United States Court of Appeals for the Federal Circuit

98-1325

PERSEPTIVE BIOSYSTEMS, INC.,

Plaintiff-Appellant,

v.

PHARMACIA BIOTECH, INC., PHARMACIA BIOTECH AS, SEPRACOR INC., PHARMACIA LBK BIOTECHNOLOGY AB, BIOSEPRA, INC., and

PHARMACIA BIOTECH

(also known as Pharmacia Biopress Technology,

also known as Procordia AB),

Defendants-Appellees.

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DECIDED: August 29, 2000

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Before NEWMAN, PLAGER, AND CLEVENGER, Circuit Judges.

Opinion for the court filed by Circuit Judge CLEVENGER. Dissenting Opinion filed by Circuit Judge NEWMAN.

CLEVENGER, Circuit Judge.

PerSeptive Biosystems, Inc. ("PerSeptive") appeals the judgment of the United States District Court for the District of Massachusetts, holding PerSeptive's United States Patents Nos. 5,019,270 ("the '270 patent"), 5,228,989 ("the '989 patent") and 5,384,042

("the ’042 patent") (collectively, "the patents") unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("PTO"). Because the district court correctly found that the named inventors of the patents made material misrepresentations regarding inventorship with intent to deceive the PTO during the prosecution of the patents, we affirm the holding of inequitable conduct.

I

In 1993, PerSeptive sued Pharmacia Biotech, Inc., Pharmacia Biotech AS, Sepracor Inc., Pharmacia LBK Biotechnology AB, and Biosepra, Inc. (collectively, "Pharmacia") for patent infringement of the ’270 and ’989 patents. In 1995, PerSeptive added a claim for infringement of the ’042 patent. All three patents, which derived from a single patent application, are concerned with high-speed chromatography, or separation of biological materials, of a type described by the patents as "perfusive" chromatography. The ’270 patent claims a method for practicing perfusive chromatography, the ’989 patent claims a particle used for perfusive chromatography, and the ’042 patent claims a matrix of particles used for perfusive chromatography. All three patents list the same inventors, Dr. Noubar Afeyan, Professor Fred Regnier, and Dr. Robert Dean.

In response to the PerSeptive allegations, Pharmacia raised, among others, the defenses that the patents were invalid for failure to name the correct inventors, and that they were unenforceable due to inequitable conduct practiced by the named inventors during prosecution. In January 1996, the district court ruled on cross-motions for summary judgment on the question of whether the patents were invalid for failure to list the correct inventive entity. See PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., No. 93-12237, slip op. at 32-33 (D. Mass. Jan. 9, 1996) ("PerSeptive I"). In that decision, the district court concluded that there was "undisputed, clear and convincing evidence" that the inventorship was incorrect, but declined to hold the patents invalid. The district court reasoned that Pharmacia had not shown an absence of genuinely disputed facts regarding whether the named inventors had omitted the unnamed inventors with deceptive intent, thereby precluding the correction of inventorship under the then-current understanding of 35 U.S.C. § 256 (1994). See PerSeptive I, slip op. at 31 ("[T]here remains a disputed issue of fact as to the named inventors’ state of mind, preventing the court from ordering the correction of the patent without hearing."). Accordingly, the court invited PerSeptive to move, under section 256, to correct the inventorship of the patents. See id.

In March 1997, after a ten-day hearing, the district court denied PerSeptive’s motion to correct inventorship, basing its conclusion on a pattern of false statements and misrepresentations by the named inventors to the PTO regarding the inventorship and timing of the invention. See PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., No. 93-12237, slip op. at 126 (D. Mass. Mar. 31, 1997) ("PerSeptive II").

Soon after that ruling, the Federal Circuit decided Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 43 USPQ2d 1321 (Fed. Cir. 1997). In Stark, this court held that section 256 authorizes correction of inventorship when there is no deceptive intent on the part

of the omitted inventors and does not require inquiry into the intent of the originally-named inventors. Because this holding was contrary to the understanding of the district court and the parties at the time of the PerSeptive II decision, the district court, in January 1998, reconsidered PerSeptive II. See PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., No. 93-12237, slip op. at 1 (D. Mass. Jan. 28, 1998) ("PerSeptive III").

In PerSeptive III, the district court vacated its denial of PerSeptive's section 256 motion, concluding that no evidence had been introduced relating to the intent of the unnamed inventors. See id., slip op. at 4. The court did, however, "reexamine the legal effect of its factual findings in PerSeptive II that [Pharmacia had] proven by clear and convincing evidence that the named inventors made a series of misrepresentations to the [PTO]." Id., slip op. at 4. Adopting all the factual findings of PerSeptive II, the district court concluded that the named inventors had committed inequitable conduct when prosecuting the application that yielded the three patents. See id., slip op. at 9. Accordingly, the court held that the patents were unenforceable, and entered final judgment under Fed. R. Civ. P. 54(b). See PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., No. 93-12237, slip op. at 2 (D. Mass. Mar. 13, 1998) (Order).

This appeal followed, vesting us with jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

II

Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178-79, 33 USPQ2d 1823, 1826-27 (Fed. Cir. 1995). The defense of inequitable conduct is entirely equitable in nature, and thus not an issue for a jury to decide. See Paragon Podiatry Lab. Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1190, 25 USPQ2d 1561, 1568 (Fed. Cir. 1993); Gardco Mfg., Inc. v. Herst Lighting Co., 820 F.2d 1209, 1211-13, 2 USPQ2d 2015, 2017-19 (Fed. Cir. 1987).

