To Be Published:

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CENTRAL DIVISION

IDEAL INSTRUMENTS, INC., a Michigan corporation, Plaintiff, vs. RIVARD INSTRUMENTS, INC., a foreign corporation, and MERIL RIVARD, a foreign national, Defendants.	No. C 05-3079-MWB **MEMORANDUM OPINION AND ORDER REGARDING THE MOTION FOR PRELIMINARY INJUNCTION BY DEFENDANT RIVARD INSTRUMENTS, INC.**

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Although this lawsuit began life as a patent infringement action, the focus of attention in this ruling is whether the plaintiff is violating the false advertising provisions of § 43 of the Lanham Act, codified at 15 U.S.C. § 1125(a)(1)(B), by selling patented "detectable" hypodermic needles for livestock that are not actually "detectable," as the defendants allege in one of their counterclaims. In a motion now before the court, the defendants asserts that the plaintiff must be preliminarily enjoined from selling its "detectable" needles and enjoined to recall all such needles in the interest of public safety. The plaintiff, however, contends that the motion for a preliminary injunction is a frivolous distraction from the real patent infringement issues in the case.

I. INTRODUCTION

A. Factual Background

1. Provisional nature of findings and conclusions

The general rule is that findings of fact and conclusions of law made in a court's disposition of a motion for preliminary injunction are provisional. *See, e.g., University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) (the general rule is that "the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits," because courts must customarily decide preliminary injunction motions "on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits"); *accord Henderson v. Bodine Alum.,* Inc., 70 F.3d 958, 962 (8th Cir. 1995) (citing *Camenisch* for this "general rule"). Thus, any findings of fact in this ruling, made either in this section or in the course of the legal analysis to follow, as well as any conclusions of law forming part of the court's determination of whether the issuance of a preliminary injunction is proper in this case, are intended to be subject to this "general rule" and are not to be considered "final."[1]

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[1] At the conclusion of the hearing on Rivard's Motion For Preliminary Injunction, the parties agreed to submit a unified set of exhibits. On March 19, 2007, the court received the parties' Stipulated Exhibits Regarding Rivard's Motion For Preliminary Injunction And Ideal's Brief In Opposition To Same (Stipulated Exhibits) and the parties' Full Deposition Transcripts Filed in Connection With Motion For Preliminary Injunction. The parties represent that they have stipulated as to authenticity, genuineness, and foundation as to all of the Stipulated Exhibits in connection with Rivard's Motion For Preliminary Injunction. On the other hand, the parties have stipulated that the court must determine whether the proffered expert testimony and reports are admissible pursuant to Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Phramaceuticals*, 509 U.S. 579 (1993). Because of the court's disposition of Rivard's Motion For Preliminary Injunction, however, the court does not reach the parties' Rule 702 or (continued…)

2. The parties, patents, and products

Plaintiff Ideal Instruments, Inc., (Ideal) is a Michigan corporation with its principal place of business in Lansing, Michigan.[2] Defendant Rivard Instruments, Inc., is a closely held for-profit Canadian corporation and defendant Meril Rivard, who is a citizen of Canada and resident of Winnipeg, Manitoba, is the president and majority, if not sole, shareholder of Rivard Instruments. Unless the context requires otherwise, the court will identify the defendants singly and collectively as "Rivard." Both Ideal and Rivard manufacture "detectable" hypodermic needles for use, for example, in hypodermic syringes for livestock. The needles are "detectable" in the sense that they are made to be easily detected in the carcasses of slaughtered animals if they break off or are otherwise inadvertently left behind using metal detectors installed in meat processing plants.

More specifically, Ideal is the assignee of United States Patent No. 6,488,668 (the '668 patent) for a "detectable heavy duty needle." The '668 patent originally issued on December 3, 2002, and was upheld on *ex parte* reexamination on December 23, 2004. The Abstract for the '668 patent describes the patented invention as follows:

> The present invention provides a detectable heavy duty needle cannula for use in hypodermic syringes and the like. Needle cannula comprises a magnetizable or magnetized stainless steel alloy, which enables needle cannula to be detectable in metal detectors that are commonly used in the meat processing industry to detect broken needle cannulas in

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[1](…continued)
Daubert challenges. All citations to exhibits and deposition excerpts in this ruling are to these joint submissions, unless a pertinent exhibit, providing what the court believes is necessary context, cannot be found therein.

[2]For present purposes, the court will not distinguish between Ideal and its parent company, Neogen Corporation.

> the flesh of slaughtered animals. Needle cannula further comprises a sidewall that is thicker than the sidewalls of prior art needle cannulas. The thicker sidewall imparts to needle cannula greater resistance to breakage during the process of injecting animal health products into an animal and greater detectability in a metal detector.

Plaintiff's Exhibit 36 (the '668 patent) (component numbers omitted). Ideal is also the assignee of another patent for a "detectable heavy duty needle," United States Patent No. 6,960,196 (the '196 patent), which issued on November 1, 2005. The Abstract for the '196 patent describes the patented invention in exactly the same terms as the Abstract for the '668 patent. Defendant's Exhibit AA (the '196 patent). Ideal manufactures, sells, and distributes a product exploiting the inventions disclosed in the '668 and '196 patents under the commercial name "D3 Detectable Needles."

Similarly, Rivard Instruments owns Canadian Patent No. 2,298,277 (the '277 patent), which is a patent for "detectable stainless steel needles for meat packing," issued March 16, 2004. *See* Defendants' Motion To Dismiss (docket no. 13), Exhibit 1, attachment to Affidavit Exhibit 1A (the '277 patent). The Abstract for the '277 patent describes the patented invention as follows:

> Magnetic stainless steel needles are detectable in processed meat. The previous non magnetic versions, made of 304 stainless steel, are not. Disposable hypodermic needles made from martensitic and ferritic stainless steel are easily detectable at the smallest size. A method of detection is also disclosed.

The '277 patent. Rivard Instruments also makes products that it claims exploit the '277 patent, although Ideal disputes that the needles marketed by Rivard Instruments use the stainless steel alloys identified in the '277 patent.

The goal of "detectable" needles, as mentioned briefly above, is to prevent broken needles that are occasionally left behind in livestock at the time of injection from making

their way through the food processing chain to consumers. Concerns about the potentially devastating effects on the pork industry if broken needles were found in pork products prompted the National Pork Board (NPB) and the National Pork Producers Council (NPPC) to institute a "One Is Too Many" campaign to make producers, packers, and veterinarians aware of the problem and to encourage them to take responsibility to prevent it. These concerns also prompted the NPB to hold a "Needle Summit" in Des Moines, Iowa, in March 2000, to make those in the industry aware of the problem and to discuss strategies to try to eliminate it. The NPB also commissioned independent testing in 2000 and 2001 by Dr. Steven Hoff, now Rivard's expert witness in this litigation, to determine the extent to which veterinary hypodermic needles were detectable by metal detectors at meat processing plants. Those tests included tests of the "detectable" needles of Rivard's predecessor company, PDN. Because Ideal's D3 needles were still in development, however, Dr. Hoff did not include D3 needles in his tests in 2000 and 2001.

In 2002, Ideal commissioned Dr. Hoff to perform a battery of tests similar to those he had performed for the NPB on Ideal's D3 needles. Following those tests, Dr. Hoff concluded in a report dated November 19, 2002, that, regardless of gauge, fragment length, or orientation, "[n]eedle detection results of the Ideal D3 needle indicate[ ] clearly that these needles are 100 percent detectable for the controlled experimental conditions used. . . . The results were quite convincing in that for the testing conditions used, clearly a 100 percent detection was experienced." Plaintiff's Exhibit 20 at 3. Ideal also commissioned Dr. Hoff to conduct further testing of its D3 needles in January 2006. In his report on that testing, dated January 17, 2006, Dr. Hoff concluded that "[n]eedle detection results of the Ideal D3 20 ga[u]ge ½" long needle indicate[ ] clearly that these needles are 100 percent detectable at the ½" long fragment length for the controlled experimental conditions used in this test." Plaintiff's Exhibit 19 at 3.

3. Ideal's advertisements of its needles as "detectable"

The packaging for Ideal's D3 needles clearly identifies them as "sterile detectable needles with metal hubs," as "detectable hypodermic needles," and as "detectable needles," and identifies them as "for veterinary use only." *See* Defendant's Exhibit A. Ideal has also disseminated marketing literature, based on the test results described above, that describes D3 needles as having "superior detectability" and as having been "found to be 100% detectable" under specified test conditions, Defendant's Exhibit B, and as made from a "detectable alloy" or "patented alloy" that allows them to be "as much as 100% detectable." Defendant's Exhibit C. Ideal also maintains, and Rivard apparently does not dispute, that Ideal has sold many millions of D3 needles in the last six years without a single reported incident of a D3 needle breaking, passing undetected through a metal detector, and finding its way into a consumer's food. Thus, Ideal contends, and the court finds, that there is no evidence that anyone has been misled or harmed by Ideal's marketing of its D3 needles as "detectable" nor is there any evidence that anyone has been physically injured by the failure of a D3 needle to be detected.

