United States District Court,
D. Minnesota.

MINNESOTA MINING AND MANUFACTURING COMPANY,
Plaintiff and Counter-Defendant.
v.
NORTH AMERICAN SCIENCE ASSOCIATES, INC,
Defendant and Counter-Claimant.

Civil No. 97-2860 (DWF/AJB)

March 31, 2000.

Gregory Madera, Esq., and Kurt Glitzenstein, Esq., Fish & Richardson, Boston, MA, Sean Daley, Esq., Merchant & Gould, Minneapolis, MN, for Plaintiff.

Floyd Chapman, Esq., and Steven Leifer, Esq., Baker & Botts, Washington, D.C., for Defendant.

MEMORANDUM OPINION AND ORDER

DONOVAN W. FRANK**, District Judge.**

Introduction

The above-entitled matter came on for hearing before the undersigned United States District Judge on December 10, 1999, pursuant to Defendant's Motion for Summary Judgment of Non-Infringement and Invalidity and Plaintiff's Motion for Summary Judgment of Infringement. For the reasons set forth below, Defendant's motion is denied and Plaintiff's motion is granted in part and denied in part.

Background

Plaintiff Minnesota Mining and Manufacturing Company ("3M") brought this action against North American Science Associates, Inc. ("NAMSA") alleging that NAMSA infringed two patents held by 3M: U.S. Patent No. 5,073,488, issued December 17, 1991 ("the 488 patent") and U.S. Patent No. 5,252,484, issued October 12, 1993 ("the 484 patent"). The patents at issue relate to a method and a device for determining the effectiveness of heat-based sterilization procedures employed primarily in laboratories and medical facilities.

Hospitals, other medical facilities, and laboratories frequently use heat- and steam-based sterilization procedures. FN1 It is essential that the facilities which use such procedures have some method for determining whether any given cycle of the procedure did effectively sterilize the equipment or instruments (for example, surgical instruments). A sterilization cycle which achieves the necessary conditions to kill all bacteria is called a "lethal cycle," while one which for some reason falls short is called a "sublethal cycle." "Historically, to confirm the effectiveness of a sterilization cycle, hospitals would place biological indicators

containing spore strips among the instruments being sterilized, and after the spores were subjected to the sterilization cycle, the hospitals would incubate the spores and check for growth." Memorandum of Fact and Law in Support of Defendant's Summary Judgment Motion on the Issues of Non-Infringement and Invalidity at 1. Because of the incubation period for the spores, using these biological indicators resulted in delays of several days between the date of the sterilization and the date the instruments could be safely used.

FN1. For example, perhaps the most common sterilizer, the autoclave, exposes instruments to be sterilized to steam at a temperature of between 250 to 270 degrees Fahrenheit for a period of at least 15 minutes.

The patents and allegedly infringing device at issue here represent a different type of sterilization indicator. Both 3M and NAMSA have developed sterilization indicators that rely upon enzymes rather than organisms. Because enzymes break down, or "denature," at certain temperatures, a successful sterilization cycle will render the enzyme defunct; placing the enzyme in the presence of some other substance (a "substrate") with which the enzyme-if active-reacts will allow the observer to determine whether the sterilization cycle reached the requisite temperature to denature the enzyme.

The NAMSA device which allegedly infringes the two 3M patents is the RSI Product. The portion of the RSI Product which is subjected to the sterilization cycle consists of a glass vial, a foam plug, and an enzyme tablet which is white in color. The enzyme tablet consists of two types of enzyme: glucose dehydrogenase ("GDH") and diaphorase ("DIA"). The RSI Product also includes a vial of "indicator solution." The indicator solution contains three substrate chemicals: glucose, NAD and INT. After the sterilization cycle, the foam plug is removed and a few drops of the indicator solution are deposited on the enzyme tablet. Assuming a sublethal cycle, the GDH reacts with the glucose and NAD to produce NADH and gluconolactone (which is inert). The DIA reacts with the NADH produced in the first enzymatic reaction and the INT in the indicator solution to produce a chemical called formazan. Formazan is red in color and will be visible to the user. In the case of a sublethal cycle, the distinctive red color of the formazan will appear within 10 to 20 seconds.

3M has moved the Court for summary judgment that the RSI Product infringes both the 488 and 484 patents. NAMSA has moved the Court for summary judgment that: (1) the RSI Product does not infringe the 488 patent; (2) the 488 patent is invalid due to anticipation and obviousness; and (3) the 484 patent is invalid due to anticipation and obviousness.

