UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, ABBOTT MOLECULAR INC., and ABBOTT LABORATORIES, INC.,

Plaintiffs,

v.

DAKO NORTH AMERICA, INC. and DAKO DENMARK A/S,

Defendants.
_____/

No. C 05-03955 MHP

MEMORANDUM & ORDER

Re: Defendants' Motions for Summary Judgment of Invalidity and Inequitable Conduct, Plaintiff's Motion for Summary Judgment of No Inequitable Conduct, and Plaintiff's Motion to Strike

The Regents of the University of California, Abbott Molecular Inc., and Abbott Laboratories Inc. (collectively, "plaintiffs") filed this action against Dako North America, Inc. and Dako Denmark A/S (collectively, "Dako" or "defendants"), alleging infringement of two United States patents related to *in situ* DNA hybridization. Now before the court are defendants' motions for summary judgment of invalidity of United States Patent No. 5,447,841 ("the '841 patent"), the sole remaining patent at issue, and unenforceability of the same based on inequitable conduct, plaintiffs' motion for summary judgment of no inequitable conduct, and plaintiffs' motion to strike an exhibit. Having considered the parties' arguments and submissions, and for the reasons set forth below, the court enters the following memorandum and order.

BACKGROUND

The Regents of the University of California ("UC Regents") owns the rights to the '841 patent-in-suit. Second Amended Compl., Docket No. 203, ¶ 2. Abbott Molecular Inc. is the wholly-

owned subsidiary of Abbott Laboratories Inc., which is the exclusive licensee of the '841 patent. Id. ¶¶ 3-5. The '841 patent relates to methods for identifying target genes through *in situ* DNA hybridization.[1] Dako manufactures and sells diagnostic kits which make use of *in situ* DNA hybridization to determine the presence and frequency of certain genes of interest, including but not limited to, the HER2 FISH pharmDx kit™, which is used for determination of *HER2* gene amplification. Id. ¶ 8. Plaintiffs filed suit against Dako on September 29, 2005, asserting claims for infringement of the '841 patent and a related patent, United States Patent No. 6,596,479 ("the '479 patent").

Further details regarding the parties' background and the technology at issue in this action can be found in prior orders issued by the court. See, e.g., Regents of Univ. of Cal. v. DakoCytomation Cal., 2006 WL 618769 (N.D. Cal. 2006), Docket No. 81 ("PI Order"), Regents of Univ. of Cal. v. DakoCytomation Cal., 2006 WL 1343950 (N.D. Cal. 2006), Docket No. 110 ("Amended PI Order"), Regents of Univ. of Cal. v. Dako N. Am., Inc., 2006 WL 1867618 (N.D. Cal. 2006), Docket No. 164 ("Claim Construction Order"), and Regents of Univ. of Cal. v. Dako N. Am., Inc., 448 F. Supp. 2d 1145 (N.D. Cal. 2006), Docket No. 178 ("First SJ Order"), aff'd in part and rev'd in part, 517 F.3d 1364 (Fed. Cir. 2008).

On October 17, 2005, plaintiffs moved for a preliminary injunction to enjoin defendants from continuing to sell, offer for sale, or import into the United States defendants' HER2 FISH pharmDx™ kit. On November 21, 2005, upon stipulation and leave of court, Dako filed its answer and asserted counterclaims for noninfringement, invalidity and unenforceability of the '841 and '479 patents. On March 10, 2006, the court denied plaintiffs' motion for a preliminary injunction. In denying the motion, the court concluded that plaintiffs failed to show a likelihood of success on the merits of their infringement claims based on the court's claim construction of several claim limitations. See PI Order at 6-13. On March 30, 2006, plaintiffs appealed the court's denial of a preliminary injunction. On May 17, 2006, while plaintiffs' appeal was pending, the court amended its preliminary injunction ruling with respect to one of its bases for finding that plaintiffs were not likely to succeed on the merits of their claims related to the '479 patent. See Amended PI Order at 3. On May 22, 2006, plaintiffs appealed the court's amended preliminary injunction ruling.

On May 22, 2006, Dako moved for summary judgment of noninfringement of the '841 and '479 patents. The court held a Markman hearing for several disputed claim limitations, and on July 5, 2006, the court issued its claim construction order. On August 1, 2006, the court issued a memorandum and order granting in part and denying in part Dako's motion for summary judgment of noninfringement. For the '479 patent, the court granted Dako's motion with respect to all of the accused products. For the '841 patent, the court granted Dako's motion with respect to two accused products—including its HER2 FISH pharmDx™ kit—but denied Dako's motion with respect to its remaining accused products. See First SJ Order at 18. Plaintiffs appealed to the Federal Circuit, during which time this court stayed any further proceedings in this action.

The Federal Circuit considered the preliminary injunction appeals and the summary judgment appeal together and issued its decision on February 28, 2008. See Regents of Univ. of Cal. v. Dakocytomation Cal., Inc., 517 F.3d 1364 (Fed. Cir. 2008). The Federal Circuit affirmed the denial of a preliminary injunction and the grant of summary judgment of noninfringement as to the '479 patent. Id. at 1380. However, it reversed and remanded the court's grant of summary judgment of noninfringement as to the '841 patent for the two products. Id. As to the '841 patent, the Federal Circuit held that plaintiffs were not precluded by prosecution history estoppel from asserting that Dako's accused synthetic nucleic acids, referred to as peptide nucleic acids ("PNA"), were equivalents that infringed the '841 patent. Id. at 1376-78. The Federal Circuit stated "[w]hether they do infringe is a question of fact for the trial court to consider on remand." Id. at 1378.

On August 4, 2008, plaintiffs filed a second amended complaint, asserting claims for infringement of the '841 patent only, and Dako filed its answer and asserted counterclaims for noninfringement, invalidity and unenforceability of the '841 patent. On December 8, 2008, Dako moved for summary judgment of invalidity of the '841 patent, arguing that the '841 patent is invalid under 35 U.S.C. section 112, paragraph 1, for failure to comply with the written description and enablement requirements. At the same time, Dako moved for summary judgment of unenforceability for inequitable conduct during the prosecution of the '841 patent. Also at that time, plaintiffs moved for summary judgment of no inequitable conduct during the prosecution of the '841 patent.

On January 12, 2009, plaintiffs moved to strike the report of Dako's expert, Dr. Robert Singer, for two reasons. Plaintiffs argue that because Dr. Singer's report was unsworn, it constitutes inadmissible hearsay, and that while Dr. Singer may be an expert in the biological sciences, he is not competent as an expert in interpreting notes, and, therefore, Federal Rules of Evidence 702 and 703 renders his opinions based on other people's handwritten notes inadmissible.

Details of the '841 patent are provided in the court's Claim Construction Order. The claims at issue in the present summary judgment motion are summarized below.

I. The '841 Patent

The '841 patent teaches methods and compositions for staining chromosomes by *in situ* hybridization using "chromosome specific staining reagents" that comprise "heterogeneous mixtures of labeled nucleic acid fragments having substantial portions of substantially complementary base sequences to the chromosomal DNA for which specific staining is desired." '841 patent at 3:62-68. There are 17 claims at issue for the '841 patent. Claim 1, the only independent claim of the '841 patent, claims as follows:

> A method of staining target chromosomal DNA comprising:
>
> > (a) providing 1) labeled nucleic acid that comprises fragments which are substantially complementary to nucleic acid segments within the chromosomal DNA for which detection is desired, and 2) blocking nucleic acid that comprises fragments which are substantially complementary to repetitive segments in the labeled nucleic acid; and
> >
> > (b) employing said labeled nucleic acid, blocking nucleic acid, and chromosomal DNA in in situ hybridization so that labeled repetitive segments are substantially blocked from binding to the chromosomal DNA, while hybridization of unique segments within the labeled nucleic acid to the chromosomal DNA is allowed, wherein blocking of the labeled repetitive segments is sufficient to permit detection of hybridized labeled nucleic acid containing unique segments, and wherein the chromosomal DNA is present in a morphologically identifiable chromosome or cell nucleus during the in situ hybridization.

Id. at 17:4-25.

Claims 2 through 5, which depend from claim 1, detail the order in which the blocking nucleic acid is hybridized with the labeled nucleic acid and the chromosomal DNA. Dependent claims 6 through 12 further characterize the labeled nucleic acid. Claim 6, for example, claims "wherein the labeled nucleic acid comprises fragments which are designed to allow detection of

extra or missing chromosomes, extra or missing portions of a chromosome, or chromosomal rearrangements." Id. at 18:1-5. Claim 11 depends from claim 1 and claims the labeled nucleic acid comprising "fragments complementary to the total genomic complement of chromosomes, fragments complementary to a single chromosome, fragments complementary to a subset of chromosomes, or fragments complementary to a subregion of a single chromosome." Id. at 18:16-22. Claims 8 and 12 limit the nucleic acid to human chromosomal DNA. Id. at 18:8-11; 18:23-25.

Defendants' invalidity argument centers around the assertion that the claims of the '841 patent encompass a broad genera of methods of *in situ* hybridization but the specification describes only one hybridization method, which uses a single example of a probe that targets one entire chromosome from one species in one type of sample. With relevance to that argument, one working example is provided, in Section VI of the patent, that describes human chromosome 21-specific staining on human metaphase spreads by using blocking nucleic acids to inhibit the binding of repetitive sequences to the target chromosome in *in situ* hybridization. Id. at 15:58-16:57. The specification cites references that teach *in situ* hybridization on cells or chromosomes in suspension and formalin-fixed paraffin-embedded ("FFPE") tissue. Id. at 10:35-38; 11:1-15; 11:45-48. The specification teaches that the nucleic acid fragments or "probes" used for *in situ* hybridization may be of different sizes. Id. at 4:2-9. In preferred embodiments, the initial chromosomal DNA sequences used to create the probes are "long sequences, e.g., 35-45 kilobases" that are "cut into smaller fragments and labeled" for use as probes. Id. at 6:21-27. The specification does not limit itself to a type of organism as the source of chromosomal DNA for probes, but expressly acknowledges the applicability of its invention to a variety of species other than human. Id. at 3:33-39, 7:44-45, and 8:11-19. Neither does the specification limit itself to the use of a particular organism as the biological target sample for detection by *in situ* hybridization.

