Conceptus, Inc. v. Hologic, Inc. Doc. 131

United States District Court
For the Northern District of California

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CONCEPTUS, INC.,

Plaintiff,

v.

HOLOGIC, INC.,

Defendant.
_____/

No. C 09-02280 WHA

ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION

INTRODUCTION

In this patent-infringement action, the patent owner moves for a preliminary injunction. For the reasons stated below, the motion is **DENIED**.

STATEMENT

Plaintiff Conceptus, Inc. sells a transcervically introduced birth-control product called the Essure system. Unlike tubal ligation, the Essure system does not involve incisions and can be performed in a doctor's office without general anesthesia. With the Essure system, fallopian-tube occlusion results from tissue growth into and around a transcervically implanted device (a metal coil). This system received approval from the Food and Drug Administration in 2002. It is plaintiff's only product.

Plaintiff holds 27 United States patents. Five are asserted in this litigation: Nos. 6,634,361; 6,709,667; 7,237,552; 7,428,904; and 7,506,650. On this motion for a preliminary injunction, only claim 39 of the '904 patent is asserted. The '904 patent issued on

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September 30, 2008. It described non-surgical methods for the placement of intrafallopian devices to prevent contraception. Claim 39 of the '904 patent covered (col. 10:34–40):

> 39. A method for sterilizing a female patient, said method comprising:
>
> delivering a body transcervically into the female patient;
>
> delivering energy to a surrounding tissue of a fallopian tube of a fallopian tube of said female patient;
>
> wherein a scar formation in a region of the surrounding tissue permanently attaches to the body.

Conceptus' own Essure system does not practice claim 39, because it does not deliver energy or use an electric current.

Accused are defendant Hologic, Inc. and its Adiana system of infringing claim 39. The Adiana technology was developed at Adiana, Inc., which was acquired by another company that eventually merged with Hologic in October 2007, so that Hologic acquired the Adiana system. The Adiana system transcervically implants a silicone device, referred to as a matrix, and uses radiofrequency energy to obstruct the fallopian tubes. This system was approved by the FDA on July 7, 2009, two days before the instant motion was filed.

ANALYSIS

"A preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted." *Nat'l Steel Car, Ltd. v. Canadian P. Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004) (internal quotation omitted). "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).

Plaintiff argues that a preliminary injunction is necessary to preserve the status quo ante. It is true that in *University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981), the Supreme Court held that "[t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." The Supreme Court described this limited purpose for granting injunctions to preface its commentary that evidentiary burdens in the

preliminary injunction setting are less than those required at trial due to the limited purpose and the speed at which the motion must be granted to preserve the status quo. In no way should the "purpose" of a provisional remedy be substituted as the "test" for a provisional remedy, the latter of which was stated in *Winter* and is quoted above.

1. LIKELIHOOD OF SUCCESS ON THE MERITS.

A. Disputed Term.

One disputed claim term is "body" as used by claim 39. Seeking to narrow the claim and thus avoid infringement, defendant proposes that "body" should mean "a resilient structure formed at least in part from copper." Plaintiff disagrees. Instead, it argues that "body" should not be so limited because it is an "obviously-generic claim term." Rather, plaintiff asserts that no additional construction is necessary. According to defendant, both sides agree that the body in the patent referred to a transcervically delivered intrafallopian device. Thus, the primary dispute surrounds whether copper must have been part of the patented body.

There are problems with defendant's proposed construction. *First*, the claim language itself did not mention a copper limitation. *Second*, the specification nowhere flat out stated that the body must always be made in part from copper. In fact, the specification did not use the term "body" anywhere as used in the claim.

Significantly, the summary of invention passage in the patent specification did state that "[t]he intrafallopian devices of the present invention are transcervically delivered, *resiliency anchored structures* which are formed at least in part from *copper*" (col. 2:37–41) (emphasis added). And the specification touted the advantages of copper. The specification further recited that the "[t]he intrafallopian device of the present invention therefore comprises a *resilient structure, usually a metallic coil*, which includes a *copper alloy*, a *copper plating*, or *copper fibers*, ideally comprising an alloy including at least 75% copper" (col. 2:52-55) (emphasis added). Although the above references, taken alone, might suggest some limitation of "body" to copper, the remainder of the specification shows that the applicants did not clearly disclaim or disavow claim scope. It is true that weight may be given to what is stated as the claim scope in "the present invention" or in the "summary of invention." *Netcraft Corp. v. Ebay, Inc.*, 549 F.3d

1394, 1398 (Fed. Cir. 2008); *ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1374–75 (Fed. Cir. 2009). But "use of the phrase 'the present invention' does not 'automatically' limit the meaning of claim terms in all circumstances, and [] such language must be read in the context of the entire specification and prosecution history." *Netcraft Corp.*, 549 F.3d at 1398 (citing *Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1094 (Fed. Cir. 2003)).

