futile. Vetmedica need only show at this stage that its inequitable conduct allegations "state a claim upon which relief may be granted." *Roquette Freres,* 2009 WL 1444835, at *3. In determining futility, the Court applies the same test as with a motion to dismiss under Rule 12(b)(6). *Id.* Under this standard, which requires taking all factual allegations and inferences in Vetmedica's pleadings as true, Vetmedica's Amended Pleading would clearly survive a 12(b)(6) motion. "Only where it is clear to the court . . . that a claim has *no* possibility of succeeding on the merits, will the court disallow it by denying leave to amend." *Id.* (citation omitted) (emphasis in original).

The Federal Circuit has held that to comply with Rule 9(b), a pleading of inequitable conduct "requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1327. The rule also requires "sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information . . . and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1328-29. "A reasonable inference is one that is plausible and flows logically from the facts alleged." *Id.* at 1329 n.5.

Vetmedica has more than adequately plead the "specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1327. The Amended Pleading identifies Lynn Joens and Robert Glock as individuals **"who"** both knew the information and deliberately withheld it. Ex. 1 at 14, 19-20, 36, 41-42. The pleading identifies **"what"** claims and limitations Stills 1991 and Joens 1997 each relate to—all of them. Ex. 1 at 14-16, 20-21, 36-38, 42-43. The pleading also demonstrates **"when"** the omission was committed before the PTO by listing the specific dates—e.g., November 9, 1992

through March 11, 1997 (Stills 1991) and "at least as early as September 3, 1996 through March 11, 1997" (Joens 1997). Ex. 1 at 18, 23, 40, 45. It demonstrates **"where"** in the references the material information is found by listing specific sections and page numbers of Stills 1991 and Joens 1997 that contain this information. Ex. 1 at 16, 21-22, 38, 43. Finally, it identifies **"how"** the examiner would have used the omitted information—namely by finding the '059 patent claims invalid as anticipated or obvious using Stills 1991 and/or Joens 1997. Ex. 1 at 16-18, 22-23, 38-40, 44-45.

The pleading also alleges sufficient facts from which the court can reasonably infer that the withheld information was material, using *Therasense's* "but-for" test for materiality. *See Therasense,* 649 F.3d at 1291. For example, the pleading explains:

> Examiner would have used such information to find the claims of the '059 Patent anticipated and/or rendered obvious under 35 U.S.C. §§ 102 and/or 103. For example, the [PTO] Examiner . . . stated that she had allowed the '059 patent because the "closest prior art does not teach or suggest the isolation of a microorganism in a mammalian host cell line wherein the microorganism causes porcine proliferative enteritis (PPE). The claimed PPE-causing agent is an obligate, intracellular microorganism. The microorganism taught by the closest prior art causes only symptoms of PPE and is not an intracellular organism." '059 patent file history, 08/28/1996 Notice of Allowance, at 2-3. Stills 1991 teaches and suggests what the Examiner explicitly believed was missing from the prior art that was in front of her and justified allowing the '059 patent over that art. [It] also would have contradicted arguments made by the applicants to obtain the '059 patent, including but not limited to their arguments that "it is clear that even for a period of at least nine years after the publication of Lomax, the art was unable to culture any organism necessary and sufficient to cause PPE", there was no "suggestion to be gleaned from the art to isolate an unknown species of bacterium," and that one of "the strongest arguments in support of the newly isolated nature of the [claimed] strain [was] that the prior art does not describe an obligate intracellular organism that can alone induce PPE." *See*, '059 file history, 6/6/1994 Resp. to Office Action, at 4-12.

Ex. 1 at 16-17, 38-39. The pleading also explains that Joens 1997 (received for publication in 1996) and the foregoing information contained within Joens 1997 would have demonstrated to the Examiner what Stills 1991 teaches and the inventors' use of Stills 1991. *Id.* at 22-23, 44-45.

Thus, the Amended Pleading provides enough facts from which the Court can reasonably infer that the Examiner would not have issued the patent if she knew about the work disclosed in Stills 1991 and Joens 1997.

The Amended Pleading also alleges sufficient underlying facts from which the Court may reasonably infer that Dr. Stills and Dr. Joens knew about both Stills 1991 and Joens 1997 and understood their materiality. With respect to Stills 1991, the pleading states:

> On information and belief, Lynn Joens knew of and understood the materiality of Stills 1991 at least through [redacted] and his co-authoring of Joens 1997 (received for publication in 1996) discussing and citing Stills 1991. Robert Glock also knew of and understood the materiality of Stills 1991. Robert Glock [redacted] and co-authored Joens 1997 discussing and citing Stills 1991. In Joens 1997, Lynn Joens and Robert Glock stated, *inter alia*, that "Stills' work with hamsters with ileitis provided researchers with a proven method for isolation of intracellular agents without risk of contamination by normal intestinal flora. These methods were adapted for isolation of a bacterial agent from necrotic intestinal lesions typical of proliferative ileitis in the pigs of [their] study.

