# **United States Court of Appeals for the Federal Circuit**

06-1156, -1157

LIEBEL-FLARSHEIM COMPANY and MALLINCKRODT, INC.,

Plaintiffs-Appellants,

٧.

MEDRAD, INC.,

Defendant-Cross Appellant.

<u>J. Robert Chambers</u>, Wood, Herron & Evans, L.L.P., of Cincinnati, Ohio, argued for plaintiffs-appellants. With him on the brief was <u>Theodore R. Remaklus</u>.

<u>W. Thomas McGough, Jr.</u>, Reed Smith LLP, of Pittsburgh, Pennsylvania, argued for defendant-cross appellant. With him on the brief were <u>Frederick H. Colen, Barry J. Coyne</u>, and <u>Kirsten R. Rydstrom</u>. Of counsel on the brief was <u>Gregory L. Bradley</u>, Medrad Inc., of Indianola, Pennsylvania.

Appealed from: United States District Court for the Southern District of Ohio

Chief Judge Sandra S. Beckwith

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DECIDED: March 22, 2007

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Before LOURIE, RADER, and BRYSON, Circuit Judges.

LOURIE, Circuit Judge.

Liebel-Flarsheim Company and Mallinckrodt Inc. (collectively "Liebel") appeal from the decision of the United States District Court for the Southern District of Ohio granting Medrad's motion for summary judgment that four of Liebel's patents are invalid under 35 U.S.C. §§ 112 and 102. <u>Liebel-Flarsheim Co. v. Medrad, Inc.</u>, No. 01-CV-98-858 (S.D. Ohio Oct. 28, 2005). Medrad cross-appeals from the decision of the district court granting Liebel's motion for summary judgment that Medrad infringed the asserted patents and that the inventorship designation on Liebel's patents is correct. Medrad

also cross-appeals from the holding that the inequitable conduct counterclaim was moot in light of the district court's invalidity rulings. Because we conclude that Liebel's patents are invalid, the front-loading patents for lack of enablement and the syringe-sensing patents on anticipation, we affirm the district court's judgment of invalidity. As a result, the cross-appeals on infringement and inventorship need not be reached. We also affirm the court's decision that the inequitable conduct counterclaim is presently moot.

#### BACKGROUND

This is the second time this case has been on appeal in our court. The detailed facts of the case are presented in our previous opinion, and we present here only those facts relevant to this appeal. See Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898 (Fed. Cir. 2004) ("Liebel I"). This appeal concerns asserted claims of four of Liebel's patents: claims 10, 11, 13, and 16-19 of U.S. Patent 5,456,669; claims 1, 8, 9, 11-13, 15, 16, 18, 22, 27, 28, 30-33, and 34-37 of U.S. Patent 5,658,261; claims 7, 8, 10, and 11 of U.S. Patent 5,662,612; and claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, and 23 of U.S. Patent 5,928,197. The '669 and '261 patents (hereinafter the "front-loading patents") share a common specification and are directed to a front-loading fluid injector with a replaceable syringe capable of withstanding high pressures for delivering a contrast agent to a patient. The '612 and '197 patents (hereinafter the "syringe-sensing patents") also share a common specification and are directed to a computer-controlled injector wherein a motor advances and retracts a plunger located within the syringe.

With regard to the asserted claims of the front-loading patents, this appeal challenges the district court's holding of invalidity following our prior claim construction regarding a pressure jacket. Claim 10 of the '669 patent is representative of the asserted claims of the front-loading patents and reads as follows:

A method of loading a tubular replacement syringe into a high pressure power injector for injecting fluid into an animal, the method comprising the steps of:

providing a power injector having:

- a syringe receiving opening with a generally circular periphery therein adapted to receive a rearward end of a syringe having a generally circular rim,
- a ram and a motor linked to the ram and operable to reciprocate the ram along a segment of a line projecting through the opening; and providing a hollow tubular syringe that includes:
- a cylindrical body having an axis, a generally circular rim, a rearward end and a closed forward end with a fluid discharge orifice therein, and
- a plunger axially slidable in the body, the syringe body being structurally capable of withstanding, at least from the rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof;

then:

inserting into the opening, by generally rearward axial movement of the syringe, the rearward end of the body;

rotating the syringe in the opening a fraction of a turn to thereby lock the body around the rim to the injector around the periphery of the opening; and

engaging the plunger with the ram;

then:

energizing the motor and thereby driving the ram forward along the line and parallel to the axis to move the plunger axially forward at a programmed speed to inject the fluid at the operating pressure from within the syringe and through the orifice at a programmed rate into the animal.

