In the Matter of

CERTAIN THERMOMETER SHEATH PACKAGES

Investigation No. 337-TA-56

USITC PUBLICATION 992

JULY 1979

United States International Trade Commission / Washington, D.C. 20436

UNITED STATES INTERNATIONAL TRADE COMMISSION

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In the Matter of CERTAIN THERMOMETER SHEATH PACKAGES	Investigation No. 337-TA-56

COMMISSION DETERMINATION AND ORDER AND COMMISSIONERS' OPINIONS IN SUPPORT OF COMMISSION ACTION

The United States International Trade Commission conducted an investigation under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) ("section 337") of unfair methods of competition and unfair acts in the unauthorized importation into the United States of certain thermometer sheath packages covered by the claims of U.S. Letters Patents No. 3,525,558, and 3,847,280, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. On July 10, 1979, the Commission determined that there is a violation of section 337 and ordered that thermometer sheath packages falling within claims 1, 4, 5, 8, 9, 13, 15, 16, 17, and 18 of U.S. Letters Patent No. 3,552,558, and claims 1, 2, and 5 of U.S. Letters Patent No. 3,847,280 be excluded from entry into the United States for the term of those patents (until January 5, 1988) 1/ unless the importation is licensed by the patent owner.

1/ A terminal disclaimer filed with the application for U.S. Letters Patent No. 3,847,280 reduces the term of that patent, granted Nov. 12, 1974, to Jan. 5, 1988, the expiration date of U.S. Letters Patent No. 3,552,558.

The purpose of this Commission determination and order, and the Commissioners' opinions, is to provide for the final disposition of the Commission's thermometer sheath packages investigation. The Commission's determination and order are set forth below; the Commissioners' opinions are included separately thereafter.

Determination

Having reviewed the record in this matter, the Commission, on July 10, 1979, determined: 1/

1. That there is a violation of section 337 of the Tariff Act of 1930, as amended, in the importation into the United States of certain thermometer sheath packages falling within claims 1, 4, 5, 8, 9, 13, 15, 16, 17, and 18 of U.S. Letters Patent No. 3,552,558 and claims 1, 2, and 5 of U.S. Letters Patent No. 3,847,280, or in their sale by their owners, importers, consignees, or agents of either, in the United States, the effect or tendency of which is to substantially injure an industry, efficiently and economically operated, in the United States; 2/

2. That the appropriate remedy for such a violation is to direct that thermometer sheath packages falling within claims 1, 4, 5, 8, 9, 13, 15, 16, 17, and 18 of U.S. Letters Patent No. 3,552,558, and claims 1, 2, and 5 of

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1/ Chairman Joseph O. Parker determined that there is no violation of sec. 337 for the reasons set forth in his dissenting opinion.

2/ The Commission determined that claims 12 and 19 of U.S. Letters Patent No. 3,552,558 are not being infringed by the imported thermometer sheath packages.

U.S. Letters Patent No. 3,847,280, be excluded from entry into the United States for the terms of said patents, except under license of the patent owner; 1/

3. That, after considering the effect of such relief upon the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, and U.S. consumers, such relief should be imposed; and

4. That the bond provided for in subsection (g)(3) of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337(g)(3)) be in the amount of 10 percent of the value of the thermometer sheath packages concerned, f.o.b. foreign port.

Order

Accordingly, it is hereby ordered that--

1. Complainant's motion 2/ to dismiss those portions of the amended complaint which allege that respondents are offering their thermometer sheath packages below their average variable cost in order to damage the business of complainant and make complainant less effective as a competitor is granted;

2. Thermometer sheath packages falling within claims 1, 4, 5, 8, 9, 13, 15, 16, 17, and 18 of U.S. Letters Patent No. 3,552,558 and claims 1, 2, and 5 of U.S. Letters Patent No. 3,847,280 are excluded from entry into the United States for the terms of said patents except where such importation is licensed by the owner of said patents; 3/

1/ Because the terminal portion of U.S. Letters Patent No. 3,847,280 has been disclaimed, the expiration date for both patents is Jan. 5, 1988.

2/ The motion is not numbered but is contained in a letter from complainant's counsel dated Feb. 7, 1979, and filed Feb. 12, 1979.

3/ See note 1, supra.

3. Thermometer sheath packages ordered to be excluded from entry are entitled to entry into the United States under bond in the amount of 10 percent of their value, f.o.b. foreign port, from the day after the day this order is received by the President pursuant to section 337(g) of the Tariff Act of 1930, as amended, until such time as the President notifies the Commission that he approves or disapproves this action but, in any event, not later than 60 days after such day of receipt;

4. That this determination and order will be published in the Federal Register and served upon each party of record in this investigation and upon the U.S. Department of Health, Education and Welfare, the U.S. Department of Justice, the Federal Trade Commission, and the Secretary of the Treasury; and

5. That the United States International Trade Commission may amend this order at any time.

By order of the Commission:

Kenneth R. Mason
Secretary

Issued: July 25, 1979

Opinion of Vice Chairman Alberger, and Commissioners Bedell, Moore, and Stern

I. Procedural history

This proceeding was instituted July 25, 1978, 1/ in response to a complaint filed by Steridyne Corporation on June 7, 1978, alleging that respondents Astra-Sjuco A.B., Medline Industries, and Caring International (a Medline division) were violating section 337 by reason (1) of the unauthorized importation and sale of certain thermometer sheath packages which infringed U.S. Letters Patent No. 3,552,558 (the '558 patent) and U.S. Letters Patent No. 3,847,280 (the '280 patent), to which complainant holds an exclusive license granted by the patentee, Mr. George Poncy, Sr., and (2) of offers for sale of the imported articles below fair value and below cost in order to encourage complainant's customers to purchase respondents' product. The Commission initially instituted the investigation solely on the patent-based allegations; however, on December 14, 1978, the Commission granted complainant's motion to amend the complaint to allege that respondents were offering the imported articles below their average variable cost with the purpose of damaging complainant's business. 2/

A. Recommended determination. -- Administrative Law Judge (ALJ) Donald K. Duvall conducted a hearing from January 25, 1979, through February 2, 1979, with all parties participating. On May 3, 1979, Judge Duvall filed his recommended determination that "there is no violation of Section 337 . . . in the unauthorized importation into the United States, and the sale of certain thermometer sheath packages by reason of the fact that these thermometer

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1/ 43 Fed. Reg. 32,195 (1978).
2/ 43 Fed. Reg. 59,140 (1978).

sheath packages do not infringe claims 1, 4, 5, 8, 9, 12, 13, 15, 16, 17, 18, and 19 of the United States Letters Patent 3,552,558, and claims 1, 2, and 5 of United States Letters Patent 3,847,280, although their importation and sale may tend to destroy or substantially injure an industry, efficiently and economically operated, in the United States ." 3/ In an amendment to his recommended determination filed June 28, 1979, Judge Duvall further recommended that the Commission grant complainant's motion to withdraw its allegation of predatory pricing activities as to all respondents. 4/

All parties filed exceptions to the recommended determination; the complainant and Commission investigative attorney objected to the findings pertaining to alleged unfair acts, while the respondents objected to the injury determination. All parties filed briefs with the Commission and participated in the Commission hearing held June 28, 1979, 5/ for the purpose of entertaining arguments concerning the recommended determination and relief, bonding, and the public interest factors which the Commission must consider when it determines there is a violation of section 337. 6/

3/ Recommended Determination (RD) at i. Other references will be abbreviated herein as follows: (1) TRJ - transcript of hearing before the administrative law judge; (2) TRC - transcript of hearing before the Commission (June 28, 1970); (3) FF - finding of fact by the administrative law judge.

4/ Two oral motions are memorialized in a letter from complainant to Judge Duvall, dated Feb. 7 and filed Feb. 12, 1979, in which counsel confirmed his previous oral agreements to withdraw the allegations. See TRJ 77-78. Although the letter refers to Astra and Medline, complainant clearly meant to include respondent Caring International, which is a division of Medline. Id. at 78. The letter now serves as a single motion, but there is no motion number.

5/ 44 Fed. Reg. 32,485 (1979).

6/ 19 U.S.C.A. 1337(d),(f) (West Supp. 1979).

B. Commission determination. -- Having considered the record of the instant investigation, the Commission, meeting in public session on July 10, 1979, and acting in accordance with section 210.55 of the Rules 7/, determined by a vote of 4 to 1 8/ that there is a violation of section 337 in investigation No. 337-TA-56, by reason of the unauthorized importation and sale by respondents of certain thermometer sheath packages which infringe claims 1, 4, 5, 8, 9, 13, 15, 16, 17, and 18 of valid U.S. Letters Patent No. 3,552,558, and claims 1, 2, and 5 of valid U.S. Letters Patent No. 3,847,280, which unfair acts have the effect or tendency of substantially injuring an industry, efficiently and economically operated, in the United States. 9/ The Commission further determined that (1) articles infringing the complainant's patent should be excluded from entry into the United States, (2) the public interest does not preclude the Commission from ordering this remedy, and (3) articles ordered to be excluded from entry are entitled to enter the United States under bond in the amount of 10 percent of their value, f.o.b. foreign port. The Commission also granted, by a unanimous vote, the complainant's motion to withdraw for all respondents its allegation of predatory pricing activities.