II. Prosecution History of the '841 Patent

UC Regents filed the first patent application in a chain of applications leading to the '841 patent on January 16, 1986. Joint Statement of Undisputed Facts Re: Defs.' Mot. for Summ. J. that '841 Is Unenforceable for Inequitable Conduct During the Patent Prosecution, Docket No. 241 ("Undisputed Facts") ¶ 1. The application described a lack of staining specificity in prior art techniques and sought to increase the specificity by disabling the hybridization capacity of repetitive nucleotide sequences, so as to limit false-positive results. The application disclosed three methods for disabling the hybridization capacity of repetitive sequences: (1) selective removal of repetitive sequences from the DNA probe; (2) creation of a probe substantially free of repetitive sequences; and (3) blocking the repetitive sequences with repetitive sequence enriched DNA. Id. ¶ 2. The '841 patent claims are directed to the third method, of blocking the repetitive sequences. Defendants' inequitable conduct allegations are based on alleged failures to disclose and misrepresentations regarding prior art relating to the blocking method.

The original application filed in January 1986 described methods of blocking repetitive sequences, but did not include a working example of a method of blocking repetitive sequences (i.e., it did not include Section VI, the working example of the '841 patent). Id. ¶ 4. Although Dr. Pinkel, one of the named inventors of the '841 patent, does not recall the date of their first successful experiment using human genomic DNA to block repetitive sequences with a unique sequence probe, the earliest records put the date of the first successful experiment as May 21, 1986. Derrick Dec., Docket No. 224, Exh. 3 at 100-02. The original application includes the following two statements regarding blocking: (1) "Hybridization capacity can be disabled in several ways, e.g., . . . selective blocking of repetitive sequences by pre-reassociation with complementary fragments . . . " and "the method [of blocking repetitive sequences] is generally described by Sealey et al., 'Removal of Repeated Sequences for Hybridization Probes,' Nucleic Acid Research, Vol. 13, pp. 1905-1922 (1985)." Id., Exh. 2 at 10:1-10 and 23:1-23; Undisputed Facts ¶ 3.

Prosecution of the '841 patent took nearly nine years, during which time the patent examiner issued numerous rejections over the prior art. During prosecution, applicants limited the claims to the blocking method. In an August 12, 1992, Office Action, the U.S. Patent and Trademark Office

("PTO") rejected most of the pending claims as allegedly being obvious, under 35 U.S.C. section 103, in view of the aforementioned Sealey reference ("Sealey et al.") and another reference, Weissman et al. Id. ¶ 5. Specifically, the patent examiner stated that "it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the conventional technique of Sealey et al. with the *in situ* hybridization technique of Weissman et al. to practice the instant invention." Id. ¶ 7.

In response, on March 4, 1993, applicants filed a declaration in which Dr. Pinkel stated that it was his opinion that "a person skilled in the art of *in situ* hybridization would not have considered the blocking technique of Sealey et al to be useful in *in situ* hybridizations prior to the filing of our grandparent application in January 1986."[2] Id. ¶¶ 8-11. In the same declaration, Dr. Pinkel also stated that prior to January 1986, "the use of blocking copies of a sequence in *in situ* hybridization had been limited to testing whether a hybridization signal was due to repeat sequences." Id. ¶ 12.

In remarks accompanying the Pinkel declaration, applicants referred to another reference, a 1987 article by Landegent et al. Applicants stated that the Landegent reference, which discussed "the use of blocking in *in situ* hybridization as a novel technique," was "another indication of the failure of the art to consider blocking in connection with *in situ* hybridization." Id. ¶ 14. The PTO ultimately issued a Notice of Allowability for the '841 patent on May 3, 1995. Id. ¶ 22. In the Notice of Allowability, the examiner cited the March 4, 1993, Pinkel declaration and the 1987 Landegent reference among the reasons for allowing the claims. Id.

LEGAL STANDARD

I. Summary Judgment

As in any other civil action, summary judgment is proper in a patent infringement action when the pleadings, discovery and affidavits show that there is "no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); see also Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995). Material facts are those which may affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute as to a material fact is genuine if there is sufficient evidence for a reasonable

jury to return a verdict in favor of the nonmoving party. Id. The party moving for summary judgment bears the burden of identifying those portions of the pleadings, discovery and affidavits that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). On an issue for which the opposing party will have the burden of proof at trial, the moving party need only point out "that there is an absence of evidence to support the nonmoving party's case." Id.

Once the moving party meets its initial burden, the nonmoving party must go beyond the pleadings and, by its own affidavits or discovery, "set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). Mere allegations or denials do not defeat a moving party's allegations. Id.; Gasaway v. Nw. Mut. Life Ins. Co., 26 F.3d 957, 960 (9th Cir. 1994). The court may not make credibility determinations, and inferences to be drawn from the facts must be viewed in the light most favorable to the party opposing the motion. Masson v. New Yorker Magazine, 501 U.S. 496, 520 (1991); Anderson, 477 U.S. at 249.

II. Patent Validity Under 35 U.S.C., Section 112, First Paragraph

An issued patent enjoys a presumption of validity, 35 U.S.C. section 282, which can only be overcome through clear and convincing evidence. U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1563 (Fed. Cir. 1997). A party asserting invalidity on summary judgment, therefore, has the burden of establishing such invalidity by clear and convincing evidence. U.S. Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d 1209, 1212 (Fed. Cir. 1996). The validity of a patent depends, among other things, on compliance with the written description and enablement requirements of 35 U.S.C. section 112, first paragraph. See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 921 (Fed. Cir. 2004). Section 112, paragraph 1, states:

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

35 U.S.C. § 112, ¶ 1.

A. Written Description

The written description requirement serves a teaching function by providing a "quid pro quo" in which the public is given "meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." Rochester, 358 F.3d at 922, quoting Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002). Although a patent specification need not include information that is already known and available to one of ordinary skill in the art to which the patent pertains, its description of the invention claimed must be sufficient to convey to such an ordinarily skilled artisan that the inventor was in possession of the invention on the date that the patent application was filed. Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1122 (Fed. Cir. 2008); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (recognizing that the written description of the invention is separate and distinct from the enablement requirement). However, even if possession can be shown, the written description requirement will still not be met if the specification does not adequately describe the claimed invention. See Enzo, 323 F.3d at 969-70. An applicant is required to "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." Vas-Cath, 935 F.2d at 1561. Whether the written description requirement has been satisfied is a question of fact that depends on the nature of the claimed invention and the knowledge of a person skilled in the art at the time the invention was made and the patent application was filed. Carnegie Mellon, 541 F.3d at 1122.

B. Enablement

To satisfy the enablement requirement of 35 U.S.C. section 112, "the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1360 (Fed. Cir. 2007). Whether a claimed invention requires undue experimentation involves consideration of a number of factors, including the quantity of the experimentation necessary, the amount of guidance provided, the availability of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, and the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Enablement is determined as of the

filing date of the patent. See AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Whether a disclosure is enabling is a question of law based on underlying facts. Id. at 1238.

III. Inequitable Conduct

A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution. Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006). The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence. Id. The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, with a greater showing of one factor allowing a lesser showing of the other. Id. "The required showings of materiality and intent are separate, and a showing of materiality alone does not give rise to a presumption of intent to deceive." Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1313 (Fed. Cir. 2008)

It is permissible, but uncommon, to determine at the summary judgment stage that a patent is unenforceable for inequitable conduct if there is no genuine issue of material fact. Monsanto Co. v. Bayer BioScience N.V., 363 F.3d 1235, 1240 (Fed. Cir. 2004). However, a genuine issue of material fact is not raised by the submission of "merely conclusory statements or completely insupportable, specious, or conflicting explanations or excuses." Id.

DISCUSSION

I. Summary Judgment of Invalidity

In its motion for summary judgment, Dako's principal argument is that the claims of the '841 patent encompass an extremely broad genera of methods of *in situ* hybridization. Dako characterizes independent claim 1 as encompassing "all *in situ* hybridization methods using probes of all lengths that target all regions of all chromosome of all species to detect all chromosomal abnormalities in all biological samples." Defs.' SJ Mot. for Invalidity, Docket No. 227, at 1-2 (emphasis in original). Dako asserts that the '841 patent specification contains only a single working example—the detection of an extra human chromosome 21 using a human whole-chromosome 21 probe—and that

this single example does not adequately describe such a broad invention or enable the full scope of the claims.

As the party moving for summary judgment, Dako bears not only the burden of demonstrating the absence of a genuine issue of material fact, Celotex, 477 U.S. at 323, but also proving invalidity by clear and convincing evidence. 35 U.S.C. § 282; U.S. Gypsum Co., 74 F.3d at 1212. Plaintiffs oppose Dako's motion for summary judgment on the ground that the '841 patent claims are not directed to a genus of probes, but rather are directed to one particular method of staining target chromosomal DNA in *in situ* hybridization by disabling the hybridization capacity of repetitive sequences through the use of blocking nucleic acids. Plaintiffs assert that the claimed blocking method can be used universally with different probes to detect different abnormalities in different organisms because, in all cases, the claimed blocking technique is the same. Plaintiffs assert the '841 patent satisfies the written description requirement by showing that the inventors had possession of the full scope of their claimed invention, and the disclosures in the specification are enabling in that they are sufficient to allow one of ordinary skill in the art to practice the claimed method without undue experimentation.

The adequacy of a written description is determined by evaluating whether the description is sufficient to show possession of the generic scope of the claims. See Enzo, 323 F.3d at 966. Similarly, the degree of enablement that is required varies depending on the scope of the claimed invention and must be commensurate with the scope of the claims. See Sitrick v. DreamWorks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008).

A. Written Description Requirement

The court begins with plaintiffs' assertion that the claimed invention is a single method rather than a genus of probes. This is true, although the plain language of the claims places few limitations on the types of probes that can be used in the method. For example, claim 1 limits the detecting probes to "labeled nucleic acid that comprises fragments which are substantially complementary to nucleic acid segments within the chromosomal DNA for which detection is desired" and the blocking probes to "blocking nucleic acid that comprises fragments which are substantially complementary to repetitive segments in the labeled nucleic acid . . . ." See '841 patent

at 17:4-25. The claim does not recite any limitations on the size of the probe fragments or on the source of the nucleic acid for the probes (e.g., the organism or genomic region from which the nucleic acid is derived). The only limitation claim 1 places on the biological target sample upon which *in situ* hybridization will be performed is that it requires the chromosomal DNA to be present "in a morphologically identifiable chromosome or cell nucleus." Id.[3] Plaintiffs dispute none of this and themselves assert that the claimed method is "broadly applicable to a wide variety of staining reagents" and "can be used with different probes to detect different abnormalities in different organisms." Pls.' Opp. to SJ for Invalidity, Docket No. 235 at 1:25-28.

