

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 125

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

JOHN M. BARKER

Junior Party,^{1,2}

v.

EDWARD E. ELSON,
CLEMMENT LIEBER, RONALD L. McCARTNEY,
WALLACE F. COOK and ERNEST LANE

¹ Patent No. 4,476,877, issued October 16, 1984, based on Application 06/408,080, filed August 16, 1982. Assignor to Ohmeda (Singapore) PTE Ltd.

² Application 08/113,991, filed August 30, 1993, for the reissue of U.S. Patent No. 4,476,877, issued October 16, 1984, based on Application 06/408,080, filed August 16, 1982. Assignor to Ohmeda (Singapore) PTE Ltd.

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Senior Party.³

Patent Interference No. 103,146

FINAL HEARING: May 11, 1999

Before URYNOWICZ, PATE and LORIN, **Administrative Patent Judges**.

PATE, **Administrative Patent Judge**.

FINAL DECISION

This is a final decision under 37 CFR § 1.658 in Interference No. 103,146. The involved subject matter concerns an external sensor for use in a thermodilution blood flow measuring system. In such a system, a known quantity of cold injectate is delivered by catheter to a patient's blood vessel. The cold injectate is mixed in the blood vessel with the patient's own blood flow, and by measuring the temperature

³ Application 06/786,999, filed October 15, 1985. Accorded the benefit of Application 06/741,396, filed June 5, 1985, abandoned, and Application 06/399,330, filed July 19, 1982, abandoned. Assignor to Baxter Int'l, Inc.

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of the injectate-blood mixture, the patient's blood flow rate can be established. It is important that the injectate temperature be accurately sensed before it is injected into the patient. The prior art used a commercial Y-shaped thermistor which required sterilization after each use. In the subject matter of the interference, a reusable thermistor is used inside a disposable plastic housing.

The count in interference reads as follows:

Count 1

For use in a cardiovascular flow measuring system wherein a cold injectate fluid is delivered in a known amount from a supply through a catheter into a patient's blood vessel and the resultant change in the temperature of the patient's blood is sensed to determine the circulatory blood flow rate, an improved injectate fluid temperature sensor comprising:

a disposable housing defining a through lumen for conducting injectate fluid therethrough;

a disposable thermally conductive receiver hermetically sealingly joined to the housing and projecting transversely into said lumen to be in heat transfer association with injectate fluid conducted through said lumen, said receiver extending substantially fully across said lumen; and

a reusable temperature sensor removably installed in said enclosure, said sensor providing a signal corresponding

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accurately to the temperature of the injectate fluid conducted through said lumen.

The claims of the parties designated as corresponding to the count are as follows:

Barker:	Claims: 1-18
Barker Reissue '991	Claims: 1-17
Elson et al.:	Claims: 1-3, 5-10, 12-20, 50-53, and 56-58.

Background Facts

John M. Barker was granted U.S. Patent No. 4,476,877 on October 16, 1984. The Barker application was filed on August 16,

1982. The Barker application is assigned to Ohmeda Medical Devices Division, Inc., a wholly owned subsidiary of the BOC Group. Pursuant to a decision on preliminary motions, Barker Reissue application 08/113,991 was added to the interference.

On July 19, 1982, Edward E. Elson, Wallace F. Cook, Ronald L. McCartney, Ernest Lane and Clement Lieber filed application Serial No. 06/399,330 which was subsequently

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abandoned in favor of continuation application Serial No. 06/741,396, which itself was abandoned in favor of continuation application Serial No. 06/786,999 filed on October 15, 1985. The Elson et al.⁴ application is assigned to Baxter International, Inc.

The Elson applications contain disclosure directed to two embodiments. The embodiment of Figures 2 and 4 is directed to the subject matter of the count. Claims directed to the embodiment in Figures 5 and 6, the so-called latex disk embodiment, were held to be unpatentable to Elson in an **ex parte** appeal to this Board in 1993. With the filing of the involved Elson '999 application, Elson filed a preliminary amendment

containing claims 50-59 which were said to have been copied from the Barker patent for interference purposes.

Both parties filed records and briefs. The junior party filed a reply brief. Counsel for both parties appeared at final hearing.

⁴ Hereinafter, party Elson et al. will be referred to as Elson.

Issues

The following issues are raised by the parties in their briefs for final hearing or in motions filed contemporaneously therewith:

- 1) priority of invention,
- 2) Elson's motion regarding suppression of Barker exhibits BX-118 through BX-128 along with pages BR8 through BR46 of the Barker record,
- 3) Elson's motion to add EX-57 to the record,
- 4) Barker's contention respecting Elson's alleged inequitable conduct rendering all claims of his application unenforceable or unpatentable raised in a 37 CFR § 1.633(a) motion deferred to this final hearing, and
- 5) Barker's contention that Elson's alleged inequitable conduct, as a matter of equity, caused such a delay that Elson should be held to have abandoned, suppressed, or concealed the invention under 35 U.S.C. § 102(g).