The Commission's statutory deadline for concluding this investigation is July 25, 1979, one year after institution by public notice in the Federal

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7/ 19 CFR 210.55 (1978).

8/ Chairman Parker determined that there is no violation of section 337 for the reasons set forth in his dissenting opinion, infra. The vote on the remaining issues was 4 to 0. Chairman Parker did not participate in the voting on these issues because he determined there was no violation of section 337.

9/ Claims 12 and 19 of the '558 patent were originally alleged to be infringed also. Because they require a sterile sheath package, however, we find they are not infringed by respondents' less than sterile TempoTek product.

Register. 10/ The issuance of this report and publication of a notice and order in the Federal Register conclude this investigation.

II. The Issues

Thermometer sheath packages are structures designed to prevent the transmission of diseases through the use of thermometers. Since at least the 1940's the medical profession evinced concern that sterilization processes were insufficient to cleanse thermometers satisfactorily for safe reuse. In the subsequent two decades a number of proposals were made for devices to protect a thermometer (or other medical instrument) from direct contact with the patient using it, thus preventing the patient from contracting bacteria already present on the thermometer while also preventing the patient from imparting his germs to the thermometer for possible transmission to future users. Simply described, these devices generally comprised disposable sheaths made of thin, flexible, transparent plastic into which the thermometer would fit; only the sheath would contact the patient while the thermometer inside it was registering the patient's temperature, and it would be disposed of after use. Packages were designed to provide quick and easy exposure of the sheath, and to insure the sheath would remain clean. This particular combination of sheath and package is known as a thermometer sheath package, although the idea is adaptable to other medical instruments.

Complainant Steridyne Corporation produces Steritemp thermometer sheath packages as sole licensee of Mr. George W. Poncy, Sr., holder of the '558 and

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10/ 19 U.S.C.A. 1337(b)(1) (West Supp. 1979); 19 CFR 210.15 (1978).

'280 patents. In general, Steritemp comprises a sheath formed of a tear seal imprinted on two plastic strips heat-sealed together, covered by a package of two outer plastic-coated paper strips also heat-sealed along the tear seal to the inner strips. After a thermometer is inserted into the sheath, the outer cover strips are peeled away to expose the sheath-covered thermometer for use.

Respondent Astra-Sjuco A.B. exports the accused TempoTek thermometer sheath packages to the United States from Sweden, where they are manufactured by Develloo A.B. Respondents Medline and its division, Caring International, distribute the imported products, which are made in accordance with U.S. Letters Patent No. 4,051,930, issued to Harry Jarund, a principal in Develloo A.B., on October 4, 1977. The Jarund thermometer sheath package may be generally described in much the same way as Steritemp: it too has a sheath formed of heat-sealed thermoplastic material, with two paper cover strips lightly sealed to the sheath to form a hygienic package. Respondents insist that the package is patentably distinct in design and function, for the reasons described below.

In response to the complaint, respondents presented the following defenses: 11/ (1) the patents are invalid over the prior art; (2) the patents are void for insufficient disclosure of the means to produce and use the allegedly patented articles; (3) the '280 patent is invalid for double patenting; (4) the patents are unenforceable because of overreaching conduct during the prosecution of the '280 patent; (5) TempoTek does not infringe

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11/ Under section 337(c), "all legal and equitable defenses may be presented."

either patent; and (6) the sale of TempoTek has not resulted in demonstrable injury to the domestic industry.

The administrative law judge found inter alia that the patents sufficiently disclose the method of manufacture and use to be valid (RD 36-37); the '280 patent was sufficiently distinct from the '558 patent to avoid invalidity on double patenting grounds (RD 40-41); there was no overreaching conduct rendering the patents unenforceable (RD 43-47); and there was sufficient evidence of injury to satisfy section 337 (RD 53-56). With the exception of the latter, respondents have not objected to these findings before the Commission. We believe the record supports the ALJ's recommended determination on these issues; to the extent they are consistent with our final determination, we adopt his specific findings of fact and conclusions of law relating thereto, and with the exception of the injury determination, will not discuss these issues further. In addition, we will not further discuss our grant of complainant's unopposed motion to withdraw its predatory pricing allegations against all respondents; the evidence clearly would not have supported continued pursuit of that claim, even had complainant desired to do so.

We have disagreed, however, with the ALJ's recommendations on the issues of patent validity (nonobviousness) and infringement. The remainder of this opinion will analyze the suit patents and describe our reasons for finding them nonobvious and infringed. We offer additional comments on our findings concerning the issues of relief, bonding, and the public interest. To the

extent the ALJ's findings of fact and conclusions of law are consistent with our discussion on these issues, we adopt them also.

III. The invention

Both the suit patents and accused product contemplate a sheath formed of heat-sealed thermoplastic material enclosed by paper cover strips releasably sealed to the sheath to form a package. But the parties paint two very different portraits of the disclosures made by the Poncy patents, each leading to opposite conclusions on the issues of validity and infringement. Contrary to the assertions of the complainant and staff at oral argument, we do not believe the ALJ misunderstood the suit patents; rather, we believe he interpreted the language of the claims too narrowly and failed to give sufficient weight first to the presumption of validity statutorily accorded regluarly-issued patents, and second to consideration of secondary indicia of nonobviousness. In a close case such as this one, these factors tip the scale for us in favor of validity and infringement. Because an understanding of the inventive concepts embodied in the patents is crucial to the resolution of the issues in this case, we undertake below to analyze in detail the meaning of the patent claims. This analysis will necessarily touch on the questions of validity and infringement, but we believe it serves best to illuminate the issues in this way.

A. The claims. -- The '558 patent contains two allegedly infringed independent claims—1 and 13--and a number of dependent claims, not all of which are alleged to be infringed. As the allegedly infringed claims of the '280 patent must stand or fall as do the independent claims of the '558 patent, only the latter will be discussed in detail here.

Claim 1 of the '558 patent claims:

1. A flexible sheath package for clinical tools and instruments comprising:
   a. a sheath body of heat sealable material having an open end for the insertion of an instrument;
      1. said sheath having a sterilizable exterior surface;
   b. a separate, disposable outer cover for said sheath comprising heat sealable material wholly enclosing the outer surfaces of the sheath and sealed thereto on each side at the area of said sheath opening;
      1. said cover having a sterilizable interior surface;
   c. said sheath being defined by a seal line in the form of a tear seal, said tear seal joining said sheath and said cover together along the line of said seal, thereby enclosing said sheath body within the interior body of said cover; and
   d. said outer cover and the waste portions of said sheath material outside of said seal line being separable from said sheath along said tear seal to expose said sheath for clinical use when said instrument is inserted therein.

Claim 13 further claims:

13. Means for sheathing instruments against transmission of infectious diseases comprising an assembly having:
   a. upper and lower layers of material with heat sealable, sterilizable facing surfaces;
   b. intermediate layers of heat sealable, sterilizable material disposed between said upper and lower layers;
      1. each of said intermediate layers being in contact with the respective adjacent heat sealable facing surface and with each other;
      2. each of said intermediate layers being sealed along a marginal portion to its adjacent outer layer;
   c. all of said layers being united by a seal defining the outline of the sheath, whereby a sheath is formed by said intermediate layers within the line defining said seal, said line forming a tear seal in said intermediate layers, said sheath having an open end and a closed end;
   d. said upper and lower layers being strippable from said sheath and from each other substantially along said tear seal to expose said sheath for clinical use when an instrument is inserted therein.

The specifications reveal a number of objectives sought to be accomplished by the invention described in the two independent and their

dependent claims. First, the specifications note "a principal object . . . is to provide, in a sterile, expendable package, a sterile, disposable sheath . . . ." (col. 1, lines 28-30). Similarly, it is further stated that "another object of the invention is to provide a transparent sheath for a thermometer in which the exterior surface of the sheath is sterilized and is maintained in a sterile condition by its enclosing package, which is also sterilized at those portions which come into contact with the sheath." (col. 1, lines 48-52). Finally, it is noted that "a further object is to provide such a device which is disposable and can be mass produced in very substantial quantities in a short space of times at such low cost that is (sic) will be competitive with prior devices and methods for using . . . devices which must be kept sterile . . . ." (col. 1, lines 53-58. See also col. 4, lines 18-23).

To accomplish these objectives, Mr. Poncy designed a sheath package of the following structure: there are two inner layers of thin, transparent, flexible plastic encased by two outer layers of thermoplastic coated paper. The inner layers are joined by a tear seal which forms a sheath between them; the outer layers are heat-sealed, in a releasable seal, to the inner layers along the tear seal. When the sheath is formed by the tear seal on the inner strips, the plastic remaining outside the seal line--so-called "waste material"--becomes part of the package, forming the side edges, together with the outer cover strips to which it is sealed. A thermometer may be inserted into the mouth of the sheath, which is enclosed by the package, after which the outer strips are peeled away to expose the sheath-enclosed thermometer. Because of the tear seal and the seal between the outer and inner strips, the

pulling away of the cover strips simultaneously strips away the inner waste material, so that only the sheath remains. After use, the sheath is simply slipped off the thermometer and thrown away. The following diagrams illustrate this structure.