Discussion

1. Standard of Review

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c). The court must view the evidence and the inferences which may be reasonably drawn from the evidence in the light most favorable to the nonmoving party. Enterprise Bank v. Magna Bank, 92 F.3d 743, 747 (8th Cir.1996). However, as the Supreme Court has stated, "summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy, and inexpensive determination of every action.' " Fed.R.Civ.P. 1. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Enterprise Bank, 92 F.3d at 747. The nonmoving party must demonstrate the existence of specific facts in the record which create a genuine issue for trial. Krenik v. County of Le Sueur, 47 F.3d 953, 957 (8th Cir.1995). A party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine issue for trial. *Anderson v.. Liberty Lobby, Inc.,* All U.S. 242, 256 (1986); Krenik, 47 F.3d at 957.

2. Validity or Invalidity of the 488 Patent

NAMSA alleges that the 488 patent is anticipated by Nelson (U.S. Patent No. 3,661,717); anticipated by Senkpiel et al. ("Kinetics of Destroying Microorganisms and Damaging Selected Bacterial Enzymes by Heat and Chemical Agents I-III"), and/or obvious in light of Nelson, Senkpiel, and other disclosed prior art.

"Under 35 U.S.C. s. 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." Akzo N.V. v. U.S.I.T.C, 808 F.2d 1471, 1479 (Fed.Cir.1986). If an independent claim (here, claim 1) is not anticipated, then none of the claims depending from that claim are anticipated. Thus, if the Court determines that claim 1 is not anticipated, then the 488 patent is not invalid for anticipation.

To invalidate the 488 patent for obviousness, NAMSA must show by clear and convincing evidence that "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. s. 103(a).

A. Anticipation by Nelson

The Nelson patent, No. 3,661,717, describes another sort of sterilization indicator. The Nelson indicator contains a quantity of some microorganism (either fungal, protozoan, or bacterial, in either the spore or vegetative state) which is exposed to the sterilization cycle. The indicator works by exposing the "sterilized" microorganism to some substrate which effects a color change in response to growth by the microorganism. Thus, if the microorganism is killed during the sterilization cycle, there is no growth and hence no color change. As 3M points out, the Nelson patent is substantially different from the method described in the 488 patent. Where the Nelson patent functions because a lethal sterilization cycle will inhibit the growth of a microorganism, the 3M method functions because a lethal sterilization cycle will denature (or inactivate) an enzyme. The substrate color change in Nelson may be a function of production of enzymes during microorganism growth. Thus, the indicator may work because a lethal sterilization cycle eliminates the source of the active enzyme necessary to precipitate a color change. However, there is a difference between a lethal cycle eliminating a "source of active enzyme" and a lethal cycle inactivating the enzyme itself. Most importantly, however, claim 1 of the 488 patent specifically references "a source of active enzyme" and defines certain characteristics which the enzyme must have; the Nelson patent makes no mention whatsoever of any enzyme, much less an enzyme or enzymes with the characteristics set forth in claim 1. In short, the Court finds that the 488 patent method is distinct from the Nelson patent as a matter of law.

B. Anticipation by Senkpiel

The referenced Senkpiel et al. article, "Kinetics of Destroying Microorganisms and Damaging Selected Bacterial Enzymes by Heat and Chemical Agents I-III," considered ways of testing the relative effectiveness of certain types of thermal and chemical sterilization processes. Senkpiel et al. noted that one way in which

sterilization was verified was by exposing particular microorganisms to the sterilization process, cultivating or incubating the microorganisms in an appropriately hospitable medium, and monitoring the rate of reproduction of the microorganism (essentially the process described in the Nelson patent above). Senkpiel et al. hypothesized that, since microorganism death is a function of the breakdown of proteins and enzymes within the microorganism, this "check" could be accomplished without the need to cultivate and incubate the microorganisms. Rather, decomposing the microorganisms to extract particular enzymes and measuring the reactivity of those enzymes could serve as a proxy for monitoring microorganism reproduction.

The Senkpiel et al. article is distinct from the 488 patent for several reasons. First, the Senkpiel et al. article focuses on extracting enzyme from the microorganism sought to be eliminated *after* the sterilization cycle; Senkpiel et al. only suggest in passing the possibility of examining the activity of other enzymes, unrelated to the target microorganisms. What is more, the Senkpiel et al. article specifically states that "[i]t is certainly still premature to comprehensively evaluate when this additional method is indicated for determining the value of sterilization procedures and disinfectants ..., especially since the method can be further developed, for instance by selecting other bacterial enzymes or enzyme systems." This further development is precisely the improvement undertaken by 3M in developing their 488 patent.