Rivard does contend, however, that Ideal has acknowledged receiving reports of needles breaking in the field, that Ideal has recalled needles on at least one prior occasion, and that Ideal had received reports of D3 needles not being detected in some situations. It is true that Mr. Bohanon, Ideal's Vice President and Rule 30(b) deponent, testified in deposition that AgProvision had notified Ideal on one occasion of a complaint that two needles broke and that seven needle cannulas pulled out of the hub. Defendant's Exhibit G, Bohanon Deposition at 167-68. However, the court finds that Mr. Bohanon testified that he had no basis to state that there had been other instances of broken needles; that Ideal responded to AgProvision's report by conducting additional testing of various lots of D3 needles to ensure that the problem was not widespread; and that the problem

with the cannula pulling out of the hub was attributed to problems with "swedging" the cannula onto the hub. *Id.* None of this testimony, or other testimony by Mr. Bohanon on which Rivard relies for its contentions, demonstrates that the needles in question were not "detectable." Mr. Bohanon also acknowledged a report from a veterinary customer and one of its customers that some needles had not been detectable depending on the orientation of the needles as they ran through a detector. Defendant's Exhibit H, Bohanon Deposition (Sealed Portion) at 170. There is no indication, however, that such a problem was extensive or occurred on more than one isolated occasion. Finally, the needle recall referred to by Rivard involved circumstances in which Ideal found that a certain lot or a specific gauge of detectable needles failed a "push-pull" test, and those lots were recalled, but again, the recall did not involve "detectability." *See* Defendant's Exhibit H, Bohanon Deposition (Sealed Portion) at 188-89.

In short, Rivard's evidence demonstrates nothing more than isolated failures and manufacturing problems that were the proverbial needles in haystacks, not persistent problems with "detectability" of D3 needles. Moreover, the lack of any evidence that these reports of problems in the field resulted in any harm to the public, the livestock industry, or the meat processing industry, and the lack of any evidence that the recall of needles did not prevent any such harm, demonstrates that there is presently no public health risk requiring a recall of any of Ideal's D3 needles or a prohibition on any sales of such needles.[3]

[3]Indeed, Ideal presented evidence that Rivard has had its own product recalls and other manufacturing problems. Thus, if the isolated incidents of problems with Ideal's products require the extensive preliminary injunctive relief that Rivard requests, then it would follow that Rivard's similar problems would justify the same relief as to its products.

4. The dispute over "detectability" of Ideal's needles

Notwithstanding Ideal's assertions in its advertising and packaging that its D3 needles are "detectable" and the test results upon which Ideal relied to support those assertions, Meril Rivard maintained at "Needle Summit II," a meeting of hog industry representatives hosted by the NPB in Kansas City, Missouri, on December 2, 2004, that the D3 needles made by Ideal are not "detectable." Rivard asserts that same argument as the basis for its motion for a preliminary injunction, which is now before the court. The basis for that contention, and Ideal's contrary evidence, requires further exploration.

a. Dr. Hoff's October 2006 tests

Rivard's motion for preliminary injunction, at least initially, relied exclusively on the results of testing of Ideal's D3 needles that Dr. Hoff conducted at Rivard's request in October 2006. That testing was performed on twenty D3 needles drawn from a box provided by Ideal during the parties' tutorial to the court in this litigation, boxes purchased in Sioux City, Iowa, on September 7, 2006, and boxes from Rivard's "archives." Dr. Hoff's conclusions in a report dated October 27, 2006, were as follows:

> 1. Large variations existed in the detection signal for the Ideal D3 needles in both the center-line and product testing conducted.
> 2. Large variations were measured for many of the Ideal D3 needles tested, within a specific test and within a specific lot of needles. For example needle ID 8 had 3 of 5 randomly selected needles from the same box that were significantly different from the other two.
> 3. For the twenty Ideal D3 needle cannulas selected from ten unique lots, eleven of the cannulas would not have been rejected as it [sic] passed through the detector. This non-detection rate corresponds to 55 percent.
> 4. The Rivard needle cannulas tested were all highly detectable and all were rejected as they passed through

the detector. This finding was not a function of the needle gauge tested.

5. The Rivard 20 gauge HDN needle cannula had a detection signal, recorded during product testing, that was far greater than eight of the ten Ideal D3 needle cannulas tested where seven of the eight Ideal D3 needles were 16 gauge sized needles.

Defendant's Exhibit E at 12-13.

Admittedly, a 55% failure rate for what are supposed to be "detectable" needles would be frightening. In his deposition, however, Dr. Hoff conceded that the procedures he used in the October 2006 testing differed significantly from the procedures used in the "detectability" testing commissioned by the NPB and Ideal. Key differences included the following: (1) using a Fortress model Phantom metal detector, provided by Rivard, with a fixture developed by Rivard that allowed a needle to be tested at the center of the detector aperture, rather than a Safeline metal detector used in prior testing; (2) using needles of an uncertain chain of custody; (3) using a 1.5 lb. boneless pork loin roast rather than the standard cut of 3.5 lb. pork shoulder roast used in Dr. Hoff's prior testing; (4) using results based on the detection signal from the Fortress metal detector provided by Rivard rather than results indicating whether or not the needles were detected; (5) using further adjustments, after the Fortress detector had automatically removed the effect of a product passing through the aperture of the detector, to adjust the sensitivity until the product was not detected as it passed through the aperture, without explanation of why further adjustments were required; (6) manually pushing product partially through the aperture and then pulling it back out, at uncertain and varying speeds in uncertain orientation to the coil of the detector, taking only two readings per test, instead of using a conveyor operating at a constant speed to carry the product all the way through the

aperture; and (7) using D3 needles in only one orientation without explanation of whether the needles were placed perpendicular or parallel to the long axis of the detector. In addition, Dr. Hoff acknowledged in a subsequent deposition that D3 needles are detectable, notwithstanding his test results. Plaintiff's Exhibit 10, Hoff Deposition at 111. Dr. Hoff also conceded that the fact that certain needles were "not rejected," as indicated in his October 27, 2006, report, did not mean that the needles were not "detectable." Plaintiff's Exhibit 6, Hoff Deposition at 181. Dr. Hoff also recanted prior testimony that the results of his October 2006 testing were "statistically" significant. Plaintiff's Exhibit 6, Hoff Deposition at 180-81. Finally, Dr. Hoff conceded that he had not had any peer reviews of the protocol he used and that his tests probably would not survive peer review for validity or reliability. Plaintiff's Exhibit 6, Hoff Deposition at 61, 79, 151.

The court finds that Dr. Hoff's testing in October 2006 has no probative value whatsoever concerning the "detectability" of Ideal's D3 needles within the meaning of the livestock and meat processing industries owing to the flawed procedures that bore no relationship to industry conditions or the conditions of prior tests commissioned by the NPB.

b. Dr. Hoff's November 2006 testing

On November 22, 2006, apparently on his own initiative, Dr. Hoff conducted further testing of D3 needles. Dr. Hoff's report from that testing states, "My main interest was to test the needle IDs listed in the 10/27/2006 report strictly with a needle imbedded in a product, and to test the detection characteristics with two product sizes." Plaintiff's Exhibit 8 at 1. Dr. Hoff's conclusions in his November 22, 2006, report were as follows:

> Needle detection is exacerbated by the fact that needles used in the agricultural industry will be imbedded in a product that is wet and salty, both conditions that result in an electrically conductive media that will be detected as it passes

> through the aperture of a three-coil detection system typically used in packing plants. Therefore, to avoid false positives, the detector's sensitivity ultimately needs to be reduced resulting in a challenging situation for detecting needles. The supplemental results given in this report tested five scenarios that could conceivably be present at the packing plant. The results pointed out the need for needles that elicit a detection signal that far exceeds the signal of a product, even after the "product-effect" has been calibrated. Several of the Ideal D3 and Monoject needles tested struggled in this regard using the Fortress® Phantom detector.
>
> As with the original testing reported in the 10/27/2006 report, large differences between the Fortress® Phantom detector signals were observed between the needles tested. For the Ideal D3 needles, representing needle IDs 1 through 10 inclusive, the needle ID groups 1, 2, 7, 8 and 9 in general exhibited higher average detection signals compared to Ideal D3 needle Ids 3, 4, 5, 6, and 10. Needle IDs 7 and 8 also exhibited large variations between the four needles tested within each needle ID even though the average detection signal was considerably higher than the Ideal D3 needles 3, 4, 5, 6, and 10. These trends in detection signal differences persisted regardless of product size or Fortress® Phantom detector setting. Also, and as shown with Test 5 where the needles entered the detector with the long axis perpendicular to the product flow direction, the differences between the Ideal D3 needles lessened. Also, the variation with needle IDs 7 and 8 lessened considerably as well when these needles entered the detector with the long axis perpendicular to the product flow direction.