Determination of inequitable conduct requires a two-step analysis. First, the trial court must determine whether the conduct meets a threshold level of materiality. The trial court must then also determine whether the evidence shows a threshold level of intent to mislead the PTO. See Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327, 47 USPQ2d 1225, 1228-29 (Fed. Cir. 1998); Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1439, 17 USPQ2d 1834, 1838 (Fed. Cir. 1991). These threshold determinations are reviewed by this court under the clearly erroneous standard of Federal Rule of Civil Procedure 52(a). See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988). Once the threshold levels of materiality and intent have been established, the trial court is required to weigh materiality and intent. See Molins, 48 F.3d at 1178, 33 USPQ2d at 1826-27. The more material the conduct, the less evidence of intent will be required in order to find that inequitable conduct has occurred. See N.V. Akzo v. E.I. Dupont de

Nemours, 810 F.2d 1148, 1153, 1 USPQ2d 1704, 1708 (Fed. Cir. 1987). In light of all the circumstances, the court must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable. See LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 958 F.2d 1066, 1070, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992). We review the district court's ultimate determination of inequitable conduct under an abuse of discretion standard. See Kolmes v. World Fibers Corp., 107 F.3d 1534, 1541, 41 USPQ2d 1829, 1834 (Fed. Cir. 1997); Halliburton, 925 F.2d at 1440, 17 USPQ2d at 1838; Kingsdown, 863 F.2d at 876, 9 USPQ2d at 1389.

A

The patent application which led to the ’270, ’989, and ’042 patents was filed in July 1989, and listed only Afeyan, Regnier and Dean as inventors. See PerSeptive II, slip op. at 69. In PerSeptive I, the district court, after extensive factfinding and analysis, determined that "undisputed, clear and convincing evidence" supported the conclusion that the named inventors were not the sole inventors of the subject matter of the three patents. PerSeptive I, slip op. at 25. The district court decided that Frank Warner and Linda Lloyd of Polymer Laboratories, Ltd. ("Polymer Labs"), a British company specializing in the area of chromatography and polymer analysis, also should have been named as inventors. See id. at 29. The district court also considered whether Mary Ann Rounds, Regnier’s research assistant at his Purdue University laboratory, should have been named as an inventor, but concluded that this question was "a hotly disputed issue of fact." Id. at 21.

There is no dispute now between the parties that Warner, Lloyd, and Rounds-- none of whom are named as inventors--worked in close collaboration with the named inventors in the development of the perfusive chromatography techniques and materials that are the subject of the three PerSeptive patents. As the district court noted, it is undisputed that it was Polymer Labs that supplied the materials and data that were critical to the named inventors’ understanding of the perfusive chromatography process. In fact, it was the Polymer Labs' particles that were the genesis of the inventions--these particles exhibited beneficial chromatographic properties, leading the named inventors to work, together with Warner, Lloyd, and Rounds, to understand the cause of these properties. But while the district court itself clearly believed that Warner, Lloyd, and perhaps Rounds should have been named as inventors of the three patents at issue, and theorized that the omission of inventors with deceptive intent would be inequitable conduct because it would involve "filing a false oath," PerSeptive III, slip op. at 7 (citing Stark, 119 F.3d at 1555, 43 USPQ2d at 1325), it noted that this conclusion was unnecessary for the purposes of its inequitable conduct judgment. See PerSeptive III, slip op. at 8 ("[A] good faith disagreement over the law of joint inventorship does not provide the basis for this [inequitable conduct] ruling."). Instead, the district court found that the named inventors intentionally misrepresented to the PTO the relationship between themselves and Polymer Labs for the purpose of concealing the issue of inventorship (i.e., whether Warner, Lloyd, and Rounds perhaps should have been listed as inventors). In particular, the district court found, by clear and convincing evidence, see PerSeptive II, slip op. at 99, the following intentional misrepresentations to the PTO:

> [1] the named inventors falsely stated that Regnier had "initiated" or "directed" the particle work at Polymer Labs, when in fact a named inventor (Dean) in a contemporaneous writing, flatly contradicted this assertion, see id., slip op. at 99-101;
>
> [2] the named inventors falsely stated that they alone discovered that certain of the Polymer Labs materials produced outstanding separations, when in fact Lloyd and Rounds discovered this characteristic, see id., slip op. at 101;
>
> [3] at least one of the named inventors "intentionally did not disclose" the extensive collaboration between his lab and Polymer Labs personnel, as supported by the contemporaneous documentation, id., slip op. at 101-02;
>
> [4] the named inventors deliberately failed to disclose the extensive exchange of data "concerning pore volume and structure" of the Polymer Labs particles, as evidenced by a named inventor's (Dean's) contemporaneous memo stating that "I should think that [Polymer Labs & PerSeptive] could get a patent on the structure of [the particles] re perfusion," id., slip op. at 102-03;
>
> [5] the named inventors misleadingly and falsely suggested that Polymer Labs was only a source of raw materials, see id., slip op. at 104-05.

The district court concluded, in PerSeptive II, that these intentional falsehoods, misrepresentations, and nondisclosures violated 37 C.F.R. § 1.56, which establishes the standard of truthful disclosure to the PTO. See id., slip op. at 105. The district court reaffirmed these findings upon reconsideration in PerSeptive III, noting that they demonstrated "the persistent course of material misrepresentations, omissions, and half-truths to the PTO that persuade me by clear and convincing evidence of deceptive intent on inventorship." PerSeptive III, slip op. at 8.

