United States District Court,
N.D. Texas, Fort Worth Division.

AMERICAN STERILIZER COMPANY,
v.
SURGIKOS, INC.

Civ. A. No. 4-89-238-K

June 19, 1990.

G. Richard Poehner, Roger N. Chauza, Bruce W. Slayden, II, Richards, Harris, Medlock & Andrews, Dallas, Tex., Robert D. Yeager, Edward L. Pencoske, Kirkpatrick & Lockhart, pro hac vice, Pittsburgh, Pa., Robert W. Turner, Kenneth R. Adamo, Daniel F. Perez, Jones, Day, Reavis & Pogue, Dallas, Tex., for plaintiff, 214/220-3939

Timothy J. O'Hearn, Samuel J. Najim, Jones, Day, Reavis & Pogue, Cleveland, Ohi o, of counsel.

Stephen F. Fink, Thompson & Knight, Dallas, Tex., Dianne B. Elderkin, Philip S. Johnson, Henrik D. Parker, Woodcock Washburn Kurtz Mackiewicz & Norris, Philadelphia, Pa., pro hac vice, for defendant.

ORDER

BELEW**, District Judge.**

Pending before the Court is the Motion for Preliminary Injunction filed by American Sterilizer Company. After a Hearing on the Motion and after careful consideration of the evidence and the applicable law, it is the opinion of this Court that the Plaintiff's Motion should be denied.

I. BACKGROUND

American Sterilizer Company, (the Plaintiff), filed its Complaint in this action alleging that the Defendant, Surgikos, Inc., (the Defendant), is infringing its U.S. Patent 4,169,123, (the 123 patent) FN1, by the use of their patent, U.S. Patent number 4,643,876, (the Jacobs Patent). FN2 The process discovered and patented by the Defendant ensued from a finding that the exposure of hydrogen peroxide vapor to radio frequency energy would result in the generation of a highly toxic plasma. The Defendant is currently seeking approval from the Food and Drug Administration to market a sterilizer incorporating the foregoing process. If the F.D.A. approves the sterilizer, the Defendant plans to market their Sterrad Sterilizer as a hospital sterilizer capable of sterilizing both heat sensitive and heat resistive surgical equipment.

The Sterrad Sterilizer incorporates four phases in its patented process. The first phase, known as the vacuum phase, consists of removing all oxygen from the sterilizer's chamber. Following the vacuum phase, hydrogen peroxide is injected into the chamber where it vaporizes. The injection phase is followed by the

diffusion phase, which allows the injected hydrogen peroxide to diffuse throughout the chamber. The cycle is then completed by the plasma phase, which involves the introduction of radio frequency energy into the chamber.

The Defendant contends that sterilization cannot be achieved without the plasma phase. During this phase, a toxic plasma cloud is created by the introduction of radio frequency energy. A radio frequency-induced electrical field is formed which reacts to the existing hydrogen peroxide vapor. During this reaction, electrons are stripped from some of the atoms and the resulting charged particles are accelerated. The electrons recombine with atoms or electrons and return from higher to lower energy states and activated atoms thereby producing a visible glow plasma.FN3 Plasma is a fourth state of matter which is separate and distinct from gas or vapor. It is the Defendant's contention that these particle collisions destroy the hydrogen peroxide by breaking it into various other species, ie. hydroxyl free radicals, activated peroxide and ultraviolet light, among others. These new components within the plasma cloud are claimed to be a sterilent capable of meeting current F.D.A. guidelines of 1 x 10 (to the minus six) probability of survival rate.

Conversely, the Plaintiff contends that the aforementioned process incorporated in the Sterrad Sterilization unit, excluding the plasma phase, is merely Claim One of the 123 patent in disguise. The Plaintiff alleges that "sterilization," commensurate with the term as used in the 123 patent, is achieved during the diffusion phase of the Sterrad process as a result of the instruments being surrounded by hydrogen peroxide vapor. It is therefore the Plaintiff's position, that the plasma phase is superfluous and is incorporated into the process only to disguise the infringement of the Sterrad system.