Motion for Suppression of Evidence

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Senior party Elson moves for suppression of Barker exhibits BX-118 through BX-128 along with pages BR8 through BR46 of the Barker record. In both the motion and Barker's opposition thereto, the parties seem to have confused the requirements for admissibility and corroboration. Authentication is a requirement of the law of evidence, and is properly raised in Elson's motion to suppress. The requirement that a proponent's evidence of conception, reduction to practice, diligence or derivation be corroborated is a substantive requirement of interference law and will be dealt with properly, *infra*, in considering the parties' cases-in-chief.

Fed. R. Evid. 901 states that the "requirement of authentication or identification as a condition precedent to admissibility is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims." Among the "illustrations" of authentication is "testimony of [a] witness with knowledge * * * that a matter is what it is claimed to be." Fed. R. Evid. 901(b)(1). There is absolutely no requirement that a corroborative

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witness is needed to **authenticate** a document in an interference or otherwise. In this instance, where the witness Barker is the originator of the

documents, the authentication is by direct proof that the exhibits are what Barker claims they are--his invention reports and other memoranda. The exhibits will be considered below.

Turning to BX-118, the pages of the exhibit that were originally prepared by Barker are not inadmissible for lack of authentication. Barker is certainly a witness with knowledge that a matter is what it is claimed to be, since he prepared these pages. It is immaterial that Barker did not know Edgell or that Edgell assembled the separate pages together as a unit after Barker had originally created them separately. As to hearsay, the document is not hearsay to the extent it is relied upon to show conception as of the date the document was created by Barker. However, since it **intrinsicly** asserts a conception date of October 1981, the document is hearsay with respect to that asserted October

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date. In summary, the cover sheet prepared and signed by Edgell is suppressed on authentication and hearsay grounds. The balance of the document is not suppressed on authentication or hearsay grounds to the extent that it provides evidence of what was conceived as per Barker's testimony at least as to the date the sketch, page 000068, was prepared, i.e., December 8, 1981, but is suppressed on hearsay grounds to the extent that it is said to offer evidence of conception as of October 1981. The same result obtains with respect to the suppression of BX-122.

With respect to BX-119, this is a series of progress reports which Barker testified that he authored. Since these reports were authored by Barker, his testimony can authenticate them. These reports will not be suppressed for lack of authentication.

With respect to the BX-120, Barker provides authentication. With respect to the date of the document, this uncertainty goes to the weight to be accorded the document not whether it can be admitted at all.

With respect to BX-121, this document is suppressed for the reasons given by the senior party. Barker is unable

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to state with any accuracy that this document is what it purports to be.

Turning to BX-123, BX-124 and BX-125, these will not be suppressed, inasmuch as Barker can provide authentication with respect to these documents. He prepared them himself.

With respect to BX-126, BX-127 and BX-128, we agree that this material is merely enlargements of exhibits attached to BX-122. They will not be suppressed.

The Barker Record at 8-46 will not be suppressed. Any suppression of exhibitory material identified therein goes merely to the weight the testimony therein will be accorded.

The Elson motion for suppression of evidence has been **GRANTED-IN-PART** as indicated.

Elson's Motion Respecting EX-57

Elson's motion to add exhibit EX-57 to the Elson record is **GRANTED** under 37 CFR § 1.645(b).

Standard of Review

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The junior party's involved patent was copending with respect to the senior party's involved application's parent case. Accordingly, for the junior party to prevail, the junior party must prove priority of invention by a preponderance of the evidence. **See Peeler v. Miller**, 535 F.2d 647, 651 n.5, 190 USPQ 117, 120 n.5 (CCPA 1976). **Accord, Bosies v. Benedict**, 27 F.3d 539, 541-42, 30 USPQ2d 1862, 1864 (Fed. Cir. 1994). **Cf. Price v. Symsek**, 988 F.2d 1187, 1191, 26 USPQ2d 1031, 1034 (Fed. Cir. 1993).

Conception has been defined as the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention. **Coleman v. Dines**, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985)(quoting **Gunter v. Stream**, 573 F.2d 77, 80, 197 USPQ 482, 484 (CCPA 1978)). It is settled that in establishing conception a party must show every feature recited in the count, and that every limitation in the count must have been known at the time of the alleged conception. **Coleman**, 754 F.2d at 359, 224 USPQ at 862.

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It is well established that proof of actual reduction to practice requires demonstration that the embodiment relied upon as evidence of priority actually worked for its intended purpose. **Newkirk v. Lulejian**, 825 F.2d 1581, 1583, 3 USPQ2d 1793, 1794 (Fed. Cir. 1987).

It is equally well established that every limitation of the interference count must exist in the embodiment and be shown to have performed as intended. **Id. See also Scott v. Finney**, 34 F.3d 1058, 1061, 32 USPQ2d 1115, 1117 (Fed. Cir. 1994).

Neither conception nor reduction to practice may be established by the uncorroborated testimony of the inventor. **See Tomecek v. Stimpson**, 513 F.2d 614, 619, 185 USPQ 235, 239 (CCPA 1975). The inventor's testimony, standing alone, is insufficient to prove conception--some form of corroboration must be shown.