Whether a patent specification satisfies the written description requirement is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date. Falkner v. Inglis, 448 F.3d 1357, 1363 (Fed. Cir. 2006). As a general principle, when the claims encompass a broad genus or when there is substantial variation within the genus, the written description requirement will not likely be satisfied by disclosing only a single species within the genus. Carnegie Mellon, 541 F.3d at 1124-25. However, a patent specification need not describe every detail of every embodiment. Vas-Cath, 935 F.2d at 1563. Examples are not required, and "[a] claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." LizardTech, Inc. v. Earth Res. Mapping, PTY, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005). An actual reduction to practice is also unnecessary to satisfy the written description requirement. Falkner, 448 F.3d at 1364 n.8; Rochester, 358 F.3d at 926 ("Constructive reduction to practice is an established method of disclosure").

In this case, the '841 patent claims a method of staining target chromosomal DNA, by disabling the hybridization capacity of repetitive sequences through the use of blocking nucleic acids. All of the asserted claims are directed to that single blocking method. Dako argues that the method comprises several broad genera, e.g., claim 1 encompasses the use of nucleic acid probes of any size and derived from any organism or genomic region, while dependent claims 5-7 and 11-13 can be applied to biological samples from all organisms, and the biological samples can take any form that presents a morphologically identifiable chromosome or cell nucleus. Dako argues that

because the patent specification provides only a single working example of a whole-chromosome nucleic acid probe for human chromosome 21 (i.e., a "single species") for use in *in situ* hybridization, it does not sufficiently describe a representative number of species of the components used in the method so as to satisfy the written description requirement. See Carnegie Mellon, 541 F.3d at 1124 (a "sufficient description of a representative number of species . . . means that the species which are adequately described are representative of the entire genus.").

The court disagrees with this reasoning, because it is not the number of probe species used in the generic method that must be described in representative number in order to meet the written description requirement. That the claimed blocking method functions with a broad range of probes is not the issue—it is the method itself that is a "genus." This is not a situation where the patent describes a method but discloses no species used to carry out the method. See, e.g., Rochester, 358 F.3d at 920 (a patent fails to satisfy the written description requirement if it claims a method of achieving a biological effect, but discloses no compounds that can accomplish that result). The '841 patent describes a method of *in situ* hybridization using blocking nucleic acids that has wide breadth and applicability and discloses one detailed, working example of that method.

The example of the claimed blocking method uses one type of probe to chromosome 21, because that example sought to specifically stain human chromosome 21. The patent specification describes that "a sensitive method for detecting chromosomal abnormalities would be a highly useful tool for genetic screening" and provides the example that Down's syndrome is caused by having an additional copy of chromosome 21. '841 patent at 1:45-55. Nowhere does the specification limit the invention to detecting trisomy 21, nor does it need to in order to meet the written description requirement. Dr. Harper testified that the claimed blocking method "utilizes DNA hybridization principles that apply equally to all types of chromosomal DNA." Harper Dec., Docket No. 242, ¶ 28. Because Dako has not refuted this testimony with clear and convincing evidence of substantial variation within the performance of the blocking method, the "representative species" requirement is low. To hold otherwise would place improper and undue limitations on the breadth of the claimed invention.

To illustrate this principle, the court offers the following analogy. Imagine that the Wright Brothers had patented a method for flying, comprising a wing with certain physical characteristics. Assume the wing material was claimed generically and the patent provided one working example of an airplane with wooden wings. Later-developed airplanes used titanium wings. Because the Wright Brothers had not described titanium wings in their application, and had admitted in depositions that it would have been undue experimentation at the time to do so (either because titanium did not exist or was not used in that manner at the time of filing the patent application), their claimed flying method was held invalid for lack of written description.

This outcome contravenes the patent laws. Yet, it represents the fundamental premise of Dako's argument. It cannot succeed because, as defendant should well know, "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001). Nor are claims perforce limited to the embodiments disclosed in the specification. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1328 (Fed. Cir. 2003). Plaintiffs are not required to describe a high number of species of the genus method because the '841 patent, and the prior art cited therein, describes little variation within the salient characteristics of that genus.[4] Nor are plaintiffs required to describe a "representative number of species" of the "broad genera" of components used in the claimed method of staining chromosomal DNA, as Dako contends, because plaintiffs are not claiming the components as novel compositions themselves.

Dako either fails to appreciate or intentionally disregards the pivotal distinction between a product claimed qua product versus a component claimed as part of a method. As a result, Dako relies upon case law inapposite to the inquiry and wholly misdirects the court to genus-species case law, while ignoring after-invented technology case law, i.e., case law that addresses the situation where a later state of the art came into existence after the filing date of the application. See infra, Section IB, Enablement.

For example, Dako relies on Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), to argue that the adequate description of claimed nucleic acid probes requires a precise definition of the types and lengths of probes, and not merely a recitation of the

probe's blocking function. Eli Lilly, however, was focused on product claims, namely, claims to recombinant plasmids and microorganisms that produce human insulin. The Federal Circuit held the disclosure of the cDNA sequence of the rat insulin gene did not provide an adequate written description of the cDNA required by the asserted claims, i.e., the cDNA sequence of the insulin gene for every vertebrate. Id. at 1569. Likewise, in Carnegie Mellon, claims directed to recombinant plasmids containing "gene coding region isolated from a bacterial source for the expression of DNA polymerase I" were held invalid for lack of written description because the coding sequence for DNA polymerase I from one specific type of bacteria (*E. coli*) did not adequately describe coding sequences originating from any bacterial source. 541 F.3d at 1125. Finally, in a third case relied on by Dako, the Federal Circuit held the disclosure of a single antibody insufficiently described a method for treating neurofibrosarcoma (a rare cancer) by administering human monoclonal antibodies targeted at a patient's tumor, because the antibodies required to perform the claimed method vary substantially in their composition. See In re Alonso, 545 F.3d 1015, 1020 (Fed. Cir. 2008).

Dako's attempt to analogize the DNA claims from Eli Lilly and Carnegie Mellon to the components of the method—namely, the probes—in the '841 patent must fail. The '841 patent does not claim probes with a particular DNA sequence from a particular source, like Eli Lilly and Carnegie Mellon, nor does it claim a specific target for treatment or diagnosis, like Alonso. The probes of the '841 patent are inherently generic, so that the method can be tailored to stain the desired target DNA, whatever it may be. Anything more limiting would be a method for identifying a particular DNA target, which was the case in Eli Lilly but is clearly not the case here. This important distinction resonates throughout Federal Circuit case law. The Eli Lilly court, for example, held that an "adequate written description of a DNA sequence claim requires a precise definition, such as structure, formula, chemical name, or physical properties . . ." for claims directed to recombinant plasmids and microorganisms containing a human insulin cDNA—a specific DNA sequence. 119 F.3d at 1566. Likewise, in Noelle v. Lederman, 355 F.3d 1343, 1349 (Fed. Cir. 2004), the Federal Circuit held that disclosure of an antibody's binding affinity to a "'fully characterized antigen,' either by its structure, formula, chemical name, or physical properties. . . "

satisfies written description for claims directed to mouse, human and genus forms of CD40CR antibodies—still specific antibodies. See also id. at 1352 (distinguishing between the patentability bounds of product and method claims, noting that "Noelle does not claim a method of isolating CD40CR antigens, CD40-Ig, or the receptor CD40 itself.").

In stark contrast to the cases claiming specific sequences, antibodies, or targets, the '841 patent contemplates the use of the staining method to detect chromosomal abnormalities on a broad scale, i.e., for genetic screening and for the total genomic complement of chromosomes. See '841 patent at 1:53-54 and 4:57-62. Dako's argument that *in situ* hybridization is an unpredictable art does not compel the conclusion that the claimed blocking method, i.e., the method of disabling the hybridization capacity of repetitive sequences by blocking in *in situ* hybridization, should be limited to any specific probes or targets. Dako's further assertion on oral argument that one exemplified probe cannot be enough because "in an unpredictable art, like biology, one example is not enough" is simply wrong. The correct law is that "a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated." Noelle, 355 F.3d at 1350, citing Enzo, 323 F.3d at 965 and Eli Lilly, 119 F.3d at 1568. The unpredictability factor only applies when there is unpredictability in the results themselves and even then the law does not preclude genus claims. If the law were to hold all of biology to a higher standard, as Dako asserts, no seminal biotechnological advancement would be patentable as anything more than a modest development limited in literal scope to its concrete examples. Prophetic examples would be worthless and the doctrine of equivalents would be nullified. Indeed, the value of the patent system itself would be diminished if every slight alteration, substitution or improvement upon a fundamental biotechnology method could escape infringement of a literally-claimed (or invalidate a more broadly-claimed) patent to a pioneer invention.[5] Put another way, "[i]f later states of the art could be employed as a basis for rejection under 35 U.S.C. section 112, the opportunity for obtaining a basic patent upon early disclosure of pioneer inventions would be abolished." In re Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977).

The case law on after-invented technology is instructive here. The Federal Circuit has held that the written description inquiry "focuses on a comparison between the specification and the invention referenced by the terms of the claim—not comparison between how the product was made as disclosed in the patent and future developments of this process that might alter or even improve how the same product is made." Amgen, 314 F.3d at 1332. The '841 patent specification describes an invention that has broad application for use with labeled probes designed for detection of a wide variety of chromosomal abnormalities. Harper Dec. ¶ 11-32. The patent need neither exemplify nor even describe prophetically the use of all possible lengths of probes generated from all possible chromosomes from all possible species, in order to sufficiently describe the claimed method. This is so even if, as Dako contends, there is unpredictability in applying the method for staining target chromosomal DNA to, e.g., a much shorter length probe than the "whole-chromosome probe" used in the example or to genomes that are not closely related to humans.[6] As the Federal Circuit has noted, "[a] general allegation of 'unpredictability in the art' is not a sufficient reason to support a rejection for lack of adequate written description." Hyatt v. Dudas, 492 F.3d 1365, 1370 (Fed. Cir. 2007) (citation omitted).[7]

Adequate written description means that, in the specification, the applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the [claimed] invention." Vas-Cath, 935 F.2d at 1563-64. Dako argues that the inventors' testimony made during prosecution of the '841 patent suggests that they were not fully in possession of the invention as defined by the claims at the date of filing. Dako cites to a March 16, 1992, declaration submitted to the PTO in which the inventors stated: "we had conceived of making a heterogeneous mixture that contains labeled nucleic acid fragments of a complexity greater than 35 kb for staining chromosomes by *in situ* hybridization." Dec. of Daniel Pinkel and Joe Gray, Docket No. 224, Exh. 13 at 3. Dako alleges that this statement constituted an admission by the inventors that limited the "conceived" scope of the probes of the invention.[8] Because the claimed method uses nucleic acid probes of any size (not just probes larger than 35 kb), Dako argues the inventors were not in possession of the full scope of the claimed invention at the date of filing and the '841 patent specification thus fails to satisfy the written description requirement.

