

PRECEDENTIAL
UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 12-1180

In Re: DIET DRUGS
(PHENTERMINE/FENFLURAMINE/
DEXFENFLURAMINE)
PRODUCT LIABILITY LITIGATION,

Carmen Cauthen and Ricky Leon Cauthen,
Appellants

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Nos. 2-99-cv-20593, 2-12-md-01203)
District Judge: Hon. Harvey Bartle, III

Argued
November 13, 2012

Before: SCIRICA, FISHER, and JORDAN, *Circuit Judges.*

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OPINION OF THE COURT

JORDAN, *Circuit Judge*.

In November 1999, Wyeth L.L.C. (“Wyeth”) entered into a nationwide class action settlement agreement (the “Settlement Agreement”) with the users of certain diet drugs linked to various health problems. The United States District Court for the Eastern District of Pennsylvania certified the settlement class and entered a pre-trial order enjoining members of the class from suing Wyeth for injuries related to those drugs. Appellants Carmen and Ricky Leon Cauthen brought a lawsuit against Wyeth in the Court of Common Pleas of Philadelphia County, Pennsylvania, seeking to redress Ms. Cauthen’s injuries from primary pulmonary hypertension (“PPH”), a condition that she alleges was caused by the diet drugs. Wyeth moved the District Court to enjoin the suit, arguing that it did not qualify under the Settlement Agreement as a cause of action that could proceed despite the settlement. The District Court agreed and enjoined the Cauthens’ lawsuit. For the reasons that follow, we will affirm.

I. Background

A. *Class Action Suit and Settlement Agreement*

Between 1994 and 1997, American Home Products Corporation, now Wyeth, marketed and sold fenfluramine and dexfenfluramine, prescription weight loss drugs. After studies linked the drugs to valvular heart disease, and following a U.S. Food and Drug Administration (“FDA”) public health advisory, Wyeth withdrew the drugs from the

market in 1997. Thousands of individuals subsequently filed suit, alleging that they had been injured by the drugs.

In December 1997, the Judicial Panel on Multidistrict Litigation entered an order transferring all diet drug cases in federal court to the United States District Court for the Eastern District of Pennsylvania for consolidated pre-trial proceedings. Nearly two years later, Wyeth entered into a Settlement Agreement with users of the diet drugs in the United States and presented the agreement to the District Court for approval. On August 28, 2000, the District Court certified the class, approved the Settlement Agreement, and entered Pre-Trial Order (“PTO”) No. 1415. That order provided that the District Court “retains continuing and exclusive jurisdiction over this action and each of the Parties, including [Wyeth] and the class members, to administer, supervise, interpret and enforce the Settlement in accordance with its terms.” (Supplemental App. at 8.)

Aside from certain narrow exceptions, the Settlement Agreement enjoins class members from suing Wyeth for all diet drug-related injuries. One of the exceptions is at issue in this case: the Settlement Agreement allows class members to sue Wyeth if they can demonstrate that they developed PPH¹ through the use of the diet drugs. To qualify for the exception, a class member must draw on “[m]edical records” to demonstrate the “exclus[ion]” of certain medical

¹ PPH is a condition that “deprives the lungs of oxygen [and] can cause hypoxemia and hypercapnia, resulting in ventilator insufficiency.” 14 Roscoe N. Gray & Louise J. Gordy, *Attorneys’ Textbook of Medicine* ¶ 205.75 (3d ed. 2011).

conditions. (App. at 787-88.) To exclude one such condition, which is referred to as “greater than mild restrictive lung disease,” a class member is required by § I.46.a(2)(c) of the Settlement Agreement to produce “pulmonary function tests”² (“PFTs”) showing that the class member’s “total lung capacity” is greater than “60% of predicted at rest.” (*Id.* (Settlement Agreement, § I.46.a(2)(c)).)

B. *The Cauthens’ Lawsuit*

In June 2011, the Cauthens filed a complaint in the Philadelphia County Court of Common Pleas, alleging that Ms. Cauthen, a member of the settlement class, developed PPH “as a result of ingesting Diet Drugs.” (*Id.* at 3.) The Cauthens produced a “[p]ulmonary consultation note” prepared by Dr. Terry Fortin (*id.* at 795-97), a cardiologist certified by the American Board of Internal Medicine. Dr. Fortin stated in the consultation note that, based on a PFT she had conducted, Ms. Cauthen’s “total lung capacity [is] 56%,” and Dr. Fortin acknowledged that Ms. Cauthen’s lungs “clearly have some restriction.” (*Id.* at 796.)