Most importantly, however, claim 1 of the 488 patent specifies that the process described will "produce a detectable enzyme-modified product within less than twenty-four hours" while the Senkpiel et al. article describes a process which takes over a week after the sterilization cycle. Again, the Court concludes as a matter of law that the 488 patent is not anticipated by the Senkpiel et al. article.

C. Obviousness

NAMSA asserts that the 488 patent is obvious in light of Nelson and Senkpiel et al.(above) in conjunction with the prior art. When determining the obviousness of a patent claim, the Court must consider "the scope and content of the prior art, differences between the prior art and the claimed invention, the level of ordinary skill in the art, and objective evidence of secondary considerations." Para-Ordnance Manufacturing Inc. v. SGS Importers International, Inc., 73 F.3d 1085, 1088 (Fed.Cir.1995), *cert. denied,* 117 S.Ct. 80 (1995).

The Court has examined the record thoroughly, including the prior art cited by both parties, and cannot conclude as a matter of law that the 488 patent is obvious. Similarly, however, the Court declines to hold that the 488 patent is "not invalid" for obviousness as a matter of law. In short, the Court finds that the record does not support summary judgment of either validity or invalidity on the grounds of obviousness.

3. Infringement or Non-Infringement of the 488 Patent

The 488 patent is entitled "Rapid Method for Determining Efficacy of a Sterilization Cycle and Rapid Read-out Biological Indicator." Claim 1 of the 488 patent, the only independent claim contained in the patent, reads:

Claim 1. A method for rapidly determining the effectiveness of a sterilization cycle, comprising the steps of:

a) subjecting to said sterilization cycle of [sic] a source of active enzyme which provides a delectable amount of said enzyme, said enzyme having sufficient activity following a sterilization cycle which is sublethal to at least one test microorganism commonly used to monitor sterilization, to react with an effective amount of a substrate system for said enzyme to produce a detectable enzyme-modified product

within less than twenty-four hours, yet said enzyme having activity which is reduced to "background" following a sterilization cycle which is lethal to said test microorganism;

b) incubating said enzyme, following the completion of said sterilization cycle, with an effective amount of an enzyme substrate system capable of reacting with any residual active enzyme to produce a detectable enzyme-modified product, for a time period and under conditions sufficient to promote reaction of any enzyme remaining active with said substrate.

NAMSA asserts that its RSI Product is non-infringing because its function does not require "incubating said enzyme ... for a time period and under conditions sufficient to promote reaction of any enzyme remaining active with said substrate." Specifically, NAMSA asserts that the "incubating" language fails for indefiniteness unless read in light of limiting language in the prosecution history to the effect that "for a time period" means from 10 minutes to 8 hours. Because the RSI Product produces a visible reaction after a sublethal cycle in less than 20 seconds, the RSI Product does not literally infringe the 488 patent. The Court cannot agree with NAMSA's analysis.

Generally speaking, the Court may not read limitations into the claims from the specification or the prosecution history. *See* Intervet Am., Inc. v. Kee-Vet Labs. Inc., 887 F.2d 1050, 1053 (Fed .Cir.1989). There are some exceptions to this rule; specifically, where incorporation of a limitation in the prosecution history is necessary to cure a defect in the claim, such a limitation will be incorporated. For example, in Modine Manufacturing Company v. U.S. International Trade Commission, 75 F.3d 1545 (Fed Cir.1996), cert. denied, 518 U.S. 1005 (1996), the Federal Circuit held that a limitation described in the prosecution history could be read as an amendment to the claim where such a limitation was necessary to distinguish the claim from another patent held by the patentee.

Here, NAMSA argues that the defect in the claim-which reference to the prosecution history is necessary to cure-is indefmiteness. However, the Court finds that the claim language is not so indefinite as to require limitation by the language in the prosecution history. The phrase "for a time period and under conditions" is modified by the phrase "sufficient to promote reaction of any enzyme remaining active with said substrate." Although the limiting language's reliance upon "sufficiency" for a particular event provides 3M with a broadly drawn patent, the Court cannot conclude, in light of existing case law, that the limitation is fatally indefinite. Accordingly, the Court has no basis for turning to the prosecution history for a further, more definite, limitation on this provision of the claim.

Given, then, that the 488 patent covers all methods which involve "incubation ... for a time period ... sufficient to promote reaction of any enzyme remaining active with [the] substrate" and the RSI Product involves incubation for a time period (of about 20 seconds) which is sufficient to promote reaction between any remaining active GDH and DIA and the indicator solution, summary judgment of non-infringement premised upon this clause of claim 1 is inappropriate.