See Price, 988 F.2d at 1194, 26 USPQ2d at 1036. While the "rule of reason," originally developed with respect to reduction to practice, has been extended to the corroboration required for

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proof of conception, the rule does not dispense with the requirement of some evidence of independent corroboration. **See Coleman**, 754 F.2d at 360, 224 USPQ at 862. As the CCPA stated in **Reese v. Hurst**, 661 F.2d 1222, 1225, 211 USPQ 936, 940 (CCPA 1981): "[the] adoption of the 'rule of reason' has not altered the requirement that evidence of corroboration must not depend solely on the inventor himself." There must be evidence independent from the inventor corroborating the conception.

The purpose for requiring some form of corroboration is to prevent fraud. The full discovery now available in interferences may be better able to root out fraud, but it is nevertheless clear that not all frauds will be discovered. Nor can such discovery substantially replace the protection against fraud that the long-standing rule of independent corroboration provides. **Reese**, 661 F.2d at 1226 n.4, 211 USPQ at 940 n.4.

Additionally, we acknowledge that there is no single formula that must be followed in proving corroboration. An

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evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached. **Price**, 988 F.2d at 1195, 26 USPQ2d at 1037.

Independent corroboration may consist of testimony of a witness, other than the inventor, to the actual reduction to practice, or

it may consist of evidence of surrounding facts and circumstances

independent of information received from the inventor. **Reese**, 661 F.2d at 1225, 211 USPQ at 940.

If a party places reliance on an embodiment of the invention in some physical form, such as a sketch or drawing, for proof of conception, the existence of the embodiment at the time must be established by testimony of a person other than the inventor. **Moran v. Paskert**, 205 USPQ 356, 359 (Bd. Pat. Int. 1979). **Accord, Price**, 988 F.2d at 1196, 26 USPQ2d at 1037-38 (testimony of secretary that she recalled seeing drawing as of critical date provides necessary evidence

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corroborating testimony of inventor as to date of conception).

See also, for conception,

Rivise and Caesar, *Interference Law and Practice*, Vol. I, § 126 and Vol. III, § 542 (Michie Co. 1947) *and for reduction to practice*, Vol. III §§ 543 and 544.

Barker's Priority Case

For proof of conception, Barker relies on Barker's testimony and the sketch attached as page 68 of BX-118 dated December 8, 1981. See Barker brief at 15, 52. Apparently, Barker is relying on the construction and photographing of a prototype on May 5, 1982 and electrical leakage tests of the same or similar prototypes "in and around May 1982"⁵ as an actual reduction to practice. Barker Brief at 19, 55. Again, Barker is relying on his own testimony (BR43-46) and Barker exhibit BX-126-128 for the photographs and memorandums BX-123, 124 ordering tests along with BX-125, test results.

⁵ BR45.

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Barker acknowledges that any proof of conception or reduction to practice must be corroborated. Brief at 53. Barker relies on **Price**, 988 F.2d at 1195, 26 USPQ2d at 1037, for the proposition that the exhibits, and specifically BX-118, provide indisputable corroboration of Barker's inventive acts and that there is no need for any further corroborating evidence. Elson argues that independent corroboration is needed, and we agree.

It is clear that the case law requires corroboration independent from the inventor. Taking the example of the **Price** case, the testimony of the secretary/spouse, Mrs. Price, was necessary to show the existence of the drawings in the files of the company to establish a date of conception. Although adoption of the rule of reason has eased the requirement of corroboration with respect to the quantum of evidence necessary to establish the inventor's credibility, it has not altered the requirement

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that corroborative evidence must not depend solely on the inventor and must be independent of information received from the inventor. **See Reese**, 661 F.2d at 1225, 211 USPQ at 940; **Mikus v. Wachtel**, 542 F.2d 1157, 1161-62, 191 USPQ 571, 575 (CCPA 1976). There is no language in the **Price** decision that would lead one to believe that the long-standing requirement for corroborative evidence, i.e., information independent from the inventor, had been altered. **Accord Finnigan v. ITC**, Case 98-1411 (Fed. Cir. June 9, 1999).

In this instance, the relied upon exhibits are all work products of the inventor and are all "self-serving" in this regard. They do not reflect the work of any other witness, and no one other than the inventor was called to testify as to the inventor's inventive activities. Furthermore, we note from the interference record that Larry Tolman, a name that appears on BX-118, was noticed as a witness, but his deposition was canceled. The unexplained failure to call a person such as Tolman, who apparently has direct knowledge of the facts sought

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to be proved, may raise an inference that the testimony of such a witness would be unfavorable or at least would not support the party's case. **See Borrer v. Herz**, 666 F.2d 569, 573-74, 213 USPQ 19, 23 (CCPA 1981); **Linkow v. Linkow**, 517 F.2d 1370, 1374, 186

USPQ 223, 226 (CCPA 1975); **White v. Habenstein**, 219 USPQ 1213, 1219 (Bd. Pat. Int. 1983). While this is not a controlling factor in our decision, it is certainly not helpful to Barker's case. **Id.**

In short, the totality of evidence, as presented by Barker, taken collectively, including the lack of any corroborating witness, does not establish by a preponderance of the evidence conception or reduction to practice before Barker's filing date of August 16, 1982. Therefore, we credit Barker with a constructive reduction to practice as of August 16, 1982.