Plaintiff's Exhibit 8 at 5. Although the procedures employed in this round of testing may have remedied some of the deficiencies in Dr. Hoff's October 2006 testing, those procedures did not confirm that D3 needles are not "detectable." Rather, in a second deposition on December 9, 2006, Dr. Hoff acknowledged that, after his November 2006

testing, "the evidence would support" that D3 needles are detectable. Plaintiff's Exhibit 10, Hoff Deposition at 111. Thus, Dr. Hoff's supplemental testing does not support a conclusion that Ideal's D3 needles are not "detectable."

c. Ideal's testing

Rivard contends that Ideal has not engaged in routine testing of the "detectability" of its needles and, until recently, did not have a metal detector available to conduct such testing, apparently suggesting that Ideal has irresponsibly relied on its manufacturer to use the correct alloy of stainless steel to ensure the "detectability" of its needles and that, as a consequence, non-detectable needles have been marketed as "detectable." Ideal contends, and the court finds, however, that both Ideal and its Chinese manufacturer have tested Ideal's D3 needles for "detectability."

First, the court finds that Toku-E Medical Appliance, located in Shanghai, China, the company that has manufactured D3 needles for the last six years, tests every lot of needles using a flatbed metal detector to ensure detectability before shipping the needles to Ideal, and every test has confirmed the detectability of the needles. Plaintiff's Exhibit 26, Pan Declaration ¶ 6. Although Rivard contends, and the court finds, that the metal detector used by Toku-E is different from the kind of metal detector used in the meat processing industry in the United States, the court also finds that Ideal has now purchased a Safeline Powerphase Plus metal detector for its Lansing, Michigan, facility, which it uses to test every lot of D3 needles that it receives from Toku-E. Plaintiff's Exhibit 14, Herbert Declaration, ¶ 20. In addition, Ideal now regularly sends out D3 needles from Toku-E to Chicago Spectro for metallurgy testing to ensure that its D3 needles are made from duplex stainless steel meeting Ideal's specifications. Plaintiff's Exhibit 14, Herbert Declaration, ¶ 20. Under the circumstances, the court finds that, at least now, Ideal

conducts adequate testing to ensure that its D3 needles are, indeed, "detectable" and are made from the kind of stainless steel identified in its manufacturing specifications.

Also, in response to Dr. Hoff's tests in late 2006, Ideal conducted its own testing of D3 needles using a Safeline Powerphase Plus metal detector at the Safeline Test Laboratory in Tampa, Florida, in which both the set-up and the testing were supervised by a Safeline employee. Ideal contends, and Rivard does not dispute, that Safeline is the largest metal detector manufacturer in the world and that its metal detectors are regularly used in the meat processing industry. Ideal's December 2006 tests were conducted in light of confirmation by Safeline technical staff that the conditions in Dr. Hoff's tests in late 2006 were unlikely to be encountered in a packing plant. Plaintiff's Exhibit 27, Cook Report at 1. More specifically still,

> The purpose of the Cook 2006 study was to test the detectability of identical or closely related lots of Ideal D3 needles as those tested by Hoff in late 2006. In the Cook 2006 study, a Safeline Powerphase system was used with machine settings that are known to be representative of the conditions found on a processing line in a packing plant. The meat product used was a 3.67 lb. pork shoulder roast which was similar in size to the cuts used in previous tests and was passed through the machine at a rate of 100 FPM on a Safeline Intralox conveyor system.

Plaintiff's Exhibit 27, Cook Report at 3. The results of the tests were also demonstrably different from the results in Dr. Hoff's October 2006 tests:

> In contrast to the results reported by Hoff, this test clearly shows that all D3 needles tested from all six lots were detected 100% of the time in any orientation. Out of 60 possible test events, 53 fragments tested recorded the maximum detection level of 20 Red Bars. The remaining seven (7) test events were detected at a level of 12 Red Bars in the most difficult orientation. It should be noted that twelve (12) Red Bars is a

> strong detection signal. A signal of at least one Red Bar is considered by Safeline to be a detection event and consequently all of these fragments would be easily detected.

Plaintiff's Exhibit 27, Cook Report at 8. The Report concluded as follows: "A meat sample containing any of the fragments from any of the six lots of D3 needles tested in any orientation would have been rejected in every case." *Id.*

Unlike the "detectability" tests by Dr. Hoff in October and November 2006, the court finds that Ideal's December 2006 tests are probative of whether or not Ideal's D3 needles are "detectable" within the meaning of the livestock and meat processing industries and that such tests demonstrate that the needles are, in fact, "detectable" within the meaning of those industries. Ideal's December 2006 tests, like Dr. Hoff's independent tests for the NPB in 2000-2001 and Dr. Hoff's tests commissioned by Ideal in 2002 and 2006, used valid samples and procedures to determine "detectability" of needles in conditions realistically approximating conditions in meat processing plants. Moreover, in light of the lack of probative value of Dr. Hoff's October 2006 tests and the probative value of the "detectability" tests commissioned by Ideal, the court finds that Ideal's D3 needles are "detectable" within the meaning of the livestock and meat processing industries.

d. The "wrong steel" dispute

Belatedly changing the basis for its motion for preliminary injunction, or at least belatedly stating an alternative to Dr. Hoff's testing as the basis for that motion, Rivard now asserts that there are also problems with the metallurgy of Ideal's D3 needles. Specifically, Rivard points to deposition testimony of Ideal representatives that Rivard characterizes as showing that Ideal relied entirely on the metallurgy of its needles to ensure detectability, without adequate routine testing; that there is potential variation in the

detectability of the needles arising from the manufacturing process for the steel; and that at least some of Ideal's D3 needles were made with a stainless steel alloy that Ideal acknowledges is not sufficiently "detectable." The court will consider the evidence on these points in turn.

The court finds that, even if Ideal has, in the past, relied substantially or entirely on the metallurgy of its needles to ensure the detectability of its needles, the evidence shows that Ideal does not now do so. Rather, as mentioned above, the court finds that Toku-E, Ideal's Chinese manufacturer, tests every lot of needles using a flatbed metal detector to ensure detectability before shipping the needles to Ideal, and every test has confirmed the detectability of the needles. Plaintiff's Exhibit 26, Pan Declaration ¶ 6. Moreover, as also mentioned above, the court finds that Ideal has now purchased a Safeline Powerphase Plus metal detector for its Lansing, Michigan, facility, which it uses to test every lot of D3 needles that it receives from Toku-E. Plaintiff's Exhibit 14, Herbert Declaration, ¶ 20. In addition, Ideal now regularly sends out D3 needles from Toku-E to Chicago Spectro for metallurgy testing to ensure that its D3 needles are made from duplex stainless steel. *Id*. Also, as mentioned above, despite the lack of routine metallurgical testing until recently, there is no convincing evidence that D3 needles have been "undetectable," not least because there have been no widespread or repeated complaints of "undetectability" in the field and no evidence of a single instance in which a D3 needle passed entirely through the livestock production and meat processing system to a consumer. Under the circumstances, the court finds that, at least now, Ideal conducts adequate testing to ensure that its D3 needles are, indeed, "detectable," without relying exclusively on the metallurgy of its needles, which could be subject to variation owing to manufacturing processes or substitution of the "wrong" alloys, and there is no convincing

evidence that its prior failure to conduct such testing resulted in a danger to the public from "undetectable" needles entering the stream of commerce.

The issue of the variations in the metallurgy of Ideal's "detectable" needles, however, still requires some further scrutiny. Rivard contends that recent metallurgical testing that it commissioned has revealed that some of Ideal's "detectable" needles have *not* been made of "duplex" stainless steel alloys, such as types 329, 2205, and 2209—which Ideal accepts as meeting its specifications—but have, instead, been made of austenitic type 304 stainless steel, which Rivard contends Ideal has acknowledged is not sufficiently "detectable" to use in its "detectable" needles. More specifically, on January 10, 2007, Rivard received a report from Edward D. Vojcak, P.E., Senior Metallurgical Engineer of Bodycote Materials Testing, Inc., of a test that Rivard had commissioned of the metallurgy of D3 needles from three boxes that had been identified by Dr. Hoff as numbers 3, 4, and 6. *See* Defendant's Exhibit L. Mr. Vojcak's report states that those D3 needles were made from type 304 stainless steel, not from duplex type 329 or type 2205. Mr. Vojcak issued another report on January 30, 2007, of tests of four samples from a second set of needles provided to him. *See* Defendant's Exhibit M. Three of those samples were D3 needles, one of which was determined to be made from duplex type 2205 stainless steel and two of which were determined to be made from a stainless steel most closely conforming to type 2205. The fourth sample was determined to be made from austenitic 304 stainless steel, but consisted of needles made by another maker, Monoject, that were not marketed as "detectable." Finally, Mr. Vojcak issued another set of reports on January 30, 2007, of five more samples of D3 needles, but not from boxes tested by Dr. Hoff. *See* Defendant's Exhibits N, O, P, Q, R. Four of the samples were from unopened boxes. Mr. Vojcak's report showed that three of the four samples from unopened boxes were determined to be made from type 304 stainless steel, while samples

from the fourth unopened box and from the fifth box were determined to be a material most closely conforming to type 304. The samples in this test bore manufacturing dates between February 2005 and June 2006.