The court disagrees. The '841 patent plainly discloses the use of a "blocking nucleic acid" probe, and the Federal Circuit has held that the scope of the "nucleic acid" limitation was not narrowed during prosecution such that it gives rise to any estoppel concerning the type of nucleic acid that could perform the blocking. Dakocytomation, 517 F.3d at 1378. Nor does the patent specification limit the scope of the probe to a specific size, as Dako seems to deem necessary to satisfy the written description requirement. Rather, the specification states that the probes could be used to detect a whole-chromosome target sequence or a target sequence much shorter than a whole chromosome. See, e.g., '841 patent at 6:28-30, describing an embodiment where "the chromosomal binding sites of the fragments are clustered in the chromosomal regions complementary to the cloned 'parent' nucleic acid sequence." See also id. at 5:63-66, noting "[t]he precise number of distinct labeled nucleic acid fragments, or probes . . . *is not a critical feature of the invention*." (emphasis added). In addition, Dr. Harper testified that "the '841 patent discloses principles for probe design to tune the length of probe depending on the requirements of the particular application." Harper Dec. ¶ 31.

Moreover, contrary to Dako's assertions, plaintiffs are not required to actually have *physical possession* of the potential universe of probe sets in order to have "possession" of the invention.[9] Dako takes the possession standard far too literally. Possession of the breadth of a genus claim can be established by showing that a person of skill in the art would glean from the written description that the inventors had made a generic invention. See Enzo, 323 F.3d at 966-67, 974 (contrasted with "a research plan" which does not show "possession" of any invention). Plaintiffs, too, advance arguments far beyond what is required to rebut Dako's assertions. Plaintiffs need not prove that the inventors were actually working with the potential universe of probes in 1986, just as the '841 patent specification need not expressly list them all to sufficiently describe the generic class of probes for use in the claimed method. See U.S. Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1252 (Fed. Cir. 1989) ("[c]ertainly, the disclosure of specifics adds to the understanding one skilled in the art would glean from a generic term, but it does not follow that such added disclosure limits the meaning thereof."). It is for Dako to prove that a skilled worker would not glean from the

specification the generic invention, directed to a specific method of staining target chromosomal DNA in *in situ* hybridization using blocking nucleic acids, as claimed. Dako has not done so.

The case law makes clear that, even in unpredictable arts, the written description requirement can be met when a patent specification frames functional descriptions of biologic materials used in related methods if those functional definitions are coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. See Enzo, 323 F.3d at 964. In this case, the "relevant identifying characteristics" between the structure and function of the nucleic acid components of the invention, therefore, need not be any more specific than the labeled nucleic acid probe being substantially complementary to the target chromosomal DNA and the blocking nucleic acid having fragments complementary to repetitive sequences in the labeled nucleic acid. To satisfy the written description requirement, "the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Alton, 76 F.3d 1168, 1172 (Fed. Cir. 1996). For the purposes of this motion, the court finds that Dako has failed to meet its burden to provide clear and convincing evidence that nucleic acid sequences, of differing lengths or types, could not be used to detect different chromosomal abnormalities in different biological samples, other than those exemplified in the '841 patent, in a manner so described and as required by the claims.

B. Enablement Requirement

Enablement requires that the specification teach those of skill in the art how to make and use the claimed invention without undue experimentation. In re Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991). There must be a "reasonable correlation" between the scope of the claims and the scope of enablement provided by the specification. Id. When, as here, a patentee chooses broad claim language, he must make sure that the broad claims are fully enabled. Sitrick, 516 F.3d at 999. "A patent applicant is not required, however, to predict every possible variation, improvement or commercial embodiment of his invention." Phillips Petroleum, 865 F.2d at 1250.

Dako asserts that undue experimentation would be required for a person having ordinary skill in the art to practice the claimed invention, in view of the breadth of the claims, the unpredictability

in the art, the single working example and the limited guidance provided in the specification. Because the adequacy of the disclosure must be judged from the perspective of a person of ordinary skill in the art, the court notes that the parties stipulated to a high level of skill in the art—a doctorate or medical degree with training and laboratory experience with specific experience in *in situ* hybridization principles and techniques. See Harper Dec ¶ 6; Hulse Dec., Docket No. 228, Exh. 1 at 6. Plaintiffs argue that based on the skill of one in the art, the predictability of *in situ* hybridization, and the state of the prior art, including the extensive background teachings described and referenced in the specification, it would not require undue experimentation to practice the claimed invention. Dako agrees that the relative skill of one in the art is high but argues that this factor alone is not sufficient to find that enablement is satisfied. Dako also contends that, at the time the application was filed, *in situ* hybridization (and specifically, *in situ* hybridization with FFPE tissue) was highly unpredictable.

For the purposes of this motion, the court does not decide whether *in situ* hybridization was a predictable art, because even assuming it was unpredictable, this still does not compel a conclusion that one of skill in the art would not be able to carry out the claimed invention without undue experimentation. Unpredictability is but one of the Wands factors, to be weighed against all the other factual considerations. 858 F.2d at 737 (holding that whether undue experimentation is required is a "conclusion reached by weighing many factual considerations . . . includ[ing] (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

As to the amount of experimentation that would be required to practice the broad scope of the claimed invention, Dako argues that it would require a great amount of experimentation to design and prepare appropriately sized probes and to apply the claimed methods to allow detection on FFPE tissue. However, "the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art." Falkner, 448 F.3d at 1365. The specification teaches that the procedures for

designing and preparing such probes and applying the methods to other types of samples were routine, and cites articles that describe using FFPE tissue in *in situ* hybridization. Dr. Harper testified that "one of ordinary skill would understand this specific technique to be broadly applicable to a wide variety of probes, targets, and organisms" and that "one of ordinary skill easily would have been able to practice the claimed method on FFPE tissue without undue experimentation." Harper Dec. ¶¶ 15, 47.

Dako hangs its hat on the argument that the '841 patent does not satisfy several of the Wands factors because the patent allegedly does not enable a skilled artisan to practice the claimed methods on FFPE tissues. Here, Dako fails to meet its burden of proof required on summary judgment. Dako's expert, Dr. Singer, distinguishes the prior art protocols for *in situ* hybridization on FFPE cited in the '841 patent on the basis that those protocols used repetitive sequence probes and did not permit detection of unique chromosomal sequences. See Hulse Dec., Exh. 1 at 15:5-21. However, plaintiff's expert, Dr. Harper, testified that in her opinion, that distinction is irrelevant, and that "[t]he techniques for carrying out *in situ* hybridization on FFPE samples using probes directed to repetitive sequences would function to detect unique sequences in the claimed invention because those techniques enable probe DNA to hybridize with target." Harper Dec. ¶ 41. Faced with this not uncommon "battle of the experts," the court observes that the record may support differing factual conclusions. As such, this dispute is not well-suited for summary judgment and the inferences to be drawn from conflicting testimony are best left for the trier of fact. See, e.g., Edwards Syst. Tech. Inc. v. Digital Control Syst. Inc., 99 Fed. Appx. 911, 921 (Fed. Cir. 2004) (noting that a classic "battle of the experts" situation renders summary judgment improper).

Dako contends that there is clear and convincing evidence that applying *in situ* hybridization to detect unique sequence chromosomal DNA on FFPE tissue was "not completely resolved" because there was allegedly still only very limited success in the field five years after the '841 patent application was filed. See Hulse Dec., Exh. 5 & 7. Dr. Singer alleges that the '841 patent fails to consider the partial penetration of probes into cell nuclei in FFPE tissue sections and the fact that the densely crosslinked FFPE tissues needed to be "undone" in order to reduce background "noise" and optimize probe penetration. See id. at Exh. 1, pages 15-18. Dr. Singer testified that "[i]t took years

to develop techniques that reduce this background and permit the detection of specific chromosomal hybridization signals in FFPE tissue." Id. at 19:18-19. In his deposition, however, Dr. Singer testified that his own patent, U.S. Patent No. 4,888,278, filed in October 1985, which claimed a rapid *in situ* hybridization method, adequately described and enabled practicing the method in tissue sections even though the patent only exemplified using *in situ* hybridization in morphologically intact chicken embryonic cells. See Supp. Chang Dec., Docket No. 321, Exh. 1 at 7-10 (Singer Deposition Transcript). More importantly, the argument that the use of *in situ* hybridization in tissue had not been perfected, in and of itself, does not weigh in favor of finding that undue experimentation is required to practice the '841 patent claims using FFPE tissue. The evidence presented by Dako fails to show that the "limited success" or at least the "passage of time" was due to any aspect of the claimed method. That the FFPE tissue was sticky and needed to be un-crosslinked in order to work has little to do with the blocking method as claimed. The '841 patent does not purport to teach the steps necessary to optimize the sensitivity of *in situ* hybridization using FFPE tissue and it does not need to.

