

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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|----------------------------------|---|---------------------|
| AEROCRINE AB and AEROCRINE INC., | : |                     |
|                                  | : |                     |
| Plaintiffs,                      | : |                     |
|                                  | : |                     |
| v.                               | : | Civ. No. 08-787-LPS |
|                                  | : |                     |
|                                  | : |                     |
| APIERON INC.,                    | : |                     |
|                                  | : |                     |
| Defendant.                       | : |                     |

**MEMORANDUM ORDER REGARDING INEQUITABLE CONDUCT ALLEGATIONS**

The plaintiffs in this patent infringement action are Aerocrine AB and Aerocrine Inc. (collectively “Aerocrine”). Now pending before the Court are two motions related to inequitable conduct allegations. They are Defendant Apieron Inc.’s (“Aperion”) Motion for Leave to File an Amended Answer to Plaintiffs’ Second Amended Complaint and Amended Counterclaims (“Motion to Amend”) (D.I. 114) and Aerocrine’s Motion For Judgment On Apieron’s Pleadings Alleging Inequitable Conduct by the ‘463 Patent Inventors (“Motion for Judgment”) (D.I. 134). For the reasons set forth below, Aperion’s Motion to Amend is **GRANTED** and Aerocrine’s Motion for Judgment is **DENIED**.

**BACKGROUND**

This is a patent case involving medical devices capable of measuring nitric oxide levels in exhaled breath. Aerocrine alleges infringement of three of its patents – U.S. Patent No.

5,922,610 (the “‘610 patent”), U.S. Patent No. 6,038,913 (the “‘913 patent”), and U.S. Patent No. 6,733,463 (the “‘463 patent”) – by Apieron’s sale of its own device for measuring exhaled nitric oxide. (D.I. 134 at 1) Aerocrine filed its complaint on October 21, 2008. (D.I. 1) In its defense, Apieron has asserted that the ‘610, ‘913, and ‘463 patents are invalid, that they are not infringed, and that the ‘463 patent is unenforceable because of the inequitable conduct of its two inventors, Drs. Eeva Moilanen and Lauri Lehtimäki, during prosecution. (*Id.*)

Apieron’s Motion to Amend, filed pursuant to Federal Rule of Civil Procedure 15(a)(2), seeks leave to file an Amended Answer to Plaintiffs’ Second Amended Complaint and Amended Counterclaims. (D.I. 114) Specifically, Apieron seeks to allege that Aerocrine’s ‘610 patent is unenforceable due to the inequitable conduct of one or more of its inventors. (*Id.* at 1)

Aerocrine responds to Apieron’s Motion to Amend (D.I. 131) with the same argument that underlies its Motion for Judgment. (D.I. 134) Aerocrine argues that the Federal Circuit’s recent decision in *Exergen Corp. v Wal-Mart Stores, Inc.*, 575 F.3d 1321 (Fed. Cir. 2009), precludes Apieron’s assertion of the inequitable conduct affirmative defense with regard to both the ‘610 and ‘463 patents. (D.I. 134 at 1)

**I. Apieron’s Allegations of Inequitable Conduct During Prosecution of the ‘610 Patent**

The basis for Apieron’s proposed amendment to add an inequitable conduct affirmative defense with respect to Aerocrine’s ‘610 patent arose during the October 14, 2009 deposition of (non-party) Dr. Benjamin M. Gaston. (D.I. 114 at 2) According to Apieron, Dr. Gaston created an invention that is of the same subject matter to which at least claims 16 and 25 of Aerocrine’s ‘610 patent are directed and which predates the earliest filing date to which the ‘610 patent can

claim priority: July 6, 1993. (D.I. 115 Ex. A (“Amended Answer”) ¶¶ 43-45) Apieron alleges that Dr. Gaston’s research into the subject matter of the ‘610 patent (the “Spring 1993 Research”) would have been material to at least claims 16 and 25 of the ‘610 patent in the view of a Patent & Trademark Office (“PTO”) examiner because the research “represents the prior invention, anticipates, and/or renders obvious at least those claims.” (Amended Answer ¶ 46)

Dr. Gaston submitted an abstract and presented a poster of his Spring 1993 Research to the organizers of a conference on the biology of nitric oxide; the conference was held in Cologne, Germany, between October 3-6, 1993 (the “1993 Cologne Conference”). (*Id.* ¶¶ 47-48 (citing D.I. 155 Ex. 2<sup>1</sup>)) Dr. Gaston submitted the abstract prior to the May 15, 1993 deadline for abstracts. (*Id.* ¶ 47) Dr. Gaston’s poster “was the subject of much discussion at the 1993 Cologne Conference because several groups were simultaneously presenting the same findings, a fact that surprised conference participants.” (*Id.* ¶ 49) Dr. Weitzberg, one of the ‘610 patent’s inventors, attended the 1993 Cologne Conference and “became aware of Gaston’s presentation” at the conference. (*Id.* ¶¶ 54-55) Drs. Alving and Lundberg, the other inventors of the ‘610 patent, “also became aware of Gaston’s presentation at the Cologne Conference, or immediately thereafter,” and they were also, along with Weitzberg, “aware” that Gaston’s Spring 1993