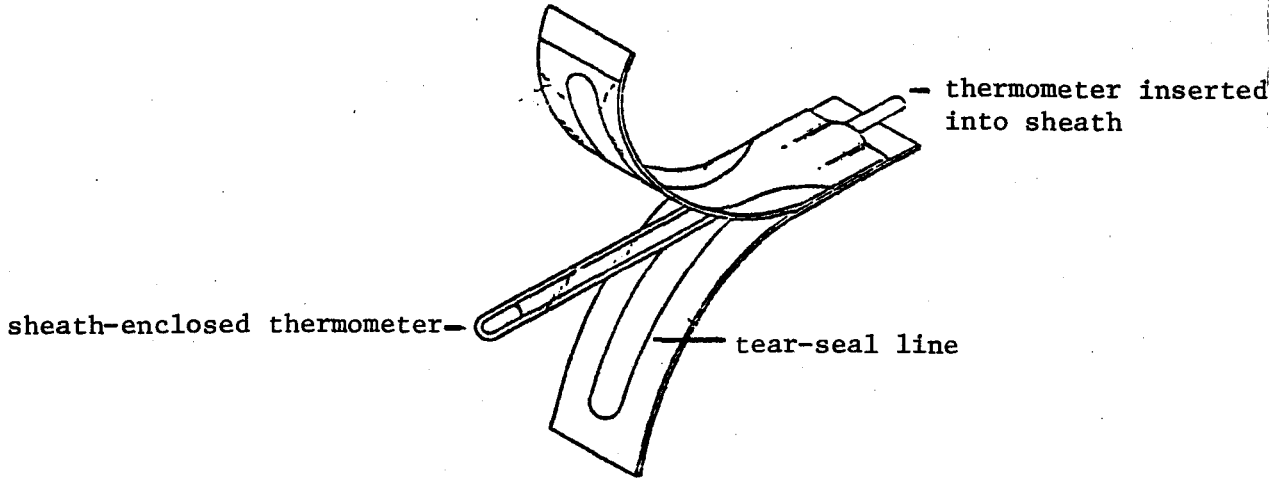

Figure 1: Product configuration

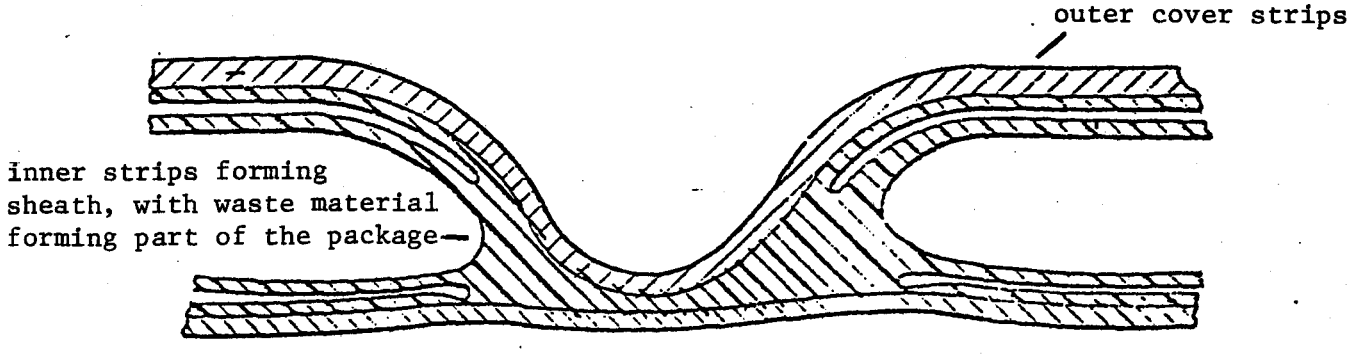

Figure 2: Cross-section

The '280 patent is based on this structure, but is intended to incorporate the additional concept of providing a prelubricated thermometer sheath. The allegedly infringed claims of the '280 patent (1, 2, and 5), unlike the corresponding claims of the '558 patent, do not require the cover strips to be joined to the sheath at the sheath opening nor the inner strips be sealed along a marginal portion to the outer strips. Thus, these claims are somewhat broader than those of the '558 patent in terms of the basic structure of the sheath package.

B. Interpretation of the claims. -- The design indeed reveals a sterile thermometer sheath package (assuming the product is sterilized when manufactured). But because others (notably Morris, exhibit D) had previously invented such packages, one must look to other features of the design to discern why the Poncy product was unique. Complainant argues that no prior sheath package had been commercially successful simply because no design had allowed for economical manufacture. To solve this problem, Mr. Poncy conceived three ideas to be incorporated in his new design: (1) the concept of having the waste material on the inner strips automatically removed when the cover strips are pulled off; (2) the concept of having the sheath and cover strips enclosing the exterior of the sheath (thus forming the package) formed in one die stroke and with one die surface; and (3) the concept of having the side edges of the sheath enclosed by the waste material of the sheath itself. (TRJ 143-54; specifications col. 2, lines 72-75; col. 3, lines 1-7; col. 4, lines 23-29). Complainant argues that the immediate commercial success of the patented product demonstrates that these concepts were novel and solved the previous manufacturing dilemma.

In contrast, respondents argue that the heart of the Poncy invention, in both concept and design, is the provision of a sterile sheath package. The prior art, in their view, clearly made the three alleged concepts old or obvious; therefore, his inventive ideas must have been directed towards the production of a sterile sheath package, as evidenced by the specifications and language of the claims. Specifically, respondents point to the plastic-coated paper covers, the construction of the tear seal, the fully enclosing package, the method of exposing the sheath, and the language of the specifications as demonstrating their thesis. When so interpreted, respondents argue, the patented subject matter must be seen as obvious and, in any case, not infringed by respondents' hygienic--but not sterile--product.

The ALJ distilled primary claims 1 and 13 as showing--

> the main elements of the Poncy sheath package are a flexible, heat-sealed sheath with an open end, whose exterior surface is wholly enclosed (and sterilizable, i.e., capable of maintaining sterility) by a disposable, heat-sealable outer cover sealed to the sheath at its open end and along a tear seal line forming the cover and the sheath, said cover and waste material outside the seal line of the sheath being separable/strippable from the sheath along the seal line when an instrument is inserted into the sheath, thus exposing the sheathed instrument for clinical use. One of the key elements in these claim provisions, construed in the light of the patent specifications and drawings and the evidence of record, is the requirement that the outer surface of the sheath and the inner surface of the cover wholly enclosing the sheath be "sterilizable". While both the Poncy and the TempoTek sheath packages are sterilizable . . . , one of the principal objects of the Poncy sheath package was to provide a sterile (sheathed) thermometer to avoid or minimize cross-contamination and transmission of infectious diseases, . . . I would therefore construe "sterilizable" as used in Claim 1 as meaning capable of maintaining a sterile (absolute absence of bacteria) condition.

RD 46-47 (citations omitted). He thus agreed with respondents' portrait of the Poncy invention, and, interpreting the claims accordingly, found no infringement because the TempoTek product clearly does not provide a sterile

sheath package. He further declined to find that the three alleged inventive concepts put forth by complainant were sufficiently unique to avoid obviousness.

It is plain from the ALJ's description quoted above that the crux of his determination is the interpretation of the word "sterilizable" in the claims language to mean "capable of maintaining a sterile condition." While it is proper to refer to the specifications, drawings, and file wrapper to determine the meaning of the claims, General Electric Co. v United States, 572 F.2d 445, 751, 757 (Ct. Cl. 1978).; CMI Corp. v. Metropolitan Enterprises, Inc., 534 F.2d 874, 881 (10th Cir. 1976); Autogiro Co. of America v. United States 384 F.2d 391, 397 (Ct. Cl. 1967), it is also true that the claims--not the other elements--define the invention. Smith v. Snow, 294 U.S. 1, 11 (1935) (cited in Coleco Industries v. United States International Trade Commission, 573 F.2d 1247, 1253 (C.C.P.A. 1978). Although there is merit in the ALJ's conclusion, we believe the claims must not be read as he suggests.