On appeal, PerSeptive does not directly challenge these findings of fact. Instead, PerSeptive argues that the district court clearly erred in not finding that the totality of the disclosures to the PTO "manifest objective good faith" by the named inventors. Appellant's Brief at 45. In particular, PerSeptive notes that the named inventors disclosed the use of Polymer Labs' particles and that Regnier had "informally consulted" with Polymer Labs prior to the conception of the invention. These facts, however, were fully considered by the district court, see PerSeptive II, slip op. at 74, and found to be supportive of a finding of intent to deceive the PTO rather than indicative of good faith. See id. at 105 ("[T]he information, which suggested that Polymer Labs was just a

'source' of 'raw materials,' was misleading because it provided the patent examiner with only a red flag for the possible issue of prior art and obviousness -- and obfuscated the threshold issue of inventorship."). A review of the exhaustive record of deceptive intent compiled by the district court, see PerSeptive III, slip op. at 10 (noting "extensive testimony and hundreds of documents reviewed"); PerSeptive II, slip op. at 1 (noting the 10-day hearing), when conducted through the lens of our standard of review, simply does not leave one with "the definite and firm conviction that a mistake has been committed." United States v. United States Gypsum Co., 333 U.S. 364, 395 (1948) (describing clear error standard of review); see also Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 31-32, 49 USPQ2d 1853, 1857 (Fed. Cir. 1999) (affirming factual findings supporting inequitable conduct); Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 719, 48 USPQ2d 1911, 1919 (Fed. Cir. 1998) (finding no clear error in an inequitable conduct analysis because "the finding on intent in particular depended heavily on the presentation of evidence and witness testimony at trial. The trial court was able to hear these matters first hand and assess witness credibility"). The district court's finding of intent to deceive was not clear error.

B

PerSeptive's primary argument on appeal is that the district court erred in concluding, in PerSeptive I, that Warner and Lloyd should have been named as joint inventors of the patents at issue in this case. See PerSeptive I, slip op. at 29. From this premise, PerSeptive asserts that "no predicate exists" for the district court's PerSeptive III judgment--that the patents are unenforceable for inequitable conduct. Appellant's Brief at 42. As noted above, however, this is a misreading of the PerSeptive III judgment. The district court specifically stated that the PerSeptive I conclusion--that inventorship of the patents was incorrect--was unnecessary to the inequitable conduct decision. See PerSeptive III, slip op. at 8 ("[A] good faith disagreement over the law of joint inventorship does not provide the basis for this ruling."). Instead, the district court noted that the PerSeptive III holding was based on the "persistent course of material misrepresentations, omissions and half-truths to the PTO" relating to inventorship. Id.

There can be no doubt that--irrespective of whether the district court was correct in holding (in PerSeptive I) that the inventorship was incorrect--the intentional "misrepresentations, omissions and half-truths to the PTO," made as a "persistent course" of conduct, are highly material. As the court found, these falsehoods and omissions were calculated to "obfuscate[] the threshold issue of inventorship." PerSeptive II, slip op. at 105. As a critical requirement for obtaining a patent, inventorship is material. See, e.g., 35 U.S.C. § 102(f) (1994) ("A person shall be entitled to a patent unless . . . he himself did not invent the subject matter sought to be patented."); 35 U.S.C. § 116 ("When an invention is made by two or more persons jointly, they shall apply for a patent jointly."). Examiners are required to reject applications under 35 U.S.C. § 102(f) on the basis of improper inventorship. See Manual of Patent Examining Procedure § 2137.01 (hereinafter "MPEP"). Accordingly, the Manual of Patent Examining Procedure details the "rules" of inventorship to be used by examiners, see id., and specifically notes that information about inventorship is

material under 37 C.F.R. § 1.56, see MPEP § 2001.06(c) (inventorship disputes are material information); MPEP § 2004 (suggesting that applicants carefully consider inventorship in the duty to disclose context).

Furthermore, the intentional falsehoods and omissions found by the district court easily meet our oft-stated test for materiality: information is material if there "is a 'substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.'" Baxter, 149 F.3d at 1327, 47 USPQ2d at 1229 (quoting 37 C.F.R. § 1.56 (1989)); see also J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984). As we noted above, an examiner must attend to the question of inventorship, pursuant to 35 U.S.C. § 102(f). A full and accurate disclosure of the true nature of the relationship between PerSeptive and Polymer Labs, and the contributions of Warner, Lloyd, and Rounds, would have been "important" to a reasonable examiner's consideration of the inventorship question.

PerSeptive's argument that the patents' claims were narrowed during prosecution, thereby curing any possible inventorship problem, misses the point. First, whether the inventorship of the patents as issued is correct does not determine the materiality of the statements in this case, just as whether concealed prior art would actually invalidate the patent is irrelevant to materiality. See, e.g., A.B. Dick Co. v. Burroughs Corp., 798 F.2d 1392, 1397, 230 USPQ 849, 853 (Fed. Cir. 1986) ("[T]he test for materiality is not whether there is anticipation or obviousness but, rather, what a 'reasonable examiner would consider . . . important in deciding whether to allow the application to issue as a patent.'") (emphasis omitted); Gardco, 820 F.2d at 1214, 2 USPQ2d at 2019-20 ("The simple fact is that a patent may be valid and yet be rendered unenforceable for misuse or inequitable conduct . . . . In determining the inequitable conduct issue, a district court need not make explicit findings on whether undisclosed art anticipates the claimed invention or whether it would have rendered the claimed invention obvious under 35 U.S.C. § 103.").