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<sup>1</sup>Dr. Gaston’s abstract provides, in pertinent part: “We compared expired NO concentrations in normal subjects, patients with advanced cystic fibrosis (CF) . . . , and patients with reactive airways disease (RAD). Subjects breathed [nitric oxide]-scrubbed air for two minutes, inspired to total lung capacity, and then performed a forced vital capacity into a teflon gas-sampling bag. These preliminary data suggest that expired [nitric oxide concentrations] are significantly elevated in patients with RAD, but are not [in patients with] advanced CF. Because of the striking differences between patients with CF and those with RAD, we speculate that primary abnormalities in epithelial cells or smooth muscle cells NOS regulation, rather than chronic leukocyte activation or obstruction physiology, may account for increased expired [NO] in patients with RAD.” (Amended Answer, Ex. 2)

Research had occurred in the U.S. (*Id.* ¶¶ 56, 58) Further, Dr. Weitzberg “knew” that the deadline for submitting abstracts to the Cologne Conference was on May 15, 1993, “which was prior to the filing of his patent application that led to the issuance of the ‘610 patent.” (*Id.* ¶ 57)

In May 1998, a workshop was held in Toronto, Canada, where “international investigators” in the field of exhaled and nasal nitric oxide met to develop recommendations for standardized procedures for measuring exhaled nitric oxide. (*Id.* ¶ 50) Dr. Alving attended the Toronto workshop. (*Id.* ¶ 59) The workshop’s proceedings were documented in the “official statement of the American Thoracic Society” in 1999 (the “1999 ATS Recommendations”). (*Id.* ¶ 51) The 1999 ATS Recommendations “reported that Gaston and other research groups had simultaneously developed the subject matter claimed in at least claims 16 and 25 of the ‘610 patent.” (*Id.* ¶ 52) Specifically, “several publications reported high levels of orally exhaled [nitric oxide] in subjects with asthma as compared with unaffected subjects (13-18).” (*Id.*) Dr. Gaston’s work was listed as reference number 13. (*Id.*)

“Upon information and belief, Alving and Lundberg became aware of Gaston’s Spring 1993 Research in the United States, that it represented that prior invention, anticipated, and/or rendered obvious the subject matter of at least claims 16 and/or 25 of the ‘610 patent at least as early as the 1998 Toronto Workshop.” (*Id.* ¶ 60) Also, “[u]pon information and belief, Alving, Lundberg, and Weitzberg became aware that the scientific community believed that the subject matter claimed in at least claim 16 and/or 25 of the ‘610 patent had been developed simultaneously by several research groups at least by the Toronto Workshop.” (*Id.* ¶ 61) Further, “Alving, Lundberg and Weitzberg became aware that . . . Gaston had invented in the United States the subject matter claim 16 [and/or] claim 25 of the ‘610 patent at least by the 1998

Toronto Workshop.” (*Id.* ¶¶ 62-63) Finally, “[u]pon information and belief, although Alving, Lundberg, and Weitzberg were aware of Gaston’s Spring 1993 Research and its disclosure prior to the issuance of their patent, and were accordingly aware of their materiality to the prosecution of their application, they intentionally misled the PTO by failing to disclose these references.” (*Id.* ¶ 64) Alving, Lundberg, and Weitzberg “failed to disclose Gaston’s Spring 1993 Research with the intent to deceive the PTO concerning the patentability of the application leading to the ‘610 patent, and therefore committed inequitable conduct, rendering the ‘610 patent unenforceable.” (*Id.* ¶ 65)

Apieron also asserts that Dr. Gaston stated during his deposition that he believes that he communicated with at least Dr. Alving about his own invention, and, thus, believes that at least Dr. Alving was aware of Dr. Gaston’s work and its relevance to the ‘610 patent. (D.I. 114 at 2)<sup>2</sup> He also testified that it would be “hard for [him] to imagine” that Dr. Lundberg was not aware of his work, because Lundberg, Alving, and Gaston went to meetings together between 1993 and 1999, “knew each other and talked about exhaled [nitric oxide].” (*Id.* at 3) Additionally, the 1999 ATS Recommendations (describing the 1998 Toronto workshop) list Dr. Gaston as a moderator and Drs. Alving, Lundberg, and Weitzberg as “workshop participants.” (*Id.*; *see also* Amended Answer Ex. 3 at 2114.) In Apieron’s view, the background portion of the 1999 ATS Recommendations shows that the subject matter of the ‘610 patent was developed independently by several groups and cites both Dr. Gaston’s work and a journal article authored by Drs. Alving,

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<sup>2</sup>Statements made by Apieron in its Motion to Amend are incorporated into the Amended Answer to the extent that they reflect documents attached to the Amended Answer. Statements made by Dr. Gaston during his deposition are thus incorporated because Dr. Gaston’s complete deposition transcript is appended to the Amended Answer as Exhibit 1. *See, e.g., Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009).