At the hearing, Rivard attempted to correlate metallurgical tests with Dr. Hoff's tests in October and November 2006 to demonstrate that D3 needles that produced poor signals in metal detector tests were made from type 304 stainless steel. Even if there is such a correlation, however, for the reasons stated above, Dr. Hoff's October 2006 tests have no probative value on "detectability," so a significant point of reference is lacking. Moreover, as Ideal points out, Dr. Hoff has admitted that needles made from type 304 stainless steel are detectable, and metallurgy tests reveal that Rivard also makes or made some of its "detectable" needles from type 304 stainless steel. Ideal has also submitted the affidavit of Terri Morrical, a Vice President of Ideal's parent company, Neogen, averring that, when Ideal learned from Rivard's tests that some of Ideal's D3 needles are made from type 304 stainless steel, not a duplex steel as required by the specifications to Ideal's manufacturer, out of an abundance of caution, she quarantined all remaining D3 needles from affected lots, and none of those quarantined needles have ever been sold or distributed. Plaintiff's Exhibit 34. Thus, there is no convincing evidence that the use of the "wrong" stainless steel alloy in some of Ideal's D3 needles resulted in needles that were not "detectable" or that were a danger to the public.

B. Procedural Background

1. Ideal's claims

Ideal filed the present lawsuit on December 30, 2005. In its original Complaint, Ideal asserted claims of infringement by Rivard Instruments and Meril Rivard of Ideal's '196 patent for "detectable" hypodermic needles for livestock, non-infringement by Ideal

of the defendants' Canadian patent for a similar device, and various commercial torts. By order dated May 8, 2006, the court dismissed Ideal's claim of non-infringement of Rivard's Canadian patent for lack of subject matter jurisdiction, but otherwise denied Rivard's motion to dismiss, *see Ideal Instruments, Inc. v. Rivard Instruments, Inc.*, 434 F. Supp. 2d 598 (N.D. Iowa 2006) (*Ideal Instruments I*), and by order dated June 21, 2006, the court granted Ideal's motion to amend its Complaint and granted Rivard's motion to stay proceedings to the extent that the court stayed Ideal's claims of defamation and tortious interference with business relations pending resolution of litigation in Canada concerning the validity and infringement of Rivard's Canadian patent. *See Ideal Instruments, Inc. v. Rivard Instruments, Inc.*, 434 F. Supp. 2d 640 (N.D. Iowa 2006) (*Ideal Instruments II*). Ideal filed further amended complaints, so that the operative document is now Ideal's Third Amended Complaint filed December 29, 2006 (docket no. 122). The claims in Ideal's Third Amended Complaint that are now before the court and not stayed are the following: infringement by Rivard Instruments of Ideal's '668 patent in Count I; infringement, including inducing infringement, by Meril Rivard of Ideal's '668 patent in Count II; infringement by Rivard Instruments of Ideal's '196 patent in Count III; infringement, including inducing infringement, by Meril Rivard of Ideal's '196 patent in Count IV; and product disparagement or trade libel by both defendants in Count VI.

2. Rivard's answer and motion for preliminary injunction

Rivard filed its Answer (docket no. 129) to Ideal's Third Amended Complaint on January 16, 2007, denying Ideal's claims and asserting numerous affirmative defenses and counterclaims. Of interest here is Rivard's Eighth Counterclaim, which asserts a "false descriptions" form of "false advertising" in violation of § 43 of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). That counterclaim alleges, in essence, that Ideal advertises its D3 needles as "detectable," but such needles are not sufficiently detectable as understood in

the detectable hypodermic needle and meat processing industries, so that Ideal's representations constitute false statements of fact.[4] Ideal denies all of Rivard's counterclaims. *See* Plaintiff's Answer And Affirmative Defenses To Second Amended Counterclaims filed February 5, 2007 (docket no. 142).

Rivard filed the original version of the Motion For Preliminary Injunction now before the court on October 30, 2006 (docket no. 85). Although the court set a hearing on the original Motion For Preliminary Injunction for December 20, 2006, various supplements to the motion and disputes about the basis for the motion delayed a hearing on the Motion For Preliminary Injunction until March 13, 2007. In the interim between the filing of its original Motion For Preliminary Injunction and the hearing, Rivard filed supplements or amendments to its Motion on November 28, 2006 (docket no. 105), December 12, 2006 (docket no. 115); and February 2, 2007 (docket no. 140). Ideal filed a comprehensive Opposition (docket no.153) to Rivard's motion on March 7, 2007. Rivard filed a Reply (docket no. 154) on March 9, 2007, and on March 10, 2007, Ideal filed two further declarations (docket no. 155) in response to what Ideal contends are "new" arguments in Rivard's Reply.

3. The hearing on the motion for preliminary injunction

At the hearing on March 13, 2007, plaintiff Ideal was represented by Mark R. Fox and Toni L. Harris of Fraser, Trebilcock, Davis & Dunlap, P.C., in Lansing, Michigan, both of whom presented portions of Ideal's argument. Defendants Rivard Instruments and Meril Rivard were represented by Terence J. Linn, who argued on their behalf, and Karl T. Ondersma of Van Dyke, Gardner, Linn & Burkhart, L.L.P., in Grand Rapids,

[4]This counterclaim includes allegations of other false statements in Ideal's advertising of its D3 needles, but those allegations are not material to the present motion for preliminary injunction.

Michigan, and local counsel Angela E. Dralle of Dorsey & Whitney, L.L.P., in Des Moines, Iowa.

Although the parties had submitted copious exhibits in support of and resistance to Rivard's Motion For Preliminary Injunction and its various supplements, neither party appeared with witnesses to establish the necessary foundation for those exhibits. Thus, much of the time set aside for the hearing in this matter was actually occupied with the parties' attempts to reach various stipulations on the admissibility of certain exhibits. Once such stipulations were reached, the parties agreed to submit to the court a unified set of exhibits within the next two business days. The court then heard arguments from both sides. The parties agreed that no further briefing would be required, once the court received the unified set of exhibits.

The logistical problems involved in assembling a unified set of exhibits exceeded the parties' expectations. Therefore, the court received the parties' Stipulated Exhibits Regarding Rivard's Motion For Preliminary Injunction And Ideal's Brief In Opposition To Same (Stipulated Exhibits) on March 19, 2007. With the receipt of the Stipulated Exhibits, however, Rivard's Motion For Preliminary Injunction was, at long last, fully submitted.

II. LEGAL ANALYSIS

A. Standards For A Preliminary Injunction

As this court has explained in past cases, it is well-settled in this circuit that applications for preliminary injunctions and temporary restraining orders[5] are generally

[5] In *Branstad v. Glickman,* 118 F. Supp. 2d 925, 937 (N.D. Iowa 2000), this court also discussed in some detail the differences between a temporary restraining order and a preliminary injunction. *See Branstad,* 118 F. Supp. 2d at 935-937. Suffice it to say that, (continued…)

measured against the factors set forth in the seminal decision in *Dataphase Systems, Inc. v. C L Systems, Inc.,* 640 F.2d 109, 113 (8th Cir. 1981) (*en banc*). *See Interbake Foods, L.L.C. v. Tomasiello*, 461 F. Supp. 2d 943, 954-55 (N.D. Iowa 2006); *Doctor John's, Inc. v. City of Sioux City, Iowa,* 305 F. Supp. 2d 1022, 1033-34 (N.D. Iowa 2004); *Branstad v. Glickman,* 118 F. Supp. 2d 925, 937 (N.D. Iowa 2000); *Uncle B's Bakery, Inc. v. O'Rourke,* 920 F. Supp. 1405, 1411 (N.D. Iowa 1996); *accord Straights and Gays for Equality v. Osseo Area Sch. Dist.*, 471 F.3d 908, 911 (8th Cir. 2006) (same factors); *Lankford v. Sherman*, 451 F.3d 496, 503 (8th Cir. 2006) (same factors). These so-called "*Dataphase* factors" include the following: (1) the movant's probability of success on the merits, (2) the threat of irreparable harm to the movant absent the injunction, (3) the balance between the harm and the injury that the injunction's issuance would inflict on other interested parties, and (4) the public interest. *Dataphase,* 640 F.2d at 114; *accord Interbake Foods, L.L.C.*, 461 F. Supp. 2d at 955; *Doctor John's, Inc.,* 305 F. Supp. 2d at 1033; *Branstad,* 118 F. Supp. 2d at 937 (quoting similar factors from *Entergy, Ark., Inc. v. Nebraska,* 210 F.3d 887, 898 (8th Cir. 2000)); FED. R. CIV. P. 65(b)(1). The Eighth Circuit Court of Appeals has applied the *Dataphase* factors to determine whether or not to enter a preliminary injunction against conduct that allegedly violates the false or deceptive advertising provisions of § 43(a) of the Lanham Act. *See, e.g., United Industries Corp. v. Clorox Co.*, 140 F.3d 1175, 1179-84 (8th Cir. 1998); *Sanborn Mfg. v. Campbell Hausfeld/Scott Fetzer Co.*, 997 F.2d 484, 488 (8th Cir. 1993) (deceptive

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[5](…continued)
in that case, the court found the following factors should be considered to distinguish a temporary restraining order (TRO) from a preliminary injunction: (1) whether the hearing was *ex parte* or adversarial; (2) whether the adversarial hearing allowed the basis for the relief requested to be strongly challenged; (3) whether the order expired, by its own terms, within the ten days provided by Rule 65(b); and (4) the "substance" of the order. *Id.*

advertising action under the Lanham Act). Therefore, the *Dataphase* factors guide the court's analysis of Rivard's Motion For Preliminary Injunction which seeks to enjoin false advertising that allegedly violates § 43(a).