Identifying an "essence" of an invention--in this case, sterility--cannot substitute for close adherence to the claims when determining their meaning. Aro Mfg. Co. v. Convertible Top Co., 365 U.S. 336, 345 (1962). The plain meaning of claims language is entitled to a strong presumption that it correctly expresses the scope of the claim. Paeco, Inc. v. Applied Moldings, Inc., 561 F.2d 870, 874 (3d Cir. 1977); Maclaren v. B-i-w Group, Inc., 535 F.2d 1367, 1373 (2d Cir. 1976); Bontrager v. Steury Corp., 457 F.Supp. 526, 536 (N.D. Ind. 1978). "Sterilizable" plainly means "capable of being sterilized," and to define the word to mean "capable of maintaining a sterile

condition" requires considerable distortion of the sentences in the claims; no dictionary definition for the word can be found broader than this plain, commonly accepted meaning. The claims describe the inner strips forming the sheath and the cover strips forming the package as having sterilizable surfaces (cl. 1(a)(1), 1(b)(1), and cl. 13(a), (b)(1)). Even read in the context of the specifications, these claims are sensible using the plain meaning of sterilizable. 12/ While the specifications make clear that providing a sterile sheath package is a principal object of the patents, (col. 1, line 28), the method by which this is accomplished is the subjection of sterilizable materials (the cover and inner strips) to ultraviolet exposure during assembly, (claim 26c), or by sterilizing the completed product "in any other suitable or appropriate manner." (column 3, lines 14-23). Presumably, when the patent was filed the author felt it logically necessary to have a material which was capable of being sterilized before the sterilization process could be successfully applied, consistent with the method claims (claims 26-29). While the package may be designed to maintain the sheath in a sterile condition, the allegedly infringed claims disclose something less; until the materials or package undergo the sterilization process, they are

12/ Even if one agreed with respondents that everything is sterilizable--and therefore the patentee must have meant more by use of this limiting word--it does not follow that respondents' definition is the correct one. The patentee clearly contemplated that a sterilization process could be used wholly apart from the manufacture of the sheath packages, and it is not surprising that he would include language making clear that the sterilization process would be effective - i.e., the materials used were indeed sterilizable. This interpretation would apply even where sterilization is a part of the manufacturing process, as suggested in claim 25. As a limitation the word may add little to the claim but as counsel pointed out (TRC 32), it was not assumed then, or now, that everything is sterilizable.

incapable of maintaining a sterile sheath--but this sterilization process is not a limitation in the allegedly infringed claims. Further, where in the specifications the patentee meant to say "capable of maintaining a sterile condition" he did so. (See, e.g., col. 1, lines 35-36, 50). In sum, we believe the ALJ incorrectly altered the plain meaning of the crucial claims.

Further, we believe another of complainant's arguments concerning interpretation of the claims is persuasive: the ALJ's definition imparts to those broad claims using "sterilizable" limitations found only--and specifically--in narrower, dependent claims. While all dependent claims inherently reflect some measure of redundancy, it is logical to assume that the patentee would not have felt it necessary to repeat identical claims. It is fundamentally improper to read limitations found only in narrow claims into broader ones, Oldroyd v. Morgan, 57 F.2d 358, 360 (C.C.P.A. 1932)--but this is the undeniable result of the ALJ's interpretation.

The ALJ's acceptance of the respondents' portrait of the Poncy invention further lead him to interpret too narrowly the other essential claim language, namely that language describing the method of removing the sheath from the package. He apparently believed the cover strips had to be peeled like a banana in order to be consistent with the design of a sterile sheath package; indeed, the specification drawings demonstrate that method. But again we believe that unspecified limitations should not be read into the claim language. The dictionary definitions of strippable 13/ and peelable 14/

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13 Strip is defined, inter alia, as "to pull, tear or scrape off . . . wrest away." Webster's Third New Int'l Dictionary.

14/ Peel is defined as "to strip off the outer layer of . . . to remove (the outer layer or covering) by stripping, tearing off or rolling back." Id.

include methods of exposure other than peeling like a banana. Indeed, the language of another claim goes to the structural design pertaining to exposure of the sheath without referring to either strippable or peelable. 15/ We believe the invention inhering in the claim language may properly be described as a method of exposure encompassing all methods of "wresting away" the sheath from the package.

We therefore believe complainant's portrait of the patents is the correct one, and the ALJ thus erred in construing the claims too narrowly, by attributing unwarranted weight to the objective of providing a sterile sheath package as stated in the specifications and by incorrectly interpreting the methods of opening the sheath package. Not all of the claims are so directed; the claims allegedly infringed address the design of a thermometer sheath package which can be produced in a commercially viable manner, an objective at least as important as sterility and clearly the impetus for the inventive features of the patent. This view of the invention leads us to conclude that the ALJ's recommended findings of invalidity and noninfringement are in error, as discussed below.

IV. Patent validity

Having concluded that the important features of the Poncy invention inhere in its structural design, and primarily relate to commercial viability, we must next decide whether these features are sufficient to make a valid patent. We accept the ALJ's determination that the novelty 16/ and

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15/ Claim 1 merely calls for the outer cover and inner waste material to be separable along the tear seal line.

16/ 35 U.S.C. 101 (1976).

utility 17/ elements of patentability are present. RD 22-26; 35. We disagree, however, that in light of prior art the Poncy invention would have been clearly obvious to a person of ordinary skill in the art in 1968.

To be valid a patent must disclose subject matter which would not have been obvious at the time of invention to a person having ordinary skill in the art. 35 U.S.C. 103 (1976); Solder Removal Co. v. United States International Trade Commission, 582 F.2d 630 (C.C.P.A. 1978). A regularly issued patent, however, is accorded a statutory presumption of validity, 35 U.S.C. 282 (1976), which can be overcome only by clear and convincing evidence. 18/ We believe respondents have not satisfied this burden in this investigation.

The universally accepted test for nonobviousness was set forth by the Supreme Court in Graham v. John Deere Co.:

> Under section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt, but unresolved needs, failure by others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

17/ Id., sec. 102.

18/ This appears to be the majority--but not unanimous--rule of the courts which have addressed the issue. See, e.g., Paeco, Inc. v. Applied Moldings, Inc., 562 F.2d 870 (3d Cir. 1977); Trio Process Corp. v. L. Goldstein's Sons, Inc., 461 F.2d 66, 70 (3d Cir. 1972), cert. denied, 409 U.S. 997 (1972); Moon v. Cabot Shops, Inc., 270 F.2d 539, 541 (9th Cir. 1959), cert. denied 361 U.S. 965 (1960); Micro-Probe, Inc. v. Wentworth Laboratories, Inc., 431 F.Supp. 238 (C.D. Cal. 1977); Scaramucci v. Dresser Industries, Inc., 427 F.2d 1309, 1313-14 (10th Cir. 1970). But cf. Eltra Corp v. Basic Inc., C.A. No. 77-3369, (6th Cir. May 21, 1979); Parker v. Motorola, Inc., 524 F.2d 518 (5th Cir. 1973) (proof greater than mere preponderance). Our court of review, the Court of Customs and Patent Appeals, has not spoken on the "clear and convincing" standard, but pointed out in Solder Removal Co. v. United States International Trade Commission, supra at 532, that "whether rebuttal (of the presumption) is achieved requires careful consideration of whether the prior art relied upon does in truth render the claimed invention anticipated or obvious."

383 U.S. 1, 17 (1966). In addition, for patents combining old elements a secondary test of synergism has often been used, under which nonobviousness may be shown by new or unusual effects resulting from the combination of old elements. Sakraida v. Ag Pro, Inc., 425 U.S. 1 (1976). We believe the Poncy patents satisfy both tests.

In finding the patents satisfied the novelty requirement, the ALJ stated that "the Poncy sheath package is substantially different from all of the preceding prior art references." RD 25-26 (emphasis added). This determination goes far beyond the necessary demonstration for novelty; as the ALJ noted, only a slight physical difference in the invention need exist for it to be novel. RD 23. Thus, the recommended determination reveals a seeming contradiction in findings at the outset, because both novelty and nonobviousness are grounded in what is revealed by prior art.

Prior to 1968, prior art had disclosed several ideas relating to these factors. The Morris patent (exhibit D) disclosed a sheath secured to the package cover at the mouth of the sheath, the sheath being formed of two inner strips of thin, flexible material with two cover strips sandwiching the sheath to form a package. The Italian patent (exhibit E) disclosed a method of making a glove by sealing together sheets of thermoplastic material and imprinting the glove between paper webs. The Orsini patent (exhibit O) disclosed making a tear seal in plastic material through paper strips and simultaneously attaching the paper strips to the plastic. The Jarund '063 patent (exhibit C) disclosed a sheath manufactured in a single die stroke with a single die surface. The Ladd patent (exhibit Q) disclosed an inner plastic

container enveloped by cover strips. Finally, the Lakso patent (exhibit P) disclosed an ampuole enclosed by foil strips.

In evaluating novelty the ALJ noted that the Morris patent--the closest prior art to the Poncy patents--"has no thermoplastic coating on its cover surfaces and no waste material is removed by the user pushing the sheathed thermometer through and free of its cover strips . . . ." RD 24. With regard to the other prior thermometer sheath packages, he stated that "none contain all of the elements" of the suit patents. Id. Further, none of the prior art references in the relevant fields of heat-sealing plastics and packaging of medical products were found to fully disclose the Poncy patents; in particular, the ALJ pointed out that the Ladd patent "does not disclose a physically identical thermometer sheath package . . . ." RD 25. He recognized, in our opinion, the unique features of the Poncy invention and correctly found that they had not been anticipated by prior art.