Because Ms. Cauthen’s only PFT showed that she had lung capacity of less than 60 percent of predicted at rest, Wyeth notified the Cauthens that they were prohibited from

² “Pulmonary function tests are a group of tests that measure how well the lungs take in and release air and how well they move gases such as oxygen from the atmosphere into the body’s circulation.” *Pulmonary function tests: MedlinePlus Medical Encyclopedia* (Dec. 12, 2011), <http://www.nlm.nih.gov/medlineplus/ency/article/003853.htm> (last visited Jan. 3, 2013).

bringing their claim, as Ms. Cauthen did not satisfy § I.46.a(2)(c) of the Settlement Agreement. The Cauthens declined to drop the lawsuit. Wyeth then filed a motion in the District Court seeking to enjoin the Cauthens' state court lawsuit for failing to satisfy the precondition for suit provided by the Settlement Agreement. Opposing Wyeth's motion, the Cauthens submitted a declaration by Dr. Fortin stating that, "to a reasonable degree of medical certainty[,] ... Ms. Cauthen has primary pulmonary hypertension secondary to her use of [one of the diet drugs] in early 1997." (*Id.* at 808.)

In her declaration, Dr. Fortin alluded to the requirement in § I.46.a(2)(c) of the Settlement Agreement that lung capacity must be greater than 60 percent of predicted at rest, and she said that "[i]nsight into underlying pathophysiology can often be gained by comparing the measured values for pulmonary function tests obtained on a patient at any particular point with normative values derived from population studies." (*Id.* at 809.) "The *percentage of predicted normal* [lung capacity]," she continued, "is used to grade the severity of the abnormality." (*Id.*) She explained that the normative values used to calculate a patient's percentage of lung capacity predicted at rest "are based upon averages for persons of similar height, weight, age, ethnicity, etc." (*Id.*) According to Dr. Fortin, the "standard average reference" used to calculate Ms. Cauthen's percentage of lung capacity was 5.37 liters, a value "taken from the Crapo/Hsu Duke modified guide at [Duke] University." (*Id.* at 810.) Dr. Fortin further explained that, through a battery of tests conducted on April 28, 2009, she had determined that Ms. Cauthen had a lung capacity of 3.03 liters. Dividing 3.03 (Ms. Cauthen's lung capacity) by 5.37 (the average lung capacity of individuals matching Ms. Cauthen's demographic

profile), yields Ms. Cauthen's percentage of lung capacity predicted at rest, 56.4 percent.

Dr. Fortin went on to downplay that result by challenging the accuracy of the denominator in the above equation. The figures used to represent average lung capacity by demographic characteristics, she asserted, "are only averages and may vary in actual practice." (*Id.* at 809.) "The 5.37 liter reference is only a reference value," she continued, "and does not actually represent M[s]. Cauthen's total lung capacity. ... [T]he 5.37 liter reference value is just a predicted average of [a] woman's total lung capacity who fits Ms. Cauthen's age, height, race and weight." (*Id.* at 810.) In fact, Dr. Fortin claimed, the value taken from the Crapo/Hsu Duke modified guide "is just one of the many references available that are out there." (*Id.*) Without providing any other reference, Dr. Fortin concluded "to a reasonable degree of medical certainty that we just do not know conclusively what the true reference value for Ms. Cauthen should be." (*Id.*) Dr. Fortin did offer, however, that, "[i]f we were to use a reference value of 5.05, just 32ccs less than the 5.37 reference originally used[,] then Ms. Cauthen's total lung capacity percent predicted calculation would be 60%." (*Id.* at 811.)

Dr. Fortin also asserted that comparing an individual's lung capacity with the average capacity of persons having a similar demographic profile is important but not determinative in diagnosing PPH. "Cardiologists," she assured the District Court, "know about the limitations of the percent predicted calculation on a [PFT] and must rely on other methods in order to determine a specific patient's true total lung capacity, such as radiology studies and an exam of

the patient's body habitus." (*Id.* at 810.) In fact, Dr. Fortin claimed, "whether [Ms. Cauthen's] total lung capacity percent predicted calculation is 56% or 60% is clinically irrelevant" (*id.*), and "Ms. Cauthen's diet drug use was the cause of her [PPH]" (*id.* at 811). Without further explanation, Dr. Fortin declared that, "[b]ased upon [her] review of the April 28, 2009 Pulmonary Function Test and other objective tests,"³ she had "ruled out any restrictive lung disease as a cause of Ms. Cauthen's [PPH]." (*Id.*)

Unconvinced, the District Court held that the Cauthens had not produced a PFT that supported their claim that Ms. Cauthen "does not have greater than mild restrictive lung disease," as required by § I.46.a(2)(c) of the Settlement Agreement. (*Id.* at 7.) Dr. Fortin's declaration did not alter the Court's conclusion for two reasons. First, the doctor acknowledged that Ms. Cauthen's only PFT demonstrated that she has a total lung capacity of only 56 percent of predicted at rest. Ms. Cauthen thus did not meet the definition of PPH provided in § I.46.a(2)(c). Second, the Settlement Agreement requires class members who wish to make a claim related to PPH to establish, "through a pulmonary function test only, the absence of greater than mild restrictive lung disease." (*Id.* at 6.). Because Dr. Fortin's declaration is not the type of medical record contemplated in the Settlement Agreement as sufficient to establish a PPH claim, the Court held that it was not relevant to determining whether Ms. Cauthen satisfies § I.46.a(2)(c).

³ Dr. Fortin did not explain what those tests were or how they led her to her ultimate diagnosis.

The District Court accordingly entered PTO No. 8753 granting Wyeth's motion and enjoining the Cauthens from prosecuting their lawsuit in state court. The Cauthens then filed this timely appeal.

II. Discussion⁴

On appeal, the Cauthens argue that the District Court erred in two general ways. First, they claim that the District Court misunderstood Dr. Fortin's declaration and that her declaration demonstrates that Ms. Cauthen in fact has PPH that was caused by her use of the diet drugs and not by mild restrictive lung disease. Second, they argue in the alternative that, even if Ms. Cauthen does not meet the technical definition of PPH provided by the Settlement Agreement, the District Court should have reformed the Settlement Agreement, given changes in diagnostic capabilities that have rendered obsolete the requirement that a putative plaintiff

⁴ The District Court had jurisdiction pursuant to 28 U.S.C §§ 1332 and 1407. The District Court's order directing the Cauthens to dismiss their complaint in the Court of Common Pleas of Philadelphia County is an injunction, and we therefore have jurisdiction under 28 U.S.C. § 1292(a)(1). We apply “plenary review to a district court’s construction of settlement agreements,” but we review any underlying factual findings for clear error. *Coltec Indus., Inc. v. Hobgood*, 280 F.3d 262, 269 (3d Cir. 2002); cf. *In re Cendant Corp. Prides Litig.*, 233 F.3d 188, 193 (3d Cir. 2000) (“[C]ontract construction, that is, the legal operation of the contract, is a question of law mandating plenary review,” while “contract interpretation is a question of fact, and review is according to the clearly erroneous standard.”).

demonstrate lung capacity greater than 60 percent of predicted at rest.

A. *The Effect of Dr. Fortin's Declaration*

Settlement agreements are interpreted according to “basic contract principles.” *In re Cendant Corp. Prides Litig.*, 233 F.3d 188, 193 (3d Cir. 2000). When the terms of a contract are clear and unambiguous, its meaning “must be determined from the four corners of the contract.” *Glenn Distrib. Corp. v. Carlisle Plastics, Inc.*, 297 F.3d 294, 300 (3d Cir. 2002); *see also Am. Eagle Outfitters v. Lyle & Scott Ltd.*, 584 F.3d 575, 587 (3d Cir. 2009) (“When the words are clear and unambiguous, the intent of the parties must be determined from the express language of the agreement.” (internal quotation marks omitted)). In contrast, “if the written contract is ambiguous, a court may look to extrinsic evidence to resolve the ambiguity and determine the intent of the parties.” *Glenn Distrib.*, 297 F.3d at 300. A contract provision is ambiguous under Pennsylvania law⁵

if, and only if, it is reasonably or fairly susceptible of different constructions and is capable of being understood in more senses than one and is obscure in meaning through indefiniteness of expression or has a double meaning. A contract is not ambiguous if the court can determine its meaning without any guide other than a knowledge of the simple

⁵ The parties agree that Pennsylvania law controls this issue. (*See* Appellants’ Opening Br. at 29 (citing Pennsylvania contract law); Appellee’s Br. at 13 (same).)

facts on which, from the nature of the language in general, its meaning depends; and a contract is not rendered ambiguous by the mere fact that the parties do not agree on the proper construction.