Elson's Case for Priority

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Barker has conceded that the flow-through housing embodiment with the probe eyelet extending substantially across the lumen was conceived by Cook, one of the senior party inventors, by at least December 24, 1980. Barker brief at 27. That day, Cook drew by hand and dated a sketch of an invention within the scope of the count. EX-27; ER168-172.

Elson

exhibit 10, EX-10, is an engineering or formal drawing prepared for manufacturing a prototype of an embodiment within the scope of the count. The drawing EX-10 has a date of February 9, 1981. The drawing is described in the testimony of Chin, Switzer and Cook, the former two witnesses being non-inventors.

The Record further establishes that a prototype of the Elson closed-loop injectate system was undergoing testing by March 1981. Anita Switzer testified that she performed bench tests of a prototype of the invention before March 26, 1981. EX-58; ER441-446.

Proof of actual reduction to practice requires demonstration that the embodiment relied upon as evidence of priority actually worked for its intended purpose. **Newkirk,**

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825 F.2d at 1583, 3 USPQ2d at 1794. As was stated in **Paine v. Inoue**, 195 USPQ 598, 604 (Bd. Pat. Int. 1976):

The nature of testing required to establish a reduction to practice depends on the particular facts of each case; a common-sense approach is required to determine if the testing is sufficient. What is required is that it be reasonably certain the invention will perform its intended function in actual use. The tests must be sufficient to establish utility beyond probability of failure, and must be sufficient to give assurance the device will operate under normal working conditions for a reasonable length of time [citations omitted].

In **Scott**, 34 F.3d at 1063, 32 USPQ2d at 1119, the interfering subject matter concerned a hydraulic, inflatable penile implant. In considering what scope of testing of such a device would establish an actual reduction to practice, the court considered the in-an-out implantation and actuation of the device in a human subject's penis sufficient to establish a reduction to practice. Clearly, mere bench testing did not suffice.

In **Medtronic, Inc. v. Daig Corp.**, 611 F.Supp. 1498, 227 USPQ 509 (D. Minn. 1985), **aff'd**, 789 F.2d 903, 229 USPQ 664 (Fed. Cir. 1986), the Minnesota District Court rejected

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the argument that an actual reduction to practice of a type of pacemaker lead could be shown by implantation of the lead onto the heart of a living dog. In that case, the court stated:

"Such a barbed lead (be it two-barbed or cloverleaf, depending on the Pacemaker witness) was never shown to have been sufficiently tested to demonstrate that it would work for its intended purpose of passively fixing a pacemaker lead within the human heart." 611 F.Supp. at 1519, 227 USPQ at 523. The court further stated that reduction to practice of a barbed or tined lead must be

accomplished through implantation in the human heart. In the footnote, the court said that because the pacemaker is intended, designed, and marketed primarily, if not exclusively, for the

therapeutic implantation in the human being, the intended purpose of a tined endocardial lead contemplates passive fixation within the human heart. Therefore, in this case, the actual implantation involved, even though the device was permanently implanted in the heart of a dog, was insufficient to prove a

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reduction to practice. Likewise, in **Antoshkiw v. Pevsner**, 224 USPQ 1049, 1051 (Bd. Pat. App. & Int. 1983), it was held that since there was no evidence in the record that the device was tested in humans, let alone satisfactorily tested therein, the evidence of merely making the device and testing it in dogs was insufficient to establish an actual reduction to practice. **Accord Samson v. Crittenden**, 14 USPQ2d 1810, 1814 (Bd. Pat. App. & Int. 1990)(testing catheter in dog that did not contain stenosis is not testing for the intended purpose, i.e., dilating stenosis in humans, and the testing therefore failed to establish an actual reduction to practice).

Thus, it appears that the cases involving reduction to practice of medical devices require testing of the medical devices under actual use conditions with human subjects. Accordingly, we disagree with the contention (Elson brief at 12-13) of the senior party that flow bench testing of at least one prototype conducted by Ms. Switzer in March 1981 establishes a reduction to practice of the invention. Likewise, bench testing of the March prototype in comparison to other similar commercial devices does not suffice as

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establishing a reduction to practice. Finally, following the above-noted cases, animal testing does not ordinarily suffice to establish a reduction to

practice of a device used to measure human cardiac output. Consequently, animal testing of the invention, as argued on page 18 of the Elson brief, also does not establish a reduction to practice of the subject matter of the count.