'669 patent, col.15 II.17-50. The claims in the originally-filed application<sup>1</sup> explicitly recited a pressure jacket in front of the syringe receiving opening. During the prosecution of the front-loading patents, Liebel removed all references in the claims to a pressure jacket. Medrad asserted, and the district court agreed, that during the prosecution of the front-loading patents, the applicants became aware of Medrad's jacketless injector system and then deleted all references to a pressure jacket in the asserted claims in order to encompass Medrad's injector within the scope of the claims. The examiner allowed the claims, and the claims as issued do not contain an explicit recitation of a pressure jacket.

Even though the claims do not expressly recite a pressure jacket, the district court initially construed the asserted claims of the front-loading patents as requiring a pressure jacket. Based on that construction, the district court granted summary judgment of noninfringement in favor of Medrad because Medrad's accused devices do not contain a pressure jacket.

In the first appeal to this court, we reversed the district court's claim construction and determined that the asserted claims of the front-loading patents do not require a pressure jacket. We first considered the language of the claims and observed that neither claim 10 of the '669 patent nor any of the other asserted claims expressly mentions a pressure jacket. We further rejected the district court's conclusion that the term "opening" in independent claim 10 of the '669 patent must be limited to an opening in a pressure jacket. We then considered the specification and determined that,

In 1991, Liebel filed Application Serial No. 07/712,110, which issued as U.S. Patent 5,300,031. The claims of the '031 patent include a pressure jacket limitation. The '669 and '261 patents, which do not recite a pressure jacket limitation, resulted from continuation applications, claiming priority from the '110 application.

although all the described embodiments include a pressure jacket, the disclosure did not clearly disavow embodiments lacking a pressure jacket. We also observed that the prosecution history indicates that the asserted claims purposefully did not include a pressure jacket limitation in order to cover devices that lacked a pressure jacket. In light of the intrinsic evidence, we declined to limit the claims to require a pressure jacket. Although Medrad argued that we should construe the claims narrowly to preserve their validity, we declined to do so, stating that the question of validity was a separate issue that could be addressed on remand. Liebel I, 383 F.3d at 912.

On remand and in light of our claim construction, the district court concluded that Medrad's devices did infringe the asserted claims of the front-loading patents, but that those claims were invalid for lack of compliance with the written description and enablement requirements of the statute. The district court reasoned that the claims were invalid for lack of written description because the specification does not describe a jacketless injector. The court noted that the written description of the invention is directed to the improvement of "loading and unloading a syringe given the constraints presented by the pressure jacket."

The district court also concluded that the asserted claims were invalid for lack of enablement after considering the specification and the factors set forth in <u>In re Wands</u>, 858 F.2d 731 (Fed. Cir. 1988). The court observed that a pressure jacket was necessary to "maintain the integrity of the syringe housing against pressures the syringe encounters during operation of the injector." The court further noted that the inventors themselves testified as to the importance of the pressure jacket around the syringe and that the experiments with and testing of jacketless systems were unsuccessful. The

court also relied on testimony of Liebel's engineers that a jacketless system was not a mere design option and that one skilled in the art would not know how to make a jacketless system. The court further found that no prototypes of a jacketless injector had been made or described at the time of filing, and that the state of the art was such that a jacketless system with a disposable syringe would have been a "true innovation." Thus, the court concluded that Medrad had proffered clear and convincing evidence that the specification does not satisfy the written description and enablement requirements.

With respect to the syringe-sensing patents, this appeal challenges the holding of invalidity following our construction of the term "physical indicia" and its relationship to the properties of the syringe. Claim 7 of the '612 patent is representative of the asserted claims of the syringe-sensing patents and reads as follows:

An injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at a distal end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

- a detector located proximate to a syringe installed on said injector for detecting a <u>physical indicia [sic]</u> on said syringe related to the <u>capacity of said syringe</u>, and generating an electrical signal representative of said physical indicia, and
- a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the location of a plunger within said syringe relative to an end of said syringe, by relating said electrical signal to the tracked location of said motor.