When applying the *Dataphase* factors, the burden is on the movant to establish that a preliminary injunction is appropriate. *Lankford*, 451 F.3d at 503; *Baker Elec. Co-op., Inc. v. Chaske*, 28 F.3d 1466, 1472 (8th Cir. 1994); *Modern Computer Sys., Inc., v. Modern Banking Sys., Inc.*, 871 F.2d 734, 737 (8th Cir. 1989) (*en banc*). "'No single [*Dataphase*] factor in itself is dispositive; in each case all of the factors must be considered to determine whether on balance they weigh towards granting the injunction.'" *Baker Elec. Co-op.*, 28 F.3d at 1472 (quoting *Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc.*, 815 F.2d 500, 503 (8th Cir. 1987) (citing *Dataphase*)); *accord Lankford*, 451 F.3d at 503 ("No single factor is dispositive, as the district court must balance all factors to determine whether the injunction should issue.") (citing *Baker Elec. Co-op.*); *Bandag, Inc. v. Jack's Tire & Oil, Inc.,* 190 F.3d 924, 926 (8th Cir. 1999) ("These factors are not a rigid formula."). "'A district court has broad discretion when ruling on requests for preliminary injunctions, and [the appellate court] will reverse only for clearly erroneous factual determinations, an error of law, or an abuse of that discretion.'" *Entergy, Ark., Inc.,* 210 F.3d at 898 (quoting *United Indus. Corp,* 140 F.3d at 1179); *accord Lankford*, 451 F.3d at 503. The court abuses its discretion "where the district court rests its conclusion on clearly erroneous factual findings or erroneous legal conclusions." *Lankford*, 451 F.3d at 503-04.

The court will apply these standards in its disposition of Rivard's Motion For Preliminary Injunction, as that motion has been repeatedly supplemented, taking each of the *Dataphase* factors in turn.

B. Application Of The Standards

1. Likelihood of success on the merits

The first "*Dataphase* factor" that courts must consider when ruling on an application for a preliminary injunction is the likelihood or probability of success on the merits. *Dataphase*, 640 F.2d at 114. When considering this factor, the court is not deciding whether the movant for a preliminary injunction will ultimately win. *Glenwood Bridge, Inc. v. City of Minneapolis*, 940 F.2d 367, 371 (8th Cir. 1991); *O'Connor v. Peru State Coll.*, 728 F.2d 1001, 1002 (8th Cir. 1984) (in such preliminary proceedings, "the court should avoid deciding with any degree of certainty who will succeed or not succeed."). Rather, to weigh in the movant's favor, the movant's success on the merits must be "at least . . . sufficiently likely to support the kind of relief it requests." *Sanborn Mfg.*, 997 F.2d at 488 (deceptive advertising action under the Lanham Act in which the court concluded that either result argued by the opposing parties was directly supported by the evidence presented, so that the district court did not err in finding the movant did not appear likely to succeed on the merits). To determine "likelihood of success," the court must recognize the speculative nature of the inquiry at the preliminary injunction phase and "'flexibly weigh the case's particular circumstances to determine whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined.'" *United Indus. Corp.*, 140 F.3d at 1179. Thus, likelihood of success on the merits requires that the movant find support for its position in governing law. *See, e.g., Baker Elec. Co-op.*, 28 F.3d at 1473-74 (Indian tribe's sovereignty to regulate electrical services); *ILQ Inv., Inc. v. City of Rochester*, 25 F.3d 1413, 1416 (8th Cir. 1994) (first amendment and prior restraint of expression); *City of Timber Lake v. Cheyenne River Sioux Tribe*, 10 F.3d 554, 556-58 (8th Cir. 1993) (Indian tribe's regulatory authority and authority of states to regulate activities on tribal

lands); *Aziz v. Moore*, 8 F.3d 13, 15 (8th Cir. 1993) (denial of injunctive relief was proper because federal courts "must abstain from imposing injunctions on prison officials [in an action under 42 U.S.C. § 1983 action] 'in the absence of a concrete showing of a valid claim and constitutionally mandated directives for relief,'" quoting *Rogers v. Scurr*, 676 F.2d 1211, 1214 (8th Cir. 1982)). The court must, therefore, consider the law applicable to Rivard's Lanham Act claim to determine Rivard's likelihood of success on such a claim. *See United Indus. Corp.*, 140 F.3d at 1179-80 (considering likelihood of success on a Lanham Act false advertising claim); *Sanborn Mfg. Co., Inc.*, 997 F.2d at 486-87 (considering likelihood of success on a Lanham Act deceptive advertising claim).

a. Elements of Rivard's false advertising claim

The purpose of the Lanham Act, generally, is "'to protect persons engaged in commerce against false advertising and unfair competition.'" *Allsup, Inc. v. Advantage 2000 Consultants, Inc.*, 428 F.3d 1135, 1138 (8th Cir. 2005); *American Italian Pasta Co. v. New World Pasta Co.*, 371 F.3d 387, 390 (8th Cir. 2004) (same). More specifically, § 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125(a), provides for a civil action as follows:

> (1) Any person who, on or in connection with any goods or services . . . uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
>
> > (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). Subsection (a)(1)(A) defines a "false endorsement" claim, while subsection (a)(1)(B) defines a "false advertising" claim. *American Ass'n of Orthodontists v. Yellow Book USA, Inc.*, 434 F.3d 1100, 1102 (8th Cir. 2006).

In its counterclaim pursuant to § 43 of the Lanham Act, Rivard alleges, in essence, that Ideal advertises its D3 needles as "detectable," but such needles are not sufficiently detectable as understood in the detectable hypodermic needle and meat processing industries, so that Ideal's representations constitute false statements of fact. Thus, the crux of Rivard's Lanham Act counterclaim is an allegation of "false advertising," in violation of 15 U.S.C. § 1125(a)(1)(B), in that Rivard alleges that Ideal has, in its commercial advertising, misrepresented the nature, characteristics, or qualities of its D3 needles by stating that they are "detectable." *See* 15 U.S.C. § 1125(a)(1)(B) (prohibiting a false or misleading statement of fact about, *inter alia*, the "nature, characteristics, qualities" of products or services). In contrast, the court finds no allegation in Rivard's Eighth Counterclaim that would fall within a "false endorsement" claim. *See* 15 U.S.C. § 1125(a)(1)(A) (prohibiting any "false or misleading description of fact, or false or misleading representation of fact, which . . . is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person"). Thus, Rivard's § 43(a) claim is cognizable, if at all, as a "false advertising" claim.

The Eighth Circuit Court of Appeals has recognized that most, but not all, of the Circuit Courts of Appeals have held that a "false advertising" claim that does not involve misuse of a trademark is actionable only when brought by competitors of the alleged wrongdoer. *American Ass'n of Orthodontists*, 434 F.3d at 1103-04 (citing cases). Here, Rivard and Ideal are plainly competitors, so such a requirement is met in this case, and Rivard has standing to assert such a claim.