The determination of nonobviousness cannot ignore this foundation of novelty. What is crucial here is the determination of what features were sufficiently novel so as not to be easily derived--obvious--to a person of ordinary skill in the art in 1968. The ALJ determined that such a person was "a college graduate with a degree in engineering and/or several years on the job training and experience in the design, development, manufacture, packaging, and marketing of small products. . . ." RD 29. 19/ Viewing the

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19/ Mr. George W. Poncy, Sr., and Mr. Robert Shotkin were both qualified as expert witnesses and as persons skilled in the art in 1968. TRJ 124-36; 263-67; FF 37. References to the testimony of these men will hereinafter be identified by their last names.

patents without the benefit of a decade's hindsight, a certain exercise of judgment must be made relating prior art to what could have been constructed had such a skilled person determined to do so.

The ALJ heavily relied on the Ladd, Jarund '063, Morris and Lakso patents for his determination. The complainant persuasively argues that these patents do not render the Poncy patents obvious. Perhaps the most significant element in the Poncy invention is the use of the waste material in the inner strips to form the side edges of the package, as shown above at page 9, and further attach the material to the outer covers in a way allowing it to be automatically torn away along the tear seal line (which outlines the sheath) with the removal of the covers. 20/ Even if, as the respondents suggest, retaining the waste material is a matter of choice by the manufacturer, it is another matter to design a sheath package structure which efficiently incorporates the waste material thereby contributing to the purpose of the package while removing a manufacturing step which would otherwise increase the product's cost. TRJ 152-54 (Poncy).

In any case, contrary to the ALJ's finding (RD 28-29), the Ladd patent does not disclose the removal by the consumer of waste material of the inner strips forming the sheath, nor is it obvious that removal of cover strips (the only "waste material" in the Ladd package, which is waste only in the sense that any packaging is waste) reveals a design like Poncy's whereby

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20/ The allegedly inventive concept of designing the sheath package so that it could be produced by a single die stroke on a single die surface was concededly old in the art. TRC 20, 22. In combination with the other inventive elements, however, it contributes to a synergistic effect that is nonobvious. See the discussion infra at page 21.

manufacturer's waste on inner strips is automatically removed with the cover strips when the package is opened. Neither do the Jarund '063 or the Lakso patents disclose this feature - again, there is no waste material, other than the outside packaging strips, which is incorporated into the structure to be automatically removed by the user.

Moreover, the concept of using the waste material--waste formed during the manufacturing process, when the sheath form is imprinted on the sealed inner two strips creating a seal line, with the "waste" being the plastic outside the seal line--as a part of the package also is not revealed directly by the prior art, nor do we believe the concept is obvious. TRJ 830-37, 866-67 (Shotkin). The numerous references cited by the ALJ (RD 31) only have the cover strips (the outside packaging) as waste, which quite naturally is "automatically removed" when the package is opened. But again we believe the idea of Poncy goes to a sheath package design that is significantly, structurally different from the cited references, which by themselves cannot be said to clearly and convincingly overcome the presumption of nonobviousness.

Although the ALJ plainly did not rely on the test of synergism set forth in Sakraida v. Ag Pro. Inc., supra, to determine obviousness, he nevertheless responded to the parties' arguments by finding that the Poncy patent had no new or unusual effects, and therefore was obvious under this test as well. RD 33-34. In our view, this test is inappropriate because the use of the waste material is a new element, while the synergism test logically applies only to combinations of old elements. In any case, assuming arguendo that the test is applicable, we disagree with his analysis and conclusion.

First, he incorporates, to a degree, his conclusion as a basis for applying the test: he states that all of the elements of the Poncy invention are "found in or . . . relatively easily developed by one skilled in the art from" the prior art. By stating that the elements are "relatively easily developed," he is stating essentially that they are obvious--a conclusion which should presumably result only after the test is applied. Moreover, the invention as a whole does reveal a synergistic effect: the combination of the tear seal joining the cover and inner strips and the releasable seal attaching the cover strips to the sheath allows the user to strip away the inner waste material simultaneously with the package cover. The design further allows the sheath package to be manufactured with a single die stroke on a single die surface. Together these synergistic features satisfy the objective of providing an inexpensive product.

Finally, we conclude that the secondary considerations of nonobviousness set forth in Graham were given insufficient weight by the ALJ. While one may draw conclusions other than nonobviousness from evidence of commercial success, satisfaction of long-felt but unresolved needs, and the overcoming of previous failures, the C.C.P.A. clearly demands that they be considered in contrast to the ALJ's opinion that such considerations only play a part in close cases. In re Fielder, 471 F.2d 640 (C.C.P.A. 1973); In re Palmer, 451 F.2d 1100 (C.C.P.A. 1971). It is especially difficult to accept that the issue of nonobviousness here is not a close question.

Despite his rejection of secondary indicia of nonobviousness, the ALJ determined that there is "considerable credible evidence of . . . commercial

success, unresolved needs, and failure of others met by the Poncy sheath package," therefore concluding that the patents satisfied the utility, if not the nonobviousness, requirement. RD 34. The record indeed reveals that (1) from at least 1957 several inventors had patented designs for thermometer sheath packages, none of which proved commercially successful; (2) the patent examiner allowed both patents while citing nearly all of the prior art references relied on by the ALJ as showing obviousness; (3) the Poncy design met with immediate commercial acceptance, and even though it was not originally extensively marketed, the public sought to acquire the product directly from the manufacturer. Respondents suggest that because other different but successful sheath packages soon followed, the evidence of commercial success is explained by market demand, not by any particular design. But this does not fully explain the fact that the Poncy design was the first to win such acceptance despite previous efforts dating back at least a decade, and the issue is obviousness over prior--not subsequent--art. In sum, we believe that this is a close case calling for examination of secondary considerations, which here fortify our determination of nonobviousness.

V. Infringement

The description of the Poncy invention detailed above 21/ inevitably leads to the conclusion that the patent is being infringed by the TempoTek sheath. Indeed, the ALJ found nearly all of the elements of the TempoTek sheath package to be "present and self-evident" in the independent claims of the '558 patent. RD 48. Only because--as discussed above--he construed

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21/ See pages 7-10, supra.

"sterilizable" to mean "capable of maintaining a sterile condition," and "peelable" or "strippable" to mean peeling like a banana only, did he find noninfringement. 22/ We disagree with his interpretations and therefore find infringement.

We agree that a primary purpose of the Poncy patent is to provide a sterile sheath package. However, unless the allegedly-infringed claims are interpreted in an incorrect manner, as was demonstrated above, the claims at issue are not so delimited in scope. Thus, if sterilizable is properly accorded its plain meaning then claims 1 and 13 of the '558 patent are literally infringed by TempoTek, which incorporates material capable of being sterilized. Indeed, the specifications for the Jarund '930 patent upon which TempoTek is based notes that a sterile sheath package can be provided using the design disclosed therein; presumably the sterilization process would be one as contemplated in the Poncy specifications previously noted. The respondents allege that their product employs uncoated paper covers and does not fully enclose and enseal the sheath surfaces, but these elements do not avoid infringing the pertinent claims. Further, respondents argue that their package does not have a tear seal and the cover strips are releasably "attached" not "sealed," but these asserted differences appear illusory: the TempoTek seal line is clearly designed to tear, and the strips are attached by a light sealing process.

22/ Specifically, the ALJ found 3 grounds for noninfringement: (1) the TempoTek sheath is not wholly enclosed and is therefore incapable of maintaining a sterile condition; (2) TempoTek lacks a thermoplastic coating on its paper covers, a feature essential to maintaining sterility; and (3) complainant's product must be peeled like a banana, consistent with maintaining sterility, while TempoTek is designed to be pulled open from the side. RD 46.

The method of opening of TempoTek is also covered by the claims. As the ALJ found, the methods of opening are interchangeable--TempoTek can be opened by peeling it like a banana. RD 49, FF 26. Moreover, "strippable" and "peelable," as used in the Poncy patents, should be broadly interpreted to encompass "any form of wresting away" the sheath from the package. In any case, this issue is not involved in the question of infringement of claims 1, 4, 5, and 7, and the ALJ erred in so finding.

We believe complainant is correct in arguing that the ALJ erred in viewing the accused product as having a different purpose than the Poncy invention, thereby revealing a patentably distinct method of construction and opening. Infringement is not avoided merely because an accused product has somewhat different objectives than the patented invention--again, the claim language is determinative. Mills Novelty Co. v. Monarch Tool & Mfg. Co., 76 F.2d 653, 654-55 (6th Cir. 1935). By neglecting to coat the cover strips and by recommending a different (if improved) method of opening, the respondents have not avoided the claims at issue. As the ALJ determined, most of the essential elements of the Poncy patents are self-evident in the TempoTek sheath packages. We conclude that only an incorrect interpretation of the language of the claims prevents the remaining elements to be found present and infringing also.

VI. Injury

The ALJ recommended that if the Commission found the patents valid and infringed, then the injury issue should also be decided in favor of complainant. He first determined that complainant constituted the domestic

industry as sole licensee of the patentee, and that complainant is efficiently and economically operated. FF 13, 48-53. We agree with his findings, and respondents have never seriously contested the evidence in this regard. Further, the ALJ determined that the importation and sale of TempoTek products had the effect or tendency to substantially injure complainant, based on the following evidence: (1) from the time TempoTek began to be imported, the ratio of its sales to Steritemp (the patented product) has exceeded 40 percent, a factor the Commission has looked to in past section 337 injury determinations (FF 59); (2) several former customers of Steridyne have been successfully solicited by respondent Medline, Steridyne's former western representative has switched to Medline (FF 57-59, 61, 63, 69); (3) Steridyne has suffered declining profitability from the time TempoTek entered the market (FF 60); (4) Medline has a substantially larger sales force than Steridyne, and Devello (the manufacturer of TempoTek for respondent Astra-Sjuco) forecasts sales of at least 10,000 cases a year (FF 64-65); and (5) other factors have not significantly contributed to Steridyne's declining profitability. (FF 66-67).

