

APPLICABLE LEGAL STANDARDS

I. Preliminary Injunction

“The grant of a preliminary injunction under 35 U.S.C. § 283 is within the discretion of the district court.” Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed. Cir. 2006). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” Winter v. NRDC, Inc., 129 S. Ct. 365, 374 (2008). The Supreme Court has held that injunctive relief is “an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” Id. at 376.

As to the requirement that the movant establish that he is likely to succeed on the merits, the Federal Circuit has held:

[T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent. In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial. . . .

Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) (citation omitted). “An accused infringer can defeat a showing of likelihood of success on the merits by demonstrating a substantial question of validity or infringement.” Trebro Mfg. v. FireFly Equip., LLC, 748 F.3d 1159, 1165 (Fed. Cir. 2014). “A preliminary injunction should not issue if an alleged infringer raises a substantial question regarding either infringement or validity, i.e., the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown lacks substantial merit.” AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1050 (Fed. Cir. 2010).

At trial, the plaintiff bears the burden of proving infringement by a preponderance of the evidence. Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1327 (Fed. Cir. 2008).

ANALYSIS

I. Plaintiffs have demonstrated that they are likely to succeed on the merits.

Plaintiffs contend that the IVA Set literally infringes claims 15-34 of the '921 patent and claims 1-3 of the '732 patent. "In order to establish the first preliminary injunction factor, [Plaintiff] must show that it will likely prove that [Defendant] infringes at least one valid and enforceable patent claim." Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196, 1201 (Fed. Cir. 2007). "To prove an accused product literally infringes the patent in suit, the product must contain each and every limitation of the asserted claim(s)." Trebro, 748 F.3d at 1166.

Acta, in opposition, does not challenge the validity of the patents in suit, but argues that they are unenforceable due to the inequitable conduct of the Plaintiffs in regard to the small entity maintenance fee. Acta makes two arguments: 1) Plaintiffs "sought to deceive the PTO about the circumstances surrounding the payment of the small entity maintenance fee so that they PTO would accept their late payment and thereby restore the '732 patent" (Def.'s Opp. Br. 3); and 2) Plaintiffs "sought to deceive the PTO about the facts and circumstances surrounding the erroneous payment of the small entity amount for the maintenance fee so that they PTO would accept their late payment and thereby restore the '921 patent and the '732 patent." (Def.'s Opp. Br. 4.)

In Therasense, the Federal Circuit set forth the fundamental principles of the law of inequitable conduct claims:

To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific

intent to deceive the PTO. The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant’s conduct before the PTO warrants rendering the entire patent unenforceable.

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011). Thus, at trial, Acta must prove that Plaintiffs misrepresented or omitted material information with specific intent to deceive the PTO. On the present record, this Court cannot discern an evidentiary basis to conclude that Acta has raised a substantial question about unenforceability due to inequitable conduct. At this juncture, Acta has deposed none of the relevant people involved, and there is nothing in the present record from which this Court could infer that Plaintiffs acted with a specific intent to deceive the PTO, much less that the evidence supports a finding of such by clear and convincing evidence. Nor is there anything in the record to support a finding that the omitted information was material. The only factual allegation Acta makes in support is that an internal note has been found that the ’732 patent no longer qualifies for small entity status. The Court has no information on who wrote this note, who saw it, when it was written, or anything else. This factual allegation is insufficient to persuade this Court that Acta has raised a substantial question of inequitable conduct under Therasense.

Acta argues as well that Plaintiffs cannot prove infringement. As to the ’732 patent, Acta argues that the IVA Set does not contain each and every limitation of any of claims 1-3. Specifically, Acta points to this limitation in independent claim 1: “at least one tubing sensor disposed in a housing of the pump.” There is no dispute that the IVA Set does not contain this element. At oral argument, the Court asked Plaintiffs how, then, Acta met this limitation. Plaintiffs answered that, at sales demonstrations, Acta representatives placed the IVA Set into a

pump unit manufactured by Plaintiffs, thus using it in a way that meets every element of one or more claims in the '732 patent and so infringes. While this is conceivably true, the Court notes that the briefs do not argue this and so they do not point to evidence supporting it, nor did counsel point to evidence of record at the hearing. At this juncture, the Court has only attorney argument to support this theory of infringement, and that is not sufficient to support a finding that Plaintiffs are likely to succeed in proving that Acta infringes the '732 patent by its acts at sales demonstrations.

Acta next argues that the IVA Sets do not contain a positionable locating member, as required by some of the claims, because the corresponding element of their set is in a fixed position, and may not be repositioned. The Court observes that this claim term appears only in independent claims 22, 26, and 30 in the '921 patent; it does not appear in claims 15-21. Because of this fact, the Court may not need – and, in fact, does not need – to reach this dispute, because it finds a likelihood of success in proving infringement of at least one claim in the group of claims 15-21.