However, the record in this interference contains sufficient evidence to establish successful human testing of the subject matter of the count by doctors working on behalf of the senior party by the end of September 1981. Elson Exhibits 17 and 18 deal with the shipping of units to doctors and/or nurses to initiate field testing in human subjects. EX-47,48; ER77-89; ER 264-268. Witness Chin further testified that the results received from the field establish that the closed loop system worked for its intended purpose. ER93-94. Elson Exhibit 20 is a synopsis of the various test experiences of the hospitals seeded with the closed loop system invention. Chin's testimony is supported by Young. EX-50; ER269-70. Viewing this evidence

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as a whole, senior party Elson has established a reduction to practice of the subject matter of the count by September 25, 1981, the date of the Edwards internal memorandum (EX-20).

Leakage

Notwithstanding the evidence that Elson has adduced with respect to actual reduction to practice, Barker argues (Brief at 30, 57-63) that Elson failed to reduce the invention to practice in the 1981 time frame because of a leakage problem with some of the closed loop injectate systems.

Barker cites the discussion of a leakage problem in Elson Exhibit 52, the October progress report at 009864-5, 009897 and in Elson Exhibit 53 at 009816. It is important to note, that the first units manufactured exhibited little or no leakage. BX-107. This Briggs memo states that only one unit of the first 529 units manufactured actually leaked. These were the units intended for field and clinical trials. No leaks, whatsoever, were reported during the clinical trials that we have held establish a reduction to practice. However,

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the same Briggs memo, BX-107, makes clear that in the next batch of housings manufactured, approximately 50% leaked. In our view, the best evidence as to the severity of this problem is the contemporaneous documents rather than the recollections of the witnesses whose testimony was well after the time frame in question. Taking BX-107, this Briggs memo does not use the word "severe" as the junior party's brief does, and the Briggs memo does not convey a tone of alarm. The memo suggests several possible solutions, and the overall tone of the document is that of reporting a minor problem. The December Young memo, BX-108, reports the solution to the leakage problem.

It is our view that the leakage problem does not negate the Elson reduction to practice. Firstly, the leakage problems occurred well after the clinical testing had shown that the device was suitable for its intended purpose. Not one of the devices leaked in clinical testing. BX-107.

Secondly, it must be emphasized that the standard for a reduction to practice is not commercial refinement.

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Steinberg v. Seitz, 517 F.2d 1359, 1363, 186 USPQ 209, 212 (CCPA 1975); **In re Dardick**, 496 F.2d 1234, 1238, 181 USPQ 834, 837 (CCPA 1974) ("To prove a reduction to practice, all that must be shown is that the invention is suitable for its intended purpose There is no requirement for a reduction to practice that the invention, when tested, be in a commercially satisfactory stage of development."). Thus, the fact that perhaps half of the injectate housings of one batch leaked around the eyelet tube would merely establish that the product was not yet commercially viable, in that every unit would need to be tested and half of all units discarded or repaired. Furthermore, even if the invention were considered to have a defect, due to crude construction, which we must emphasize the junior party has not proven here, the reduction to practice is not negated, if the solution to the defect is obvious to one of ordinary skill.

Austin Powder Co. v. Atlas Powder Co., 219 USPQ 707, 713 (D. Del. 1983). In this instance, it appears that the leakage

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problem was mitigated by the manufacturing expedient of cleanliness, i.e., providing the assembly workers with finger cots. BX-107. Cleaning up the manufacturing work area would not have been unobvious.

Attention is also directed to *Leichsenring, Jr. v. Freeman*, 103 F.2d 378, 41 USPQ 478 (1939), wherein it was held that a vehicle braking system was reduced to practice notwithstanding a leakage problem. In that instance, it was only necessary to show that the invention in question performed satisfactorily with respect to the generic problem the invention was designed to solve.

Most importantly, in the present case, the **apparatus** has been shown to be successful for its intended purpose, notwithstanding some examples of the apparatus leaked after pilot production, during testing. That some examples of the **article** leaked might have been conclusive evidence of no reduction to practice, if the interference count were directed to the **method of making** the closed loop injectate unit. Here, of course, the invention is directed to an article, and as long as the article is successfully tested for its intended

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purpose, it is immaterial that the article was difficult to manufacture or that in the manufacture of the article difficulties were encountered.

Priority

We have credited the junior party with a constructive reduction to practice as of his filing date of August 16, 1982. We have credited the senior party with an actual reduction to practice of September 25, 1981. The junior party has not overcome the senior party's date of invention. Accordingly judgment will be entered against the junior party and in favor of the senior party, hereinbelow.

Inequitable Conduct

Barker alleges that Elson's claims designated as corresponding to the count should be held to be unpatentable in that one embodiment of the closed loop injectate device was on sale more than a year before the filing date of the Elson benefit application. Although this embodiment was held to be

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unpatentable to Elson in a prior *ex parte* appeal to this Board, Barker argues that failure to disclose that this embodiment was on sale during the prosecution of the involved Elson application constitutes failure-to-disclose type inequitable conduct under

37 CFR § 1.56 and renders all claims in the Elson application, including Elson's involved claims, unpatentable. See Barker Brief at 40.

The embodiment said by Barker to have been offered for sale is illustrated in Figures 5 and 6 of the Elson involved application. It uses a stretchable latex membrane or disk to surround the thermistor probe as the probe projects into the injectate stream.