To establish a "false advertising" claim, Rivard would ultimately have to prove the following: (1) Ideal made false statements about its own product; (2) Ideal's statements actually deceived or had the tendency to deceive a substantial segment of its audience; (3) the deception created was material; (4) Ideal caused the false statement to enter interstate commerce; and (5) Rivard has been or is likely to be injured as a result of Ideal's alleged false advertisement. *Allsup, Inc.*, 428 F.3d at 1138; *American Italian Pasta Co.*, 371 F.3d at 390 (in turn citing *United Indus. Corp.*, 140 F.3d at 1180); *Blue Dane Simmental Corp. v. American Simmental Ass'n*, 178 F.3d 1035, 1042 (8th Cir. 1999) (same). "'In addition, to recover money damages under the Act, a "[p]laintiff must prove both actual damages and a causal link between defendant's violation and those damages."'" *Blue Dane*, 178 F.3d at 1042 (quoting *United Indus. Corp.*, 140 F.3d at 1180, in turn quoting *Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 515 (8th Cir. 1996)). For present purposes, of course, where the court is considering a preliminary injunction based on alleged false advertising, the question is whether Rivard has sufficient likelihood of proving these elements to satisfy the "likelihood of success" factor. *See Dataphase,* 640 F.2d at 114.

b. Analysis

i. Factual statement. A "false advertising" claim must, first and foremost, be based on a *factual* statement. *See American Pasta Co.*, 371 F.3d at 391; *see also* 15

U.S.C. § 1125(a)(1)(B) ("Any person who, on or in connection with any goods or services . . . uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description *of fact*, or false or misleading representation *of fact*, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.") (emphasis added). As the Eighth Circuit Court of Appeals has explained,

> A factual claim is a statement that "(1) admits of being adjudged true or false in a way that (2) admits of empirical verification." *Pizza Hut[, Inc. v. Papa John's Int'l, Inc.]*, 227 F.3d [489,] 496 [(5th Cir. 2000)] (quoting *Presidio Enters., Inc. v. Warner Bros. Distrib. Corp.*, 784 F.2d 674, 679 (5th Cir. 1986)). To be actionable, the statement must be a "specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact." *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999); *cf. United Indus.*, 140 F.3d at 1180 (noting puffery does not include "false descriptions of specific or absolute characteristics of a product and specific, measurable claims of product superiority"). Generally, opinions are not actionable. *Coastal Abstract*, 173 F.3d at 731.

American Italian Pasta Co., 371 F.3d at 391. To put it another way, false descriptions of specific or absolute characteristics of a product and specific, measurable claims of superiority based on product testing are actionable. *United Indus. Corp.*, 140 F.3d at 1180. On the other hand, statements that are "puffery" are not actionable. *American Italian Pasta Co.*, 371 F.3d at 390. "Puffery exists in two general forms: (1) exaggerated statements of bluster or boast upon which no reasonable consumer would rely; and (2)

vague or highly subjective claims of product superiority, including bald assertions of superiority." *Id.* at 390-91 (citing *Pizza Hut, Inc.*, 227 F.3d at 496-97; *United Indus. Corp.,* 140 F.3d at 1180).

Thus, as the Eighth Circuit Court of Appeals has explained,

> Puffery and statements of fact are mutually exclusive. If a statement is a specific, measurable claim or can be reasonably interpreted as being a factual claim, i.e., one capable of verification, the statement is one of fact. Conversely, if the statement is not specific and measurable, and cannot be reasonably interpreted as providing a benchmark by which the veracity of the statement can be ascertained, the statement constitutes puffery. Defining puffery broadly provides advertisers and manufacturers considerable leeway to craft their statements, allowing the free market to hold advertisers and manufacturers accountable for their statements, ensuring vigorous competition, and protecting legitimate commercial speech.

American Italian Pasta Co., 371 F.3d at 391; *accord United Indus. Corp.*, 140 F.3d at 1180. To determine whether a statement is an actionable statement of fact, the statement must be considered both standing alone and in the context in which it is used. *Id.* at 391-92 (holding that "America's Favorite Pasta" is not a specific, measurable claim and cannot be reasonably interpreted as an objective fact either standing alone or in context).

Rivard argues that Ideal's packaging and advertising, which represents Ideal's D3 needles as "detectable," unambiguously states specific and absolute characteristics of the product. Any other interpretation, Rivard contends, is untenable. Ideal, however, contends that "detectable" is not a statement of fact, where Rivard's own expert could not settle on a single definition of the term, and the "detectability" attribute of Ideal's D3 needles is unquantifiable and greatly affected by various factors and sources of error introduced by metal detector manufacturers and meat processors. Thus, Ideal contends

that, standing alone and in context, "detectable" or "as much as 100% detectable" is not a specific, measurable claim conveying a quantifiable threshold in number, percentage, or place in a series. Ideal contends, further, that the word or phrase in question provides no methodology or reason and that Ideal nowhere contends that its D3 needles will be detectable all of the time in all circumstances.

Whether or not "detectable" is a statement of fact may be the one point on which Rivard has the better argument. Clearly, "detectable" or "as much as 100% detectable," whether standing alone or in context, is not mere "puffery." *See id.* at 390 (in contrast to statements of fact, "puffery" is not actionable). Describing needles as "detectable" is not merely an exaggerated statement of bluster or boast upon which no reasonable consumer would rely, nor is it a vague and highly subjective claim of product superiority or a bald assertion of superiority. *See id.* at 390-91 (defining "puffery"). While there may be some merit to Ideal's assertion that "detectable," standing alone, does not provide any benchmark by which the veracity of the statement can be ascertained, such an argument disregards the particular context in which Ideal's representations concerning the "detectable" nature of its D3 needles are made. *See id.* at 391-92 (whether a statement is actionable under § 43(a) of the Lanham Act depends, in part, on the context in which the statement appears, citing *Pizza Hut, Inc.*, 227 F.3d at 495 n.5). D3 needles are described as "detectable" in the context of packaging that identifies the needles as "for veterinary use only." Defendant's Exhibit A. Thus, the word "detectable" on the packaging is used in a context that invokes the meaning of the term in the veterinary, livestock, and meat processing industries. As the parties have been at some pains to convince the court, "detectable" needles in that context means that the needles so labeled will be detected in animal carcasses by metal detectors routinely used in the meat processing industry. Similarly, the advertising literature identified by Rivard describes the D3 needles as "found

to be 100% detectable" and to have "superior detectability" in the context of, and by explicit reference to, specific testing, using specific procedures, to quantify and measure "detectability" for purposes of predicting whether needles would be detected in animal carcasses under circumstances reasonably likely to occur during meat processing. *See* Defendant's Exhibits B and C. Thus, in these contexts, the "detectability" representations do "'admit[] of being adjudged true or false in a way that . . . admits of empirical verification,'" *American Italian Pasta Co.*, 371 F.3d at 391 (quoting *Pizza Hut, Inc.*, 227 F.3d at 496, in turn quoting *Presidio Enters., Inc.*, 784 F.2d at 679), or at the very least, "'of being reasonably interpreted as a statement of objective fact.'" *Id.* (quoting *Coastal Abstract Serv., Inc.*, 173 F.3d at 731). Indeed, Ideal's very reliance on specific test results in its advertising materials to demonstrate the "detectability" of its D3 needles demonstrates that it was Ideal's intent that the representations of "detectability" be interpreted as statements of objective fact based on empirical verification. Thus, the statements at issue are actionable statements of fact.

ii. Falsity. Rivard contends that Ideal's representations that its D3 needles are "detectable" are not only statements of fact, but are inherently deceptive, because those representations are literally untrue. Rivard's contention is apparently based on Dr. Hoff's October 2006 and November 2006 testing and the use of a purportedly non-detectable alloy, type 304 stainless steel, in at least some of the D3 needles. Ideal contends that its representations that its D3 needles are "detectable" are literally true, assuming that they are even actionable statements of fact.

For purposes of the first element of a § 43 "false advertising" claim, "a statement is false if it is either 1) literally false, or 2) literally true or ambiguous, but renders a 'false impression' when viewed in context." *Allsup, Inc.*, 428 F.3d at 1138. Whether a

statement is literally false can be determined by the court as a matter of law, but whether a statement is misleading must be determined by a jury as a matter of fact. *Id.*

Where the claimant relies on the "false impression" alternative, the claimant bears "'the ultimate burden of proving actual deception by using reliable consumer or market research.'" *Blue Dane*, 178 F.3d at 1043 (quoting *United Indus. Corp.*, 140 F.3d at 1180-82); *and compare Untied Indus. Corp.*, 140 F.3d at 1180 ("If a plaintiff proves that a challenged claim is literally false, a court may grant relief without considering whether the buying public was actually misled; actual consumer confusion need not be proved."). Rivard relies on no such evidence of consumer or market research showing consumer confusion. Therefore, Rivard must demonstrate that it has sufficient likelihood of proving that Ideal's representations that its D3 needles are "detectable" are "literally false" to obtain the preliminary injunction it seeks.