Duquesne Light Co. v. Westinghouse Elec. Corp., 66 F.3d 604, 614 (3d Cir. 1995) (internal quotation marks omitted). Under those standards, we cannot credit the Cauthens' arguments that Dr. Fortin's declaration either supplanted the requirements of the Settlement Agreement or otherwise satisfied them.

First, the Cauthens contend that, because a board certified cardiologist "determined that Ms. Cauthen's PPH is not related to ... restrictive lung disease," Ms. Cauthen "has the right to make a claim against [Wyeth] for PPH under the definition of PPH in the Settlement Agreement" (Appellants' Opening Br. at 27), notwithstanding that her sole PFT showed her total lung capacity to be less than 60 percent of predicted at rest. Specifically, the Cauthens point to Dr. Fortin's statements that "whether [Ms. Cauthen's] total lung capacity percent calculation is 56% or 60% is clinically irrelevant" (App. at 810), and that, "to a reasonable degree of medical certainty[,] ... Ms. Cauthen's diet drug use was the cause of her primary pulmonary hypertension." (*Id.* at 811.) According to their argument, the District Court should have disregarded the requirements of the Settlement Agreement because a physician unilaterally declared that Ms. Cauthen has PPH that was caused by the diet drugs and not restrictive lung disease.

The Settlement Agreement, however, clearly and unambiguously states that a putative PPH plaintiff must demonstrate, through a PFT, that her total lung capacity is greater than 60 percent of predicted at rest. That is the only way, under the specific terms of that agreement, to rule out “greater than mild restrictive lung disease” as a cause of PPH. Ms. Cauthen produced only one PFT, which showed that her lung capacity was only 56 percent of predicted at rest. Her physician’s confident assertion that Ms. Cauthen’s PPH was caused by the diet drugs is therefore irrelevant in the face of the Settlement Agreement, which requires a showing that a putative plaintiff’s lung capacity is greater than 60 percent of predicted at rest.

Second, the Cauthens argue that Dr. Fortin’s declaration is not meant to replace the requirements of § I.46.a(2)(c), but rather that the declaration is a “medical record” that confirms the absence of greater than mild restrictive lung disease. (*See* Appellants’ Opening Br. at 25 (when considered in light of Dr. Fortin’s declaration, “Ms. Cauthen *has* presented a pulmonary function test to demonstrate that she has PPH in accord with the settlement”).) Dr. Fortin’s declaration, they contend, “demonstrates a lung capacity of at least 60% when the 5.37 total lung volume ... is even slightly reduced to reflect the Plaintiff’s true lung capacity in the algorithmic formula used to calculate lung function.” (Appellants’ Opening Br. at 25-26.) The District Court therefore erred, the Cauthens argue, when it did not interpret the declaration to mean that Ms. Cauthen’s percentage of lung capacity predicted at rest was actually greater than 60 percent, or, at least, a jury should be given the chance to so conclude.

Even if the Settlement Agreement could be read to allow Dr. Fortin’s declaration to be an adequate substitute for or adjunct to a PFT, however, the Cauthens have overstated Dr. Fortin’s position. She never said that Ms. Cauthen’s lung capacity is actually greater than 60 percent of predicted at rest, only that it cannot be known “what the true reference value for Ms. Cauthen should be.” (App. at 810.) Accordingly, the Cauthens cannot credibly say that Dr. Fortin’s declaration establishes that Ms. Cauthen’s lung capacity is greater than 60 percent.⁶ The District Court