The alleged on sale activity pointed to by Barker is a series of field visits made by Eric Shore on December 10-12, 1980. The field visits are described in the Shore memorandum, BX-16, dated December 16, 1980. We will consider the memo and Shore's activities in detail.

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Applicants for patents, including their patent attorneys, are required to prosecute patent applications in the Patent and Trademark Office (PTO) with candor, good faith, and honesty. **See *Molins PLC v. Textron, Inc.***, 48 F.3d 1172, 1178, 33 USPQ2d 1823, 1826 (Fed. Cir. 1995); see also 37 CFR § 1.56.

A breach of this duty may constitute inequitable conduct.

Inequitable conduct due to failure to disclose material information must be proven by **clear and convincing evidence** of: (1) prior art that was material; (2) knowledge chargeable to

an applicant of that prior art and of its materiality; and (3) failure of the applicant to disclose the art resulting from an intent to mislead the PTO. **See *Molins***, 48 F.3d at 1178, 33 USPQ2d at 1826; ***FMC Corp. v. Manitowoc Co.***, 835 F.2d 1411, 1415, 5 USPQ2d 1112, 1115 (Fed. Cir. 1987). Such proof of inequitable conduct may be rebutted by a showing that: (a) the prior art was not material; (b) if the prior art was material, a showing that the applicant did not know of

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that art; (c) if the applicant did know of that art, a showing that the applicant did not know of its materiality; or (d) a showing that the applicant's failure to disclose the art did not result from an intent to mislead the PTO. **Id.**

Information is "material" when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent. **See Molins**, 48 F.3d at 1179, 33 USPQ2d at 1827. However, an otherwise material reference need not be disclosed if it is merely cumulative of or less material than other references already disclosed. **See Halliburton Co. v. Schlumberger Tech. Corp.**, 925 F.2d 1435, 1440, 17 USPQ2d 1834, 1839 (Fed. Cir. 1991); **Baxter Int'l, Inc. v. McGaw, Inc.**, 149 F.3d 1321, 1328, 47 USPQ2d 1225, 1229 (Fed. Cir. 1998).

With regard to the intent of the applicants to deceive the PTO, Federal Circuit precedent has recognized that intent need not, and rarely can, be proven by direct evidence.

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See Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422, 10 USPQ2d 1682, 1686 (Fed. Cir. 1989). Rather, this element of inequitable conduct must generally be inferred from the facts and circumstances surrounding the applicants' overall conduct. **See Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.**, 984 F.2d 1182, 1190, 25 USPQ2d 1561, 1567 (Fed. Cir. 1993); **Merck**, 873 F.2d at 1422, 10 USPQ2d at 1686. Moreover, the Federal Circuit has recognized that the more material the omission, the less the degree of intent that must be shown to reach a conclusion of inequitable conduct. **See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.**, 120 F.3d 1253, 1256, 43 USPQ2d 1666, 1668 (Fed. Cir. 1997), **cert. denied**, 118 S.Ct. 1511 (1998) and **cert. denied**, 118 S.Ct. 1510 (1998); **Akzo N.V. v. U.S. Int'l Trade Comm'n**, 808 F.2d 1471, 1481-82, 1 USPQ2d 1241, 1247 (Fed. Cir. 1986), **cert. denied**, 482 U.S. 909 (1987).

No single factor or combination of factors can be said always to require an inference of intent to mislead; yet a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it

difficult to establish "subjective good faith"

sufficient to prevent the drawing of an inference of intent to mislead. A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances. *LaBounty Mfg. Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076, 22 USPQ2d 1025, 1033 (Fed. Cir. 1992), *quoting FMC Corp.*, 835 F.2d at 1416, 5 USPQ2d at 1116.

Public Use

Barker has included arguments in his brief respecting public use of the invention during the Shore field visits. Barker Brief at 66-67. However, the junior party can point to no specific evidence that the device was used during the field visits. Shore's memo does not state that the device was used, and Shore's testimony is that it was not used. ER10, ¶9. We categorically reject Barker's argument that a public use occurred and that an inequitable conduct holding could be based properly thereon.

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On Sale

Section 102(b) may create a bar to patentability either alone, if the device placed on sale is an anticipation of the later claimed invention or, in conjunction with 35 U.S.C. § 103 (1988), if the claimed invention would have been obvious from the

on-sale device in conjunction with the prior art. **In re Corcoran**, 640 F.2d 1331, 1333, 208 USPQ 867, 869 (CCPA 1981). As stated in **Baker Oil Tools v. Geo Vann, Inc.**, 828 F.2d 1558, 1563, 4 USPQ2d 1210, 1213 (Fed. Cir. 1987):

If a device was in public use or on sale before the critical date, then that device becomes a reference under section 103 against the claimed invention.