'612 patent, col.18 II.36-52 (emphases added). The remaining asserted claims of the '197 and '612 patents differ from representative claim 7 of the '612 patent in that some are directed to a method of controlling an injector (claims 4, 5, 10, 11, 16, 17, 22, and 23 of the '197 patent and claim 10 of the '612 patent), and some are dependent claims that recite the additional limitation of ceasing motion of the motor and plunger when the

plunger or ram connected to the plunger has reached the end of the syringe (claims 2, 5, 8, 11, 14, 17, 20, and 23 of the '197 patent and claims 8 and 11 of the '612 patent). In addition, the asserted claims of the syringe-sensing patents recite physical indicia related to properties of the syringe other than the "capacity of said syringe" as recited in representative claim 7 of the '612 patent. Such properties include the distance of the plunger or ram coupled to the plunger from an end of the syringe (claims 1, 4, 13, and 16 of the '197 patent), the range of travel of an injector ram coupled to the plunger (claims 19 and 22 of the '197 patent), and the amount of fluid in the syringe (claims 7 and 10 of the '197 patent).

In its claim construction prior to our decision in <u>Liebel I</u>, the district court had considered the meaning of the term "physical indicia." It disagreed with Medrad that the term should be limited to indicia representing the length of the extender. The court determined that the claim language was broader than Medrad's proposed construction because the claims recited syringe properties other than the length of the extender.

On appeal, in <u>Liebel I</u>, Medrad had argued that we should construe the term "physical indicia" to be limited to features that indicate the length of the extender. <u>Liebel I</u>, 358 F.3d at 912. After considering the language of the claims, the specification, and the prosecution history, we determined that the district court correctly concluded that the term "physical indicia" is not limited to indicia related to the length of an extender. <u>Id.</u> at 914. We again stated that we would not construe the claims narrowly because of invalidity concerns, and that the issue of invalidity could be addressed on remand. Id.

On remand and in light of our construction, the district court determined that Medrad's accused device did infringe the asserted claims of the syringe-sensing

patents, but that those claims were invalid for failure to comply with the requirements of § 112 and because of anticipation by Medrad's U.S. Patent 5,383,858. With regard to written description, the district court stated that there was "nothing in the written description that describes an invention for detecting indicia (e.g., 'a tangible mark') on the syringe—other than the limited, alternative reference to physical indicia relating to the length of the extender." The district court noted that the preferred embodiment "teaches that it is the injector's face plate, which is removable and interchangeable, that is 'detected' by a sensor, which in turn tells the circuit board the size of the syringe installed." The court also observed that the written description and enablement requirements often rise and fall together and determined that the asserted claims of the front-loading patents "are of a far greater scope than [Liebel's] specification of what it invented or possessed when it filed its application." The court concluded that the specification failed to fulfill both the written description and enablement requirements set forth in § 112, ¶ 1.

With regard to anticipation, the court found that even if it had concluded that Liebel's patents were not invalid under § 112, the asserted claims of the syringe-sensing patents were anticipated by the prior art '858 patent. The court found that the '858 patent clearly describes an indicator mechanism for injecting fluid from a syringe into a patient, and that mechanism includes an injector controller and a sensor. The court further determined that the '858 patent discloses "physical indicia" by describing the use of a bar code or another readable device on the syringe that stores information about the syringe and that can be read by a sensor. The court determined that the only difference between the asserted claims of the syringe-sensing patents and the invention

disclosed in the '858 patent was the description of the types of indicia detected. For example, the '858 patent describes that the bar code on the syringe can include information relating to the "dimensions" of the syringe, whereas the asserted claims recite the "capacity" of the syringe. The court found that these were "semantic differences" that did not affect its conclusion of anticipation. Hence, the court concluded that the '858 patent anticipates the syringe-sensing patents.

In a separate order, the district court considered whether the inventorship designated on the patents was correct, and granted Liebel's motion for partial summary judgment that it was correct. The court determined that the alleged omitted inventor, Kelly, did not contribute to the conception of the design and thus was not properly a coinventor. The court found that the evidence established that Kelly only attended "brainstorming" sessions, but that there was no clear and convincing evidence of his being an inventor.