In determining whether or not an advertising claim is "literally false," the court must "analyze the message conveyed within its full context." *United Indus. Corp.*, 140 F.3d 1180. In the full context in which Ideal's representations were made, the court finds as a matter of law that those representations are not literally false. *Allsup, Inc.*, 428 F.3d at 1138 (whether a statement is literally false can be determined by the court as a matter of law). As noted above, the advertising literature identified by Rivard describes the D3 needles as "found to be 100% detectable" and to have "superior detectability" in the context of, and by explicit reference to, specific testing, using specific procedures, to quantify and measure "detectability" for purposes of predicting whether needles would be detected in animal carcasses under circumstances reasonably likely to occur during meat processing. *See* Defendant's Exhibits B and C. D3 needles are also described as "detectable" in the context of packaging that describes them as "for veterinary use only." Defendant's Exhibit A. Thus, the word "detectable" on the packaging is used in a context

that invokes the meaning of the term in the veterinary, livestock, and meat processing industries. As also explained above, "detectable" in that context means that the needles so labeled will be detected in animal carcasses by metal detectors routinely used in the meat processing industry. Ideal's testing, and even the deposition testimony of Rivard's expert, Dr. Hoff, supports the conclusion that, in these contexts, the D3 needles are, indeed, "detectable." As also explained above, the court finds that Dr. Hoff's testing for Rivard in October 2006 has no probative value whatsoever concerning the "detectability" of Ideal's D3 needles within the meaning of the livestock and meat processing industries owing to the flawed procedures that bore no relationship to industry conditions or the conditions of prior tests commissioned by the NPB, and his November 2006 testing simply does not demonstrate that the D3 needles are not "detectable." Finally, there is no anecdotal evidence of *any*—let alone any frequent or recurrent—instances in which D3 needles have passed undetected through a metal detector, and found their way into a consumer's food, while the evidence shows that Ideal is now taking reasonable measures to ensure that all D3 needles are actually detectable and made from specified alloys.

Thus, on the present record, the court finds that Rivard has little or no chance of proving the "literal falsity" element of its "false advertising" claim under § 43(a) of the Lanham Act. *Allsup, Inc.*, 428 F.3d at 1138 (the first element of a § 43(a) "false advertising" claim is proof that the defendant made false statements about its own product).

iii. Other elements. For much the same reason that Rivard has little or no chance of proving a false statement by Ideal, Rivard has little or no chance of proving that Ideal's statements that its D3 needles are "detectable" actually deceived or had the tendency to deceive a substantial segment of its audience, *see id.* (second element), or injured Rivard, *see id.* (fifth element), even assuming that the statements were material,

and caused by Ideal to enter interstate commerce. *See id.* (third and fourth elements). Again, there is no evidence of a single reported incident of a D3 needle breaking, passing undetected through a metal detector, and finding its way into a consumer's food, so that no one has been misled, deceived, or otherwise harmed by Ideal's marketing of its D3 needles as "detectable," nor is there any evidence that anyone has been physically injured by the failure of a D3 needle to be detected. *See id.* ("deception" element). That being so, there is also no evidence that Rivard has been injured by any alleged misrepresentation of the "detectability" of Ideal's D3 needles. *See id.* ("injury to claimant" element).

In short, the lack of any convincing evidence on three of the five elements of Rivard's "false advertising" claim—false representation, deception, and injury to claimant—means that Rivard has little or no likelihood of success on such a claim under governing law, and such limited likelihood of success clearly does not support the sweeping preliminary injunctive relief Rivard seeks. *See Sanborn Mfg.*, 997 F.2d at 488 ("likelihood of success" means that the movant's success on its claim is "sufficiently likely to support the kind of relief it requests"); *see also Baker Elec. Co-op.*, 28 F.3d at 1473-74 ("likelihood of success on the merits" requires that the movant find support for its position in governing law).

In isolation, the likelihood of success on the merits is meaningless, however, even if, contrary to the court's findings here, the movant had a substantial likelihood of success on the merits. *Glenwood Bridge*, 940 F.2d at 371 (quoting similar language in *Dataphase*); *accord Lankford*, 451 F.3d at 513 ("Likelihood of success on the merits is only one of the four factors determining whether a preliminary injunction should issue.").

Therefore, the court must consider other factors, especially the threat of irreparable harm. *Id.*[6]

2. Irreparable harm

The second "*Dataphase* factor" is the threat of irreparable harm to the movant absent the injunction. *Dataphase,* 640 F.2d at 114. Thus, in this circuit "a party moving for a preliminary injunction is required to show the threat of irreparable harm," *Baker*

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[6]Another circuit court of appeals has described the meaning of likelihood of success on the merits and its interplay with the balance of harms as follows:

> What is true is that if the party seeking the preliminary injunction would suffer more harm from the denial of it than his opponent would suffer from its being granted, the injunction should be granted even if the party seeking it has no more than a 50-50 chance of winning, and even, in some cases, if the odds are worse. If for example the party seeking the injunction would lose $10,000 if it was denied, and has a 40 percent chance of being in the right, and the other party would lose only $1,000 if the injunction is granted and has (necessarily) a 60 percent chance of being in the right, then the cost of denial of the injunction to the party seeking it, when discounted by the probability that he is in the right, would exceed the cost of granting the injunction to the other party, when discounted by the probability of his being in the right. (That is, $4,000 ($10,000 x .40) is greater than $600 ($1,000 x .60).). *E.g., Green River Bottling Co. v. Green River Corp.,* 997 F.2d 359, 361 (7th Cir. 1993); *Curtis v. Thompson,* 840 F.2d 1291, 1296 (7th Cir. 1988). But if as in this case the judge, having obtained in the preliminary hearing all the facts that [the judge] believes pertinent to deciding which party is in the right, is able to make up [his or her] mind that the party seeking the injunction has no legal ground for his case, [the judge] should not only deny the injunction, [he or she] should dismiss the suit; for [the judge] knows how it will come out.

Curtis 1000, Inc. v. Suess, 24 F.3d 941, 945 (7th Cir. 1994).

Elec. Co-op., 28 F.3d at 1472 (citing *Modern Computer Sys.*, 871 F.2d at 738, and *Dataphase*), and the lack of irreparable harm is sufficient ground for denying or vacating a preliminary injunction. *Aswegan v. Henry*, 981 F.2d 313, 314 (8th Cir. 1992) (citing *Modern Computer Sys.*, 871 F.2d at 738). Stated differently, "[t]he threshold inquiry is whether the movant has shown the threat of irreparable injury." *Glenwood Bridge*, 940 F.2d at 371 (quoting *Gelco Corp. v. Coniston Partners*, 811 F.2d 414, 418 (8th Cir. 1987)). Thus, the Eighth Circuit Court of Appeals has held that

> the movant's failure to sustain its burden of proving irreparable harm ends the inquiry "and the denial of the injunctive request is warranted." [*Gelco*, 811 F.2d] at 420. *Accord Modern Computer Sys.*, 871 F.2d at 738; *Dataphase*, 640 F.2d at 114 n.9. We must inquire, then, whether [the movant] has met its burden of proving that it will suffer irreparable harm absent a preliminary injunction.

Id. As the Eighth Circuit Court of Appeals has also explained,

> "[T]he basis of injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies." *Beacon Theaters, Inc. v. Westover,* 359 U.S. 500, 506-07 (1959). Thus, to warrant a preliminary injunction, the moving party must demonstrate a sufficient threat of irreparable harm. *See Adam-Mellang v. Apartment Search, Inc.,* 96 F.3d 297, 299 (8th Cir. 1996).

Bandag, Inc. v. Jack's Tire & Oil, Inc., 190 F.3d 924, 926 (8th Cir. 1999); *see Baker Elec. Co-op.,* 28 F.3d at 1472 ("No single factor in itself is dispositive; in each case all of the factors must be considered to determine whether on balance, they weigh towards granting the injunction. However, a party moving for a preliminary injunction is required to show the threat of irreparable harm.") (internal quotation marks and citations omitted).

Sufficient showing on this second factor in the *Dataphase* analysis can be made, for example, by showing that the movant has no adequate remedy at law. *Baker Elec. Co-op.*,

28 F.3d at 1473. Conversely, where the movant has an adequate legal remedy, a preliminary injunction will not issue. *Frank B. Hall & Co. v. Alexander & Alexander, Inc.*, 974 F.2d 1020, 1025 (8th Cir. 1992) (but finding in that case that the district court's conclusion that there was an adequate remedy was based on an erroneous legal premise, and requiring a proper balance of *Dataphase* factors). More specifically still, for present purposes, the Eighth Circuit Court of Appeals has explained "irreparable harm" as follows:

> When injunctive relief is sought under the Lanham Act, the finding of a tendency to deceive satisfies the requisite showing of irreparable harm. *See Black Hills Jewelry [Mfg. Co. v. Gold Rush, Inc.],* 633 F.2d [746,] 753 [(8th Cir. 1980)] ("To obtain an injunction under section 43(a) appellees need only show that the falsities complained of had a tendency to deceive."); *McNeilab, Inc. v. American Home Products Corp.,* 848 F.2d 34, 38 (2d Cir. 1988) (where challenged advertisement directly, but falsely, proclaims superiority of defendant's product over plaintiff's, irreparable harm may be presumed). Absent such a showing, however, irreparable harm cannot be presumed where, as here, plaintiff has not established any prospect of success upon the merits. *See Sanborn,* 997 F.2d at 489; *Johnson & Johnson v. Carter-Wallace, Inc.,* 631 F.2d 186, 192 (2d Cir. 1980) ("While proof of actual diversion of sales is not required for a § 43(a) injunction to issue, proof that the advertising complained of is in fact false is essential.").