Second, the materiality of intentional false statements may be independent of the claims of the patent. See, e.g., General Electro Music Corp. v. Samick Music Corp., 19 F.3d 1405, 1411, 30 USPQ2d 1149, 1154 (Fed. Cir. 1994) (finding a false statement that the patentee had conducted a prior art search to be material); Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556, 1571, 220 USPQ 289, 300 (Fed. Cir. 1983) ("[T]here is no room to argue that submission of false affidavits is not material."); see also 18 U.S.C. § 1001 (1994) (making intentionally false statements to federal agencies punishable by fines and/or imprisonment of up to five years). Accepting PerSeptive's argument that the narrowing of the claims here renders immaterial the false statements misdirects the focus of the inquiry: the issue is not inventorship per se, but misinformation about inventorship. The district court found that the named inventors intentionally presented falsehoods and omissions to the PTO on the subject of inventorship. There is no clear error in the district court's finding that these statements were material.

C

Our final question is whether the district court abused its discretion in holding the patents unenforceable. See, e.g., Critikon, 120 F.3d 1253, 1255, 43 USPQ2d 1666, 1668 (stating that the ultimate conclusion of inequitable conduct is reviewed for abuse of discretion). To recap, the district court found at least five specific instances of intentional falsehoods, misrepresentations, and omissions to the PTO. We have concluded that there is no clear error in these findings. The district court also found that these falsehoods, misrepresentations and omissions were all directed towards a central issue -- whether the named inventors were the sole inventors -- and that this issue (inventorship) was material. Again, there is no clear error in these findings. Given the absence of clear error in the factual findings on which the district court's judgment stands, we cannot conclude that the district court abused its discretion in determining that the behavior of the applicants constituted inequitable conduct. Accordingly, we affirm the district court’s holding of inequitable conduct.

COSTS

No costs.

AFFIRMED

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98-1325

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v.

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PHARMACIA LBK BIOTECHNOLOGY AB, BIOSEPRA, INC., and

PHARMACIA BIOTECH (also known as Pharmacia Biopress Technology,

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Defendants-Appellees.

NEWMAN, Circuit Judge, dissenting.

One would not know, from the censorious tone of the majority opinion, that the inventors were correctly named and that the origin of the patented inventions was fully disclosed to the patent examiner.

The named inventors did not claim to have invented the particles that were provided by Polymer Laboratories. To the contrary, these particles were reported in the patents as provided by "Polymer Laboratories of Shropshire, England," as the subject of the experiments that led the named inventors to the claimed invention, and as prior art to the claimed invention. The Polymer Laboratories scientists, as the district court found, did not know about the perfusive behavior and the properties at very high throughput, or its structural basis, until they were told about it. Indeed, the district court recognized that the Polymer Laboratories scientists did not conceive the patented inventions, and explicitly found that the scientists who the district court found were "co-inventors" did not have a "definite and permanent idea of the complete and operative invention." PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., No. 93-12237-PBS, slip op. at 28 (D. Mass. Jan. 9, 1996) (PerSeptive I). The panel majority does not find otherwise.

The district court, in ruling that the patents are unenforceable for inequitable conduct based on the naming of incorrect inventors, explained that the omission of Polymer Laboratories scientists as "co-inventors" was "material as a matter of law." The district court stated:

> In re-examining the record evidence, as described in PerSeptive II, under this equitable balancing test, I conclude that the named inventors, particularly Professor Fred Regnier, engaged in inequitable conduct by omitting the names of Warner and/or Lloyd as co-inventors on the patent with deceptive intent, and that this omission is material as a matter of law. Accordingly, the patents are unenforceable.

PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 12 F. Supp. 2d 69, 73 (D. Mass. 1998) (PerSeptive III).

However, the inventors were not incorrectly named. Although the panel majority disclaims the relevance to inventorship of the invention that is claimed, the disclosure to the examiner concerning the claimed invention is accurate and adequate, and not grounds of inequitable conduct.

The Claimed Inventions

The three patents in suit derive from a common patent application and contain the same specification. The invention is the separation of biological molecules by "perfusion" chromatography, using a matrix of particles having a defined structure of throughpores and solute interactive surfaces, whereby a fluid containing biological molecules is passed through the matrix at a velocity that produces a higher rate of convective flow than diffusive flow through the throughpores, measured as a Peclet number greater than 1.0. The method is broadly set forth in claim 1 of the '270 patent:

> 1. A chromatography method comprising the steps of:
>
> (A) forming a chromatography matrix by packing a multiplicity of particles defining throughpores and solute interactive surface regions therewithin; and
>
> (B) passing a fluid mixture of solutes comprising biological molecules through said matrix at a velocity sufficient to induce a convective fluid flow rate through said throughpores greater than the rate of solute diffusion through said throughpores and to produce a Peclet number in said throughpores greater than 1.0.