The court further determined, after resolving the invalidity motions, that Medrad's inequitable conduct claim was moot in light of its invalidity rulings.

Liebel timely appealed, and Medrad cross-appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

#### DISCUSSION

We review the district court's grant of summary judgment <u>de novo</u>, reapplying the standard applicable at the district court. <u>See Rodime PLC v. Seagate Tech., Inc.</u>, 174 F.3d 1294, 1301 (Fed. Cir. 1999). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admission on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the

moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In addition, in deciding a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Whether a claim satisfies the enablement requirement of 35 U.S.C. § 112, ¶ 1 is a question of law. Invitrogen Corp. v. Clontech Labs. Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005). Anticipation is a question of fact, but validity is a question of law. Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 995 (Fed. Cir. 2006). Because a patent is presumed to be valid, the evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence. AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1238-39 (Fed. Cir. 2003).

#### A. The Front-Loading '669 and '261 Patents

On appeal, Liebel argues that the court erred in determining that the asserted claims of the front-loading patents are invalid for lack of written description and enablement. With regard to enablement, Liebel contends that the court erroneously considered whether an injector without a pressure jacket was enabled, rather than limiting its inquiry to whether an injector with a pressure jacket was enabled, as it clearly was. Liebel points out that the asserted claims do not recite or require the absence of a pressure jacket and the court improperly focused on such an embodiment. Because it is undisputed that Liebel provided an enabling disclosure of what it calls its preferred embodiment, viz., an injector with a pressure jacket, Liebel asserts that the court should have held that the disclosure was enabling for the full scope of the claims. Liebel further asserts that the court erred in concluding, after considering the Wands factors, that undue experimentation would be required to practice the claimed invention without

a pressure jacket. According to Liebel, the testimony that the court relied upon only showed that additional work, not undue experimentation, was required to develop an injector without a pressure jacket. Liebel also ascribes error to the court's consideration of various other pieces of testimony as support for its determination that producing the invention without a pressure jacket would require undue experimentation.

Medrad responds that the district court correctly determined that, under our claim construction, the asserted claims are invalid for lack of enablement. Medrad argues that the court was correct in determining that the full scope of the invention, including the injector without a pressure jacket, is not enabled. According to Medrad, although every embodiment of a claim does not need to be disclosed in the specification, the disclosure must teach the full range of embodiments in order for the claims to be enabled, and here the disclosure does not teach an injector without a pressure jacket. According to Medrad, consideration of the <u>Wands</u> factors also supports a determination that the asserted claims are not enabled. Medrad observes that Liebel's own inventors admitted that they could not produce a successful pressure-jacketless system and that that was compelling evidence of lack of enablement. Medrad also cites other testimony that supports a finding of undue experimentation.

We agree with Medrad that the district court correctly determined that the asserted claims of the front-loading patents are invalid for lack of enablement. The enablement requirement is set forth in 35 U.S.C. § 112, ¶ 1 and provides in pertinent part that the specification shall describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

and use the [invention]." We have stated that the "enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." AK Steel, 344 F.3d at 1244; see also Wands, 858 F.2d at 736-37.

We have previously construed the claims of the front-loading patents such that they are not limited to an injector with a pressure jacket, and therefore the full scope of the claimed inventions includes injectors with and without a pressure jacket. That full scope must be enabled, and the district court was correct that it was not enabled.

Turning first to consideration of the specification, we find that nowhere does the specification describe an injector with a disposable syringe without a pressure jacket. In fact, the specification teaches away from such an invention. In the "Background of the Invention," the specification describes general injectors and explains that during the injection phase, a plunger is driven forward and pressure develops in the syringe, ranging from 25 psi to over 1000 psi. Without a pressure jacket, syringes that are able to withstand such high pressures are "expensive and therefore impractical where the syringes are to be disposable. Accordingly, many such injectors . . . have been provided with pressure jackets fixed to the injector units and into which the syringes are inserted." '669 patent, col.1 II.23-31. The specification thus teaches away from a disposable syringe without a pressure jacket by stating that such syringes are "impractical." As we have held previously, where the specification teaches against a purported aspect of an invention, such a teaching "is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention." AK Steel, 344 F.3d at 1244. Moreover, consideration of the

remainder of the specification reveals that there is no guidance or suggestion of how to make or use a disposable syringe for high pressure use without a pressure jacket. All the figures in the patents depict a pressure jacket and all discussion of them refers to the pressure jacket.