To further support its argument, defendant relies on *ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1375 (Fed. Cir. 2009). In that decision, the Federal Circuit affirmed the district court's construction of "spike" as requiring a "pointed tip" because the summary of invention and other parts of the specification never suggested that the spike could be anything other than pointed. In contrast, the specification here suggested that the body could be something other than copper; it could be another resilient metal. It stated (col. 5:59–67) (emphasis added):

> Preferably, primary coil 12 is formed from a beryllium copper alloy wire. Beryllium copper provides the resilience 60 necessary to avoid expulsion of the device, and also provides the increased effectiveness of a copper contraceptive intrafallopian device. *Alternatively, primary coil 12 is formed from a resilient metal, such as stainless steel, platinum, a shape memory alloy, or the like*. If such materials are used, primary 65 coil 12 is preferably plated with copper or a copper alloy or otherwise has copper attached.

This language indicated that copper was preferred but did *not* go so far as to say it was required. The foregoing would, however, militate in favor of limiting "body" to materials that include, at least in part, a resilient metal.

B. Infringement and Anticipation.

Due to the extraordinary nature of a preliminary injunction, "a patentee carries the burden of showing likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991). The Federal Circuit has stated:

> [T]he trial court first must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings. Then, as explained in New England Braiding, if the trial court concludes there is a "substantial question" concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue.

Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1379 (Fed. Cir. 2009).

Plaintiff has not met its burden on the likelihood of success. In light of the foregoing construction of "body," plaintiff's infringement argument seems dubious. The accused Adiana system uses an intrafallopian device made out of silicone, not a resilient metal (Martin Decl. ¶ 14). This alone is dispositive.

Moreover, plaintiff's infringement argument regarding "scar formation" is also questionable. Rather than advancing a consistent definition, plaintiff has set forth multiple and different definitions of scar formation in the course of litigating this motion. For example, in the opening motion, plaintiff's expert refers to fibroblasts as an example of scar tissue (Br. 14). Later abandoning its expert, plaintiff's reply brief merely points to Stedman's Medical Dictionary that defined "scar" as "the fibrous tissue replacing normal tissues destroyed by injury or disease" (Reply Br. 3). The reply further states that scar formation is the repair response resulting in permanent replacement of original tissue with fibrous tissue (*id.* at 4). Using any of the various definitions set forth by plaintiff for scar formation, it is doubtful on the present record whether any would cover the accused method. The primary evidence that there was scar formation was a statement that Adiana made many years ago in a business plan regarding a different proposed product (*i.e.*, a metal implantable device) and method, not the accused method. In the description of the real Adiana method (a description given prior to this litigation and before any incentive to distort), Adiana made a studied point stating that no scar tissue would be formed. For instance, in 1999, Adiana stated that its method "does not intentionally promote scarification," and in 2004, it stated "the Adiana system does not create scar tissue" (Altemus Exh. QQ; Exh. Z). Possibly the term scar formation will ultimately be stretched far enough to cover the accused method but it is doubtful, but plaintiff has not proven it should be at this stage. As such, for this second reason, plaintiff has not shown it is likely to succeed at trial on infringement of claim 39.

* * *

As for validity, plaintiff is once again in trouble, a third independent ground to reject an injunction. If "body" were construed to go beyond a resilient metal so as to include material such as silicone, as plaintiff urges, then claim 39 would seem to have been anticipated by United States

Patent No. 5,095,917 ("the Vancaillie patent"), which issued in 1992. The earlier patent taught of "a method for providing an outpatient technique for sterilization of females" (the '917 patent col. 1:8–10). It described a biodegradable plug that would be delivered into a female patient, the delivery of energy that would promote growth of scar tissue, and the scar tissue forming so as to occlude the fallopian tubes. Defense expert Dr. Ted Anderson explained that every element of claim 39 was previously disclosed in the Vancaillie patent (Anderson Decl. ¶¶ 40–44). "A determination that a claim is invalid as being anticipated or lacking novelty under 35 U.S.C. § 102 requires a finding that each and every limitation is found either expressly or inherently in a single prior art reference." *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003) (internal citation omitted).

Plaintiff counters that a single feature of claim 39 was missing from the Vancaillie patent. According to plaintiff, the relevant difference between the two is that claim 39 described a *permanent* implant and the Vancaillie patent only disclosed a "fallopian tube blocking technique that tried to rely on scar tissue *rather than* a permanent implant to achieve sterilization" (Reply Br. 9). Indeed, the Vancaillie patent described using a biodegradable plug, made of sutures or some other biodegradable material, that would be digested by microphages and replaced with scar tissue.

Put differently, plaintiff seeks to narrow the scope of claim 39 so as to avoid the Vancaillie disclosure and thus save claim 39 from invalidity. To narrow it, plaintiff would read into claim 39 a requirement that the implant be permanent (which would arguably distinguish Vancaillie whose plug was biodegradable). True, claim 39 read, in pertinent part, "delivering a body" and "wherein a scar formation in a region of the surrounding tissue permanently attaches to the body" (col. 10:34–40). This implies that the body remains in the fallopian tubes permanently. But, dependent claim 43 covered the case where the "body is *not expelled* from said fallopian tube" (col. 10:51–52). To read claim 39 to require a permanent body would render the "not expelled" limitation redundant or meaningless. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (stating that "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent

claim"). The canons of construction are at war. The prosecution history may have helped on this issue, but none was provided.