II. APPLICABLE LAW

Injunctive relief in patent actions is authorized by 35 U.S.C. s. 238. The Party seeking a preliminary injunction must establish four factors before the issuance of an injunction is appropriate. Those factors are: 1. reasonable likelihood of success on the merits; 2. irreparable harm; 3. a balance of hardships tipping in its favor; and 4. that the issuance of the injunction is in the public interest. T.J. Smith v. Consol. Med. Equip., 821 F.2d 646 (Fed.Cir.1987). In order to establish reasonable likelihood of success on the merits in a patent infringement action, the claims must be properly construed to determine their scope and then it must be determined whether the properly interpreted claims encompass the accused structure. Mannesmann Demag Corp. v. Engineered Metal Products Co., 793 F.2d 1279, 1282 (Fed.Cir.1986).

The threshold requirement in claim construction is an examination of the claim in issue. ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1579 (Fed.Cir.1988). The terms of the claim are to be given their ordinary meaning unless it appears that the inventor used them differently. id. at 1579. Resort to extrinsic evidence, such as the prosecution history, is necessary to interpret disputed claims to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance. id. at 1580.

III. DISCUSSION

As noted earlier, the Plaintiff contends that the accused device's diffusion phase is in reality the sterilization phase. The definition of the term "sterilization," by necessity, is of pivotal concern in determining the scope of the 123 patent's claim 1. As the Court will demonstrate, it is precisely this issue which denies the Plaintiff the relief it so earnestly desires.

The Court is persuaded that the term "sterilization" as used in Claim 1 and its Preamble is defined and

limited to the current Food and Drug Administration recommendation of a probability of spore survival of less than 1 x 10 (to the minus six). The Court bases its interpretation on the prosecution history and the definition incorporated in the 123 patent. The inventors of the 123 patent argued to the patent examiner the following:

The applicants contend that the differences are not obvious. Egger describes how tests with hydrogen peroxide gas (120-150 degrees C) were discarded because of extremely poor kills (survival probability reduction of 1 log cycle max). *This would not be a suitable process to meet the very stringent requirements by FDA for sterile medical and surgical products*. Def.Ex. 120 p. 31

In the Amendment After Final, which was entered two days before the allowance of the 123 patent, the inventors again argued the following:

In the past, the problem has been to find a gas sterilent which could provide a kill on the order of 10 to the minus six probability of survival at temperatures below 80 degrees C. Def.Ex. 208 p. 66.

and again:

Exhibit A is a schematic sketch of the 4 tests run by Egger. Test 1 is the only one in which hydrogen peroxide gas contacted the web. Even though the temperature was at 120-150 degrees C., Egger rejected this as non-workable because it was not sterile at a 10 to the minus one probability of survival. The extremely large quantum jump between 10 to the minus one (barely a weak disinfectant) and 10 to the minus six (sterility sufficient for surgical products) could hardly be considered obvious, particularly since Egger rejected the process of this test as totally worthless. Def.Ex. 120 p. 53.

The 123 patent itself contains the following definition for the term "sterilization."

The Food and Drug Administration (FDA) is currently recommending that all medical and surgical products be sterilized to a probability of survival for spores, which are the most resistent of cell to kill, of 10 to the minus six or better. This means that the sporicidal activity of a sterilizing process must be so reliable as to assure the probability of less that 1 organism out of 1,000,000 will survive a sterilization cycle.

The term "sterilization" as used herein means a method of treating microorganisms so that the probability of survival of spores can be less that 1 x 10 (to the minus six).

It is this definition which was argued to the patent examiner and thissame definition which was incorporated in the 123 patent and consequently this definition must set the standard by which alleged infringers are judged. Therefore, to establish a reasonable likelihood of success on the merits, the Plaintiff must establish that at the conclusion of the diffusion phase, the probability of spore survival is less than 1 x 10 (to the minus six): so reliable as to assure the probability of less than 1 organism out of 1,000,000 will survive the diffusion cycle.