The divisional '989 patent is directed to particles for perfusion chromatography, having a mean diameter greater than 20μ m (microns) and pores of at least bimodal distribution, the larger throughpores sized for convective mass transport, and smaller pores 300Å-700Å in diameter sized for diffusive mass transport. Claim 1 of the ‘989 patent follows:

> 1. A particle defining a pore structure at least
>
> bimodal in its distribution that, when packed, produces a matrix suitable for perfusion chromatography,
>
> the particle comprising a rigid solid defining interactive surface regions,
>
> having a mean diameter greater than 20μ m, and defining a plurality of throughpores sized for convective mass transport and a plurality of smaller pores having diameters within the range of 300Å-700Å for diffusive mass transport to said interactive surface regions,

the ratio of the mean diameter of the particle to the mean diameter of the throughpores being less than 70.

The divisional '042 patent claims the perfusion chromatography matrix and includes the particle limitations of the '989 patent. Claim 1 follows:

> 1. A chromatography matrix comprising a plurality of packed particles, the particles defining a pore structure at least bimodal in its distribution that produces a matrix suitable for perfusion chromatography,
>
> the particles comprising a rigid solid,
>
> having a mean diameter greater than 20μ m, and defining a plurality of throughpores for convective mass transport and a plurality of smaller pores having diameters within the range of 300Å-700Å for diffusive mass transport, and comprising solute interactive regions in fluid communication with the throughpores,
>
> the ratio of the mean diameter of the particle to the mean diameter of the throughpores being less than 70.

The district court did not discuss the content of the claims. The panel majority states that the claims are irrelevant to the issue of inequitable conduct. However, they are extremely relevant to inventorship, and it is on inventorship that the ruling of inequitable conduct was grounded.

Inventorship

"Inventorship" in the law of patents arises from conception, not development or reduction to practice. As explained in Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227-28, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994), "[c]onception is the touchstone of inventorship, the completion of the mental part of invention." Conception requires "an idea that was definite and permanent enough that one skilled in the art could understand the invention." Id. at 1228, 32 USPQ2d at 1919.

"Inventorship is a question of who actually invented the subject matter claimed in a patent," Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248, 26 USPQ2d 1572, 1582 (Fed. Cir. 1993). The selection of the inventors depends on what is claimed. In Burroughs Wellcome the court explained that for joint invention "each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice." 40 F.3d at 1229, 32 USPQ2d at 1921. Although a patented invention may involve the work of more than one person and although each person need not make the same type or amount of contribution, see 35 U.S.C. §116, each inventor must contribute to the conception of the claimed subject matter. See Burroughs Wellcome, 40 F.3d at 1227-29, 32 USPQ2d at 1919-21; see also Sewall v. Walters, 21 F.3d 411, 417, 30 USPQ2d 1356, 1360 (Fed. Cir. 1994) (inventorship relates to the

claimed subject matter); Coleman v. Dines, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985) (same).

Collaboration on a project with a common goal does not of itself produce joint invention. Conception requires a definite concept of the invention that is patented. The district court found, and it is not disputed, that Dr. Warner of Polymer Laboratories at first rejected the perfusion concept and its basis in bimodal throughpore flow at high throughput velocity. This rejection can not be fairly viewed as a contribution by Warner to the conception of the claimed invention, which is limited to the perfusion concept and its parameters. Warner's omission as a named inventor could not be a material misrepresentation "as a matter of law."

The district court described the history of the relationship between Professor Regnier and Dr. Warner, starting with the application of Regnier's coatings to improve the chromatographic performance of Polymer Laboratories' particles. This was the background upon which the particles that led to the patents in suit were sent to Professor Regnier, along with the information that these particles exhibited good chromatographic properties. These particles were tested by Mary Ann Rounds in Professor Regnier's laboratory. These tests confirmed the good chromatographic properties, and were followed by tests at very high flow rates, which produced performance that Regnier described as "spectacular." The results were reported back to Polymer Laboratories. The record showed frequent conversations among the scientists, and the provision of additional samples by Polymer Laboratories.

Professor Regnier and Drs. Afeyan and Dean are the named inventors in the patents in suit. Dr. Afeyan is a biochemical engineer and Dr. Dean's field is fluid mechanics. They undertook to study and understand the exceptional performance obtainable using some particles and the conditions of that performance. Drs. Afeyan and Regnier obtained scanning electron micrographs of the pore and surface structure of the Polymer Laboratories particles, and Dr. Dean conducted fluid engineering studies. They applied various methods for measuring mass transfer in a chromatographic matrix, including dynamic capacity and plate height measurements.

Drs. Regnier, Afeyan, and Dean found that certain particles contained throughpores as well as smaller pores and interactive surfaces. They determined the ratio of convective to diffusive flow through the pore structure. They concluded that there was a "perfusive" domain wherein the convective velocity could be higher than the diffusive velocity, when the flow rate of the solutes through the matrix was sufficiently high. They determined the pore and flow characteristics that produced the exceptional chromatographic performance obtained at high throughput. It is undisputed that the Polymer Laboratories scientists did not initiate and did not conduct these studies or otherwise determine these characteristics. The district court described the Polymer Laboratories role as to "assist the program of research and experimentation." PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., No. 93-12237-PBS, slip op. at 53 (D. Mass. March 31, 1997) (PerSeptive II). There was no evidence, or even argument, that the discovery of the

throughpore structure and the convective/diffusive mechanism of perfusion was made by anyone other than the named inventors.