⁶ The Cauthens contend that this case should be governed by PTO No. 3699, a case in which the District Court considered and accepted a medical expert’s declaration as a means of satisfying a separate provision of the Settlement Agreement. There, the District Court interpreted a provision of the PPH exception that requires a putative plaintiff to produce “a diagnosis based on examinations and clinical findings … by cardiac catheterization” that the plaintiff’s “normal pulmonary artery wedge pressure” is less than or equal to 15 mm Hg. (App. at 42.10 (Settlement Agreement, § I.46.a(1)(a)).) The putative plaintiff produced a “Cardiac Catheterization Report” showing a wedge pressure range of 14 to 16 mm Hg. (App. at 14.) Because the report straddled the range of the PPH exception, the District Court considered a declaration by the plaintiff’s medical expert who reviewed the cardiac catheterization report and opined that the plaintiff’s “wedge pressure [was] 14 mm Hg” and thus fell under the wedge pressure requirement. (App. at 14.) Based on that declaration, the Court found that the plaintiff satisfied the PPH exception and declined to enjoin his claims.

The facts of PTO No. 3699 are much different than those of this case. Whereas the results of the cardiac

therefore did not err in concluding that the Settlement Agreement unambiguously requires a showing through a PFT that a putative plaintiff's lung capacity is greater than 60 percent of predicted at rest and that Dr. Fortin's declaration did not provide that showing.⁷

catheterization report in PTO No. 3699 spanned the threshold wedge pressure value required by the Settlement Agreement, hindering the District Court's ability to determine whether the putative plaintiff's pressure fell outside the PPH exception (greater than 15 mm Hg), or within it (less than or equal to 15 mm Hg), Ms. Cauthen's PFT unambiguously falls short of the PPH exception embodied in § I.46.a(2)(c). The District Court did not need the assistance of a medical expert to understand that a lung capacity percentage that is less than 60 percent of predicted at rest falls outside the exception.

⁷ The Cauthens also argue that the District Court should have allowed a jury to consider Dr. Fortin's declaration under rule 702 of the Federal Rules of Evidence. They assert that because Dr. Fortin is unquestionably an expert in the field of cardiac medicine, her opinion "would be admissible in a court of law" (Appellants' Opening Br. at 37), and because her opinion would be admissible, it would "[b]y definition ... have a reasonable medical basis in fact." (*Id.*) The District Court accordingly exceeded its authority as a gatekeeper, they argue, by rejecting Dr. Fortin's expert opinion as "evidence that could not be considered under the strictures of the Settlement Agreement." (*Id.* at 38.)

But the Cauthens have not established the requirements of rule 702. First, Dr. Fortin's specialized medical knowledge, as embodied in her declaration, would not "help the trier of fact to understand the evidence or to

determine a fact in issue.” Fed. R. Evid. 702(a). To determine whether a declaration is helpful, this Court looks to the ““proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.”” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994) (quoting *United States v. Downing*, 753 F.2d 1224, 1237 (3d Cir. 1985)); *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993) (adopting *Downing*’s connection requirement). A court “must examine the expert’s conclusions in order to determine whether they could reliably flow from the facts known to the expert and methodology used.” *Oddi v. Ford Motor Co.*, 234 F.3d 136, 146 (3d Cir. 2000) (internal quotation marks omitted). Even if a party proffers expert testimony based on scientific knowledge, “[a] court may conclude that there is simply too great a gap between the data and the opinion proffered.” *Id.* (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). “Rule 702’s ‘helpfulness’ standard requires a valid *scientific* connection to the pertinent inquiry as a precondition to admissibility.” *In re Paoli*, 35 F.3d at 743 (internal quotation marks omitted).

Dr. Fortin’s declaration did not conclude that Ms. Cauthen’s total lung capacity is greater than 60 percent of predicted at rest. She asserted only that Ms. Cauthen’s lung capacity percentage cannot be determined because “we just do not know conclusively what the true reference value for Ms. Cauthen should be.” (App. at 810.) That cannot help the trier of fact reach the necessary conclusion that Ms. Cauthen’s total lung capacity, demonstrated by a PFT to be 3.03 liters, is greater than 60 percent of predicted at rest. At best, Dr. Fortin’s declaration would provide evidence that Ms. Cauthen’s total lung capacity predicted at rest might not be 56