In an attempt to establish the Plaintiff's allegations, three tests were administered using a modified software package which allowed the Sterrad Sterilizer to abort its normal process at the conclusion of the diffusion phase. Although the Sterrad instruction manual called for the test chamber to be fully loaded with two large instrument trays, the Plaintiff used one small tray. Although the Sterrad instruction manual called for the trays to be wrapped in the heavy sterile wraps, the Plaintiff wrapped the one tray with the lightest. The

Plaintiff also allowed the diffusion phase to continue for one and one half minutes beyond its normal cycle. All of the foregoing deviations would allow for a greater concentration and penetration of the hydrogen peroxide. That coupled with the fact that the Plaintiff used an all metal instrument load in violation of the operating instructions, enhanced indeterminably the antimicroorgasmic effect of the diffusion phase. Even in the event that sterilization, as it is defined in the 123 patent, had been achieved at the conclusion of the diffusion phase, the deviations taken as a whole would have eviscerated the test result of any probative value.

Notwithstanding these deviations, at the conclusion of all three tests there was a 22.2% failure to sterilize rate which translates to a 1 x 10 (to the minus one or zero) chance of a spore surviving the diffusion cycle. FN4 This admittedly falls well below a probability of spore survival rate of 1 x 10 (to the minus six) as is required for sterilization in claim 1 of the 123 patent. The Plaintiff's expert, Mr. White, testified that a probability rate, as low as was evinced in the protocols, was not within the scope of claim 1 of the 123 patent.FN5 Accordingly, the Court finds that the Plaintiff has failed to show a reasonable likelihood of success on the merits.

In light of the Plaintiff's failure to demonstrate a reasonable likelihood of success on the merits, the Court finds that it would be the Defendant, rather than the Plaintiff, which would suffer irreparable harm if an injunction was ordered. The evidence demonstrates that an injunction would result in an irretrievable loss of important Surgikos employees.

Further, the Court finds that an injunction in this action would be deleterious to the public interest; the public has a vested interest in reducing the toxic emissions produced by Ethylene Oxide sterilizers. Consequently, American Sterilizer's Motion for Preliminary Injunction must be denied.

IV. CONCLUSION

Finally, the Court is aware of the inherent tendency of patent actions to evolve into dismal swamps of erudite technicality. The Court wishes therefore, to congratulate the attorneys on their clear and simple presentation of this case. Your ability and professionalism was much appreciated by the Court.

The Motion for Preliminary Injunction filed by the Plaintiff, AMSCO, is hereby DENIED.

IT IS SO ORDERED.

FN1. Claim 1 of the Moore patent, patent 123, reads:

1. A method of "cold" gas sterilization which comprises:

surrounding an article to be sterilized with hydrogen peroxide gas; and

maintaining said gas in contact with such article at temperatures below 80 degrees Centigrade until such article is sterile, whereupon sterility of said article is established,

and including the step of maintaining said article in a sterile condition protected from recontamination until use.

FN2. Originally, AMSCO alleged infringement of its U.S. Patent No. 4,169,124 (the 124 patent) however, AMSCO has since sought to reissue the 124 patent. Consequently, AMSCO has withdrawn the 124 patent from issue in its preliminary injunction motion.

FN3. This explanation of plasma creation was taken directly from Defendant's Exhibit 300 and the expert testimony of Dr. Tralance Addy.

FN4. The Plaintiff has strenuously sought to focus the Court's attention on test load # 2 which resulted in the complete eradication of spores on all inoculated instruments. This however, would seem to fly in the face of logic and the scientific method. The annals of science are replete with accounts of scientists achieving some notable result once: only later to find that result incapable of repetition. Accordingly, the Court is persuaded that today's decision must be based upon the overall test results and not solely test load # 2.

FN5. Transcript of Hearing, Vol II page 70 lines 4 through 9.

N.D.Tex.,1990.
American Sterilizer Co. v. Surgikos, Inc.