Similarly, Acta argues that the IVA Sets do not contain “a length of straight line, resilient tubing.” Again, the Court need not reach this issue, because this claim term appears only in independent claims 22, 26, and 30 in the '921 patent; it does not appear in claims 15-21. Because of this fact, the Court may not need – and, in fact, does not need – to reach this dispute, because it finds a likelihood of success in proving infringement of at least one claim in the group of claims 15-21.

Acta also argues that the IVA sets do not contain “a length of resilient tubing,” which is a limitation in claims 15-21, because the Court should import a further claim limitation from a

preferred embodiment in the specification.¹ At oral argument, however, it appeared that Acta applied this argument to all of the '921 claims at issue. At the hearing, Acta pointed to this language in the specification sections of both patents:

In the tubing assembly 12, the tubing locator pin 92 and shut-off valve 14 may be added or attached to lengths of resilient tubing of differing diameters. Additionally, the use of off-the-shelf straight line, continuous PVC tubing in the present tubing assembly 12 as opposed to a segment of silicone tubing having segments of PVC tubing mechanically secured thereto as is required by many prior art peristaltic pumps substantially reduces the costs associated with the present tubing assembly 12, in addition to providing increased reliability thereto due to the absence of any mechanical joints therein.

'921 patent, col.13 ll.23-33; '732 patent, col.13 ll.21-31. Acta contends that this operates as a disclaimer of claim scope, limiting all claims to tubing sets constructed from continuous, unsegmented PVC tubing. This is not persuasive, when viewed in the context of the three claims in the '732 patent. Claim 1 includes this limitation: "a length of straight line, resilient tubing." Claim 3 states: "The administration set of claim 1 wherein the tubing is fabricated as a continuous polyvinyl chloride member." In construing the meaning of claim 1 and claim 3, the doctrine of claim differentiation is helpful:

In the most specific sense, "claim differentiation" refers to the presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim. Thus, the claim differentiation tool works best in the relationship between independent and dependent claims. Indeed the statute stresses that a dependent claim must add a limitation to those recited in the independent claim. Thus, reading an additional limitation from a dependent claim into an independent claim would not only make that additional limitation superfluous, it might render the dependent claim invalid.

Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006)

¹ The Court notes that this is a perhaps overgenerous reading of Acta's opposition brief, which does not in fact apply this argument to claims 15-21, but only to claims 22-33. (See Def.'s Opp. Br. at 11.)

(citations omitted). Thus, under the doctrine of claim differentiation, claim 3 presents this additional limitation to independent claim 1: “the tubing is fabricated as a continuous polyvinyl chloride member.” To differentiate these two claims, then, claim 1 does not require the tubing to be “fabricated as a continuous polyvinyl chloride member.” As a consequence of this interpretation, the specification language cited by Acta cannot limit every claim to “the use of off-the-shelf straight line, continuous PVC tubing.” Continuous PVC tubing is required by claim 3 of the ’732 patent, but not claim 1.

Furthermore, not one of the claims in the ’921 patent contains the word “continuous.” Independent claims 22, 26, and 30 all require “a length of straight line, resilient tubing.” The parties did not address the meaning of this phrase, and the Court sees no basis to construe it to mean “only one continuous piece of PVC tubing.”

Furthermore, in asking the Court to import a limitation from the specification, Acta follows a path well-worn by patent challengers, and Federal Circuit law disfavors this path:

The claims, not specification embodiments, define the scope of patent protection. The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.

Kara Tech. Inc. v. Stamps.com Inc., 582 F.3d 1341, 1348 (Fed. Cir. 2009). Furthermore:

It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that. To constitute disclaimer, there must be a clear and unmistakable disclaimer.

Thorner v. Sony Computer Entm’t Am. LLC, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012).

Applying this standard, Acta has not raised a substantial question about infringement, as it has not raised a substantial question that the “clear and unmistakable disclaimer” standard has been

met, so as to limit “a length of resilient tubing” to a single length of continuous PVC tubing without any joints.

Acta next argues that the IVA Sets do not include the following element in claims 21 and 34: “a single pinch arm . . . being movable between an open position whereat the tubing passing through the valve body is not compressed by the pinch arm.” Acta argues that Plaintiffs’ expert conceded that the pinch arm slightly compresses the tubing even when disengaged, but this is not correct: as Plaintiffs pointed out, their expert clarified on reply that it is his position that it is the valve body, and not the pinch arm itself, that slightly compresses the tubing. (Meyst Reply Dec. ¶¶ 43-45.) This Court concludes that Acta’s argument on this point does not raise a substantial question of the infringement of claims 21 and 34.

As to claims 15-20 in the ’921 patent, then, Acta’s only defense to infringement is the argument that this Court should import the “continuous PVC” limitation from the specification as a claim limitation. The Court finds no basis to conclude that Acta can meet the high bar set by the Federal Circuit, that the patentees made a “clear and unmistakable disclaimer.” This Court finds that, as to claims 15-21, Acta has made no substantial challenges to Plaintiff’s infringement case, and thus that Plaintiffs have shown a likelihood of success on the merits in proving that Acta has infringed claims 15-21 of the ’921 patent.