Weitzberg, and Lundberg as examples of those groups. (D.I. 114 at 2; *see also* Amended Answer Ex. 3 at 2114.)

## **II. Aerocrine’s Response to the Proposed ‘610 Patent Inequitable Conduct Allegations**

Aerocrine opposes Apieron’s proposed additions in its Amended Answer based on the Federal Circuit’s decision in *Exergen*, which outlined heightened pleading requirements for pleading inequitable conduct under Federal Rule of Civil Procedure 9(b). (D.I. 131 at 1) Aerocrine argues that Apieron’s proposed amendments do not provide the specificity required under either Rule 9(b) or *Exergen* because they “plead no facts that demonstrate – or are sufficient to reasonably infer – either knowledge of materiality or intent to deceive the [PTO].” (*Id.*) Specifically, Aerocrine contends that the allegations in the Amended Answer, “at best,” demonstrate only the “opportunity” for the ‘610 patent’s inventors to have become aware of Dr. Gaston’s work at the 1993 Cologne Conference or 1998 Toronto workshop. (*Id.* at 5) “The only facts that Apieron avers . . . are that . . . Dr. Weitzberg attended the 1993 Germany conference and . . . Dr. Alving, attended a workshop in Toronto in 1998 . . . that cited the six-sentence abstract [of Dr. Gaston’s work] among the 158 references in its bibliography.” (*Id.*) Moreover, some 357 abstracts were presented at the 1993 Cologne Conference and, of those, 300 (including Dr. Gaston’s) were presented solely as posters. (*Id.* (citing D.I. 132 Ex. 2)) Apieron also does not have a copy of Dr. Gaston’s poster from the 1993 Cologne Conference. (D.I. 131 at 5)

Aerocrine further faults Apieron’s Amended Answer for alleging “awareness of Dr. Gaston’s work, his poster, or its allegedly material nature” and intent to deceive the PTO only based on “information and belief,” not facts. (*Id.* at 7-8) According to Aerocrine:

Apieron (1) *infers* that the '610 inventors were aware of the poster at the conference because one of them attended the conference on information and belief; (2) *infers*, based on their inferred awareness of the poster, that the '610 inventors also were aware of the materiality of the poster and abstract on information and belief, and (3) based on their inferred awareness of the poster and its supposed materiality, *infers* that the '610 inventors then failed to disclose the abstract with intent to deceive the PTO.

(*Id.* at 8) (emphasis in original) Aerocrine asserts that Apieron's repeated reliance on information and belief is only permitted if Apieron also sets forth the "specific facts upon which the belief is reasonably based," which it did not do. (*Id.* at 9 (quoting *Exergen*, 575 F.3d at 1330-31)) Thus, Aerocrine argues that Apieron has failed to allege facts from which it would be reasonable to infer that the '610 patent's inventors either knew of the withheld material information or had a specific intent to deceive the PTO. (*Id.*)<sup>3</sup>

Aerocrine also contends that, under *Exergen*, inequitable conduct pleadings must "identify the particular claim limitations, . . . that are supposedly absent from the information of record." (*Id.* at 6) Such allegations go to both "why the withheld information is material and not cumulative, and how an examiner would have used this information in assessing the patentability of the claims." (*Id.* (citing *Exergen*, 575 F.3d at 1329-30)) To Aerocrine, the Amended Answer does not refer to the "information of record" at all nor does it explain why the allegedly material information is not cumulative. (*Id.*) With respect to the abstract of Dr. Gaston's work published at the 1993 Cologne Conference, Aerocrine argues that it is at best "equivocal" on the point that Aerocrine claims is "material." (*Id.*) "Aerocrine confuses the '610 inventors' discovery that

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<sup>3</sup>Aerocrine also objects that Dr. Gaston, whose testimony lays the foundation for the Amended Answer, is an interested witness, because he is Apieron's retained expert in this case. (D.I. 131 at 5)

asthmatics have elevated exhaled nitric oxide concentrations” with the ‘610 patent’s invention, which covers “more than a relationship between elevated nitric oxide concentrations and inflammatory conditions in the lower airways.” (*Id.* (citing Amended Answer ¶ 45 and D.I. 132 Ex. 4, ‘610 patent, cols. 9-12))

### **III. Apieron’s Allegations of Inequitable Conduct During Prosecution of the ‘463 Patent**

Apieron alleges that the ‘463 patent is unenforceable due to the inequitable conduct of its two named inventors, Drs. Moilanen and Lehtimäki, before the PTO during the prosecution of the application leading to the ‘463 patent. (Amended Answer ¶¶ 66-80)<sup>4</sup> Specifically, Apieron contends that the prior art reference Tsoukias (1998) “discloses every element of, and anticipates and/or renders obvious” at least claims 4 and 5 of the ‘463 patent. (*Id.* ¶¶ 69-70) Tsoukias (1998) does so with respect to claim 4 by describing the use of measuring equipment to measure nitric oxide concentrations in exhaled air, including a blow tube, a means to measure nitric oxide, a flow meter, and a flow rate adjuster.<sup>5</sup> (*Id.* ¶ 69) With respect to claim 5, Tsoukias (1998) describes “a means to measure the flow rate of the exhaled air consecutively to at least two different flow rates, and to measure the nitric oxide in the exhaled air at each flow rate.” (*Id.* ¶ 70)

Apieron also alleges that the prior reference Högman (2000) anticipates and/or renders

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<sup>4</sup>Although Apieron’s inequitable conduct defense in connection with the ‘463 patent appeared for the first time in its Answer to the Second Amended Complaint (D.I. 74), for convenience the Court will refer to the paragraph numbers as they appear in the Amended Answer.