Once again, the case law on after-invented technology is applicable here. With after-invented technology, it does not matter whether performing the full range of was "completely resolved" or even possible when the application was filed. Hogan explains that enablement is not to be judged by a later publication or other evidence which shows that, *as of the application's filing date*, undue experimentation would have been required to practice the claims with that later-existing state of the art technology. 559 F.2d at 605. Simply put, later existing state of the art cannot be used in determining enablement under 35 U.S.C. section 112. As such, Dako's argument that the '841 patent specification fails to enable one skilled in the art to practice the claimed invention cannot be couched in terms of the "claimed invention" being defined as the blocking method of *in situ* hybridization using FFPE tissue to permit detection of hybridized labeled nucleic acid containing unique segments with all non-specific background issues "completely resolved." The '841 patent claims contain no sensitivity measurement or parameter requiring any particular level of detection of target chromosomal DNA to achieve diagnostic certainty or commercial viability in its results. That there were outstanding issues at the time the application was filed concerning the partial penetration

of probes into cell nuclei in FFPE tissue sections does not speak to the scope of enablement. See Phillips Petroleum, 865 F.2d at 1251 ("application sufficiency under § 112, first paragraph, must be judged as of the filing date" and "[r]ejections . . . on the ground that the scope of enablement is not commensurate with the scope of the claims, orbit around the more fundamental question: To what scope of protection is the applicant's particular contribution to the art entitled?"). In sum, that the '841 patent claims may cover a later version of the claimed method (using FFPE tissue) relates to infringement, not to patentability. Id. To hold differently would "impose an impossible burden on inventors and thus on the patent system." Hogan, 559 F.2d at 606.

Dr. Harper testified that "a person of ordinary skill would recognize that the basic problem of background staining and the solution of using blocking to diminish background noise described in the '841 patent would be generally applicable to *in situ* hybridization reactions." Harper Dec. ¶ 12. Dr. Singer's counter-testimony that the '841 patent "provides no teaching . . . on how to use the described techniques on samples that contain only hybridized cells lacking the full complement of cellular DNA" as might occur when, e.g., only partial cell nuclei were present in thin tissue sections or less than the entire FFPE tissue slice was accessible by the probes, is somewhat of a non-sequitur. See Singer Dec., Docket No. 228, at 14:10-21. The Federal Circuit has already ruled that the '841 patent claims do not require that the cell nucleus retain its full complement of DNA. See supra n.3; Dakocytomation, 517 F.3d at 1379. It is a moot point, therefore, whether the patent enables any subject matter outside the scope of the claims. Now, if Dako is alleging that a person of ordinary skill in the art would have been wholly unable to determine whether the claimed blocking method could be carried out using FFPE tissue at all, i.e., to permit *any* observable detection of stained target chromosomal DNA, that is an assertion directly controverted by plaintiff's expert. In viewing the facts in a light most favorable to plaintiffs, as the case law requires at this stage, the court finds Dako's allegation unavailing as it requires a credibility determination not appropriate for summary judgment.

Beyond that, the court agrees with plaintiffs that a patent need not disclose every possible way to practice an invention in order to satisfy the enablement requirement, albeit noting that plaintiffs' reliance on Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052 (Fed. Cir. 2005) is

somewhat misplaced. There, the claims described a compound—an enzyme containing a genetic mutation—without regard to the method used to create the genetic mutation. Id. at 1070. Because the claims did not limit the method of making the mutation, the disclosure of one method of making the compound satisfied the enablement requirement. Id. at 1071. Here, by contrast, the issue is whether the specification teaches one of skill in the art how to make and use the claimed method, that is, a method of staining DNA using blocking probes in *in situ* hybridization to permit detection of unique nucleic acid segments in a target chromosome. In order to claim a broad method, the specification must teach those of skill in the art how to make and use the full scope of the claimed method. The method may be broad, but the method is still limited to the terms of the claims, unlike the method of making the claimed compound in Invitrogen. Thus, it is not enough to disclose one way of carrying out the method, if it does not teach one how to carry it out to a degree at least commensurate in scope with the claim under consideration. See, e.g., Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1337 (Fed. Cir. 2005) ("The purpose of [the enablement] requirement is to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.").

It is also not enough, however, to allege that the claimed method is not enabled because the specification does not teach technology that arose after the time the patent application was filed. See Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) ("new technology [that] arose after the filing date . . . was, by definition, outside the bounds of the enablement requirement"). It is not enough, therefore, for Dako to allege that the '841 patent fails to teach how to pre-treat FFPE tissue so that the labeled probes have optimal access to the target chromosomal DNA. This measure of diagnostic certainty in labeling results was not achieved, or indeed even possible, in *in situ* hybridization using FFPE tissue at the time the '841 application was filed. Because the optimization of such a protocol required significant experimentation in 1986, and apparently for several years thereafter, it is enough that the the '841 patent provided "reasonable detail" of how to modify its specific teachings in order to successfully carry out the claimed *in situ* hybridization method for a broad variety of applications. See Genentech, Inc. v. Novo Nordisk A/S,

108 F.3d 1361, 1366-68 (Fed. Cir. 1997) (contrasting an enabling "specific and useful teaching" with a non-enabling "mere germ of an idea").

The court finds that Dako has failed to prove that the claimed *in situ* hybridization methods would not have generally been understood by one of ordinary skill in the art to apply similarly to the chromosomal DNA of different organisms, using different probes directed to different chromosomal targets. "Stripped to its basics, defendants' argument is one of "overbreadth," but that word alone has long ago been discredited as a basis for determining sufficiency of a specification." Phillips Petroleum, 865 F.2d at 1251. A broad concept, which works in practice, is entitled to broad claims. See Hogan, 559 F.2d at 606. Because Dako has failed to present clear and convincing evidence that the specification does not satisfy the written description and enablement requirements of 35 U.S.C. section 112, defendants' motion for summary judgment of invalidity of the '841 patent is **DENIED**.

II. Summary Judgment on the Issue of Inequitable Conduct

Inequitable conduct is a judicially created doctrine designed to prevent fraudulent conduct before the PTO. Those who participate in proceedings before the PTO have a duty to do so with the "highest degree of candor and good faith." Kingsland v. Dorsey, 338 U.S. 318, 319 (1949); see also 37 C.F.R. § 1.56(a) (The "duty of candor and good faith in dealing with the [PTO] . . . includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability . . . "). The inequitable conduct doctrine was "borne out of a series of Supreme Court cases in which the Court refused to enforce patents whereby the patentees had engaged in fraud in order to procure those patents." Digital Control, 437 F.3d at 1315. As one court explained:

> No man should be granted a patent where his conduct has been such that any grant to him will be clouded with forgery and perjury or fraud practiced upon the Patent Office; and where it appears, at any stage of the proceedings, that an applicant has been guilty of conduct of this sort, he should be denied all further relief.

Mas v. Coca-Cola Co., 163 F.2d 505, 510 (4th Cir. 1947); see also Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 819 (1945) (recognizing "the public policy against the assertion and enforcement of patent claims infected with fraud and perjury").

Dako has moved for summary judgment that the '841 patent is unenforceable for inequitable conduct during the prosecution of the patent, on the grounds that one of the named inventors, Dr.

Pinkel, made three highly material false and misleading statements to the PTO during the prosecution of the patent application with an intent to deceive. Plaintiffs, in turn, have moved for summary judgment of no inequitable conduct. Plaintiffs contend that there is no clear and convincing evidence that Dr. Pinkel's statements were material misrepresentations, and even if Dr. Pinkel's statements were misrepresentations, there is no clear and convincing evidence that Dr. Pinkel intentionally lied, rather than erred, in making the statements. Both parties' motions turn on three specific statements made in Dr. Pinkel's declaration and in accompanying remarks that were submitted to the PTO in response to the patent examiner's rejection of then-pending claims. The court addresses each of the three allegedly material misrepresentations/omissions in the Pinkel declaration in turn.

(i) Usefulness of Sealey Reference

The first alleged misstatement is from a 1993 declaration to the PTO in which Dr. Pinkel stated it was his opinion that "a person skilled in the art of *in situ* hybridization would not have considered the blocking technique of Sealey et al[.] to be useful in *in situ* hybridizations prior to the filing of our grandparent application in January 1986." Derrick Dec., Exh. 6 ¶ 10. Dako argues that Dr. Pinkel knew this statement was false based on personal information he received from colleagues in the field. Dako alleges that before January 1986, several of Dr. Pinkel's colleagues brought the Sealey reference to Dr. Pinkel's attention as a reference that could be useful in *in situ* hybridization. In support of this allegation, Dako submitted internal notes sent in 1985 and deposition testimony from a colleague who recalled bringing up the Sealey reference to Dr. Pinkel because he believed it "was directly applicable" to Dr. Pinkel's work. Derrick Dec., Exh. 27; Exh. 28 at UCAT00000067-68. Therefore, Dako alleges, Dr. Pinkel knew his sworn statement about the lack of usefulness of the Sealey reference was false.

Plaintiffs, however, argue that Dr. Pinkel's statement regarding the applicability of the Sealey reference was not false because it was phrased as an opinion—Dr. Pinkel's advocacy of his own view of the prior art, a view that the examiner was free to accept or reject, and a view that Dr. Pinkel continues to stand by today. See Tyz First Dec., Docket No. 218, Exh. 10 at 129-31; see also Akzo N.V. v. U.S. Int'l Trade Comm'n, 808 F.2d 1471, 1482 (Fed. Cir. 1986) (holding that it was

not a material misrepresentation to advocate for a particular interpretation of the art, because the examiner was free to reach his own conclusion regarding how to interpret the art). Plaintiffs also contend that the inventors received the Sealey reference only after requesting references for blocking techniques from their colleagues, so the fact that the reference was provided does not show that one of skill in the art would have thought it useful without such a request. See Tyz Second Dec., Docket No. 233, Exh. 4 at 62:25-64:13, 65:17-66:1. Finally, plaintiffs argue that evidence of the work of other research groups in the field does not undermine the statement, because Dr. Pinkel does not recall learning before January 1986 that either group had successfully used the Sealey technique in *in situ* hybridization, and because the published articles from these groups that explicitly suggested using the Sealey technique were not published until after January 1986.

(ii) Limited Use of Blocking Copies

The second alleged misstatement comes from the same 1993 declaration. In it, Dr. Pinkel stated that prior to January 1986, "the use of blocking copies of a sequence in *in situ* hybridization had been limited to testing whether a hybridization signal was due to repeat sequences." Derrick Dec., Exh. 6 ¶ 8. Dako argues that Dr. Pinkel knew this statement was false because he knew that prior to January 1986, the van der Ploeg research group had used blocking DNA in *in situ* hybridization to detect unique sequences. In September 1985, Dr. Pinkel visited the van der Ploeg laboratory, although Dr. Pinkel has no notes from the visit and has no recollection of what was discussed during the visit. Undisputed Facts ¶¶ 23-25. Dako asserts, and plaintiffs do not dispute, that Dr. Pinkel returned with a collection of protocols from the van der Ploeg lab. Shortly thereafter, on December 4, 1985, Dr. Pinkel presented a seminar at Lawrence Livermore National Laboratories ("LLNL"). Id. ¶ 26. On December 6, 1985, Dr. Pinkel and a colleague, Dr. Langlois, attended an internal meeting at LLNL. Id. ¶¶ 28-29. Dr. Langlois took notes at that meeting which referred to a European Meeting. Id. ¶ 30. The parties dispute the substance of Dr. Langlois's notes. Dr. Langlois testified that he did not recall the meeting, but interpreted his note as saying that someone thought the pre-hybridization blocking technique to detect unique sequences in *in situ* hybridization might work. See Derrick Dec., Exh. 18 at 130:11-22.

Dako also points to language in a February 1986 grant application to support its contention that Dr. Pinkel knew others, specifically the van der Ploeg group, were using blocking DNA to detect unique sequences. In this grant application, Dr. Pinkel wrote that a method of "blocking of repetitive sequences by prehybridization of the probe and target with genomic DNA . . . has been demonstrated on Southern blot, but its effectiveness for *in situ* hybridization is not established except in specific instances (M van der Ploeg, private communication)." Id., Exh. 21 at UCA003850 (emphasis added). According to Dako, this language further demonstrates that prior to January 1986, Dr. Pinkel knew that the van der Ploeg group had used blocking DNA to detect unique sequences, at least in limited instances, and therefore his 1993 declaration to the contrary was a misrepresentation to the PTO.

Plaintiffs argue that Dr. Pinkel's statement was not a misrepresentation because it was another advocacy of an opinion—introducing and summarizing Dr. Pinkel's opinion of two prior art references that were before the examiner. Plaintiffs argue that the language in the declaration is an excerpt of a sentence that, when viewed in full and in the context of the entire declaration, could not be considered a material misrepresentation of fact by any rational fact-finder. See Chiron Corp. v. Abbott Labs., 902 F. Supp. 1103, 1114 (N.D. Cal. 1995) (Patel, J.). The relevant paragraph in Dr. Pinkel's declaration reads:

> *8. Until our grandparent application was filed in January 1986, the use of blocking copies of a sequence in in situ hybridization had been limited to testing whether a hybridization signal was due to repeat sequences.* Yunis et al, cited by the examiner, state at page 335, the last three lines that:
>
> > The experimental design used in this work favored hybridization of repeated gene sequences and provides cytological evidence for their widespread distribution in the human genome.
>
> Yunis further states in the first three lines at the top of page 342 that:
>
> > This suggests that, under the in situ hybridization conditions used, the majority of the chromosomal labeling observed represents repeated rather than non-repeated gene sequences.
>
> Thus, the focus of Yunis et al was on hybridization of sequences that are repeated in the normal genome, and there is no hint from the results of Yunis et al that unique sequences of chromosomal DNA could be targeted. Moreover, there is nothing to suggest what the remainder of the signal was due to.

Tyz First Dec., Exh. 4 at Tab 21, UCA001593 (emphasis added).

Plaintiffs argue that in this context, it is evident that Dr. Pinkel was advocating his view of the prior art that the examiner was free to accept or reject.[10] Plaintiffs also argue that Dr. Pinkel's statement was accurate on its face, because there was no *prior art* disclosing the use of blocking in *in situ* hybridization to detect unique sequences and because the notes and comments in the grant application, taken together, do not prove by clear and convincing evidence that the van der Ploeg laboratory had used blocking in *in situ* hybridization prior to January 1986. Plaintiff also note that Dako does not contend the van der Ploeg work invalidates the '841 patent.

Dako counters that this statement should not be viewed as an opinion of the cited art, first because on its face the statement is not prefaced with qualifying language such as "in my opinion" or "in the cited references," and second because Dr. Pinkel admitted in his deposition that the statement was essentially not true in light of the notes taken at the December 6, 1985, seminar, i.e., "that [blocking] had been used" in *in situ* hybridization to detect unique sequences before the January 1986 filing date. Derrick Dec., Exh. 3 at 133-34. More fundamentally, Dako contends the statement was inaccurate because it was inconsistent with personal knowledge that Dr. Pinkel had gained and had a duty to disclose to the PTO.

(iii) Landegent Reference

The third alleged misstatement comes from remarks accompanying the 1993 Pinkel declaration, in which applicants stated that a 1987 article by Landegent et al. was "another indication of the failure of the art to consider blocking in connection with *in situ* hybridization" because the article, published more than a year after applicants' January 1986 filing date, discussed "the use of blocking in *in situ* hybridization as a novel technique." Derrick Dec., Exh. 5 at 12. Dako contends that this statement was grossly misleading because Dr. Pinkel knew the research group had used blocking in *in situ* hybridization long before the article was submitted for publication in 1987.

In support of its argument, Dako points to the February 1986 grant application in which Dr. Pinkel referred to "specific instances" in which the research group had used blocking in *in situ* hybridization. Id., Exh. 21 at UCA003850. Additionally, because they were in the same field, Dr. Pinkel and Dr. Gray were likely aware of a 1986 publication by that research group in which the authors stated they were currently investigating whether background in *in situ* hybridization could be

eliminated by competitive hybridization such as that taught by the Sealey reference. Id., Exh. 30. Plaintiffs, however, argue that the statement was not misleading because the examiner was not misled by applicants' characterization of the article but rather was influenced by the unsuccessful attempts at using blocking that were described in the article. See id., Exh. 12 at 4-5.

A. Dako's Motion for Summary Judgment of Unenforceability for Inequitable Conduct

Dako has moved for summary judgment that the '841 patent is unenforceable for inequitable conduct during the prosecution of the patent, on the grounds that these three statements were false or misleading, highly material and made with an intent to deceive the PTO. As the party asserting inequitable conduct, Dako must prove by clear and convincing evidence that "the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]." Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008). If Dako proves a threshold level of both materiality and intent, the court will then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, with a greater showing of one factor allowing a lesser showing of the other. Digital Control, 437 F.3d at 1313; Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1128 (Fed. Cir. 2006).

At the outset, plaintiffs argue that this court has already determined that these types of allegations are not sufficient to justify granting summary judgment on the issue of inequitable conduct. In an action brought by UC Regents against another party, Oncor, for infringement of the '841 patent, Oncor filed a motion for summary judgment of unenforceability for inequitable conduct during the prosecution of the '841 patent. Regents of Univ. of Cal. v. Oncor, Inc., 1997 U.S. Dist LEXIS 15068, 44 U.S.P.Q.2d 1321, 1329-30 (N.D. Cal. 1997) (Walker, J.). Oncor alleged that Dr. Pinkel's statement that one of skill in the art would not have considered the blocking technique of Sealey to be useful in *in situ* hybridization was a half-truth because Dr. Pinkel was exposed to information that others in the field had recognized the applicability of Sealey to *in situ* hybridization. Id. at 1329-30. Oncor also alleged that the inventors committed inequitable conduct by withholding

from the examiner information that blocking techniques for *in situ* hybridization had already been successfully used and reported by others.

Oncor's motion for summary judgment of unenforceability based on Dr. Pinkel's statement regarding his opinion of the usefulness of the Sealey reference was denied, on the grounds that Dr. Pinkel was "merely engaging in argumentation of his case on obviousness" rather than trying to deceive the examiner. Id. With regard to the allegation of inequitable conduct by withholding information—that others had successfully used and reported on the use of blocking techniques for *in situ* hybridization—the Oncor court struck this inequitable conduct defense for not being specifically pled in Oncor's answer. Id.

On a renewed motion for summary judgment on the unenforceability of the '841 patent, however, the Oncor court addressed on the merits the issue of whether Drs. Gray and Pinkel had specific knowledge that other scientists had developed similar blocking techniques and failed to disclose such knowledge to the PTO. In its order denying summary judgment, the Oncor court found evidence that some of the information concerning blocking techniques for *in situ* hybridization used and reported by others, namely, the Dutch scientists in Holland, may have been material. See Order, Case No. 95-03084-VRW, Docket No. 178 (unpublished, entered 12/23/1997) at 6:3-7. However, the court denied summary judgment on the basis that genuine issues of material fact existed with respect to intent. The court concluded by stating "[o]f course, it would have been wiser for Gray and Pinkel to disclose this material, but at this stage of the litigation the court refuses to equate, as a mater of law, apparently bad judgment an intent to defraud the PTO." Id. at 7:5-8.[11] The case later settled.

Here, plaintiffs argue that Dako's inequitable conduct allegations offer nothing new to justify a finding of inequitable conduct in this case. The court rejects plaintiffs' contention that there is no issue for this court to consider and proceeds with the analysis. The first factor, materiality, may be judged by the "reasonable examiner" standard. Digital Control, 437 F.3d at 1316. That is, materiality embraces any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent. McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 913 (Fed. Cir. 2007); In re Jerabek, 789 F.2d 886,

890 (Fed. Cir. 1986). Information concealed from the PTO may be material even though it would not invalidate the patent, although withheld information that is merely cumulative to the information already considered by the examiner is not material for the purpose of inequitable conduct even if it would be considered material in isolation. McKesson, 487 F.3d at 913. The second factor, intent to deceive, "need not, and rarely can, be proven by direct evidence." Impax Labs., Inc. v. Aventis Pharms., Inc., 468 F.3d 1366, 1375 (Fed. Cir. 2006). Rather, intent to deceive may be inferred from the facts and circumstances surrounding the applicant's overall conduct. Id.. A showing of materiality alone, however, does not give rise to a presumption of intent to deceive. Praxair, 543 F.3d at 1313.

Turning first to materiality, the court finds that two of the three challenged statements cannot properly be called misrepresentations of material fact. Firstly, Dr. Pinkel's statement regarding whether a person skilled in the art would have considered the Sealey reference to be useful in *in situ* hybridizations was not a statement of fact, but rather was an assertion of opinion during the course of advocacy before the PTO. An argument for distinguishing prior art is generally not a material misrepresentation when it does not contain any factual assertions. See, e.g., Life Techs., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000); see also Akzo, 808 F.2d at 1482. Dako's assertion to the contrary, that opinions are no different from statements of fact, stems from its improper reliance on a case that stated "affidavits are inherently material." See Refac Int'l., Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1583 (Fed. Cir. 1996). This quote referred to the fact that affidavits are not rendered less meaningful if they are cumulative to other affidavits. In Refac, the affidavit in question involved an affiant's failure to disclose a prior association, and the court held that the non-disinterested nature of the affiant "would have been important to the examiner . . . particularly when the examiner had *no way of otherwise obtaining the omitted information about Jones's background*." Id. at 1582 (emphasis added).