The general purpose behind § 102(b) bars is to require inventors to assert with due diligence their right to a patent through the prompt filing of a patent application. 2 Donald S. Chisum, Patents § 6.01 (1991). However, a patentee may escape the § 102(b) bars on the ground the use or sale was experimental. **Id.**

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In *Pfaff v. Wells Elecs. Inc.*, 48 USPQ2d 1641, 1646-

47 (US Sup. Ct.)(1998) the Court stated:

[T]he on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. An inventor can both understand and control the timing of the first commercial marketing of his invention. The experimental use doctrine, for example, has not generated concerns about indefiniteness, and we perceive no reason why unmanageable uncertainty should attend a rule that measures the application of the on-sale bar of § 102(b) against the date when an invention that is ready for patenting is first marketed commercially

Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. In this case the second condition of the on-sale bar is satisfied because the drawings Pfaff sent to the manufacturer before the critical date fully disclosed the invention [footnotes omitted].

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Thus, the Supreme Court has done away with the "totality of circumstances test" previously articulated by the Federal Circuit, in favor of the above-noted two-prong analysis. **See Weatherchem Corp. v. J.L. Clark Inc.**, 163 F.3d 1326, 1332, 49 USPQ2d 1001, 1006 (Fed. Cir. 1998). **Cf. Envirotech Corp. v. Westech Eng'g, Inc.**, 904 F.2d 1571, 1574, 15 USPQ2d 1230, 1232 (Fed. Cir. 1990); **UMC Elecs. Co. v. United States**, 816 F.2d 647, 656, 2 USPQ2d 1465, 1472 (Fed. Cir. 1987), **cert. denied**, 484 U.S. 1025 (1988); **King Instrument Corp. v. Otari Corp.**, 767 F.2d 853, 860, 226 USPQ 402, 406 (Fed. Cir. 1985), **cert. denied**, 475 U.S. 1016 (1986).

With respect to the second prong of the **Pfaff** analysis, we are in agreement that the latex membrane embodiment of the closed loop injectate system was ready for patenting as of

December 1980. We acknowledge that Shore, in his declaration, states that the invention was not ready for sale, inasmuch as there was no product to sell, no clinical trials had been conducted, the device had not achieved regulatory approval for

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sale, and the design was not finalized. BX-18 at 2-3. However, in our view, the Supreme Court has put these arguments to rest to the extent that it has held that the device need only be "ready for patenting." We regard the latex disk embodiment as ready for patenting, because the inventors had prepared drawings, descriptions, and, indeed, a prototype, sufficiently specific to enable a person skilled in the art to practice the invention.

Our further analysis must be directed to the scope of any commercial activities, the first prong of the **Pfaff** test, specifically directed to whether the December activities constitute an offer for sale as contended by Barker. The December 1980 activities referred to are the field visits by Eric Shore described in the Shore memorandum BX-16. Therefore, the evidence Barker is relying upon are the Shore memorandum BX-16, Shore's declaration with respect thereto, and the cross-examination of Shore with respect to the memorandum and declaration. The following represents our findings of fact with regard to the above-enumerated evidence.

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At the time of the Shore field visits, Eric Shore was employed by Edwards as a product manager in the marketing department. BR1429. It was one of his jobs to act in a liaison role with the engineers to make sure that the products they developed would be acceptable to the segment of the public that used the equipment. BR1435. Shore also was to determine the features that Edwards' customers wanted, and he talked to customers and sale reps to find this out. BR1453-54. He also had input into pricing decisions. BR1459. Shore typically did not get formal confidentiality agreements from hospital personnel to whom he showed prototypes, although he testified that he would sometimes orally inform them that information he imparted was disclosed confidentially. BR1458.

On the dates of December 10-12, 1980, Shore, along with the Edwards sales representative for the respective areas, visited hospitals in Cleveland and Columbus, Ohio and Chicago, Illinois to demonstrate a somewhat crude prototype of the latex disk embodiment of a closed loop injectate system. BX-16; BR1472-1476. The prototype demonstrated was crude, i.e., handmade, not to manufacturing tolerances, unsterile, "strictly [for] show and tell." BR1488-9. The prototype was

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not used during the field visit on either animals or humans.
BR1527.

ER10, ¶9. The prototype's design had not been finalized.
BR1489. Shore had no specific recollection of putting anyone
visited on the December field visit under an obligation of
confidentiality. BR1482. From our close review of the
transcript and declaration, we regard Shore as a cooperative
and credible witness.

Shore's declaration is emphatic in that the purpose
of the field visits was to solicit comments on the design of
the crude prototype latex disk device. ER10, ¶10. The best
evidence for this is the express language of the Shore memo
itself wherein it is stated:

The purpose of the field visits was to
present our prototype closed injectate
system to prospective users, obtain their
comments, and **finalize design criteria** for
the construction of 500-1000 prototype
systems. BX-16, ¶1 (emphasis supplied).

We find it extremely relevant that an internal Edwards
memorandum states that design issues were the reason for the
field visit. Shore had nothing to hide from his coworkers, and

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if the purpose of the visits were marketing or to offer a commercial embodiment for sale, in our view, Shore would have so stated in the memo. Therefore, we accept Shore's testimony that the purpose of the trip was to finalize the design.