<sup>5</sup>Alternatively, Apieron alleges “it would have been obvious to keep the flow rate substantially constant through use of a resistance device such as that disclosed, for example, in Tsoukias (1998).” (Amended Answer ¶ 71)



obvious every element of at least claim 4 of the '463 patent. (*Id.* ¶ 71) Högman (2000) describes the use of measuring equipment to measure nitric oxide concentrations in exhaled air, including a blow tube, a means to measure nitric oxide, a flow meter, and a flow rate adjuster. (*Id.*) Högman (2000) also “discloses every element of, and anticipates and/or renders obvious,” at least claim 5 of the '463 patent. (*Id.* ¶ 72) “Högman (2000) describes a means to measure the flow rates of the exhaled air consecutively to at least two different flow rates, and to measure the nitric oxide in the exhaled air at each flow rate.” (*Id.*)

In Apieron's view, a reasonable examiner would have found Tsoukias (1998) and Högman (2000) material to the allowance of at least claims 4 and 5 of the '463 patent because both of these references “anticipate and/or render obvious these claims of the patent.” (*Id.* ¶ 73) Further, a reasonable examiner would have found Tsoukias (1998) and Högman (2000) material to the prosecution of the '463 patent because the examiner (who was unaware of these two references) stated that claims directed to two or more flow rates covered allowable subject matter, since “the prior art does not teach at least two different flow rate values are set for the flow rate during the measurement.” (*Id.* ¶ 74 (citing Office Action); D.I. 146 at 5) Moreover, a reasonable examiner would have found at least Tsoukias (1998) material to the '463 patent's prosecution because the applicants distinguished prior art on the basis that “[i]t is clear that if the flow resistance element cannot be adjusted, this step of the inventive method cannot be met.” (*Id.* ¶ 75 (citing Reply to Office Action); D.I. 146 at 5)

“Upon information and belief,” Drs. Moilanen and Lehtimäki were aware of both Tsoukias (1998) and Högman (2000) prior to filing the application leading to the '463 patent, as demonstrated by their citations to these references in scientific publications they co-authored.

(*Id.* ¶ 76) One such publication is “Lehtimäki et al., Increased Bronchial Nitric Oxide Production in Patients with Asthma Measured with a Novel Method of Different Exhalation Flow Rates” (“Lehtimäki (2000)”), published on or around May 9, 2000, which was prior to the filing date of the ‘463 patent. Lehtimäki (2000) cites to Tsoukias (1998) as reference number 11. (*Id.* ¶ 77) The other is “Lehtimäki et al., Extended Exhaled NO Measurement Differentiates between Alveolar and Bronchial Inflammation” (“Lehtimäki (2001)”), published on or around March 7, 2001, also prior to the ‘463 patent application. (*Id.* ¶ 78) Lehtimäki (2001) cites to Högman (2000) as reference number 23. (*Id.*)

Therefore, “[u]pon information and belief,” Drs. Moilanen and Lehtimäki were “aware” of the Tsoukias (1998) and Högman (2000) prior art references and their disclosures prior to filing the ‘463 patent application; the inventors “were accordingly aware of their materiality to the prosecution of their application.” (*Id.* ¶ 79; D.I. 146 at 6-7) Apieron argues in its brief that the citations to Tsoukias (1998) and Högman (2000) in Lehtimäki (2000) and Lehtimäki (2001) necessarily mean that the inventors understood the material portions of the references (how Tsoukias and Högman set up their experiments), “because such an understanding would have been necessary for [them] to assess whether the reference was reliable and worthy of being relied upon in their own publication.” (D.I. 146 at 8-9) Further, Drs. Moilanen and Lehtimäki are listed as the first and last authors, respectively, on each paper. (*Id.* at 10) “This likely signifies that [Lehtimäki] did the majority of the work and writing of the article, and the research was conducted in [Moilanen’s] laboratory,” and also that both inventors were involved in drafting and editing the papers. (*Id.*) Thus, they “intentionally misled the PTO by failing to disclose these references” and did so “with the intent to deceive the PTO concerning the patentability of the

application leading to the '463 patent.” (*Id.* ¶¶ 79-80)