Respondents' arguments on lack of injury rest essentially on two grounds: (1) the only evidence of specific lost customers showed a total amount of approximately $815 in sales by respondents to these purchasers; and (2) the declining profitability of Steridyne is explained by factors other than the presence of competing imports. These factors include: (a) Steritemp was found difficult to use by consumers, who preferred other brands like Tempaway (which has 70 percent of the market); (b) electronic thermometers (which do not use these sheaths) are capturing an increasing market, and (c) a major

former customer of Steridyne's (Electromedics) has purchased TempoTek for the consumer, not clinical market for which it purchased Steritemp with some unfavorable results. Respondents believe the inferences of injury are simply too weak to find affirmatively here.

While the specific instances of lost sales are few, their presence combined with the clearly superior marketing ability of respondents strongly supports a finding of a tendency to substantially injure. 23/ Further, complainant persuasively argues that because specific lost sales are difficult to identify since Steridyne primarily sells to dealers who are directly competing with respondents, the overall picture of declining profitability is the important factor because it represents the lost sales to dealers who are in turn losing sales to respondents. Finally, there is sufficient evidence to support the ALJ's finding that the emergence of electronic thermometers in the field and the outside litigation has not significantly affected complainant's sales. We therefore agree with the ALJ that the contrary inferences which can be drawn from this record are insufficient to overcome the evidence supporting an affirmative injury determination.

VII. Relief, bonding, and the public interest

Having found the suit patents are valid and infringed, and that the importation or sale of the infringing TempoTek sheath packages has the effect

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23/ See In the Matter of Reclosable Plastic Bags, investigation No. 337-TA-22, USITC Publication No. 801 at 14; In the Matter of PTFE Tape, investigation No. 337-TA-4, USITC Publication No. 769 at 19. Compare In the Matter of Centrifugal Trash Pumps, investigation No. 337-TA-43, USITC Publication No. 943, at 20-26 (concurring opinions of Commissioners Alberger and Stern).

We note in addition that thermometer sheath packages made by Develio A.B. for respondent Astra-Sjuco A.B. already hold the dominant market share in Europe. TRJ 511.

or tendency to substantially injure complainant, an efficiently and economically operated domestic injury, we have determined that there is a violation of section 337, and we therefore turn to issues of relief, bonding, and the public interest.

A. Relief. -- There is no dispute among the parties that an exclusion order is the relief appropriate in this case. As we have often noted in the past, the essential right of the patentee is the right to exclude others from his monopoly. In the Matter of Reclosable Plastic Bags, 337-TA-23, USITC Pub. 801, at 15 (1977). Further the unfair act inheres in the infringing design of the imported articles, a fault unremediable except by exclusion. In the Matter of Chain Door Locks, 337-TA-5, USITC Pub. 770, at 42 (1976). We therefore order that the infringing articles be excluded from entry into the United States until January 5, 1988, the expiration date of the '558 patent, and also of the '280 patent by virtue of a terminal disclaimer filed with its application.

B. Public Interest. -- Under section 337(d) we are to consider the effect of our exclusion order upon the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive products, and U.S. consumers. Because there are several other competitors in the thermometer sheath package field, including the dominant producer, Becton-Dickinson, there would appear little likelihood that hospitals or consumers will not be able to obtain thermometer sheath packages in any desired quantity. Further, nothing suggests that Steridyne should be precluded from exercising a lawful monopoly over its small market share. To the extent

TempoTek has proven attractive to the new consumer market, other brands may easily substitute for it. Finally, TempoTek does not provide a sterile sheath, as does Steritemp - its loss to the market therefore would appear comparatively harmless in a public health sense. We thus believe the pertinent public interest factors do not preclude the remedy of exclusion.

C. Bonding. -- Under section 337(g)(3) we are to impose a bond under which the imported articles may enter the United States pending the outcome of the President's review of our decision. The information in the record on pricing is sparse, but the ALJ found that respondent Medline was actually selling TempoTeks for a higher price than complainant--$12.80/1000 compared with $12.57/1000--based on purchases by Electromedics, a common customer. FF 63. Under the Rules the Commission is to determine a bond "taking into consideration . . . the amount which would offset any competitive advantage resulting from" the violation. 19 CFR 210.14(a)(3)(1978). Because respondents' prices are apparently higher than complainants, a mere price differential calculus would suggest no bond is necessary. Respondents in their brief thus argue for a 1-percent bond. On the other hand, in view of the advantage in marketing capacity enjoyed by respondents, and the right to a patent monopoly belonging to complainant, the latter argues for a 100-percent bond. The Commission investigative attorney originally supported a 30-percent bond based on rough figures suggesting that respondent Caring International sold TempoTeks at an average of 21 percent less than complainant per 5000 units; however, at oral argument he apparently agreed with respondents' alternative suggestion discussed below.

It is true that the Commission has in the past imposed a 100-percent bond as appropriate to protect the legal monopoly constitutionally afforded a patentee. Perhaps inspired by Doxycycline, 24/ however, respondents at oral argument offered a persuasive case that here--when their prices are higher and a consumer market exists for their product separate from the clinical market which complainant primarily supplies--a more appropriate bond is one based upon a reasonable royalty; for example, that paid by Johnson and Johnson to Steridyne under a previous licensing arrangement. This figure was suggested to be approximately 10 percent.

We adopt a 10-percent bond for the reasons offered by respondents. In addition, we note that a previous license presumably represents what complainant views as the price competition it can bear absent its monopoly (although, of course, complainant receives no fees from the bond), and respondents represent a small share of the present market. Therefore, until the 60-day period has expired, we order that respondents be allowed to import the infringing thermometer sheath packages subject to a bond of 10 percent of their value, f.o.b. foreign port.

24/ In the Matter of Doxycycline, investigation No. 337-TA-3, USITC Publication 964, at 21 (1979)(concurring opinion of Commissioner Alberger).

Dissenting Opinion of Chairman Joseph O. Parker

I believe the administrative law judge correctly concluded there is no violation of section 337 in this investigation. Briefly stated, my determination rests on the record which requires a narrow interpretation of the '558 patent's independent claims: the expansive interpretation adopted by the majority teaches an invention which would be invalid for obviousness in light of prior art, while the proper, narrower construction of the claims preserves the validity of the patents but compels a finding that the patents are not infringed. In either case, no unfair act has been established.

I.

Some twenty prior art references are in the record in this investigation. These prior patents reveal a number of teachings directed to the allegedly inventive concepts embodied in the '558 and '280 patents. The most pertinent are fully discussed in the recommended determination, but I especially note the following. In the art of packaging, the Italian patent 511,535 (exhibit E) demonstrates a method of heat sealing a plastic glove (i.e., a sheath) between paper covers, the glove being formed with a tear seal to allow separation from its webbing. Further, releasably sealing plastic foils to paper backing was a technique disclosed in the Orsini (exhibit D), Rosenberg (exhibit M), and Jarund '063 (exhibit C) patents. With specific regard to thermometer sheath packages, the prior art Jarund '063 patent (from which the Swedish Steritemp product derived) disclosed sheaths formed of plastic foils heat-sealed to continuous paper backing, from which the sheaths could be levered away along a tear seal after inserting a thermometer.

Finally, the Morris patent (exhibit CS-7) disclosed an plastic thermometer sheath enclosed by outer covers sealed together to ensure sterility.

Complainant alleges that its design reflects three inventive concepts as advances over this prior art: (1) the concept of having the waste material on the inner strips automatically removed when the cover strips are pulled off; (2) the concept of having the sheath and cover strips formed in one die stroke and with one die surface; and (3) the concept of having the side edges of the package formed by the waste material of the inner strips. The majority focuses on the third alleged concept as the key to nonobviousness, because the second concept was--as complainant admitted (see TRC 22, 24)--a manufacturing method widely recognized at the time of the patent application, while the first could not be a more obvious result of an exercise of choice by the manufacturer to leave the waste material on the sheath to be sealed to the covers like the other portions of the inner strips. See exhibits C, E, M, and O; TRJ 688-95, 813-18; FF 34. Assuming this "concept" is indeed reflected in claims 1 and 13 (the independent claims) of the '558 patent as complainant argues, it cannot save the patented subject matter from obviousness. Leaving the waste material in the product was clearly a matter of choice. TRJ 694-95, 817-18. Incorporating such waste into a package structure was also disclosed in the Italian patent and other prior art. TRJ 813-14; RD 31; FF 34. Indeed, if claims 1 and 13 were construed in the manner adopted by the majority, who ignore the importance of sterility in the Poncy design, the '558 and '280 patents would have been fully anticipated by the Italian and Jarund '063 patents.