Shore expressly states in his declaration that there was no "offer for sale or effort to

solicit offers [to buy?]." ER8, ¶7. Likewise, he expressly stated that Edwards received no payment or promise of payment from hospital personnel. ER8, ¶7.

We find Shore's characterization of the prototype as crude and not suitable for use as plausible. Barker's brief at 43-44 quotes BX-86 to imply that the prototypes were fully functional, but the part of BX-86 quoted merely states that the prototypes will be "suitable for demonstration purposes." This does not conflict with or contradict Shore's testimony.

At this remove, far from the time of the field visits, we doubt that it is possible to determine if Shore orally asked the doctors and nurses to keep the information respecting the prototype confidential. Whether confidentiality was requested is not dispositive of whether an

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offer for sale was made, however. It is but one factor to be considered.

Shore candidly admitted under cross-examination that marketing was an incidental or ancillary purpose to the field visits. BR1487. Barker also points to the \$15 conversation with Dr. Estafanous and at St. Luke's. Barker brief at 23, 25. Interestingly enough the \$15 comments were probably solicited by Shore in that he had been tasked to find out if doctors would pay this amount of additional cost for a closed loop system. BX-2 at

11588; BR1453, 1454. And the testimony of Shore makes clear that Dr. Etr would not be obtaining the device as a sold item but obtaining a sample for evaluation purposes. BR1480. Here again we find none of these circumstances dispositive of an offer for sale.

Two important principles from the case law impact our findings with respect to Edward's commercial activities. First, the "on sale" bar of § 102(b) does not arise simply because the intended customer was participating in development and testing. ***Continental Can Co. USA, Inc. v. Monsanto Co.,***

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948 F.2d 1264, 1269, 20 USPQ2d 1746, 1750 (Fed. Cir. 1991) (*citing Great Northern Corp. v. Davis Core & Pad Co.*, 782 F.2d 159, 164-65, 228 USPQ 356, 358 (Fed. Cir. 1986)). Secondly, where there is no sale, a definite offer to sell is an essential requirement of the on-sale bar. *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989). The requirement of a definite offer excludes merely indefinite or nebulous discussion about a possible sale. *Id.*

In short, we have not found that Shore's declaration did not withstand cross-examination as alleged in Barker's Brief at 43. Considering all the evidence concerning the scope of commercial activities during Shore's field visits, it is our

determination that Barker has not shown that Elson's assignee offered for sale the latex disk embodiment more than one year prior to the effective filing date by a preponderance of the

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evidence.⁶ Furthermore, since the on sale bar runs to materiality under the inequitable conduct test, the proper burden in this instance would certainly be the clear and convincing standard of proof. Barker has not shown by clear and convincing evidence that the latex disc embodiment was offered for sale by Shore in his field visits of December 1980.

Inasmuch as we have determined that the assignee of the senior party did not offer for sale the latex disc embodiment in December 1980, we necessarily find that information respecting the field visits lacks the materiality necessary to establish an instance of inequitable conduct on the part of the senior party. Accordingly, Barker's motion for judgment under 37 CFR § 1.633(a) based on the ground of inequitable conduct, deferred to final hearing, is hereby

DENIED.

⁶ If the on sale bar were concerned with anticipation of the latex disk embodiment, then the burden of proof would be a mere preponderance of the evidence to render claims of the latex disk embodiment unpatentable. Where, as here, the issue is the unpatentability or unenforceability of a separate embodiment, not offered for sale, by inequitable conduct or "taint" as the junior party argues, the proper burden is clear and convincing evidence.

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Equitable Abandonment, Suppression, and Concealment

As we understand it, the junior party Barker is requesting that we enter judgment in his favor based on the premise that one who has committed inequitable conduct before the PTO, and delayed the issuance of its patent or the abandonment of its application by said inequitable conduct, has abandoned, suppressed, or concealed the invention under 35 U.S.C. § 102(g). In this instance, as noted above, Barker has failed to prove that Elson has engaged in inequitable conduct. Thus, a contingency on which the request is based has not occurred. Therefore, we decline to entertain the request.

Judgment

Judgment in Interference No. 103,146 is entered against John M. Baker, the junior party. John M. Baker is not entitled to his patent claims 1 through 18 or his Reissue application claims 1 through 17, all of which claims correspond to the count in interference. Judgment is entered

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in favor of Edward E. Elson, Wallace F. Cook, Ronald L. McCartney, Ernest Lane and Clement Lieber, the senior party. Edward E. Elson, Wallace F. Cook, Ronald L. McCartney, Ernest Lane and Clement Lieber are entitled to a patent containing claims 1 through 3, 5 through 10, 12 through 20, 50 through 53, and 56 through 58, which claims were designated as corresponding to the count in interference.

	STANLEY M. URYNOWICZ, JR.)	
	Administrative Patent Judge)	
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	WILLIAM F. PATE, III)	APPEALS AND
	Administrative Patent Judge)	
INTERFERENCES)	
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	HUBERT C. LORIN)	
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