Ex. 1 at 18, 40. With respect to Joens 1997, the pleading states:

> On information and belief, Lynn Joens and Robert Glock knew of and understood the materiality of Joens 1997 (received for publication in 1996) and the information contained within Joens 1997 at least through and a result of their co-authorship of Joens 1997 and their use of the Stills 1991 method in connection with their own work.

Id. at 23-24, 45.

Finally, the Amended Pleading alleges sufficient facts to show that Drs. Joens and Glock intended to mislead the PTO. At the pleading stage, "an inference of deceptive intent must be reasonable and drawn from a pleading's allegations of underlying fact to satisfy Rule 9(b)." *Exergen*, 575 F.3d at 1329 n.5; *see also Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011) (inequitable conduct claim must survive motion to dismiss

where court can reasonably infer specific individual had intent to deceive the PTO); *see also Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS, 2012 WL 600715, at *8-9 (D. Del. Feb. 3, 2012), *report and recommendation adopted*, 2012 WL 749378 (D. Del. Mar. 1, 2012). It need not be the "single most reasonable" inference as would be required by the clear-and-convincing standard used to demonstrate inequitable conduct on the merits. *Wyeth,* 2012 WL 600715, at *12; *Exergen*, 575 F.3d at 1329 n.5. Furthermore, "[i]ntent rarely can be, and need not be, proven by direct evidence. Instead, an intent to deceive is usually inferred from the facts and circumstances surrounding the conduct at issue." *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007) (citation omitted); *see also Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189-90 (Fed. Cir. 1993) (noting that "smoking-gun" evidence is not required to establish an intent to deceive). Deceptive intent may be pled on "information and belief . . . when the essential information lies uniquely within another party's control . . . if the pleading sets forth specific facts upon which the belief is reasonably based." *Exergen,* 575 F.3d at 1330.

Here, Vetmedica's pleading sets forth sufficient facts from which the Court may reasonably draw an inference of deceptive intent. As outlined in paragraphs 44-50 (p. 14-16) and 55-61 (p. 36-38) of Vetmedica's Amended Pleading, Ex. 1, Stills 1991 is Section 102(b) prior art to the '059 patent and anticipates ***every*** one of the '059 patent claims. There is no doubt Dr. Joens and Glock knew about the existence of Stills 1991 and knew that it was directly relevant to their claimed invention while the '059 patent was being prosecuted. [redacted] In Joens 1997, Dr. Joens and Glock described Stills 1991 as providing "researchers with a proven method for isolation of intracellular agents without risk of contamination" and admitted that they had done nothing more than adapt these methods.

Yet despite all of this knowledge, and despite the fact that both Drs. Joens and Glock were informed of and acknowledged their duty of candor before the PTO, they conspicuously never cited it to the PTO. All of this raises a reasonable inference of deceptive intent. In fact, no other reasonable explanation exists.

Vetmedica has thus provided sufficient facts to plead inequitable conduct. At the very least, its inequitable conduct allegations "state a claim upon which relief may be granted." *Roquette Freres,* 2009 WL 1444835, at *3. Therefore, the Amended Pleading is not futile.

Because Vetmedica did not unduly delay amending its pleading, and did so in good faith after gathering enough evidence to support its claims, and because the amended pleading will not unduly prejudice Plaintiffs and is far from futile, the Court should give Vetmedica leave to amend.

VI. Conclusion

For the reasons stated above, Vetmedica respectfully asks that the Court grant its motion to amend its Answer and Counterclaims.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ David E. Moore*
Richard L. Horwitz (#2246)
David E. Moore (#3983)
Bindu A. Palapura (#5370)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com
bpalapura@potteranderson.com

Attorneys for Defendant/Counterclaim Plaintiff Boehringer Ingelheim Vetmedica, Inc.

OF COUNSEL:

Mark Pals
Amanda Hollis
Hari Santhanam
Brian S. Hales, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, Illinois 60654
Tel: (312) 862-2011

Dated: August 29, 2012
Public Version Dated: September 5, 2012
1072830 / 37150

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on September 5, 2012, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on September 5, 2012, the attached document was Electronically Mailed to the following person(s):

Mary B. Graham
Stephen J. Kraftschik
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
Wilmington, DE 19899-1347
mgraham@mnat.com
skraftschik@mnat.com

Raymond N. Nimrod
Gregory D. Bonifield
Aaron S. Kaufman
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
raynimrod@quinnemanuel.com
gregbonifield@quinnemanuel.com
aaronkaufman@quinnemanuel.com

By: */s/ David E. Moore*
Richard L. Horwitz
David E. Moore
Bindu A. Palapura
POTTER ANDERSON & CORROON LLP
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com
bpalapura@potteranderson.com

1021568/37150