This is not the case for the Sealey reference here, where the examiner was able to reach his or her own conclusion regarding that cited piece of prior art. Pinkel's statement about the Sealey reference was qualified by the phrase "it is my opinion," which can reasonably be understood to be summarizing the preceding explanations of the prior art—art that was all before the examiner.

Although Dako presented evidence that the inventors were provided with the Sealey reference by colleagues before the filing date, plaintiffs have countered with evidence that the inventors prompted their colleagues to provide blocking references such as Sealey. Furthermore, there is no conclusive evidence that the inventors knew before January 1986 whether other labs, such as the van der Ploeg lab, specifically considered the Sealey reference to be useful.

Similarly, the court finds that applicants' statement that the Landegent article was another indication of the failure of the art to consider blocking in connection with *in situ* hybridization was an opinion without misrepresentation of material fact. Applicants were not asserting that the use of blocking had never been attempted before the Landegent article's submission date, but rather they were arguing generally for patentability by showing that a later-published article discussed the use of blocking in *in situ* hybridization as a novel technique. This assertion plainly does not render the Pinkel declaration a "false affidavit" that would be "inherently material." See Digital Control, 437 F.3d 1309, 1318 (Fed. Cir. 2006), citing Refac, 81 F.3d at 1583.

However, the court finds that Dako has shown clear and convincing evidence that Dr. Pinkel's statement that "the use of blocking copies of a sequence in *in situ* hybridization had been limited to testing whether a hybridization signal was due to repeat sequences" was a misrepresentation of a material fact. Although this statement precedes a discussion of the art before the patent examiner, the statement on its face is phrased as an assertion, not an opinion. The statement is not qualified with a phrase like "in my opinion," nor does it limit itself to *use in the prior art*, but rather it implies *any* use.

Even if plaintiffs are correct that the prior art did not disclose the use of blocking in *in situ* hybridization to detect unique sequences, Dako has presented evidence that applicants knew of such a use that was not in the prior art. Following a visit to the van der Ploeg laboratory, Dr. Pinkel acknowledged that laboratory's limited use of blocking in *in situ* hybridization in a February 1986 grant application. Dr. Langlois's notes from the December 1985 seminar also indicated that blocking had been done in *in situ* hybridization before January 1986. Furthermore, Dr. Pinkel admitted in his deposition that the statement in his declaration was not accurate in light of this evidence. Omission of a prior use of blocking in *in situ* hybridization to detect unique sequences is

also material, as a reasonable examiner would consider information that is inconsistent with an applicant's position regarding patentability to be important when examining the application. See Eli Lilly, 119 F.3d at 1575 ("[w]hat is relevant is whether [the withheld material] discloses subject matter relevant to the examination of the . . . patent application that is not taught by the [material already before the PTO].")

Indeed, the prosecution history of the '841 patent indicates that the examiner considered Dr. Pinkel's statement concerning the use of blocking copies in *in situ* hybridization as being limited to testing whether a hybridization signal was due to repeat sequences at the time, important in that she relied on it in her decision to allow the application to issue as a patent. See McKesson, 487 F.3d 897 at 912-14. Specifically, in the Notice of Allowability, the examiner cited the March 4, 1993, Pinkel declaration among the reasons for allowing the claims, stating:

> The Declaration of Daniel Pinkel, Ph.D., filed 3/4/93, also supports the direction in the art as being away from the procedure of the instant invention. That is as summarized therein, in situ hybridization as performed in the art at the time of the instant invention was directed to labeling single copy sequences in situ by using labeled probes prepared so as to remove any repetitive sequences prior to hybridization rather than to use complex probes as given in the instant invention and then to block repetitive sequences by repetitive competitor nucleic acid molecules.

Tyz First Dec., Exh. 4 at Tab 21, UCA001756.

This reasoning in the prosecution history evidences a clear reliance by Examiner Parr on Dr. Pinkel's declaration to determine that others in the art were not using blocking DNA to detect unique sequences in *in situ* hybridization. Plaintiffs' position is that Dr. Pinkel's statement regarding the limited use of blocking copies in *in situ* hybridization was not a misrepresentation based on what Dr. Pinkel knew about the art when he described his invention to his patent attorney in August 1985, i.e., before his visit to the van der Ploeg lab. This position is entirely unavailing, however, because Dr. Pinkel's statement regarding the use of blocking copies expressly stated that the use was limited "until our grandparent application was filed in January 1986 . . . ." Thus, it is irrelevant when Dr. Pinkel disclosed his invention to his patent attorney. A reasonable examiner would have concluded that Dr. Pinkel was speaking about the general direction in the art as of the filing date of the application, as Examiner Parr concluded. Accordingly, the court finds that the evidence presented by Dako, taken together, provides clear and convincing evidence that Dr. Pinkel's statement that

"the use of blocking copies of a sequence in *in situ* hybridization had been limited to testing whether a hybridization signal was due to repeat sequences" was a misrepresentation of a material fact.

Although Dako has met its burden with respect to the materiality prong for one statement, the court finds that Dako has not met its burden with respect to proving intent to deceive the PTO. An accused infringer must prove that "an applicant had the *specific intent* to . . . mislead or deceive the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold" information. Star Scientific, 537 F.3d at 1366, quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995) (emphasis in original). "[M]ateriality does not presume intent, and nondisclosure, by itself, cannot satisfy the deceptive intent element." Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods., Ltd., --- F.3d ----, 2009 WL 691322, *16 (Fed. Cir. 2009). Even gross negligence is insufficient to prove intent to deceive. Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc* in relevant part).

The Federal Circuit has suggested that an inference of intent may be drawn when "(1) highly material information is withheld; (2) 'the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.'" Praxair, 543 F.3d at 1313-14, quoting Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006). However, this inference must "not only be based on sufficient evidence and be reasonable in light of that evidence, but it also must be the *single most reasonable inference* able to be drawn from the evidence to meet the clear and convincing standard." Star Scientific, 537 F.3d at 1366-67 (emphasis added). The Federal Circuit has recently given specific guidance with respect to the deceptive intent prong, cautioning district courts not to infer intent without clear and convincing circumstantial evidence and reminding courts to "take into account any evidence of good faith, which militates against a finding of deceptive intent." Larson, 2009 WL 691322 at *16.

Here, Dako's evidence of intent is that Dr. Pinkel knew his statements were false, (2) he knew or should have known the information was material and (3) he had no credible explanation for submitting false statements or withholding material information. Dako argues that intent should be

inferred because Dr. Pinkel felt a heightened sense of competition with the van der Ploeg laboratory and because he affirmatively submitted his false statement, the truth of which could not be investigated by the examiner, in a sworn affidavit that was meant to persuade the examiner to withdraw his rejections. Dako also argues it is not believable that Dr. Pinkel would not remember to disclose this information in light of a 1993 time line he assembled of events from the 1985-1986 period related to blocking. Derrick Dec., Exh. 39 at UCA004197. This time line included the comment, "I presented blocking in my divisional seminar at LLNL [the December 4, 1985, seminar]." Id.

Although the court finds Dako's inference—that Dr. Pinkel made a deliberate decision to withhold this information from the PTO out of a sense of competition with the van der Ploeg laboratory—to be a reasonable one, it is not convinced that this inference meets the "elevated evidentiary burden" that is required for the inequitable conduct defense. See Star Scientific, 537 F.3d at 1365. "Inequitable conduct requires not intent to withhold, but rather intent to deceive." Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1367 (Fed. Cir. 2003). The fact that information later found material was not disclosed is insufficient, by itself, to satisfy the deceptive intent element of inequitable conduct. See M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1340 (Fed. Cir. 2006). Furthermore, the court does not give weight to plaintiffs' lack of a credible explanation, because the patentee need not offer any good faith explanation unless the accused infringer first carries his burden to prove a threshold level of intent to deceive. Star Scientific, 537 F.3d at 1368; see also Dayco, 329 F.3d at 1367 ("[i]ntent to deceive cannot be inferred simply from the decision to withhold . . . where the reasons given for the withholding are plausible.").

The court is mindful of the Federal Circuit's caution that summary judgment of inequitable conduct is a "draconian result" that should be used sparingly, particularly where motive and intent play leading roles. Kangaroos U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 1573-74, 1577 (Fed. Cir. 1985); see also M. Eagles Tool Warehouse, 439 F.3d at 1341-43. Here, it is appropriate to leave it to the fact finder to evaluate all of the facts and circumstances of this case in determining whether Dr. Pinkel intended to deceive the PTO through his false statement and failure to disclose

information. Accordingly, Dako's motion for summary judgment of unforceability for inequitable conduct is **DENIED**.

B. Plaintiffs' Motion for Summary Judgment of No Inequitable Conduct

Plaintiffs have moved for summary judgment of no inequitable conduct on the grounds that Dako cannot show by clear and convincing evidence that the statements at issue were material misrepresentations or that Dr. Pinkel intentionally lied, rather than erred, in making the statements. Although at trial Dako would bear the burden of proving inequitable conduct by clear and convincing evidence, at the summary judgment stage plaintiffs, as the moving party, must show the absence of a genuine issue of material fact in order for the court to grant their motion. Celotex, 477 U.S. at 323.

Turning first to the materiality factor, the court finds that Dako has shown clear and convincing evidence that Dr. Pinkel's 1993 statement regarding whether blocking had previously been used in *in situ* hybridization to detect unique sequences was a misrepresentation of a material fact. As discussed above, Dr. Pinkel did not qualify the statement as an opinion or as only addressing the cited art in front of the examiner. Rather, it was an assertion of fact that was contradicted by his knowledge, through private communications with the van der Ploeg laboratory, that blocking had been used in *in situ* hybridization to detect unique sequences in at least some limited instances. Dr. Pinkel even acknowledged the statement was inaccurate; that blocking had been used in in situ hybridization to detect unique sequences before the January 1986 filing date. This failure to disclose information was also material because it was inconsistent with applicants' position regarding the patentability of the invention.