The PerSeptive patent specifications refer to the collaboration between Professor Regnier and Polymer Laboratories, and state that two types of particles produced by Polymer Laboratories were "used by the inventors named herein in the initial discoveries [of the claimed inventions]":

> [one particle type having] interactive surfaces . . . which interact with the hydrophobic patches on proteins [and the second having] interactive surface elements derivatized with polyethyleneimine and act as a cationic surface useful for anionic exchange. Both types of particles were produced in an ongoing effort initiated by F.E. Regnier[] to increase intraparticle diffusion of large solutes such as proteins by increasing pore size. These particles were used by the inventors named herein in the initial discoveries of the perfusive chromatography domain.

'270 patent, col. 17, line 58 to col. 18, line 3; '989 patent, col. 17, line 62 to col. 18, line 8; '042 patent, col. 17, line 66 to col. 18, line 11.

Polymer Laboratories had published scientific papers describing its particles and their chromatographic properties as determined by the Polymer Laboratories scientists. Various of these publications were included in the disclosure statements filed in the PTO. During patent prosecution the examiner contacted Polymer Laboratories to obtain additional information. The examiner initially rejected the claims, citing Polymer Laboratories publications and other references. In response, PerSeptive further explained that its discovery was that "certain of the [Polymer Laboratories] supplied materials produced outstanding separations at extraordinarily high flow rates." PerSeptive explained its discovery as follows:

> The inventors thereafter experimented with various [Polymer Laboratories] supplied materials in various ways, including scanning electron microscopy, to determine the structure responsible for the properties, to understand how such properties could occur, and to determine how they could be reproduced reliably. Applicants discovered that these materials defined throughpores.

'270 patent application, Amendment C (emphases in original). PerSeptive stated to the examiner that 8μ m and 10μ m 1000D Polymer Laboratories particles were available more than one year before the PerSeptive filing date and that these products "can be made to perfuse as applicants have disclosed." The patent specifications state that:

> PL produced and subsequently marketed two "macroporous" chromatography media comprising particles having an average diameter of 8μ m to 10μ m and a particle-mean pore diameter of 1000Å and 4000Å.

'270 patent, col. 17, lines 44-48. During prosecution PerSeptive argued patentability over the Polymer Laboratories and other prior art, stating that "[t]here simply is no suggestion in the art to run specific types of materials having an appropriate ratio of particle size to throughpore size at high flow rates." The district court agreed that the mechanism of perfusive behavior was discovered by the named inventors, using the particles received from Polymer Laboratories. The court expressly found that "the named inventors seem to be the first to have recognized that the existence and size of the throughpore in the Polymer Laboratories packing particle had an effect on the separation of liquids under high pressure." PerSeptive I, slip op. at 24.

No Polymer Laboratories scientist was asserted, in these proceedings, to have discovered the structure and conditions necessary for perfusion. All the claims, as originally filed and as issued, contained limitations relating to perfusion. Having discovered the throughpores and the dimensions of the pore structure and the ensuing perfusive criteria, it was reasonable for the named inventors to believe that they were the correct inventive entity for claims limited by these parameters. The district court expressly found that the throughpore information was generated by the named inventors and communicated by them to Polymer Laboratories, and in PerSeptive I appeared to apply the correct law of inventorship:

> Prior to the throughpore discovery, Polymer Labs did not have a "definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986). PerSeptive reported to the Patent Office that only some of the experimental batches of PL-SAX widepore materials exhibited unusual behavior. The named inventors also testified there were inconsistent test results on the samples. Without understanding the significance of the throughpore and its dimensions, Polymer Labs did not have a basis for controlling for this feature.

PerSeptive I, slip op. at 28-29.

These findings support PerSeptive's position that even on the district court's view that inventorship was incorrectly designated, it was not inequitable conduct to have made a selection that omitted persons who did not participate in the discoveries that constituted the claimed inventions. See Pro-Mold and Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1576, 37 USPQ2d 1626, 1632-1633 (Fed. Cir. 1996) ("an error in determining inventorship is not by itself inequitable conduct"). Also applicable is the ruling in Pro-Mold that "[w]hen an alleged omitted co-inventor does not claim to be such, it can hardly be inequitable conduct not to identify that person to the PTO as an inventor." Id.

The panel majority holds, quoting the district court, that "a good faith disagreement" on inventorship is not "the basis for this [inequitable conduct] ruling." PerSeptive III, 12 F. Supp. 2d at 73. However, the court can not ignore the correct inventorship, for when

inventorship is correctly viewed as directed to that which is claimed, the information that the district court held should have been disclosed to the examiner is not material.

The panel majority says that PerSeptive "does not directly challenge" the district court's findings of material misrepresentation and deceptive intent. Maj. op. at 8. That is incorrect. The entire appeal is from these findings. Although the district court ruled that the omission of the additional co-inventors was "material as a matter of law" and that this was the basis of the court's decision, the district court also described various statements as material "omissions and misrepresentations" upon which the panel majority now relies.

It was undisputed that the named inventors discovered the claimed subject matter. No "omission or misrepresentation" was shown to be material to the inventorship of this subject matter. The district court, having stated that it was not relying on any misrepresentations, rejected PerSeptive's proffer of expert testimony on the issue of materiality. The court explained:

> This expert testimony might have been helpful if the Court were relying on the misrepresentations as the basis of [the] inequitable conduct claim. However, the basis of my conclusion that there was inequitable conduct is my finding of a deliberate omission of a true inventor. This omission is material as a matter of law. I conclude that expert testimony would not be helpful on the issue of materiality on the joint inventorship issue.