United Indus. Corp., 140 F.3d at 1183-84.

For essentially the same reasons that the court found it was highly unlikely that Rivard could prove either the first, second, or fifth elements of its "false advertising" claim—a false statement that deceived the public and caused injury to the claimant, *Allsup, Inc.*, 428 F.3d at 1138—the court finds that Rivard cannot establish the "irreparable harm"

factor in the preliminary injunction analysis. *Cf. United Indus. Corp.*, 140 F.3d at 1183-84 (absent a showing of a tendency to deceive, for purposes of a Lanham Act claim, "irreparable harm" cannot be presumed for purposes of a preliminary injunction where the claimant cannot establish any prospect of success on the merits). Quite simply, where there has been no convincing proof of false advertising, there is no likelihood of harm, let alone irreparable harm, to a competitor from that alleged false advertising that would justify a preliminary injunction on the sale of the products in question or a preliminary injunction requiring the recall of such products. *Cf. id.* This is not a case in which preliminary injunctive relief should be denied, because a legal remedy is adequate, *see Baker Elec. Co-op.*, 28 F.3d at 1473 ("irreparable harm" can be shown by demonstrating that the movant has no adequate remedy at law"); rather, it is a case in which preliminary injunctive relief should be denied, because the movant is not entitled to any remedy at all. Thus, even though Rivard has also failed to prove likelihood of success on the merits, denial of injunctive relief would be justified solely by Rivard's failure to demonstrate irreparable harm. *Glenwood Bridge*, 940 F.2d at 371 ("[T]he movant's failure to sustain its burden of proving irreparable harm ends the inquiry 'and the denial of the injunctive request is warranted.'") (quoting *Gelco*, 811 F.2d at 420).

3. Balance of harms

Although lack of "irreparable harm," standing alone, would warrant denial of Rivard's motion for preliminary injunction, the third "*Dataphase* factor," "balance of harms," also warrants denial. *See Dataphase,* 640 F.2d at 114 (the third factor is the balance between the harm and the injury that the injunction's issuance would inflict on other interested parties). The "balance of harms" analysis is not identical to the "irreparable harm" analysis. *Pottgen*, 40 F.3d at 929. Irreparable harm focuses on the harm or potential harm to the movant of the opposing party's conduct or threatened

conduct. *Dataphase*, 640 F.2d at 114. In contrast, the balance of harms analysis examines the harm of granting or denying the injunction upon both of the parties to the dispute and upon other interested parties, including the public. *Id.*; *see also Glenwood Bridge*, 940 F.2d at 372 (considering the effect of granting or denying the injunction on the public's interest in a public works construction project as well as upon the parties in the balance of harm analysis); *Modern Computer Sys.*, 871 F.2d at 737-38 (harm to other interested parties also considered).

In conducting the "balance of harms" analysis required under *Dataphase*, it is obvious that an illusory harm to the movant will not outweigh any actual harm to the non-movant. *Frank B. Hall*, 974 F.2d at 1023. To determine what must be weighed, the court finds that courts of this circuit have looked at the threat to each of the parties' rights that would result from granting or denying the injunction. *Baker Elec. Co-op.*, 28 F.3d at 1473. Also, the potential economic harm to each of the parties and to interested third parties of either granting or denying the injunction is relevant. *Id.* Another consideration in the balance of harms calculus is whether the defendant has already voluntarily taken remedial action. *Sanborn Mfg.*, 997 F.2d at 489. Where the non-movant has taken such action, the balance of harms is readjusted, because the potential for economic or other harm to the movant has been eliminated. *Id.* (citing *Burndy Corp. v. Teledyne Indus., Inc.*, 748 F.2d 767, 774 (2d Cir. 1984), which held that injunctive relief was "wholly unnecessary" when the defendant had voluntarily brought his product labeled with the UL mark into compliance with UL standards and where there was not a likelihood of repetition or hazard to the public). Similarly, present harm as the result of past misconduct is not sufficient to justify the injury to the non-movant of granting a preliminary injunction requiring some additional corrective action, because such relief "goes beyond the purpose of a preliminary injunction." *Id.* at 490. Finally, the Eighth Circuit Court of Appeals has

held that, where a movant seeking a preliminary injunction against alleged Lanham Act violations has failed to demonstrate a probability of ultimate success, the possibility that the movant will suffer any harm from the continuing use by the non-movant of its challenged advertising "is highly speculative and therefore does not serve to tip the balance of equities in [the movant's] favor." *United Indus. Corp.*, 140 F.3d at 1184.

Here, as explained above, Rivard's harm is so unlikely as to be illusory, so that it has little or no weight in the calculus. *Frank B. Hall*, 974 F.3d at 1023 (an illusory harm to the movant will not outweigh any actual harm to the non-movant). On the other hand, the potential economic harm to Ideal of a preliminary injunction of the breadth that Rivard seeks would be substantial, if not huge, because of its deleterious effect not only on Ideal's immediate business, but because of the lasting harm to its reputation with no offsetting *justified* economic benefit to Rivard, only an unjustified windfall. *Baker Elec. Co-op.*, 28 F.3d at 1473 (the court must consider the potential economic harm to the parties). Moreover, as the court has repeatedly pointed out, whatever potential for harm might have existed has been substantially reduced by Ideal's recent remedial actions to ensure that all of its "detectable" needles are tested for "detectability" using an industry standard metal detector and regular metallurgical testing to ensure that the specified alloys of steel are used in the actual manufacturing of the D3 needles. *See Sanborn Mfg.*, 997 F.2d at 489 (voluntary remedial action by the non-movant requires readjustment of the "balance of harms" calculus, because the potential for economic or other harm to the movant has been eliminated). Even imagining, contrary to all of the evidence showing that no D3 needles have ever passed through the meat processing system to arrive on the plate of a consumer, that there was some past misconduct—in the form of lax production standards that allowed needles of questionable "detectability" or made of the "wrong" alloy to reach the market—there is no showing of a present harm from such past misconduct requiring some

additional corrective action, because such relief "goes beyond the purpose of a preliminary injunction." *Id.* at 490. Indeed, the lack of any evidence that isolated reports of problems in the field resulted in any harm to the public, the livestock industry, or the meat processing industry, and the lack of any evidence that actions by Ideal did not prevent any such harm, demonstrates that there is presently no public health risk requiring a recall of any of Ideal's D3 needles or a prohibition on any sales of such needles. Ultimately, this is another Lanham Act case in which the movant has failed to demonstrate a probability of ultimate success, so that the possibility that it will suffer any harm from the continuing use by the non-movant of its challenged advertising "is highly speculative and therefore does not serve to tip the balance of equities in [Rivard's] favor." *United Indus. Corp.*, 140 F.3d at 1184.

Thus, the "balance of harms" weighs decidedly against granting Rivard the relief that it seeks.

4. The public interest

The final factor in the *Dataphase* analysis is the impact of granting or denying the preliminary injunction upon the public interest. *Pottgen*, 40 F.3d at 929; *Dataphase,* 640 F.2d at 114. The "public interest" factor frequently invites the court to indulge in broad observations about conduct that is generally recognizable as costly or injurious. However, the Eighth Circuit Court of Appeals has recognized, in comparable contexts, that the public interest favors enjoining false statements, and enjoining the safety risks arising from false labeling of products. *United Indus. Corp.*, 140 F.3d at 1184 (citing *Sanborn*); *Sanborn Mfg.*, 997 F.2d at 490. Here, however, such a public interest would not be served, because the court has found no false statements or safety risks from allegedly false labeling to be enjoined. *See id.* ("[A]bsent a more substantial showing that [the movant] has a viable [Lanham Act] claim, this factor likewise does not tilt the equities toward granting

preliminary injunctive relief."). Thus, this final "*Dataphase* factor" also does not weigh in favor of the preliminary injunction that Rivard seeks.

III. CONCLUSION

None of the "*Dataphase* factors" weighs in favor of the preliminary injunctive relief that Rivard seeks. Thus, Rivard has failed to carry its burden to establish that a preliminary injunction is appropriate. *Lankford*, 451 F.3d at 503; *Baker Elec. Co-op., Inc.*, 28 F.3d at 1472. No preliminary injunction shall issue under these circumstances.

THEREFORE, Rivard's October 30, 2006, Motion For Preliminary Injunction (docket no. 85), as supplemented or amended on November 28, 2006 (docket no. 105), December 12, 2006 (docket no. 115); and February 2, 2007 (docket no. 140), is **denied**.

IT IS SO ORDERED.

DATED this 28th day of March, 2007.

Mark W. Bennett

MARK W. BENNETT
U. S. DISTRICT COURT JUDGE
NORTHERN DISTRICT OF IOWA