II. Plaintiffs have demonstrated irreparable harm.

Plaintiffs have shown that they are likely to suffer irreparable harm in the absence of preliminary relief, due to price erosion. There is no dispute that Acta has sold its product to customers who would have otherwise purchased Plaintiffs’ tubing set, and that Acta sells its product at a substantial discount. The Federal Circuit has recognized price erosion as an

irreparable injury in similar cases: “Under this court’s precedent, price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.” Aria Diagnostics, Inc. v. Sequenom, Inc., 726 F.3d 1296, 1304 (Fed. Cir. 2013). The Federal Circuit has further explained:

Competitors change the marketplace. Years after infringement has begun, it may be impossible to restore a patentee’s (or an exclusive licensee’s) exclusive position by an award of damages and a permanent injunction. Customers may have established relationships with infringers. The market is rarely the same when a market of multiple sellers is suddenly converted to one with a single seller by legal fiat. Requiring purchasers to pay higher prices after years of paying lower prices to infringers is not a reliable business option.

Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 975-976 (Fed. Cir. 1996).

Plaintiffs have pointed to evidence that Acta has imported at least 10,000 units of the IVA Set, and that it has sold at least 1,200 of these units. (See Pls.’ Supp. Br. at 5 n.7.) Plaintiffs contend that Acta sells its competing product for as much as 35% less than Plaintiffs’ price. This suggests that, unless enjoined, Acta is poised to take a large chunk of Plaintiffs’ future administration set sales. This Court finds that Plaintiffs have demonstrated that, in the absence of injunctive relief, they are likely to suffer this kind of harm, price erosion, a harm that cannot be redressed by money damages alone.

III. The balancing of the hardships weighs in Plaintiffs’ favor.

Acta argues that the balancing of hardships favors it because, in short, the IV sets at issue, on a percentage basis, form a much larger share of its total business than of the combined Plaintiffs’ total business. This implies that the balancing of hardships generally tilts in favor of the small company over the large one, and rests on a misunderstanding of Federal Circuit law. The Court does not weigh in a vacuum the harm to one party from the grant of the injunction

against the harm to the other party from the denial of the injunction. Rather, the Federal Circuit has explained:

The magnitude of the threatened injury to the patent owner is weighed, in the light of the strength of the showing of likelihood of success on the merits, against the injury to the accused infringer if the preliminary decision is in error.

H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 390 (Fed. Cir. 1987). Robertson

makes clear that the balancing of the harms must be performed in light of the strength of the showing of likelihood of success on the merits. In this case, Plaintiffs have made a strong showing of a likelihood of success on the merits, and the risk that the grant of a preliminary injunction will later be found to have been in error appears small to this Court. Because this Court has found that there is a strong likelihood that Plaintiffs will be irreparably injured were the injunction denied in error, and a weak likelihood that Acta will be harmed were the injunction granted in error, the balance of hardships weighs in Plaintiffs' favor.

IV. The public interest factor is neutral.

Here, both parties argue that the other's product is potentially unsafe due to quality control issues, and that it is in the public interest to protect people from unsafe medical products. This Court finds that neither party has made a stronger case in support of this argument, and this factor is neutral.

The Court finds that Plaintiffs have demonstrated that they are likely to succeed on the merits of proving infringement, that they are likely to suffer irreparable harm in the absence of preliminary relief, and that the balance of equities tips in their favor. The fourth factor, whether an injunction is in the public interest, favors neither party. The Court therefore grants Plaintiffs' application for a preliminary injunction against Acta.

The parties did not brief or address the issue of the amount of the bond. Federal Rule of Civil Procedure 65(c) states:

Security. The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.

Rule 65(c) requires the Court to set a bond amount that is proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained. In the absence of any briefing or argument on this issue, this Court sets the bond amount at \$25,000.00.

For these reasons,

IT IS on this 12th day of January, 2017 hereby

ORDERED that Plaintiffs' motion for a preliminary injunction (Docket Entry Nos. 6, 49, 51) is **GRANTED**; and it is further

ORDERED that Defendant ACTA Medical, LLC, and its employees, agents, officers, directors, subsidiaries, affiliates, parents, and all other persons or entities within its control or supervision or acting in concert with it, during the pendency of this litigation, are enjoined from making, selling, offering for sale, using and/or importing their "IV Administration Infusion Pump Sets" or other products that infringe on plaintiffs' patents, U.S. Patent Nos. 6,164,921 and 6,371,732, or from otherwise committing further acts of infringement on those patents either directly or indirectly; and it is further

ORDERED that this Order shall remain in place unless and until modified by further Order of this Court; and it is further

ORDERED that, pursuant to Federal Rule of Civil Procedure 65(c), Plaintiffs shall post a preliminary injunction bond with the Clerk of the Court in the amount of \$25,000.00.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.