II.

I nevertheless believe the '558 and '280 patents are valid, albeit only because I interpret the independent claims in a more limited manner than do the majority. Where the field is crowded with prior art, the claims must be narrowly construed. Fletcher v. United States, 478 F.2d 1380 (Ct. Cl. 1973); Quickey Manufacturing Co. v. City Products Corp., 409 F.2d 876 (6th Cir. 1969). Moreover, claims should be interpreted narrowly where necessary to avoid invalidity. Parker v. Motorola, Inc., 524 F.2d 518 (5th Cir. 1975), cert. denied 425 U.S. 975 (1976).

The inescapable conclusion to be drawn from an examination of the specifications, file wrapper, and drawings, Autogiro Co. of America v. United States, 384 F.2d 391 (Ct. Cl. 1976), is that the '558 and '280 patents were intended as a design for a sterile sheath package. The plastic-coated paper covers, the ensealment of the sheath at its mouth, the sterilization process embodied in claim 25, and even the use of the waste material to enclose the sides of the package, are all essential ingredients of a design for a sterile sheath package. The language of the specifications underline this purpose. Column 1, lines 28-30, 48-52, 57-58 of the '558 patent. The primary, independent claims of the '558 patent, which set forth the basic structure of the invention, must reflect no less. These elements in the Poncy patent which contribute to sterility, as well as commercial viability, are, in total, sufficient to represent a new, nonobvious design; but without them the claims would otherwise merely teach an unsterile sheath package too similar to the prior art to avoid obviousness.

Further, while I agree with the majority that secondary considerations should play an important part in the determination of nonobviousness in this case, I believe that (1) commercial success may be attributed to the introduction of a sterile sheath package; (2) the problems Poncy solved related to a sterile sheath prackage; and, (3) as the specifications emphasize (col. 1, lines 21-26), the long-felt need accommodated by the Poncy invention was for a sterile sheath package. The secondary indicia of nonobviousness would be meaningless if the Poncy design (embodied in claims 1 and 13) was for something less than a sterile sheath package; after all, the unsterile Swedish Steritemp (Exhibit CB) was previously available in Europe, and presumably would have been commercially successful in the United States had there been a demand for it.

I therefore believe the ALJ was correct in narrowly interpreting claims 1 and 13 as requiring cover strips capable of maintaining the sheath in a sterile condition (although I disagree with him that the result was obvious). This interpretation, fairly derived from the specifications and file wrapper, may properly be attributed to the modifier "sterilizable" when it describes the materials used in the sheath package. The broad interpretation of the claims adopted by the majority has no place here where its application would render the claims invalid. Because a narrow interpretation of the independent claims is necessary to preserve the validity of the patent, I reject the argument that a broad interpretation is necessary to prevent the dependent claims from being rendered redundant; further, with specific regard to dependent claims 2 and 14, it appears that no redundancy in fact results since those two claims merely specify a more precise location for the thermoplastic coating than is expressed in claims 1 and 13.

III.

Having concluded the patents are valid if the claims are narrowly construed, I turn to the issue of infringement. It is well settled that claims cannot be narrowly construed for the purpose of determining validity, yet be broadly construed to find infringement. Fletcher v. United States, supra; Tate Engineering, Inc. v. United States, 474 F.2d 1336 (Ct. Cl. 1973); International Glass Co. v. United States, 408 F.2d 395 (Ct. Cl. 1969); Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F.Supp. 948 (S.D. Fla. 1972). The accused TempoTek product employs, among other things, porous paper covers which prevent it from maintaining a sterile condition. FF 41-43. Moreover, claims 8 and 13 of the '558 patent, and 1 and 5 of the '280 patent, are not infringed because TempoTek is designed to be pulled away from the side, not to be peeled like a banana. The drawings in the '558 and '280 patents demonstrate the latter method. Indeed, in view of the design of the Poncy sheath package, I believe the majority incorrectly departs from the plain meaning of strippable and peelable to find that those words technically encompass all forms of "wresting away." While the methods of opening the two products may be--tortuously--interchangeable, I do not believe it consistent with a sterile package of Poncy's design to rip the sheath-encased thermometer through the side of the package. TRJ 256, 557-59, 648-49, 708-10, 728-30. The structure of the TempoTek tear seal, on the other hand, is plainly suited to this purpose. When properly, narrowly construed, therefore, I believe the claims of the '558 and '280 patents are not infringed by respondents' product.

IV.

Because there is no infringement, I must determine that there is no unfair act or method of competition in this investigation within the meaning of section 337. In the Matter of Certain Centrifugal Trash Pumps, investigation No. 337-TA-43 (USITC Publication 943). Because I find in the negative, I offer no comments on the remaining issues addressed by the majority.

Library Cataloging Data

U.S. International Trade Commission.
In the matter of: certain thermometer sheath packages. Investigation no. 337-TA-56. Washington, 1979.

30, A 6 p. 28 cm. (USITC Publication 992)

1. Thermometers and thermometry, medical. I. Title. II. Title: Certain thermometer sheath packages.

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In the Matter of CERTAIN THERMOMETER SHEATH PACKAGES	Investigation No. 337-TA-56

NOTICE OF COMMISSION HEARING ON THE PRESIDING OFFICER'S RECOMMENDATION AND ON RELIEF, BONDING, AND THE PUBLIC INTEREST, AND OF THE SCHEDULE FOR FILING WRITTEN SUBMISSIONS

Recommendation of the presiding officer

In connection with the U.S. International Trade Commission's investigation under section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), of alleged unfair methods of competition and unfair acts in the importation and sale of certain thermometer sheath packages in the United States, the presiding officer filed his recommended determination on May 3, 1979, that the Commission determine that there is no violation of section 337. The presiding officer certified the evidentiary record to the Commission for its consideration. Interested persons may obtain copies of the presiding officer's recommendation (and all other public documents) by contacting the office of the Secretary to the Commission, 701 E Street NW., Washington, D.C. 20436, telephone (202) 523-0161.

Commission hearing scheduled

The Commission will hold a hearing beginning at 10:00 a.m., e.d.t., on June 28, 1979, in the Commission's Hearing Room (Room 331), 701 E Street NW.,

Washington, D.C. 20436, for two purposes. First, the Commission will hear oral arguments on the presiding officer's recommendation that there is no violation of section 337 of the Tariff Act of 1930, as amended. Second, the Commission will hear oral presentations concerning appropriate relief, bonding, and the public-interest factors for consideration in the event that the Commission determines that there is a violation of section 337. These matters are being heard on the same day in order to facilitate the completion of this investigation within time limits established under law and to minimize the burden of this hearing upon the parties to the investigation. The procedure for each portion of the hearing follows.

Oral argument concerning the presiding officer's recommendation

A party to the Commission's investigation or an interested agency wishing to present to the Commission an oral argument concerning the presiding officer's recommendation will be limited to no more than 30 minutes. A party or interested agency may reserve 10 minutes of its time for rebuttal. The oral arguments will be held in this order: complainants, respondents, interested agencies, and Commission investigative staff. Any rebuttals will be held in this order: respondents, complainants, interested agencies, and Commission investigative staff.

Oral presentations on relief, bonding, and the public interest

Following the oral arguments on the presiding officer's recommendation, a party to the investigation, an interested agency, a public-interest group, or any interested member of the public may make an oral presentation on relief, bonding, and the public interest.

1. Relief. If the Commission finds a violation of section 337, it may issue (1) an order which could result in the exclusion from entry of certain thermometer sheath packages into the United States or (2) an order which could result in requiring respondents to cease and desist from alleged unfair methods of competition or unfair acts in the importation and sale of these thermometer sheath packages. Accordingly, the Commission is interested in what relief should be ordered, if any.

2. Bonding. If the Commission finds a violation of section 337 and orders some form of relief, such relief would not become final for a 60-day period, during which the President would consider the Commission's report. During this period the thermometer sheath packages would be entitled to enter the United States under a bond determined by the Commission and prescribed by the Secretary of the Treasury. Accordingly, the Commission is interested in what bond should be determined, if any.

3. The public interest. If the Commission finds a violation of section 337 and orders some form of relief, it must consider the effect of that relief upon the public. Accordingly, the Commission is interested in the effect of any exclusion order or cease and desist order upon (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) the production of like or directly competitive articles in the United States, and (4) U.S. consumers.

Those persons making an oral presentation on any or all of the above topics will be limited to 15 minutes, with an additional 5 minutes each for summation after all presentations have been made. Participants with similar interests may be required to share time. The order of oral presentations will

be as follows: complainants, respondents, interested agencies, public-interest groups, other interested members of the public, and Commission investigative staff. Summations will follow the same order.

How to participate in the hearing. Any person desiring to appear at the Commission's hearing must file a written request to appear with the Secretary to the U.S. International Trade Commission, 701 E Street NW., Washington, D.C. 20436, no later than the close of business (5:15 p.m., e.d.t.) on June 21, 1979. The written request must indicate whether such person wishes to present an oral argument concerning the presiding officer's recommendation and/or an oral presentation concerning relief, bonding, and the public interest. While only parties to the Commission's investigation, interested agencies, and the Commission investigative staff may present an oral argument concerning the presiding officer's recommended determination, public-interest groups and other interested members of the public are encouraged to make an oral presentation concerning the public interest.