PerSeptive III, 12 F. Supp. 2d at 74. Thus the district court rejected PerSeptive's attempt to contest materiality. The record before us does not contain the details of the proffered expert testimony, but "the patentee can not be deprived of the right to rebut an inequitable conduct charge by showing lack of materiality . . . ." Allied Colloids Inc. v. American Cyanamid Co., 64 F.3d 1570, 1578, 35 USPQ2d 1840, 1845 (Fed. Cir. 1995).

The panel majority also states that it is "undisputed" that Polymer Laboratories provided "the materials and data that were critical to the named inventors' understanding of the perfusive chromatography process." Slip op. at 6. That is incorrect, and is vigorously disputed. What was "critical" to the named inventors' understanding were the electron micrographs, the plate measurements, the pore size determinations, the discovery of the throughpores and the bimodal structure, and the relation between convective and diffusive transport, all of which were determined by the named inventors. If the panel majority is simply saying that Polymer Laboratories provided the "materials," the particles, that was never disputed, and was disclosed to the PTO. But the particles did not provide the "understanding of the perfusive chromatography process," as the panel majority proposes. That understanding came from the investigations done by the named inventors.

The patents all state that the Polymer Laboratories particles were used in making the claimed inventions, and the relationship was explained to the examiner. That should have resolved the issue of inequitable conduct, for neither material withholding nor

deceptive intent was shown by clear and convincing evidence. My colleagues, however, insist that there was more to tell the examiner, and enumerate five aspects that the panel majority states should have been disclosed to the examiner:

No. [1]. The first of the five fatal flaws identified by my colleagues is the subject of footnote 5, supra, and derives from the statement in the patent specification that two types of Polymer Laboratories "particles were produced in an ongoing effort initiated by F.E. Regnier to increase intraparticle diffusion of large solutes such as proteins by increasing pore size." '270 patent, col. 17, lines 65-68. The district court found that this statement was untrue and a misrepresentation. PerSeptive states it is true, and not a misrepresentation.

I must point out that the panel majority inaccurately reports the district court's finding. The district court did not find that the named inventors falsely stated that Regnier "initiated or directed" (quoting the panel majority) the particle production. As the district court observed, an earlier draft had used the word "directed" but the patent application as filed replaced it with "initiated," for Dr. Dean had commented that "I was not aware that Fred 'directed' Polymer Laboratories's particle fabrication effort." (Emphasis by Dean.) It was undisputed that Fred Regnier was not concerned with "particle fabrication," but with "diffusion of large solutes" such as proteins. The district court viewed the change from "directed" to "initiated" as "cosmetic" and not changing the "thrust of the misrepresentation." There are, however, obvious differences between initiating and directing. Further, there was no evidence of falsity of the statement in the patent.

As to the initiation of the collaboration, the district court found the following facts: Well before the events now at issue Ms. Rounds, Dr. Regnier's research assistant, contacted Polymer Laboratories, inquiring about the availability of chromatographic packing material. Dr. Warner responded that Polymer Laboratories "would be pleased to collaborate with [Rounds] and Professor F. Regnier by supplying" such material. Rounds and Regnier told Dr. Warner that it was their objective "to make ion-exchange chromatographic media for biomolecules." The district court found that "Rounds hoped to evaluate the materials for use in the chromatography of large materials," and to evaluate the performance of an interactive surface chemical coating known as SAX, which had been patented by Regnier for chromatographic particles. Regnier and Rounds applied the SAX coating to the 300Å and 1000Å media from Polymer Laboratories, found that it produced superior chromatographic properties, and sent the results to Polymer Laboratories. Ms. Lloyd of Polymer Laboratories later applied Regnier's coating to make the PL-SAX 4000 particles. These findings all support the usage of "initiated" in the patent's statement of the background of the collaboration, and negate the panel majority's conclusion of a material misrepresentation based on this use of "initiated."

Because the district court explicitly found that no Polymer Laboratories scientist had a "definite and permanent idea" of the claimed invention, whoever "initiated" the

collaboration is irrelevant. This aspect can not support the court's ruling of inequitable conduct based on incorrect inventorship.

No. [2]. The district court found that the named inventors misstated that they discovered that certain of the Polymer Laboratories materials produced outstanding separations at extraordinarily high flow rates. According to the district court, this discovery was made by Rounds, "working under Regnier's supervision," and by Lloyd of Polymer Laboratories. The panel majority concludes that this was a material misrepresentation and was made with intent to deceive the PTO.

It is not disputed that Rounds, working under Regnier's direction at Purdue, tested the sample received from Lloyd, in accordance with Regnier's standard protocol, at what the district court called "high flow rates" of 1ml/min and 2ml/min. Rounds observed "really good" chromatographic separation. At Regnier's instruction, Rounds ran the separations at very high flow rates, up to 4ml/min, and reported the results to Regnier, who concluded that the material was "spectacular." The district court did not attribute any of these observations to anyone from Polymer Laboratories, and did not decide whether Rounds should have been named a co-inventor. There was neither evidence nor findings that Ms. Lloyd, or anyone else from Polymer Laboratories, participated in these tests or in the observation of spectacular performance at very high throughput velocity.

The PTO record shows various Polymer Laboratories publications by Lloyd and others, reporting the chromatographic behavior that was found by Polymer Laboratories. Some of this work was cited as prior art by the examiner. The panel majority's ruling that the work done by Lloyd and Rounds should have been submitted to the patent examiner is unsupported by any finding related to the substance of the claims, and can not constitute a material misrepresentation or omission with deceptive intent.