#### **IV. Aerocrine’s Response to Apieron’s Allegations of Inequitable Conduct During Prosecution of the ‘463 Patent**

Aerocrine argues that Apieron’s allegations of inequitable conduct against Drs. Moilanen and Lehtimäki during prosecution of the ‘463 patent do not contain the facts necessary to show that the inventors: (1) knew of specific disclosures in the Tsoukias (1998) and Högman (2000) references that Apieron alleges are material and (2) intentionally withheld these references with the specific intent to deceive the PTO. (D.I. 134 at 1)

Aerocrine contends that Apieron’s allegations fall short of establishing how a general awareness of Tsoukias (1998) and Högman (2000) “evidences any knowledge of the specific portion” of the references that Apieron alleges are material. (*Id.* at 6) According to Aerocrine, neither Lehtimäki (2000) or Lehtimäki (2001) “quotes or cites the allegedly material portions” of Tsoukias (1998) or Högman (2000). (*Id.*) Lehtimäki (2000) cites Tsoukias (1998) for its relevance “to a model for assessing the relative contributions of alveolar and bronchial levels to exhaled NO,” which led to the findings of “similar bronchial NO flux but a slightly higher alveolar NO concentration.” (*Id.*) The Amended Answer alleges, however, that Tsoukias (1998) is material because it discloses a blow tube, a means to measure nitric oxide, a flow meter, a flow rate adjuster, and consecutive measurement of flow rate and exhaled NO to at least two different flow rates. (*Id.* (citing Amended Answer ¶¶ 69-70)) Likewise, Lehtimäki (2001) cites Högman (2000) for the proposition that “[r]ecent publications show that bronchial NO flux can be divided into bronchial wall NO concentration and bronchial NO diffusion factor, if very low exhaustion flow rates are used in NO measurements.” (*Id.*) The Amended Answer alleges that Högman

(2000) is material because it discloses a blow tube, a means to measure nitric oxide, a flow meter, a flow rate adjuster, and consecutive measurement of flow rate and exhaled NO to at least two different flow rates. (*Id.* at 7 (citing Amended Answer ¶¶ 71-72)) Given the Federal Circuit’s observation in *Exergen* that “[o]ne cannot assume that an individual, who generally knew that a reference existed, also know of the specific material information contained in that reference,” 575 F.3d at 1330, Aerocrine insists that Apieron has not pleaded facts sufficient to show that Drs. Moilenan and Lehtimäki were aware of the specific disclosures that Apieron now alleges to be material. (*Id.* at 7)

Aerocrine also argues that Apieron has not pleaded any facts suggesting that Drs. Moilenan and Lehtimäki intentionally withheld the Tsoukias (1998) and Högman (2000) references in an effort to deceive the PTO. (*Id.* at 8) “Instead, Apieron relies upon the inventors’ inferred awareness of the material portions of Tsoukias and Högman to then infer intent on ‘information and belief.’” (*Id.* (citing Amended Complaint ¶¶ 79-80)) To Aerocrine, such allegations based on “compounded inference” are “plainly insufficient, even at the pleading stage.” (*Id.*) Although a party may plead facts “upon information and belief,” it must also set forth the “specific facts upon which the belief is reasonably based.” (*Id.* (quoting *Exergen*, 575 F.3d at 1330-31)) In *Exergen*, the court found that allegations of an applicant’s failure to disclose a reference previously cited during prosecution of a related application was “insufficient to meet the threshold level of deceptive intent.” (*Id.* (quoting *Exergen*, 575 F.3d at 1331)) Here, Aerocrine asserts, deceptive intent cannot be inferred from citations to Tsoukias (1998) and Högman (2000) in articles co-authored by Drs. Moilanen and Lehtimäki that were not communicated to the PTO during prosecution of the ‘463 patent. (*Id.*)

Moreover, Aerocrine argues that Drs. Moilanen and Lehtimäki specifically disclosed to the PTO examiner two contemporaneous Tsoukias publications on the same subject matter as Tsoukias (1998) and Högman (2000). (D.I. 156 at 1-2) Specifically, the inventors disclosed “the Tsoukias 782 international patent publication” (“Tsoukias 782 ”). (*Id.* at 3) According to Aerocrine, Tsoukias 782 is cumulative of the Tsoukias (1998) reference in several aspects, and, thus, “because the same information was already before the examiner in Tsoukias 782, Tsoukias (1998) was neither ‘highly material’ nor ‘anticipatory.’” (*Id.* at 4 (citing D.I. 146 at 1, 3, 6-7)) To Aerocrine, Högman (2000) is also cumulative of two other prior art references, Tsoukias 782 and an article by Pietropaoli, and, thus, it also cannot be highly material nor anticipatory. (*Id.* at 5) Finally, Aerocrine contends that the sentence from Lehtimäki (2000) that supposedly describes Tsoukias (1998) actually refers to another prior art reference, Tsoukias-George, that was specifically disclosed to the PTO. (*Id.* at 6-7)

## LEGAL STANDARDS

### I. Motion for Leave to Amend

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that on a motion to amend a pleading, a court “should freely give leave when justice so requires.” “The Third Circuit has adopted a liberal approach to the amendment of pleadings to ensure that a particular claim will be decided on the merits rather than on technicalities.” *Abbott Labs. v. Johnson & Johnson, Inc.*, 524 F. Supp. 2d 553, 557 (D. Del. 2007) (internal quotation marks omitted). A court should not, however, permit amendment in the presence of “undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice to the opposing party . . . , [or] futility of amendment.”

*Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also CCPI Inc. v. Am. Premier, Inc.*, 967 F. Supp. 813, 815 (D. Del. 1997).

In the Third Circuit, “[t]he non-moving party has the burden of proving that actual prejudice will result from amendment of the complaint.” *Clark v. Williams*, 2008 WL 1803648, at \*1 (D. Del. Apr. 18, 2008) (internal quotation marks omitted); *see also Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989). The prejudice factor “requires [the Court to] focus on the hardship to the defendants if the amendment were permitted.” *Cureton v. NCAA*, 252 F.3d 267, 273 (3d Cir. 2001) (internal citation and quotation marks omitted). A party suffers undue prejudice if the proposed amendment causes surprise, results in additional discovery, or adds costs to the litigation in defending against the new facts or theories alleged. *See id.*

## **II. Pleading Inequitable Conduct Under Rule 9(b)**

Federal Rule of Civil Procedure 9(b) requires that “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” Inequitable conduct, “while a broader concept than fraud, must be pled with particularity” pursuant to Rule 9(b). *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). An individual associated with the filing and prosecution of a patent application engages in inequitable conduct when he or she makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information to the PTO, with a specific intent to deceive the PTO. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008); 37 C.F.R. § 1.56 (2008). Thus, “[a] pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule

9(b).” *Exergen*, 575 F.3d at 1326.

Additionally, while Rule 9(b) allows “[m]alice, intent, knowledge, and other conditions of a person’s mind [to] be alleged generally, . . . ‘generally’ is a relative term. In the context of Rule 9, it is to be compared to the particularity requirement applicable to fraud or mistake. Rule 9 merely excuses a party from pleading discriminatory intent under an elevated pleading standard.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1954 (2009). “Although ‘knowledge’ and ‘intent’ may be averred generally, [Federal Circuit] precedent . . . requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.” *Exergen*, 575 F.3d at 1327. “In sum, to plead the ‘circumstances’ of inequitable conduct with the requisite ‘particularity’ under Rule 9(b), the pleading must identify the specific *who, what, when, where and how* of the material misrepresentation or omission committed before the PTO.” *Id.* at 1327 (emphasis added).

### **III. Motion for Judgment on the Pleadings**

A motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), alleging a failure to state a claim upon which relief can be granted, is analyzed under the same standard as a Rule 12(b)(6) motion to dismiss. *See Turbe v. Gov’t of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss all or part of an action for “failure to state a claim upon which relief can be granted.” A motion to dismiss requires a court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). “The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation

marks omitted). Thus, a court may grant a motion to dismiss only if, after “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.” *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

However, “[t]o survive a motion to dismiss, a civil plaintiff must allege facts that ‘raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).’” *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1965, 167 L. Ed. 2d 929 (2007) (internal citations omitted)). While heightened fact pleading is not required, “enough facts to state a claim to relief that is plausible on its face” must be alleged. *Bell Atlantic*, 127 S. Ct. at 1974. At bottom, “[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element” of a plaintiff’s claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.*, 522 F.3d 315, 321-22 (3d Cir. 2008) (internal quotation marks omitted). Nor is the Court obligated to accept as true “bald assertions,” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997), “unsupported conclusions and unwarranted inferences,” *Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are “self-evidently false,” *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

## DISCUSSION

### I. Inequitable Conduct Allegations Relating to the ‘610 Patent

Aerocrine’s opposition to Apieron’s Motion to Amend has not established any of the



factors weighing against amendment, such as “undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice to the opposing party . . . , [or] futility of amendment.” *Foman*, 371 U.S. at 182. Apieron’s Motion to Amend was filed less than a month after Apieron took Dr. Gaston’s deposition and became aware of the basis for its allegations of inequitable conduct, so delay is not an issue. Also, while Aerocrine has emphasized that Dr. Gaston is Apieron’s paid expert consultant in this case, Apieron has not pointed to any evidence of bad faith or dilatory motive in Dr. Gaston’s testimony or related documents.<sup>6</sup> Also, Aerocrine has not met its burden to prove it would suffer undue prejudice if Apieron’s proposed amendments are allowed. With respect to futility of amendment, Apieron’s Amended Answer satisfies the pleading requirements of Rule 9(b) and *Exergen* with respect to its averments of inequitable conduct by Drs. Alving, Lundberg, and Weitzberg during prosecution of the ‘610 patent.