B. *The Cauthens' Reformation Argument*

In the alternative, the Cauthens contend that the District Court, which “retains a special responsibility to see to the administration of justice” in a class action settlement (Appellants’ Opening Br. at 35 (internal quotation marks omitted)), should have reformed the Settlement Agreement. Although they never sought reformation of the Settlement Agreement before the District Court, they now argue that the Court should have reformed the Settlement Agreement because diagnostic procedures for PFTs have changed. They claim support for that argument in the following statement in Dr. Fortin’s declaration:

Automated spirometry systems usually have built-in software that can generate a preliminary interpretation, especially for spirometry. Today, most clinical pulmonary function testing laboratories use a microprocessor-driven pneumotachometer to measure air flow directly and then to mathematically derive volume. These pre-programmed values are based upon averages for persons of similar height, weight, age, ethnicity, etc.

percent. But a trier of fact could not use the declaration to conclude that Ms. Cauthen’s total lung capacity is actually greater than 60 percent, and Dr. Fortin failed entirely to provide the “scientific connection” needed to bridge the gap between a percentage of lung capacity that falls below 60 percent and one that does not. Accordingly, Dr. Fortin’s declaration is not an expert opinion that could be “helpful” to a trier of fact, even if there were a fact question.

(App. at 809.) Placing emphasis on the word “today,” the Cauthens interpret that statement to mean that “on the modern pneumotachometers used at the present time, pre-programmed algorithms measure air flow directly and then mathematically derive volume, precluding manual adjustments to the algorithms that were permitted on the older machines in use when the Settlement Agreement was negotiated and entered.” (Appellants’ Opening Br. at 23-24.) Essentially, the Cauthens argue that modern diagnostic instruments are cause for reformation of the agreement.

Because they did not raise that argument below, it is waived. “It is axiomatic that arguments asserted for the first time on appeal are deemed to be waived and consequently are not susceptible to review in this Court absent exceptional circumstances.” *Tri-M Grp., L.L.C. v. Sharp*, 638 F.3d 406, 416 (3d Cir. 2011) (internal quotation marks omitted). That “general rule serves several important judicial interests,” including “protecting litigants from unfair surprise; promoting the finality of judgments and conserving judicial resources; … preventing district courts from being reversed on grounds that were never urged or argued before them,” *id.* (alteration and internal quotation marks omitted), “ensuring that the necessary evidentiary development occurs in the trial court, and preventing surprise to the parties when a case is decided on some basis on which they have not presented argument,” *Barefoot Architect, Inc. v. Bunge*, 632 F.3d 822, 835 (3d Cir. 2011).

It is true that the waiver rule “is one of discretion rather than jurisdiction, and it may be relaxed whenever the public interest so warrants.” *Id.* at 834-35 (citation, alteration, and internal quotation marks omitted). “[W]e will

still address arguments raised for the first time on appeal in exceptional circumstances,” and we retain the discretion, “exercised on the facts of individual cases,” to determine “what questions may be taken up and resolved for the first time on appeal.” *Tri-M Grp.*, 638 F.3d at 416 (internal quotation marks omitted). But there are no exceptional circumstances in this case that would permit us to ignore the waiver rule. “The waiver rule applies with greatest force where the timely raising of the issue would have permitted the parties to develop a factual record.” *Barefoot Architect*, 632 F.3d at 835. The parties did not develop in the District Court the arguments in favor and against reformation, and that Court was not allowed to perform its vital function of developing a complete factual record on the relevant changes, if any, in diagnostic technology and procedures. Without the aid of factual development by the District Court, we cannot adequately evaluate the merit of Dr. Fortin’s assertion that diagnostic technologies have changed to such a degree that reformation is called for.⁸

⁸ Even in the absence of a waiver, it appears that the Cauthens would have difficulty with the merits of their argument. While a district court retains “general equitable power to modify the terms of a class action settlement,” *In re Cendant*, 233 F.3d at 194, when the plaintiff demonstrates that there has been “a significant change either in factual conditions or in law,” *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 384 (1992), Dr. Fortin’s declaration alone provides little proof that diagnostic procedures have indeed changed to the degree that reformation is warranted. Dr. Fortin said that “[t]oday, most ... laboratories use a microprocessor-driven pneumotachometer.” (App. at 809.) She did not, however, explain how diagnostic procedures

III. Conclusion

For the foregoing reasons, we will affirm the decision of the District Court.

were different in the past or why the recent changes create the need to reform the Settlement Agreement.