Turning next to the intent to deceive factor, the court finds that Dako has raised a genuine issue of material fact as to whether Dr. Pinkel failed to disclose this information with intent to deceive the PTO. Plaintiffs argue that Dako has no evidence of intent and they suggest the most credible explanation for Dr. Pinkel's failure to disclose the information from the van der Ploeg laboratory is that he forgot about it in the intervening eight years. Dako, however, argues that intent can be inferred from the fact that Dr. Pinkel affirmatively submitted his false statement in a sworn affidavit to the examiner where the examiner was unable to investigate the truth or falsity of the

statement. See, e.g., eSpeed, Inc. v. BrokerTec USA, L.L.C., 480 F.3d 1129, 1138 (Fed. Cir. 2007); Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1191 (Fed. Cir. 1993). Furthermore, Dako presented evidence to refute plaintiffs' explanation that Dr. Pinkel forgot about the information. Specifically, Dako presented Dr. Pinkel's detailed time line of events from 1985-1986 relating to the development of the blocking technique, which included references to Dr. Pinkel's December 4, 1985, seminar in which he presented blocking, even though at that time he and Dr. Gray had not yet been successful in using blocking. See Derrick Dec., Exh. 3 at 100-02. This evidence is sufficient to raise a genuine issue of material fact as to whether Dr. Pinkel intended to deceive the PTO in making the statement and in failing to disclose information. Accordingly, plaintiffs' motion for summary judgment of no inequitable conduct is **DENIED**.

CONCLUSION

For the foregoing reasons, defendants' motion for summary judgment of invalidity of the '841 patent is **DENIED**; defendants' motion for summary judgment of unenforceability for inequitable conduct is **DENIED**; and plaintiffs' motion for summary judgment of no inequitable conduct is **DENIED**.

Plaintiffs' motion to strike the report of Dr. Singer is **DISMISSED** as moot, as the report has been later sworn to, Dr. Singer confirmed the opinions expressed therein, and the objected-to testimony did not form a basis upon which the court decided the parties' respective motions for summary judgment.

IT IS SO ORDERED.

Dated: April 22, 2009

MARILYN HALL PATEL
United States District Court Judge
Northern District of California

ENDNOTES

1. In *in situ* DNA hybridization, sections of nucleic acid that are labeled, usually with a fluorescent dye ("hybridization probes"), are bonded to complementary "target" regions of chromosomal DNA—typically, sections which encode a protein of interest. See, e.g., '841 patent at cols. 2–3. The fluorescent label provides visual confirmation of the presence of the target gene. Id.

2. Dr. Pinkel's declaration and the accompanying amendment and remarks were submitted February 12, 1993, but the declaration was unsigned at that time. Applicants submitted a signed version of the declaration on March 4, 1993. Derrick Dec., Exhs. 5 & 6.

3. The Federal Circuit has construed "morphologically identifiable cell nucleus" as one that is capable of being identified by its form or structure, such that the "morphologically identifiable" language imposes no requirement that the cell nucleus must retain its full complement of chromosomal DNA. Regents of Univ. of Cal. v. Dakocytomation Cal., Inc., 517 F.3d 1364, 1380 (Fed. Cir. 2008).

4. This is not a case where the potential variation in the ways in which a generic method claim could be performed is so vast that the patent could not possibly describe the scope of such a claim. The classic instance of this is the patent Professor Morse obtained for his invention of the telegraph. The patent was directed to "a method of recording permanently electrical signs, which . . . convey intelligence between two or more places" and claimed, *inter alia*, "the use of the motive power of the electro or galvanic current, which I call electromagnetism, however developed, for making or printing intelligible characters, signs or letters at any distances . . .." The Supreme Court held that claim invalid because "any one may lawfully accomplish the same end without infringing the patent, if he uses means substantially different from those described." O'Reilly v. Morse, 56 U.S. 62, 113 (1853). The Supreme Court effectively found a lack of written description, stating "he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent."

5. In Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 561-62 (1898), the Supreme Court defined a "pioneer" invention as follows:

> This word, although used somewhat loosely, is commonly understood to denote a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what has gone before.

The Supreme Court explained that a patent to a pioneer invention "is to receive a liberal construction," in view of the fact that the inventor was a pioneer in the field, and the patent is not to be limited to the particular devices or instrumentalities described by the inventor. See Morley Sewing-Mach. Co. v. Lancaster, 129 U.S. 263, 286 (1889). Subsequent case law has applied this principle to give claims to pioneer patents an enhanced breadth of interpretation. See, e.g., Sealed Air Corp. v. U. S. Int'l Trade Comm'n, 645 F.2d 976, 984 (C.C.P.A. 1981) ("A pioneer invention, performing a function never before performed, is entitled to liberal application of the doctrine of equivalents."); Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532 (Fed. Cir. 1987) (noting that a pioneer invention is entitled to a broad range of equivalents); Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 846 F.2d 1369, 1370 (Fed. Cir. 1988) (explaining that the judicial "liberal" view of both claim interpretation and equivalency for pioneer patents "flows directly from the relative sparseness of prior art in nascent fields of technology."); Augustine Med., Inc. v. Gaymar Indus., Inc., 181 F.3d 1291, 1301 (Fed. Cir. 1999) ("Without extensive prior art to confine and cabin their claims, pioneers acquire broader claims than non-pioneers who must craft narrow claims to evade the strictures of a crowded art field."); Abbott Labs. v. Dey, L.P., 287 F.3d 1097, 1105 (Fed. Cir. 2002) ("[a] pioneer patent by definition will have little applicable prior art to limit it, whereas an improvement patent's scope is confined by the existing knowledge on which the improvement is based.").

6. The court places "whole-chromosome probe" in quotation marks because the term implies, incorrectly, that the probe itself is the length of a whole chromosome. Dako uses this connotation to argue that probes of much shorter lengths were neither described nor enabled in the '841 patent. Dako states, for example, "the specification's description of one whole-chromosome probe does not constitute a representative species of the thousands or millions of whole and partial chromosome probes claimed in the patent." See Defs.' SJ Mot. for Invalidity, Docket No. 227, at 2:10-12 (emphasis in original); and "the specification fails to describe any chromosomal region or probe length other than the entire human chromosome 21." Id. at 10:4-5 (emphasis added). In so doing, Dako is misrepresenting the disclosure in the '841 patent. The "whole-chromosome probes" described in the patent are not each the length of a whole chromosome, but rather are short, distinct nucleic acid fragments. The average size of the chromosome 21 DNA insert used in the working example was 5 kbs. See '841 patent at 16:26-28. The patent teaches that:

> [E]ach chromosome-specific staining composition of the invention can be viewed as a large collection of hybridization probes to unique sequence regions of a specific chromosome. In fact, the preferred method of making the compositions of the invention entails generating a heterogeneous mixture on a fragment-by-fragment basis . . . and selecting . . . hybridization probes to unique sequence regions of a particular chromosome.

'841 patent at 5:54-63. Thus, they are only called "whole-chromosome probes" because the binding sites of the labeled fragments, when taken together, permit detection of a whole chromosome.

7. To the extent that Dako makes specific allegations concerning the unpredictability in the "art of *in situ* hybridization," the court finds these arguments not compelling, because they have been infected by Dako's reliance on inapposite case law. Dako misapplies the unpredictability factor to argue that plaintiffs have not adequately described a representative number of species in the claimed genus, per the Carnegie Mellon, Alonso, and Eli Lilly holdings. For the reasons stated, this analysis is flawed.

8. Conception is a prerequisite to an adequate written description. See Fiers v. Sugano, 984 F.2d 1164, 1171 (Fed. Cir. 1993) ("[O]ne cannot describe what one has not conceived.").

9. Dako argues, for example, "[w]hile the claims encompass *in situ* hybridization methods using probes directed to any region of any chromosome of any organism, it is undisputed that the inventors were not in possession of such an expansive set of probes." Defs.' SJ Mot. for Invalidity at 15:11-13. And, "[i]t is undisputed that the inventors did not have possession of probes to the entire human genome in 1986, as they had only isolated "a few" by that time." Id. at 17:26-27. And, "[the inventors] did not, however, have possession of probes directed to subregions of chromosomes—Dr. Gray admitted that such subregion libraries did not even exist in 1986." Id. at 18:12-14.

10. The court takes note of plaintiffs' assertion that "[n]otably, the examiner opted to reject the claims notwithstanding Dr. Pinkel's view of the art." Pls' Opp. To SJ for Inequitable Conduct, Docket No. 231 at 5:21-22. This is either a disingenuous statement or a splitting of hairs that the court finds too fine to pass the so-called "red face" test. The truth of the matter is, in the next Office Action, the examiner specifically stated that applicant's arguments filed 2/12/93 (which included Dr. Pinkel's declaration) "have been fully considered and they are deemed to be persuasive to overcome the previously applied rejections. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn." See Tyz First Dec., Exh. 4, at Tab 21, UCA001628. The examiner then proceeded to issue a series of *new* rejections. Plaintiffs' above assertion cited to the Office Action's final page, concluding only after the old rejections were withdrawn and the new rejections were applied, that "no claim is allowed." Plaintiffs also fail to acknowledge that Dr. Pinkel's declaration was again relied upon to argue the new rejections, and the examiner subsequently withdrew those rejections. See Derrick Dec., Exhs. 8 & 9. This pattern repeated itself once more, id., Exhs. 10 & 11, and the examiner finally allowed the application, citing Dr. Pinkel's declaration among the reasons for allowance. The court notes, with some irony, that it would have behooved plaintiffs to acknowledge the true "full context" in which Dr. Pinkel's declaration was considered.

11. The court specifically asked the parties at the hearing on this matter what the outcome was of the renewed motion for summary judgment on this issue in the Oncor litigation, and was incorrectly informed that the issue had not been addressed on the merits. Apparently neither party took the time or effort to determine the correct answer. In fact, the court had addressed the issue and found materiality but also found genuine factual issues concerning an intent to deceive. While the decision was unpublished, it was also public, and plaintiff certainly should have had ready access to these related litigation files of its client. Yet, plaintiff began its opposition brief on this issue before this court by pointing to the published Oncor denial of summary judgment *only* (in which the allegations in question were struck on procedural grounds) and argued that Dako's inequitable conduct allegations offer "nothing new to justify a different conclusion a decade later"-- an audacious maneuver given that the court file is readily available to the court.