Apieron has alleged the “specific *who, what, when, where and how* of the material misrepresentation or omission committed before the PTO” in its Amended Answer. See *Exergen*, 575 F.3d at 1327. The “who” are the ‘610 patent’s inventors: Drs. Alving, Lundberg, and Weitzberg. The “what” is Dr. Gaston’s Spring 1993 research, as disclosed in the abstract and poster submitted to the 1993 Cologne Conference and/or during the 1998 Toronto Workshop (memorialized by the 1999 ATS Recommendations), and which is alleged to be material to at least claims 16 and 25 of the ‘610 patent. The “when” – describing when the inventors became aware of the allegedly material prior art – is either during the 1993 Cologne Conference, or, at the latest, by the 1998 Toronto Workshop; in either case the art was not disclosed to the PTO

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<sup>6</sup>In an abundance of caution, however, the Court has not relied solely on Dr. Gaston’s testimony in reaching its decision to allow the amendment, as discussed *infra* note 8.

during prosecution of the '610 patent. The “where” of the allegations, meaning where in the prior art the allegedly material information is found, is Dr. Gaston’s abstract submitted to the 1993 Cologne Conference (attached as an exhibit to the Amended Answer). The “how” – how a reasonable examiner would have used the omitted prior art references in determining patentability – is that a reasonable examiner would have found Dr. Gaston’s Spring 1993 Research material to the allowance of at least claims 16 and 25 of the '610 patent because it represents the prior invention, anticipates, and/or renders obvious at least those claims.

Aerocrine argues that Apieron’s failure to expressly allege that the Gaston reference was not “cumulative” renders these allegations insufficient under *Exergen*. But merely reciting that a prior art reference is not “cumulative” does not satisfy the relevant standard. In fact, it was the unexplained assertion that references were not cumulative that the Federal Circuit found to be unsatisfactory in *Exergen*. See 575 F.3d at 1327 (“[T]he pleading states generally that the withheld references are ‘material’ and ‘not cumulative to the information already of record,’ but does not identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record. Such allegations are necessary to explain both ‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.”). It follows that the failure to include an unexplained allegation that withheld prior art is not “cumulative” does not doom a pleading. The requirement is that the pleading *explain* the “why” and the “how.” Here, Apieron’s Amended Answer does so, by identifying the particular claim limitations that are purportedly absent from the information of record (at least Dr. Gaston’s abstract and poster submitted to the 1993 Cologne Conference and attached to the Amended Answer as Exhibit 2)

and explaining that a reasonable examiner would have found this art material to at least claims 16 and 25 of the '610 patent, because it represents the prior invention, anticipates, and/or renders obvious at least those claims.<sup>7</sup>

With respect to Apieron's allegations of deceptive intent on the part of the inventors during the '610 patent's prosecution, the Court notes that "the heightened pleading requirements of Rule 9(b) do not require that [Aperion] definitively prove the merits of its claim. What is determinative here is that [Aerocrine] was given fair notice of the basis for [Aperion's] inequitable conduct defense." *The Braun Corp., v. Vantage Mobility Int'l, LLC*, 2010 U.S. Dist. LEXIS 6839, at \*15 (N. D. Ind. Jan. 27, 2010) (internal quotation marks omitted). Indeed, "knowledge and intent may be averred generally" from the alleged facts. *Exergen*, 575 F.3d at 1327. What is really at issue in this dispute is whether the allegations set forth in the Amended

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<sup>7</sup>There is some disagreement in the reported caselaw on this point. *Compare Somanetics Corp. v. CAS Med. Sys.*, 2010 U.S. Dist. LEXIS 17006, at \*18 (E.D. Mich. Feb. 25, 2010) ("[Plaintiff] does not need [Defendant], for purposes of notice pleading, to explain why a three page article comparing [Plaintiff's] product to a pre-existing product that embodies the invention claimed in the '065 Patent is not cumulative or how the examiner would have applied it."); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 2010 U.S. Dist. LEXIS 556, at \*39 (W.D. Wis. Jan. 5, 2010) (inferring that withheld prior art was not cumulative from defendant's allegations that plaintiffs submitted incomplete versions of prior art to PTO); *Konami Digital Entm't Co. v. Harmonix Music Sys.*, 2009 U.S. Dist. LEXIS 117468, at \*7 (E.D. Tex. Dec. 14, 2009) ("[Defendant] pleads the 'how' required under *Exergen* by compiling analysis that incorporates Examiner statements to support its theories. *These statements suggest* that the disclosed Konami prior art may not be cumulative of all of the information on record, and therefore, gives [Defendant] a reasonable basis on which to allege undisclosed prior art references.") (emphasis added) *with Advanced Micro Devices v. Samsung Elecs. Co.*, 2010 U.S. Dist. LEXIS 24243, at \*42-43 (N.D. Cal. Mar. 15, 2010) (finding inequitable conduct allegations deficient under *Exergen* where defendant "stop[ped] short" of alleging that withheld references were non-cumulative of any prior art) *and Correct Craft IP Holdings, LLC v. Malibu Boats, LLC*, 2010 U.S. Dist. LEXIS 13577, at \*17 (M.D. Fla. Feb. 17, 2010) (dismissing inequitable conduct allegations in part because defendant failed "to identify the particular aspects of the drawings, notes, and early sale of the wakeboard tower that are supposedly absent from the information of record").