Furthermore, consideration of the testimonial evidence presented supports a conclusion that no genuine issue of material fact exists as to whether undue experimentation would have been required to make and use the injector without a pressure jacket. The inventors admitted that they tried unsuccessfully to produce a pressure-jacketless system and that producing such a system would have required more experimentation and testing. The inventors decided not to pursue such a system because it was "too risky." The district court relied on various statements in the record by the inventors that testing of a syringe without a pressure jacket proved unsuccessful and that the inventors were not aware of any other similar testing being conducted at that time. Moreover, there was no indication of any prototype of a pressure-jacketless injector having been made.

Liebel argues that language in <u>Spectra-Physics</u>, <u>Inc. v. Coherent</u>, <u>Inc.</u>, 827 F.2d 1524 (Fed. Cir. 1987), that states that if an invention pertains to an art where the results are predictable, <u>e.g.</u>, in the mechanical arts, then disclosure of a single embodiment can enable a broad claim, supports its position. Liebel asserts that because the specification enables one mode of making and using the invention in its preferred embodiment, <u>viz.</u>, an injector with a pressure jacket, the enablement requirement is satisfied and the inquiry should end there. <u>See Engle Indus.</u>, <u>Inc. v. Lockformer Co.</u>, 946 F.2d 1528 (Fed. Cir. 1991).

Liebel's reliance on Spectra-Physics is misplaced. In that case, the specification disclosed different "attachment means" for making the claimed invention such as molymanganese brazing and pulse-soldering, but failed to disclose the best attachment means known to the inventors. We held that the asserted claims of the patent were invalid for failure to comply with the best mode requirement of § 112, even though the specification enabled the practice of the claims. We did note that the specifications of other patents identified TiCuSil brazing as a suitable alternative attachment technique and thus that the asserted patent's failure to mention TiCuSil brazing as an attachment means was "not fatal to enablement under § 112." Spectra-Physics, 827 F.2d at 1533. Indeed, in that case, disclosure of one attachment means permitted one skilled in the art to make and use the invention as broadly as it was claimed, which included other attachment means known to one of ordinary skill in the art. In contrast, in this case, disclosure of an injector system with a pressure jacket does not permit one skilled in the art to make and use the invention as broadly as it was claimed, including without a pressure jacket.

The facts of this case are, in fact, more analogous to AK Steel than to Spectra-Physics. In AK Steel, the patentee argued, as it does here, that the patent disclosed several embodiments within the properly construed claim, and that the specification need not teach the full claimed scope in order for the claims to be enabled. 344 F.3d at 1243. The claims in AK Steel read on steel strips containing either a Type 1 or a Type 2 aluminum coating. The specification clearly described only Type 2 aluminum coating. We stated, however, that "as part of the quid pro quo of the patent bargain, the applicant's specification must enable one of ordinary skill in the art to practice the full

scope of the claimed invention." <u>Id.</u> at 1244 (latter emphasis added). We explained that the specification need not necessarily describe how to make and use every embodiment of the invention "because the artisan's knowledge of the prior art and routine experimentation can often fill in the gaps." <u>Id.</u> However, because the full scope of the claims included both Type 1 and Type 2 aluminum coating, the relevant inquiry became whether one skilled in the art would have been able to make and use a steel strip containing a Type 1 aluminum coating at the time of the patent's effective filing date. <u>Id.</u> We held that the specification taught against using a Type 1 aluminum coating, and therefore that the claims were invalid for lack of enablement.

Similarly, in this case, the asserted claims read on, and the full scope of the claimed invention includes, an injector system with and without a pressure jacket. There must be "reasonable enablement of the scope of the range" which, in this case, includes both injector systems with and without a pressure jacket. <u>Id.</u>

The specification's reference that teaches away from an injector system with a disposable syringe without a pressure jacket, combined with the testimonial evidence that such a system could not have been produced at the time of filing, supports the district court's conclusion that the specification fails to fulfill the enablement requirement of § 112. Because we are resolving this issue on the enablement ground, we do not need to consider the written description holding of invalidity.