3M claims that it is entitled to summary judgment of infringement with respect to the 488 patent. Specifically, 3M claims that the RSI Product literally infringes claims 1, 3, 4, 8, 10, 11, 16, and 20-25 of the 488 patent. NAMSA contends that the RSI Product does not literally infringe the 488 patent because: (1) the term "incubate" means to cultivate a controlled environment, specifically one with an elevated temperature, and the RSI Product works at room temperature; (2) as discussed above, the phrase "for a time period" cannot be construed, in light of the prosecution history, as covering a process which takes only 20 seconds; and (3) the enzymes used in the RSI Product are different from the enzymes identified in the 488 patent and

their activity levels are not reduced to "background" when subjected to a lethal sterilization cycle. The Court has already addressed the second argument of NAMSA, above, and found it unpersuasive; the Court now considers the meaning of the term incubate, the identity of the enzymes in the RSI Product, and the meaning of the term "background."

First, with respect to the term "incubate," whatever meaning the term generally has, the claim specifically states that the process involves "incubating [the] enzyme ... under conditions sufficient to promote reaction of any enzyme remaining active with [the] substrate." If the "condition [ ] sufficient to promote reaction" is simply the ambient air temperature, then room temperature conditions could be the conditions of incubation. In other words, the Court finds that the plain meaning of the term "incubate" is to foster conditions necessary for a particular event; the language of the claim specifies that "incubation" in this context means to foster conditions necessary for the promotion of the reaction between any remaining active enzyme and the substrate. While most enzymatic reactions would only be promoted under elevated temperature conditions, there are no limitations on what those conditions might be which would suggest that exposure to the ambient environment could not constitute "incubating."

With respect to NAMSA's claim that a lethal sterilization procedure does not reduce enzymatic activity in the RSI Product to "background," 3M correctly notes that NAMSA's contention seems to rely upon defining "background" as "zero activity." NAMSA argues that the GDH and DIA activity levels, in the wake of a lethal sterilization cycle, are not reduced to background because eventually the residual enzymatic activity results in a color change on the tablet-it simply takes longer than 20 seconds. However, as 3M points out, the 488 patent provides a functional definition of "background":

[t]he enzyme when subjected to sterilization conditions which would be [lethal] has residual enzyme activity which is equal to "background" .... Preferably, the activity of the enzyme after [sublethal] sterilization conditions ... most preferably is at least 10 percent above background. It is understood that the residual enzyme activity level which is defined as "background" for purposes of this invention, may be higher than that achieved by the spontaneous conversion of enzyme substrate to product after the enzyme has been totally and irreversibly inactivated.

Declaration of Floyd B. Chapman, Ex. 1 at Col 4, lines 23-59. Thus, the 488 patent clearly states that "background" enzymatic activity is likely to be above zero (indeed, for sublethal-cycle activity to be "10 percent above background," background must necessarily be above zero). Rather, "background" is circularly defined as the level of enzymatic activity which remains after a lethal sterilization cycle. The key is that "background" activity and sublethal-cycle activity must be distinguishable by sublethal-cycle activity being at least 2 percent and preferably at least 10 percent above "background" activity.

Finally, NAMSA asserts that the enzymes used in its RSI Product are different from those listed in the 488 patent. However, the 488 patent claims do not limit the enzymes which could be utilized in practicing the patent. Rather, the patent states that "[t]he enzymes useful in the practice of the present invention are enzymes including extracellular and intracellular enzymes, whose activity correlates with the viability of at least one microorganism commonly used to monitor sterilization efficacy...." Declaration of Floyd B. Chapman, Ex. 1 at Col. 4, lines 4-8. The patent goes on to specify a number of enzymes which meet that criterion, but there is no language in the claims limiting its scope to the listed enzymes.

In light of the defects in NAMSA's arguments, the plain meaning of the 488 patent, and the description of the RSI Product, the Court concludes that the RSI Product literally infringes claims 1, 3, 4, 8, 10, 11, 16, and

20-25 of the 488 patent. FN2

FN2. NAMSA only challenges 3M's Motion for Summary Judgment of Infringement on the terms of claim 1. The Court has reviewed the allegedly infringed dependent claims and finds that the RSI Product does, without much controversy, infringe those claims.