Complaint comprise a plausible factual scenario from which the Court can reasonably infer knowledge and deceptive intent on the part of the ‘610 patent’s inventors. *See id.* at n.5 (“A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith.”).

Aerocrine complains that Apieron alleges only that the ‘610 inventors had an *opportunity* to know of Dr. Gaston’s Spring 1993 Research, and such “information and belief” are insufficient to establish the inventors’ actual, subjective knowledge of the material. However, Apieron’s allegations provide a reasonable basis to infer that the ‘610 inventors were aware of the prior art: Drs. Alving, Lundberg, and Weitzberg were all attendees of the 1993 Cologne Conference and the 1998 Toronto Workshop, where Dr. Gaston’s work was presented (as a poster and/or abstract) and/or discussed; and the 1999 ATS Recommendations (summarizing the 1998 Toronto Workshop) specifically reported that several research groups had simultaneously developed inventions relevant to at least claims 16 and 25 of the ‘463 patent, citing both Dr. Gaston’s work and an article by Drs. Alving, Weitzberg, and Lundberg as examples. It can reasonably be inferred from these allegations that the ‘610 inventors were aware of Dr. Gaston’s work.<sup>8</sup> For the same reasons, the Court finds that Apieron has sufficiently alleged deceptive intent on the ‘610 inventors’ parts at the pleading stage. Therefore, Apieron’s inequitable conduct allegations relating to the ‘610 patent satisfy the pleading requirements of Rule 9(b) and *Exergen*.

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<sup>8</sup>Dr. Gaston’s testimony supplies further factual bases for this conclusion which may or may not be borne out through further discovery; however, at this point the Court relies on the documentary evidence supplied in and attached to the Amended Answer to reach its conclusion.

## II. Inequitable Conduct Allegations Relating to the '463 Patent

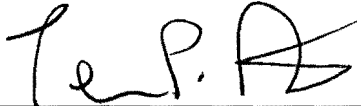
Apieron's Amended Answer also satisfies Rule 9(b) and *Exergen* with respect to its averments of inequitable conduct by Drs. Moilanen and Lehtimäki during prosecution of the '463 patent. Apieron has alleged the "specific *who, what, when, where and how* of the material misrepresentation or omission committed before the PTO" in its Amended Answer. *See Exergen*, 575 F.3d at 1327. The "who" is Drs. Moilanen and Lehtimäki, inventors of the '463 patent. The "what" are Tsoukias (1998) and Högman (2000), alleged to be material to at least claims 4 and 5 of the '463 patent. The "when" is either when Lehtimäki (2000) or Lehtimäki (2001) was published – both were published prior to the filing date of the '463 patent, and both disclose, respectively, the allegedly material prior art, although the prior art was not cited to the PTO. The Amended Answer also identifies "where" in the allegedly material prior art the improperly withheld information is found by citing to specific page ranges within Tsoukias (1998) and Högman (2000). *See, e.g.*, Amended Answer ¶¶ 69-72. The "why and how" a reasonable examiner would have utilized this withheld information is also sufficiently alleged: a reasonable examiner would have found Tsoukias (1998) and Högman (2000) material to the allowance of at least claims 4 and 5 of the '463 patent, because both of these references "anticipate and/or render obvious these claims of the patent." Further, Aerocrine acknowledges that, regardless of the accuracy of Apieron's allegations as to the materiality of these references to the '463 patent, "they do purport to 'identify the particular claim limitations . . . that are supposedly absent from the information of record,' and must be taken as true for purposes of the instant motion." (D.I. 134 at 4 n.1 (citing *Exergen*, 575 F.3d at 1329))

The Amended Answer also satisfies the requirements of Rule 9(b) and *Exergen* with respect to allegations of scienter. Apieron has sufficiently alleged a factual basis from which it may be reasonably inferred that Drs. Moilanen and Lehtimäki were aware of the Tsoukias (1998) and Högman (2000) prior art during prosecution of the '463 patent – namely, that both references were cited for relevant propositions in articles co-authored by both inventors (and, apparently, both principally authored by Dr. Lehtimäki). From that predicate, it is reasonable to infer that the inventors would have been aware of the material portions of the prior art (how the experiments were set up), because they would have had to know whether they were reliable and worthy references for use in their own publications. It is similarly reasonable to infer that the inventors deliberately withheld this material prior art from the PTO, based on the allegations of knowledge and materiality. Whether these allegations of inequitable conduct by Drs. Moilanen and Lehtimäki (like the other similar allegations discussed in this Order) are ultimately provable or accurate is not an issue before the Court today.

### CONCLUSION

**IT IS HEREBY ORDERED THAT** Apieron's Motion to Amend (D.I. 114) is **GRANTED** and Aerocrine's Motion for Judgment (D.I. 134) is **DENIED**.

Dated: March 30, 2010

  
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Leonard P. Stark  
UNITED STATES MAGISTRATE JUDGE