Written submissions to the Commission

The Commission requests that written submissions of three types be filed no later than the close of business on June 21, 1979.

1. Briefs on the presiding officer's recommendation. Parties to the Commission's investigation, interested agencies, and the Commission investigative staff are encouraged to file briefs concerning exceptions to the presiding officer's recommendation. Briefs must be served on all parties of record to the Commission's investigation on or before the date they are filed with the Secretary. Statements made in briefs should be supported by references to the record. Persons with the same positions on the issues are encouraged to consolidate their briefs, if possible.

2. Written comments and information concerning relief, bonding, and the public interest. Parties to the Commission's investigation, interested agencies, public-interest groups, and any other interested members of the public are encouraged to file written comments and information concerning relief, bonding, and the public interest. These submissions should include a proposed remedy, a proposed determination of bonding, and a discussion of the effect of the proposals on the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, and U.S. consumers.

3. Requests to participate in the hearing. Written requests to appear at the Commission hearing must be filed by June 21, 1979, as described above.

Additional information

The original and 19 true copies of all briefs and written comments and any written request to participate must be filed with the Secretary to the Commission.

Any person desiring to discuss confidential information, or to submit a document (or a portion thereof) to the Commission in confidence, must request in camera treatment. Such request should be directed to the Chairman of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. Documents or arguments reflecting confidential information approved by the Commission for in camera treatment will be treated accordingly. All nonconfidential written submissions will be open to public inspection at the Secretary's Office.

Notice of the Commission's investigation was published in the Federal Register of July 25, 1978 (43 F.R. 32195).

By order of the Commission.

Kenneth R. Mason
Secretary

Issued: June 1, 1979

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of:	
CERTAIN THERMOMETER SHEATH PACKAGES	Investigation No. 337-TA-56

COMMISSION ORDER

Procedural history

A Motion to Amend the Complaint was filed on September 5, 1978, 1/ pursuant to sections 210.20(d) and 210.22(a) of the Commission's Rules of Practice and Procedure (19 C.F.R. 210.20(d), 22(a)) by Steridyne Corporation, complainant in investigation No. 337-TA-56. The motion sought to add an additional paragraph alleging that respondents were offering the imported thermometer sheath packages below their average variable costs in order to damage the business of the complainant and make the complainant less effective as a competitor, in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337). On September 18, 1978, the Commission's investigative attorney filed a response to the motion to amend, supporting the complainant but suggesting that additional language be included to set forth an allegation that the alleged unfair methods of competition and unfair acts also have a tendency to restrain trade and commerce in the United States. The presiding officer, acting pursuant to sections 210.20(d), 210.22(a), and 210.24(a) of the Rules (19 C.F.R. 210.20(d), 210.22(a), and 210.24(a)), concluded that good cause had been demonstrated in support of the motion

1/ Motion Docket No. 56-2.

to amend and neither the public interest nor the rights of the parties would be prejudiced by such an amendment. He therefore certified his recommendation, on September 29, 1978, that the motion to amend, including the language suggested by the investigative attorney, be granted.

Determinations and orders

Having considered (1) the Motion to Amend filed by complainant Steridyne Corporation (Motion Docket No. 56-2) and supporting documents, (2) the response of the Commission investigative attorney filed September 18, 1978, (3) the response of the respondent filed September 18, 1978, (4) the transcript of the hearing on the Motion to Amend held on September 20 and 21, 1978, and (5) the presiding officer's recommendation of September 29, 1978, THE COMMISSION DETERMINES (Chairman Parker dissenting) that good cause to amend the complaint has been shown upon such conditions as are necessary to avoid prejudicing the public interest and the rights of the parties to the investigation. THE COMMISSION FURTHER DETERMINES that there is good and sufficient reason for waiving strict adherence to certain procedural rules in testing the sufficiency of the complaint in this case.

Accordingly, THE COMMISSION GRANTS Motion No. 56-2 AND ORDERS that the complaint be amended by adding the following paragraph to paragraph (2) of the original complaint:

> On information and belief, respondents are offering the imported sheath packages below their variable cost in order to damage the business of complainant and make complainant less effective as a competitor.

These sales and offers for sale below the average variable cost have a tendency to substantially injure an efficiently and economically operated industry in the United States. These unfair methods of competition and unfair acts also have a tendency to restrain trade and commerce in the United States.

By order of the Commission:

KENNETH R. MASON
Secretary

Issued: December 14, 1978

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of CERTAIN THERMOMETER SHEATH PACKAGES	Investigation No. 337-TA-56

NOTICE OF INVESTIGATION

Notice is hereby given that a complaint was filed with the United States International Trade Commission on June 7, 1978 under section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), on behalf of Steridyne Corporation, 3670 East Industrial Way, Riveria Beach, Florida 33404. The complaint alleges that unfair methods of competition and unfair acts exist in the importation of certain thermometer sheath packages into the United States, or in their sale, by reason of the alleged coverage of such articles by U.S. Letters Patents 3,552,555 and 3,847,280, and that such articles are being offered at prices below fair value and below cost. The complaint alleges that such unfair methods of competition and unfair acts have the effect or tendency to destroy or substantially injure an industry, efficiently and economically operated, in the United States. Complaintant requests an order permanently excluding such articles from entry into the United States, and an order to cease and desist from selling or offering for sale such articles below their fair value.

Having considered the complaint, the United states International Trade Commission, on July 6, 1978, ORDERED--

(1) That pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), an investigation be instituted to determine under subsection (c) whether, on the basis of the allegations set forth in the complaint and the evidence adduced, there is a violation of subsection (a) of this section in the unauthorized importation of certain thermometer sheath packages into the United States, or in their sale by reason of such thermometer sheath packages allegedly being covered by claims 1, 4, 5, 8, 9, 12, 13, 15, 16, 17, 18 and 19 of U.S. Letters Patent 3,552,558 and claims 1, 2 and 5 of U.S. Letters Patent 3,847,280, the effect of tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

(2) Those portions of the complaint which allege a violation of section 337 by reason of the imported articles being offered for sale at prices "below fair value and below cost" are dismissed for the reason that they do not, as presently set forth, allege an unfair method of competition or unfaor act within the meaning of section 337. 1/

1/ Commissioners Minchew and Alberger voted to dismiss those portions of the complaint that allege sales "below fair value and below cost" because they believe mere low pricing is not an unfair method or act, even if the prices are unreasonably low, below total cost or average total cost, or below "fair value" as complainant alleged. Low pricing is an unfair method or act when it occurs as a result of predatory intent, that is, an intent to destroy competition and dominate a market. This intent can be inferred, if low prices are present, from specific occurrences which have a commercial context that strongly suggest predation; and the Commission has held that, where prices of an imported article are set below marginal cost for a sustained period without commercial justification, intent can be inferred. However, in such a complaint the specifics of predatory intent should be pleaded. On the basis of this complaint, there is no possibility of such intent, since the complaint itself alleges that the low prices are for the purpose of getting "customers and dealers of complainant to switch from complainant's sheath package to the imported infringing product." This is hardly an anticompetitive, or predatory, motive.

(3) That, for the purpose of this investigation so instituted, the following are hereby named as parties:

(a) The complainant is:

Steridyne Corporation
3670 East Industrial way
Riveria Beach, Florida 33404

(b) The respondents are the following companies alleged to be involved in the unauthorized importation of such articles into the United States, or in their sale, and parties upon which the complaint and this notice are to be served.

(1) Astra-Sjuco, AB
Fack
S-402 20 Goteborg 5
Sweden

(2) Medline Industries
1825 Sherman Road
Northbrook Illinois 60062

(3) Caring International
Division of Medline Industries
P. O. Box 777
Northbrook, Illinois 60062

(c) Louis S. Mastriani, U.S. International Trade commission, 701 E street, N.W., Washington, D.C. 20436, is hereby named Commission investigation attorney, a party to this investigation.

(4) That, for the purpose of the investigation so instituted, Chief Administrative Law Judge Donald K. Duvall, U.S. International Commission, 701 E Street, N.W., Washington, D.C. 20436, is hereby granted the power to designate the presiding officer.

Responses must be submitted by named respondents in accordance with section 210.21 of the Commission's Rules of Practice and Procedure, as amended

(19 C.F.R. 210.21). Pursuant to section 201.16(d) and 201.21(a) of the Rules such response will be considered by the Commission if received not later than 20 days after the date of service of the complaint. Extensions of time for submitting a response will not be granted unless good and sufficient cause therefore is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complainant and of this notice, and will authorize the presiding office and the Commission, without further notrice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter both a recommended determination and a final determination, respectively, containing such findings.

The complaint is available for inspection by interested persons at the Office of the Secretary, U.S. International Trade Commission, 701 E Street, N.W., Washington, D.C. 20436, and in the New York City Office of the Commission, 6 World Trade Cenmter.

By order of the Commission:

Kenneth R. Mason
Secretary

Issued: July 20, 1978