The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, "beware of what one asks for," might be applicable here.

### B. <u>The Syringe-Sensing '612 and '197 Patents</u>

On appeal, Liebel argues that Medrad failed to provide clear and convincing evidence that the '858 patent anticipates the asserted claims of the syringe-sensing patents. In particular, Liebel asserts that the '858 patent does not disclose a control circuit that computes the location of the plunger within the syringe, stops the motor and plunger, or determines that the plunger is at the end of the syringe, as required by the claims.

Medrad responds that the district court correctly decided that the '858 patent anticipates the asserted claims of the syringe-sensing patents. Medrad asserts that the the '858 patent expressly discloses an injector control that controls a motor and plunger by computing the location of the plunger. Medrad also asserts that the district court held that measuring actual plunger movement is accomplished by "long-established potentiometer technology," and that the '858 patent incorporates two patents that discuss measuring plunger movement. Medrad finally contends that the '858 patent discloses detecting the same physical indicia as the syringe-sensing patents.

We agree with Medrad that the district court correctly determined that there is no genuine issue of material fact that the '858 patent anticipates<sup>2</sup> the asserted claims of the syringe-sensing patents. A determination that a patent is invalid as anticipated under 35 U.S.C. § 102 requires that a prior art reference disclose every limitation of the claimed invention, either explicitly or inherently. <u>Telemac Cellular Corp. v. Topp Telecom, Inc.</u>, 247 F.3d 1316, 1327 (Fed. Cir. 2001). The prior art reference in this

Because we determine that the asserted claims of the syringe-sensing patents are invalid by reason of anticipation by the '858 patent, we need not address written description or enablement issues, which were the other grounds on which the district court found the syringe-sensing patents to be invalid.

case is Medrad's '858 patent, which was cited to the PTO during the prosecution of the syringe-sensing patents. Although the burden of showing invalidity is "especially difficult" when the prior art reference was before the examiner during prosecution, we find that Medrad has met that burden here. See Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004).

Liebel first argues that the '858 patent fails to disclose the closed control circuit that computes the location of a plunger, as required by claim 7 of the '612 patent. We disagree. There is no genuine issue of material fact as to what the '858 patent discloses. The '858 patent discloses a syringe that is rotatably mountable on a front wall of an injector housing with an interference fit. Although that patent expressly mentions an injector controller, it does not discuss the details of how the controller interacts with the motor and plunger. However, the '858 patent incorporates by reference<sup>3</sup> U.S. Patent 4,006,736, assigned to Medrad, which clearly does discuss the details of the control circuit and its interaction with the plunger. The '736 patent discloses a system for injecting fluid into a patient and it is replete with discussion of the control unit of that system operating the motor and tracking the plunger movement. For example, the patent expressly states that "as the motor drives the plunger, the potentiometer tracks it, so that the rate of movement and position may be derived." '736 patent, col.20 II.21-24 (reference characters omitted). The '736 patent further states that "the volume circuit monitors the position of plunger after an injection begins to

We have stated that "material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document." <u>Advanced Display Sys., Inc. v. Kent State Univ.</u>, 212 F.3d 1272, 1282 (Fed. Cir. 2000). We have further explained that material incorporated by reference "is effectively part of the host document as if it were explicitly contained therein." Id.

determine how much volume of contrast media has been delivered. And when the plunger has delivered the set volume, the volume circuit sends a signal to the time circuit to stop injecting." '736 patent, col.19 II.32-37 (reference characters omitted). The '858 patent, which incorporates by reference the '736 patent, therefore discloses a claimed control circuit that computes the location of a plunger. In addition, the limitation recited in some of the dependent claims of the syringe-sensing patents—using the control circuit to stop movement of the motor and plunger when the plunger is at the end of the syringe—is similarly disclosed in the '736 patent in the discussion pertaining to moving and retracting the plunger.

Liebel next asserts that the '858 patent fails to disclose physical indicia related to various parameters or properties of the syringe. We disagree again. In our claim construction, we determined that the term "physical indicia," as Liebel has argued, is not limited to indicia related to the length of the extender. Thus, the full scope of the claims includes the detection of physical indicia other than detection of the length of the extender. Those physical indicia recited in the claims are: the capacity of the syringe, the distance of the plunger from an end of the syringe, the amount of fluid in the syringe, and the end of the travel position of an injector ram coupled to the plunger.