No. [3]. The district court found that Regnier "intentionally did not disclose the extensive collaboration between Rounds and Lloyd to the PTO." The record shows that Rounds and Lloyd were indeed in frequent communication, and could be deemed to collaborate. The panel majority's requirement that collaborative relationships must be reported to the PTO, whether or not any collaborator is an inventor of what is claimed, is as incorrect as it is unworkable. This ruling will outdistance any earlier "plague" of attacks on patents.

No. [4]. The panel majority's fourth enumerated wrong is the district court's finding that it was a material omission or misrepresentation that the named inventors did not disclose to the PTO that they "exchanged data" with Polymer Laboratories regarding pore volume and structure. There were indeed frequent conversations among the scientists. However, "exchange of data" is a loose term for so serious a consequence as loss of the patent. There is no finding, and indeed no allegation, that Polymer Laboratories scientists discovered the pore volume and structure. The ensuing exchanges of data did not convert the Polymer Laboratories scientists into joint inventors. There is no basis whatsoever for suggesting that such technical exchanges must be reported to the patent examiner for review of inventorship.

The panel majority reports Dr. Dean's statement about the possibility of "joint inventorship" as evidence of bad intent by Regnier. However, Dr. Dean's expression of a legal opinion, before any patent application was filed or the claims defined, does not establish inequitable conduct based on the exchanges of information among these scientists.

No. [5]. The panel majority also relies on what it describes as a district court finding that the named inventors misleadingly and falsely suggested that Polymer Laboratories was only a source of raw materials. The district court indeed called this statement "misleading," although not "false," the district court expressing the view that more should have been said "because it provided the patent examiner with only a red flag for the possible issue of prior art and obviousness -- and obfuscated the threshold issue of inventorship." PerSeptive II, slip op. at 105-106. The district court referred to the statement in the specifications that Polymer Laboratories was a "source of particles suitable for the practice for perfusion chromatography." It is undisputed that Polymer Laboratories was such a source. The statement is not false, and can not be viewed as misleading in view of the disclosures made in the specification and during prosecution. Surely this true statement is not clear and convincing evidence of inequitable conduct. There is no indication that more information was needed or appropriate. The record makes clear that the claimed invention was made by the Regnier team, using the particles provided by Polymer Laboratories; no further disclosure was necessary.

The five acts with which the panel majority impeaches the named inventors are overstated if not irrelevant. By no stretch do they represent clear and convincing evidence of material omission or misrepresentation with intent to deceive the examiner as to inventorship.

The Erroneous Ruling On 35 U.S.C. §102(f)

The panel majority states that "[e]xaminers are required to reject applications under 35 U.S.C. ***§***102(f) on the basis of improper inventorship," citing ***§***2137.01 of the Manual of Patent Examining Procedure. This section of the MPEP states that examiners may make a rejection under ***§***102(f) in specified circumstances, not here applicable. The relevant portion of MPEP ***§***2137.01 follows:

> If a determination is made that the inventive entity named in a U.S. application is not correct, such as when a petition under 37 C.F.R. 1.48(a) is not granted or is not entered for technical reasons, but the admission therein regarding the error in inventorship is uncontroverted, a rejection under 35 U.S.C. 102(f) should be made.
>
> . . . .
>
> The party or parties executing an oath or declaration under 37 C.F.R. 1.63 are presumed to be the inventors.

MPEP §2137.01 (7th ed. 1998). Section 102(f) is also mentioned in MPEP §605.07, as follows:

> Under 35 U.S.C. 116, an examiner may reject claims under 35 U.S.C. 102(f) only in circumstances where a named inventor is not the inventor of at least one claim in the application; no rejection under 35 U.S.C. 102(f) is appropriate if a named inventor made a contribution to the invention defined in any claim of the application.

MPEP §605.07 (7th ed. 1998). Pursuant to PTO procedures, the examiner could not have made a rejection under §102(f).

The panel majority also refers to MPEP §2001.06(c) and MPEP §2004. MPEP §2001.06(c), entitled "Information From Related Litigation," requires the applicant to disclose material information arising from a related litigation and relating to the subject matter of a pending patent application, including questions of inventorship. It is undisputed that PerSeptive complied with MPEP §2001.06(c). PerSeptive submitted the entire PerSeptive I opinion and sixteen related litigation documents. They were received by the same examiner who had examined the three patents in suit and who was then examining a divisional application of the '042 patent on the same specification. Upon reviewing these submissions the examiner stated that "the inventorship of the instant application would appear to be correct."

MPEP §2004 states that in connection with the duty of disclosure "[i]t is desirable to ask questions about inventorship" and that "if there are questions, call them to the attention of the Patent and Trademark Office." It is apparent that PerSeptive's attorney did so, for the specification describes the genesis of the invention.

None of these practices requires any behavior beyond what was done, or provides support for the ruling of inequitable conduct.

Summary

There has been no showing that the named inventors acted with intent to deceive or that they withheld material information that they should have disclosed to the examiner. See Allied Colloids, 64 F.3d at1578, 35 USPQ2d at 1846 ("It is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability.") The panel majority finds inequitable conduct in inventorship while ruling irrelevant the claimed invention and the correct inventorship. The court thus ignores, or trivializes, the role of claims to define the invention, and imposes an irrational and unsupported ruling that denies the law of inventorship. The premises as well as the conclusion of the panel majority are seriously flawed. I must, respectfully, dissent.