4. Validity or Invalidity of the 484 Patent

NAMSA also challenges the validity of the 484 patent. Where the 488 patent described a method for determining the effectiveness of a sterilization cycle, the 484 patent describes a particular sterilization indicator device employing that method. NAMSA challenges the 484 patent as anticipated by Nelson, anticipated by Senkpiel et al., and/or obvious in light of those references and the prior art. NAMSA's arguments in that regard mirror NAMSA's invalidity arguments with respect to the 488 patent. For the same reasons that the Court rejected those arguments in the context of the 488 patent, the Court rejects them here. Accordingly, NAMSA's Motion for Summary Judgment of Invalidity with respect to the 484 patent is denied. FN3

FN3. Similarly, however, for the reasons stated above, the Court does not find that the 484 patent is valid as a matter of law either.

5. Infringement of the 484 Patent FN4

FN4. NAMSA has not moved for summary judgment of non-infringement of the 484 patent.

3M moves the Court for Summary Judgment of Infringement with respect to the 484 patent. Specifically, 3M contends that claims 1 and 6-9 of the 484 patent are literally infringed by the RSI Product. Claims 6-8 of the 484 patent relate to read-out times, specifying times of less that twelve, eight, and three hours respectively. Claim 9 simply describes the amount of residual enzyme activity following lethal and sublethal sterilization cycles. On their face, these claims are infringed by the RSI Product if the RSI Product infringes the independent 484 claim, namely claim 1.

Claim 1 of the 484 patent reads:

1. A sterility indicator comprising

a) an outer container having liquid impermeable and substantially gas non-absorptive walls, said container having at least one opening therein; and

b) a gas-transmissive, bacterial impermeable means covering said opening; and

c) contained within said outer container, a detectable amount of active enzyme isolated from an appropriate microorganism, said enzyme having sufficient activity following a sterilization cycle which is sublethal to at least one test microorganism commonly used to monitor sterilization, to react with an effective amount of a substrate system for said enzyme to produce a detectable enzyme-modified product within less tan [sic] twenty-four hours, yet said enzyme having activity which is reduced to "background" following a

sterilization cycle which is lethal to said test microorganisms.

Declaration of Floyd B. Chapman, Ex. 2 at Col. 35, lines 40-57. There is no question that the RSI Product meets the description in subpart (a) of claim 1: the RSI Product consists of a small glass vial which is liquid impermeable, substantially gas non-absorptive, and has a single opening in one end. The Court has already discussed the elements of subpart (c) of claim 1, which mirror similar language in the 488 patent and found that the RSI Product meets the criteria described in subpart (c).

The parties disagree about whether the RSI Product conforms with the criteria of subpart (b) of claim 1. The parties do agree that the language of subpart (b) is so-called "means-plus function" language. As NAMSA notes, to fall within a means-plus-function limitation, an accused device must employ an identical or equivalent structure *and* that structure must perform the identical function as recited in the means-plus-function limitation. *See, e.g.,* Micro Chem. Inc. v. Great Plains Chem. Co. Inc., 103 F.3d 1538, 1547 (Fed.Cir.1997), *cert. denied,* 521 U.S. 1122(1997).

The structure recited in the limitation is a "tortuous pathway that is bacteria-impermeable." NAMSA argues that the foam plug which is inserted in the opening of the RSI Product is not a "tortuous pathway" within the meaning of the 484 patent and even questions whether the plug is sufficiently "bacteria-impermeable" to comprise a structure equivalent to that described in the patent.

However, the Court need not determine whether the structure of the foam plug is equivalent or identical to that described in the 484 patent, because the Court finds that the foam plug does not perform a function identical to that described in the 484 patent. Specifically, NAMSA contends, and there is no evidence to contradict, that the foam plug in the RSI Product does nothing more than keep the enzyme tablet from falling out of the vial. Thus, to the extent that the foam plug is bacteria-impermeable, that characteristic is incidental and is not the "function" of the foam plug at all.

Because the Court finds that the foam plug on the RSI Product does not satisfy the "means-plus-function" criteria of subpart (b) of claim 1, the Court concludes that it would be inappropriate to grant summary judgment of infringement of the 484 patent. FN5

FN5. The Court notes that 3M has not moved for summary judgment on the 484 patent pursuant to the doctrine of equivalents.

For the reasons stated, **IT IS HEREBY ORDERED:**

1. Plaintiff's Motion for Summary Judgment of Infringement (Doc. No. 121) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Plaintiff's Motion for Summary Judgment of Infringement is **GRANTED** as to U.S. Patent No. 5,073,488.

b. Plaintiff's Motion for Summary Judgment of Infringement is **DENIED** as to U.S. Patent No. 5,252,484.

2. Defendant's Motion for Summary Judgment of Non-Infringement and Invalidity (Doc. No. 106) is **DENIED.**

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Minnesota Mining and Mfg. Co. v. North American Science Associates Inc.