The '858 patent discloses using an encoding device, such as a bar code, located on the syringe, and a sensor, located on the injector, for reading the encoded device and forwarding signals to the injector controller to modify the injector apparatus accordingly. '858 patent, col.6 II.31-45. The '858 patent also states that as an alternative to the encoding device being a bar code with spaced bars, the encoding device can include raised surfaces corresponding to the spaced bars that would be read

by an injector sensor, or can include mechanically readable devices such as a slot, hold, or projection on the syringe or plunger that would send information concerning the type of syringe used to the circuits of the injector. '858 patent, col.6 II.51-65. The '858 patent provides the following examples of the information that can be included in the encoding device: "dimensions of the syringe, content of the syringe in the case of a prefilled syringe, manufacturing information such as lot numbers, dates and tool cavity number, recommended contrast media flow rates and pressures, and loading/injection sequences." '858 patent col.6 II.45-51. Thus, the '858 patent clearly discloses the detection of various parameters of the syringe through the use of a bar code or other marks on the syringe.

Liebel asserts that "dimensions of the syringe" are not the same as "capacity of the syringe," as recited in the asserted claims. As the district court observed, detecting dimensions of the syringe permits calculation of capacity using a basic volumetric formula. Moreover, the '858 patent expressly lists as an example of the type of information that can be included in the bar code the "content of the syringe," which can encompass the capacity of the syringe as well as the amount of fluid in the syringe. The '858 patent also states that the encoding device can include the "loading/injection sequences," which can encompass information related to the initial position of the plunger. Moreover, although the '858 patent only provides a few examples of the types of information that can be stored in the encoding device, the list is not exclusive and may include other information logically related to the "dimensions" of the syringe or the "content" of the syringe, such as the initial plunger position. Thus, there is no genuine issue of material fact that the '858 patent, including the disclosure of the '736 patent that

is incorporated by reference, clearly discloses the limitations of the asserted claims of the syringe-sensing patents. The district court therefore did not err in concluding that the syringe-sensing patents are invalid for anticipation as a matter of law.

Liebel argued for a broad construction of the term "physical indicia" and in fact broadened its claims during prosecution to recite physical indicia other than those indicating the length of an extender. Once again, Liebel argued for a broad meaning, and succeeded, but suffers a Pyrrhic victory.

#### C. Cross-Appeals

Because we affirm the district court's conclusion that the asserted claims of the patents at issue are invalid, we need not reach Medrad's cross-appealed issues concerning infringement and inventorship, the latter actually being an alternative ground for a holding of invalidity, not a proper basis for a cross-appeal.<sup>4</sup>

### D. <u>Inequitable Conduct</u>

Medrad finally argues that the district court should not have dismissed as moot its counterclaim asserting inequitable conduct. Medrad asserts that that counterclaim is independent and distinct from an invalidity claim, and it may be the basis for two additional remedies: a determination that the entire patent is unenforceable and an award of attorney fees under 35 U.S.C. § 285.

We agree with the district court that the inequitable conduct counterclaim is moot. With regard to the argument that an inequitable conduct determination may render the entire patent unenforceable, Medrad admitted during oral arguments that such relief is

Medrad concedes that the arguments made on infringement provide alternate bases to find in its favor and that the arguments need only be addressed if we were to reverse on the issue of validity. Reply Br. n.1

not meaningful to Medrad at this time. The only other additional relief that may be available to Medrad by an inequitable conduct determination is attorney fees under 35 U.S.C. § 285. Medrad admitted during oral arguments that, although it plans to predicate an attorney fee application on inequitable conduct, it has not filed that application yet. We therefore affirm the decision that the inequitable conduct counterclaim is presently moot.

#### CONCLUSION

Because the district court correctly granted summary judgment that Liebel's patents are invalid, we affirm the conclusion that all the asserted claims are invalid, the front-loading patents on enablement and the syringe-sensing patents on anticipation grounds. Because we find no error in the district court's holding that the inequitable conduct counterclaim is moot, we affirm that decision as well.

### <u>AFFIRMED</u>