Claim 20 seems to show further that claim 39 did not require a permanent body. Both Claim 20 and 39 recited that the scar formation "permanently attaches" to the second portion/body (col. 9:38–40; 10:39–40). Claim 20, however, further required the second portion "to *remain permanently* within said fallopian tube" (col. 9:37) (emphasis added).[1] This italicized language is missing from claim 39. Again, this arguably demonstrates that the patentee did not intend to limit claim 39 to a permanent body. *See Phillips*, 415 F.3d at 1314 (stating that "[d]ifferences among claims can also be a useful guide in understanding the meaning of particular claim terms"). Apparently appreciating the difference, when Dr. Glasser discussed claim 20, he stated that it referred to "a second portion [that will] *remain in the fallopian tube permanently (as opposed to being expelled or absorbed)*" (Glasser Decl. ¶ 25). In contrast, Dr. Glasser did not refer to the body *permanently* remaining in the fallopian tube in his discussion of claim 39.

Plaintiff next argues that Vancaillie "taught away" from using a permanent implant and disparaged such use. But, "the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis" and pertains only to questions of obviousness. *Upsher-Smith Labs. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1323 (Fed. Cir. 2005).

Plaintiff points out that the Vancaillie patent was "already considered" by the United States Patent and Trademark Office when it granted the '904 patent. Realizing this may have been addressed in the prosecution history, the Court turned to the record. No one supplied any prosecution history on this point. Put differently, the Court read all of the prosecution history supplied on the motion and nothing therein addressed the problem presented by the Vancaillie patent, much less removes the "substantial question" raised by defendant. This failure of proof falls on plaintiff, not defendant. It is plaintiff's burden on a motion for a preliminary injunction. "Instead of the alleged infringer having to persuade the trial court that the patent is invalid, at this stage it is the patentee, the movant, who must persuade the court that, despite the challenge

[1] Claim 20 referred to the term "second portion" and claim 39 referred to the term "body." Plaintiff's own expert, Dr. Mark Glasser, states that these terms have the same meaning (Altemus Exh. V at 163:7–13).

presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue." *Titan Tire Corp.*, 566 F.3d at 1377.

C. Enablement.

A fourth independent ground to reject an injunction concerns enablement. The enablement requirement of Section 112 requires that "the specification of a patent . . . teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (internal quotations omitted). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Factors used to determine whether a disclosure would require undue experimentation include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Ibid.

The claim in dispute, claim 39, recited the limitation of "delivering energy." Defendant argues that the specification did not enable the use of delivering energy or "electric current" as it allegedly only made a passing reference to its use. Among other things, defendant argues that the specification did not explain the type of current to be used, the type of device used to deliver the current, how to determine the correct placement of the device, how much current is needed or safe, and how long to apply the current. Defendant contends that the use of this invention would require undue experimentation. This order agrees.

The Federal Circuit has noted that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (internal citations omitted). The Federal Circuit has stated that:

> Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the

> specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

Ibid. When there are no details describing a starting material or the conditions required to carry out a process, undue experimentation is required. It is not sufficient to claim that all these details are within the skill of the art. *Ibid.*

In this action, the specification referred to the use of electric current as an idea but *never* provided any detail. This is evidenced by the following bare references to the use of electric current (col:4:22–24; 5:35–38; 7:63–65):

- "Optionally, an electric current is applied through the resilient structure . . .";
- "Alternatively, an electrical current is applied to the device . . ."
- "The present invention further encompasses permanent sterilization by passing a current through the shaft . . . ."

None of these statements provided any clue as to how to practice the invention. This appears to be nothing more than the tossing out of a mere idea. It is a dubious proposition that these three deficient statements would teach those using the method how to safely get the electricity into the human body at a level strong enough to generate scar tissue but low enough to be safe.

Furthermore, the *Wand* factors favor defendant. For example, the specification did not (1) provide direction or guidance for using electric current, (2) working examples of the use of electric current, and (3) describe prior art involving electric current. In sum, defendant raises a substantial question with regard to whether the specification enables the use of electric current. Accordingly, plaintiff has failed to prove that this invalidity defense lacks substantial merit or that it will likely succeed on the merits.

2. IRREPARABLE HARM.

Turning to irreparable harm, there is a fifth ground to reject a preliminary injunction. In order for plaintiff's motion to be granted, plaintiff must show that the injury is irreparable. "Only a viable threat of serious harm *which cannot be undone* authorizes exercise of a court's equitable power to enjoin before the merits are fully determined." *Cordis Corp. v. Medtronic, Inc*., 780 F.2d 991, 996 (Fed. Cir. 1985) (internal citations omitted) (emphasis added). It is true that we are concerned with a one-product market, namely the Essure system. If a second product

is allowed into the market, the Essure system will lose market share. Granted. But it will be reasonable and practical to estimate the extent of damages, given the track record over the last seven years. If plaintiff prevails at trial, then damages will reparable and defendant will be able to respond to an award — or at least no convincing showing has been made to the contrary.

CONCLUSION

For the foregoing reasons, plaintiff's motion for a preliminary injunction is **DENIED**.

IT IS SO ORDERED.

Dated: November 6, 2009.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE