United States District Court,
N.D. New York.

CONMED CORPORATION, and NDM, Inc,
Plaintiffs.
v.
LUDLOW CORPORATION, and The Ludlow Company, LP,
Defendants.

No. 5:00-CV-633

Dec. 9, 2002.

Owner of patent for diagnostic medical electrode sued competitor for infringement. On cross-motions for summary judgment, the District Court, Hurd, J., held that: (1) patent claim was not literally infringed, and (2) prosecution history estopped owner from asserting equivalent infringement.

Plaintiff's motion denied; defendant's motion granted.

Subject matter disclosed but not claimed in patent application is dedicated to public.

Hancock & Estabrook LLP, Syracuse, NY (James R. Muldoon, Esq., John R. Powers, of counsel), for Plaintiffs.

Milbank, Tweed, Hadley & McCloy LLP, New York City (Jeffrey A. Barist, Esq., John M. Griem, Esq., Christopher E. Chalsen, Esq., Parker H. Bagley, Esq., Of Counsel), for Defendants.

MEMORANDUM-DECISION and ORDER

HURD**, District Judge.**

I. *INTRODUCTION*

Plaintiffs, ConMed Corporation and NDM, Inc. (collectively "ConMed"), commenced the instant action against defendants, Ludlow Corporation and Ludlow Company, LP (collectively "Ludlow"), pursuant to 35 U.S.C. s.s. 271, *et. seq.,* asserting one count of patent infringement. Specifically, plaintiffs allege continuing infringement of its U.S. Patent No. 4,674,511 by defendants' manufacture and sale of the Kendall Care 210 Resting ECG Electrode. Ludlow asserts counterclaims seeking (1) a declaratory judgment of non-infringement; and (2) a declaratory judgment that ConMed's patent is invalid. Both parties have moved for summary judgment.

Oral argument was heard on April 12, 2002 in Utica, New York. Decision was reserved.

II. *FACTS*

ConMed owns U.S. Patent No. 4,674,511 (" the '511 patent") entitled "Medical Electrode." FN1 A medical electrode is a device placed on a patient's skin that senses electrical stimulus emitted from the body. The electrode is connected to a machine, such as an electrocardiogram, that collects and interprets the signals sensed by the electrode.

FN1. ConMed acquired the rights to the '511 patent during the course of its business operations.

A. *Prosecution History of* the '511 Patent

The initial application for the '511 patent was made by James Cartmell ("Cartmell") in 1984.FN2 Cartmell's application contained twenty-four claims. The first claim provided as follows:

FN2. The application was a continuation of a previously abandoned application and a previously granted patent.

In a medical electrode of the type having a conductor and electrolyte means comprising a conductive adhesive for providing an electrolyte between said conductor and the skin of the patient and for adhering said electrode to the skin, the improvement wherein said electrode further comprises patient adhesive means which is more aggressive than said conductive adhesive for adhering an electrode to the skin for a longer period of time or with greater security than is possible with said conductive adhesive alone.

The patent application disclosed ten different embodiments, or configurations, of the electrode. Each embodiment was a variation of the basic invention and was supported by separate figures depicting the features of the particular embodiment. The United States Patent and Trademark Office ("USPTO") determined that the application contained two or more independent and distinct inventions. In the initial office action, serial 06/608-188, dated October 3, 1985, the USPTO restricted the invention claims under 35 U.S.C. s. 121 for (a) inclusion of both product and process claims, and (b) inclusion of five independent and distinct embodiments (*i.e.*, separately patentable products). (*See* Griem Aff. Ex. 2(D) at 104.) Accordingly, Cartmell was required to restrict the proposed inventions to either the product claims (claims 1-20) or the process claims (claim 21-24). The USPTO further found that

[a]pplicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are deemed to be generic.

(Id. at 105.)

In response to the USPTO, Cartmell elected to prosecute product claims 1-20. Cartmell traversed the USPTO's requirement that he elect a single disclosed species for prosecution on the merits. Specifically, Cartmell argued that it was inappropriate to elect between FIGS. 15-16 and FIGS. 17-18 of the application because the inventions "are not patentably distinct." (Id. at 108.) In response to the USPTO's requirement that a single species be elected, together with a listing of all claims readable thereon, Cartmell elected "the species contained in FIGS. 15 and 16. Claims 1, 2, 3, 4, 6 and 7 are readable thereon." (Id.)

In February 1986, the USPTO found that

Claims 5 and 8-24 stand withdrawn from further consideration ... as being drawn to a nonelected invention and species, the requirement having been traversed ... [by Cartmell]. The election requirement is deemed to be proper since the embodiments of Figures 15-16 and 17-18 are not obvious variants and therefore patentably distinct. Generic claims do not evidence obviousness. The requirement is therefore made *FINAL*.

(Id. at 110.)

The USPTO rejected claims 1 and 6 under 35 U.S.C. s.s. 102(b) FN3 and 102(e) FN4 "as being clearly anticipated by" certain other patents. (Id.) The USPTO rejected claims 2 and 7 pursuant to 35 U.S.C. s. 103 FN5 "as being unpatentable" over certain other patents because "[t]he use of a conductive paint would have been obvious." (Id. at 111.) Finally, the USPTO rejected claims 3 and 4 pursuant to 35 U.S.C. s. 103 because "[t]he particular structure of conductive adhesive overlying the paint would have been obvious over" another patent. (Id.)

FN3. 35 U.S.C. s. 102(b) provides that a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."

FN4. 35 U.S.C. s. 102(e) provides that a person shall be entitled to a patent unless:
The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(A) of such treaty in the English language; or (2) a patent granted on an application for a patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

FN5. 35 U.S.C. s. 103(a) provides, in part, that "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such 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."

Cartmell responded to the USPTO by amending his application. Cartmell's response to the USPTO action, dated August 11, 1986, amended claims 1, 6 and 7, canceled claims 2, 3, and 4 and retained claims 5 and 8 through 24 under 37 C.F.R. 1.142(b). (Id. at 114-16). In his papers amending his application, Cartmell stated that:

Claims 1, 4, 6 and 7 are presented for prosecution at this time..... [C]laim 1 is amended to recite that the conductor comprises a sheet of flexible material and conductive paint adhered to one face of said sheet, that the conductive adhesive forms a layer engaging said sheet in overlying relationship to at least a portion of

said paint, and that the patient adhesive means is a layer on said one face of said sheet. This structure is in clear contrast to the prior art relied upon by the [PTO] in which, with the exception of Anderson et al '215, the patient adhesive is on a piece of tape or the like separate from the conductor.... [T]he Engel patent is most similar in appearance. However, its backing 20 and adhesive coating 22 are clearly on the side of the plate 12 opposite its skin-contacting face.

(Id. at 115).FN6

FN6. Claim 1 was amended to read as follows (the underlined portions indicate language that was added to the original claim):
In a medical electrode of the type having a conductor and electrolyte means comprising a conductive adhesive for providing an electrolyte between said conductor and the skin of a patient and for adhering said electrode to the skin, the improvement *wherein said conductor comprises a sheet of flexible material and a conductive paint adhered to one face of said sheet, wherein said conductive adhesive forms a layer engaging said sheet, in overlying relationship to at least a portion of said paint, and* wherein said electrode further comprises *a layer of* patient adhesive means *on said one face of said sheet* which is more aggressive than said conductive adhesive for adhering the electrode to the skin for a longer period of time or with greater security than is possible with said conductive adhesive alone.

In the final office action, dated October 3, 1986, the USPTO allowed claims 1 and 6; canceled claims 2 through 4; rejected claim 7 stating that it would be allowed if amended to overcome rejection under 35 U.S.C. s. 112; and withdrew from consideration claim 5 and claims 8 through 24. (Id. at 119-120.)

Cartmell's response, dated December 3, 1986, amended claim 7 and added a new claim 25 based on an interview with the patent examiner. (Id. at 121.) Additionally, Cartmell's response canceled claim 5 and claims 8 through 24, placing the application in condition for allowance. (*See* id.) The USPTO January 5, 1987 Notice of Allowability confirmed the allowance of claims 1, 6, 7 and 25, and renumbered these claims 1 through 4. Cartmell canceled claims 5 and 8-24 in response to USPTO's final office action.FN7 (*See* Id. at 123.)

FN7. For the final language of claim 1, see fn 6.

B. *Ludlow's Product*

Ludlow manufactures and sells a diagnostic medical electrode called the Kendall Care 210 (the "210"). The 210 consists of the following components. The 210 has a substrate of flexible polymeric foam (the "backing layer"). The surface of the backing layer closest to the patient (the "patient side") is completely covered by an adhesive. A polyester layer is adhered centrally on the patient side of the adhesive. The polyester layer is smaller than the polymeric foam backing, so as to leave the adhesive exposed around the margin on three sides of polyester layer. A conductive layer of silver/silver chloride film paint is applied onto the polyester layer.FN8 A blue hydrogel is adhered to the conductive paint layer on the patient side so as to leave exposed a "tab" portion of the conductive paint layer.FN9 The "tab" portion of the conductive paint layer is used to provide electrical engagement to peripheral equipment, such as an ECG. A liner is placed over the patient side of the electrode to protect it during storage. The liner is removed from the electrode prior to being used.

FN8. The parties dispute whether the conductive paint covers the entire surface of the polyester. It is undisputed that the conductive paint is not applied to the backing layer.

FN9. The parties dispute whether the hydrogel extends only as far as conductive paint layer or whether it extends beyond the conductive paint layer onto the polyester layer.

C. *ConMed's Claim*

In it's Complaint, ConMed claims that the 210 infringes upon its '511 patent. ConMed contends that the 210 contains all the elements of the '511 patent, that is: (1) a flexible sheet of backing comprised of both foam and polyester (substrate); (2) a coating of conductive paint adhered to the face of the flexible sheet that faces the patient's skin; (3) a hydrogel conductive adhesive that overlies the conductive paint; and (4) a conductive adhesive adhered to the patient side of the flexible sheet backer that is more "aggressive" than the hydrogel adhesive. (Plaintiffs' Mem. in Opp'n, at 2).

Ludlow denies this, arguing that the '511 patent includes two elements not present in the 210. Specifically, Ludlow contends that "[t]he first element not found in the Care 210 electrode is a 'sheet of flexible material' that has a layer of conductive paint adhering to the same face of the sheet as the required layer of patient adhesive." (Ludlow Mem. of Law at 1.) In this regard, Ludlow contends that its product is different because it does not contain a single layer of material that contains both the patient adhesive and the conductive paint as is required by the '511 patent, but that its product contains separate layers: (1) a polymeric foam backer containing the patient adhesive; and (2) a polyester layer to which the conductive paint layer is applied. (*See* Griem Aff. Ex. 2, at 20-21.)

The second element that Ludlow insists is missing from the 210 is a "conductive adhesive that 'forms a layer engaging' the sheet of flexible material." (Ludlow Mem. of Law at 2.). Ludlow contends that the 210 is different from the '511 patent because its conductive adhesive (the hydrogel) is coterminous with the edges of the conductive paint layer, and therefore, does not engage the flexible backer material as required by the '511 patent. (*See* Griem Aff., Ex. 2, at 23.)

III. *STANDARD OF REVIEW*

A moving party is entitled to summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). The ultimate inquiry is whether a reasonable jury could find for the nonmoving party based on the evidence presented, the legitimate inferences that could be drawn from that evidence in favor of the nonmoving party, and the applicable burden of proof. *See* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

In determining a motion for summary judgment, all inferences to be drawn from the facts contained in the exhibits and depositions "must be viewed in the light most favorable to the party opposing the motion." United States v. Diebold, Inc., 369 U.S. 654, 655, 82 S.Ct. 993, 8 L.Ed.2d 176 (1962); Hawkins v. Steingut, 829 F.2d 317, 319 (2d Cir.1987). Nevertheless, "[t]he nonmoving party may not rely on conclusory allegations or unsubstantiated speculation." Scotto v. Almenas, 143 F.3d 105, 114 (2d Cir.1998). The court's

function "is not ... to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial." Liberty Lobby, 477 U.S. at 249, 106 S.Ct. 2505. To withstand a summary judgment motion, sufficient evidence must exist upon which a reasonable jury could return a verdict for the nonmovant. Liberty Lobby, 477 U.S. at 248, 106 S.Ct. 2505; Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986).

IV. *DISCUSSION*

[2] The second step involves comparing the properly construed claim to the alleged infringing device. *PIN/NIP Inc.,* at 1243. This latter step ordinarily involves questions of fact for a jury. *Id.; see also* Markman, 517 U.S. at 384, 116 S.Ct. 1384. Infringement can occur in two ways, either directly as literal infringement or as infringement under the doctrine of equivalents. "Literal infringement of a claim exists when each of the claim limitations 'reads on,' or in other words is found in, the accused device." Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1345 (Fed.Cir.2002).

Even if one or more of the claim limitations are not literally present in the accused device, thus precluding a finding of literal infringement, the claim may still be held infringed if equivalents of those limitations are present. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 24, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). Equivalents are assessed on a limitation-by-limitation basis; this focus on individual limitations, rather than on the accused device as a whole, aids the court in being specially vigilant against allowing the concept of equivalence to eliminate any claim limitations completely. *Id.* at 40, 520 U.S. 17, 117 S.Ct. 1040, 137 L.Ed.2d 146. Equivalence may be established by a showing by preponderant evidence that an element of an accused device " 'does substantially the same thing in substantially the same way to get substantially the same result' as the claim limitation." Toro Co. v. White Consol. Indus., Inc., 266 F.3d 1367, 1370 (Fed.Cir.2001) (quoting Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1260 (Fed.Cir.1989)). " 'A claim element is equivalently present in an accused device if only insubstantial differences distinguish the missing claim element from the corresponding aspects of the accused device.' " Leggett & Platt, Inc. v. Hickory Springs Mfg. Co., 285 F.3d 1353, 1359 (Fed.Cir.2002) (quoting Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed.Cir.1997)).

Id.

A. *Claim Construction*

[3] Construing a claim necessitates reference to three primary sources-the claims, the specification and the prosecution history. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577.

In interpreting the claim limitations, the court should look first to the intrinsic evidence, or in other words "the written description, the drawings, and the prosecution history, if in evidence." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 63 USPQ2d 1374, 1380 (Fed.Cir.2002). The words of the claims themselves define the scope of the invention, and are given their ordinary and customary meaning, unless the patentee has chosen to use terms in some other manner. Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1366 (Fed.Cir.2001); *see also* Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed.Cir.), *cert. denied,* 519 U.S. 911, 117 S.Ct. 275, 136 L.Ed.2d 198 (1996). It is thus necessary to review the specification to determine whether the patentee has assigned any special meaning to claim terms; the specification is "the single best guide to the meaning of a disputed term." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576,

1582 (Fed.Cir.1996). The court may also consider the prosecution history, if in evidence. *Id*.; Markman, 52 F.3d at 980. The prosecution history "is often of critical significance in determining the meaning of the claims." Vitronics, 90 F.3d at 1582.

Allen Eng'g Corp., 299 F.3d at 1345. If the intrinsic evidence is not dispositive, a court may also refer to extrinsic evidence, such as expert and inventor testimony, dictionaries and treatises, that "may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history." Markman, 52 F.3d at 980.

As previously set forth, *see supra* at 114, the '511 patent consists of four elements. The only disputed elements are one and four; that is, whether (1) the 210 consists of "a sheet of flexible material," and (2) the 210's conductive adhesive (the hydrogel) "engages" the flexible backing of the electrode.

[4] The parties argue extensively over what constitutes a "sheet of flexible material." Ludlow contends that a sheet consists of a single layer of material, while ConMed posits that a "sheet," as used in the '511 patent, can consist of one or more layers. The distinction is important because, whereas the '511 patent contemplates the conductive paint, conductive adhesive and patient adhesive all applied directly to one side of the flexible backer, the 210 has a small layer of polyester between the flexible backer and the conductive paint and conductive adhesive. If, as ConMed contends, a "sheet of flexible material" includes both the flexible backer and the smaller, polyester layer affixed thereto, then the 210 is substantially similar to the '511 patent such that, provided all the other elements of the claim are present in the 210, it infringes upon the '511 patent's monopoly. If, on the other hand, a "sheet of flexible material" cannot be so defined, then the 210 does not contain all the elements of the '511 patent, and therefore, does not infringe upon it.

The '511 patent itself does not explicitly define the term "sheet." The use of the term within the patent suggests that it refers to a thin, continuous, flat layer of material. Nowhere within the claims or the specification of the '511 patent does the term "sheet" refer to multiple layers of different materials or elements or multiple layers of dimensionally different materials. For example, that portion of the specification discussing Figures 17 and 18 provides, in part, as follows:

[R]eference number 212 identifies a substrate such as a paper tape substrate and the reference number 214 identifies a pressure sensitive patient adhesive adhered to and entirely covering one surface of the substrate 212. The substrate 212 is ... a relatively narrow strip having an indefinite length. Adhered centrally to the exposed surface of the patient adhesive and extending longitudinally the entire length of the substrate 212 is a thin carrier sheet 216 of flexible and dimensionally stable material such as polyethylene terephthalate. The width of the sheet 216 is less than the width of the substrate 212 so as to leave to each side of the sheet 216 a margin 218 comprising the more aggressive patient adhesive. Applied longitudinally and centrally to the lower face of the sheet 216 is a stripe 220 of a conductive paint. The stripe 220 is narrower than the sheet 216 so that margins 222 remain on the sheet 216 for receiving a layer 224 of conductive adhesive which fully covers the conductive stripe 220 and also shields the side edges of such stripes.

(*See* Griem Aff. Ex. C, Col. 13 at line 64.) The specification references item 216 as a "thin carrier sheet of a flexible and dimensionally stable material such as polyethylene terephthalate." (*See* Powers Aff., Ex. A at col. 14.) Item 216 is a single layer element (plastic) that attaches to the substrate. (Id.) This portion of the application never refers to the substrate together with the flexible material (*i.e*. multiple layers) as a sheet as ConMed now argues. Rather, the specification refers solely to the flexible material 216 (which is dimensionally different than the underlying substrate) as the sheet. As another example, the specification

states that "[i]n a tenth embodiment.... [e]ach of the electrodes comprises a substrate having the jigsaw puzzle shape and coated on one face by a patient adhesive to which is mounted a relatively narrow sheet of dimensionally stable plastic material." (Id. at col. 2.) Again, this does not contemplate multiple layers or different materials. Similarly, when discussing the fifth embodiment, the specification states that "a medical electrode is formed from a conductor comprising a suitably formed plastic sheet having a thin layer of electrically conductive, paintable material adhered to one face thereof...." (*See* id. at col. 2.) FN10

FN10. *See also* id. ("In an eighth embodiment, a substrate is covered on one face thereof ... to which is centrally adhered a sheet of dimensionally stable nonconductive materials, such as plastic ...."); id. at col XXX ("Conductive adhesives available in sheet form can be applied directly to the surface of the substrate 132 over the conductive layer 134 or the conductive adhesive could be applied by spraying, silk screen, casting, or other processes.")

This use of the term "sheet" throughout the specification and the claims accords with the ordinary dictionary definition, which provides that a "sheet" is

2. a broad, relatively thin, surface, layer, or covering. 3. a relatively thin, usually rectangular form, piece, plate, or slab.... 4. material, as metal or glass, in the form of broad relatively thin pieces.

The Random House Dict. of the English Language at 1313 (Random House 1979); *see also* Oxford English Dict., at http://dictionary.oed.com (Oxford Univ. Press 2002) ("A broad expanse or stretch of something lying out flat ... forming a relatively thin covering or layer."); Webster's II New Riverside Univ. Dict. at 1073 (Riverside Publ.1994) ("a broad, thin, usually rectangular piece of material, as paper, metal, glass or wood."); The Am. Heritage Dict. of the English Language, at http://www.bartleby.com (4th ed. 2000) ("A broad, flat, continuous surface or expanse.").

Nothing in the patent itself or the ordinary use of the term defines the term "sheet" to include multiple layers or a piece of material with a dimensionally different (*i.e.* smaller) type of material affixed to it. Of course, the materials comprising the sheet may be composites made up of different elements. For example, sheets of plywood, paper or plastic may be composites of different elements. A sheet of plywood is made up of thin layers of wood that are glued together. A sheet of plastic is comprised of the various elements that make up the plastic. This, however, should be distinguished from multiple layers of different materials and multiple layers of dimensionally different materials. Thus, a sheet of plywood with a smaller piece of plywood attached to it is no longer referred to as a sheet of plywood. Similarly, a sheet of plywood with a smaller piece of plastic adhered thereto is not ordinarily referred to as a sheet.FN11 To summarize, the term "sheet" may include material made up of different elements and may even include multiple layers of material that are dimensionally the same. When various layers are pressed together, however, to retain the characteristics of a "sheet," the material must have a continuous, flat surface (*e.g.* a bed sheet, a sheet of wood, a sheet of paper, or a sheet of ice). By placing a dimensionally different (*e.g.* a smaller) material on top of a sheet of flexible material, it loses its sheet-like characteristics because it loses its continuous, flat shape. Thus, as used in the '511 patent's claims, the term "sheet of flexible material" does not include dimensionally different materials affixed to the flexible backer.

FN11. ConMed's reference to the use of the term "sheet" in prior art in the field of invention is unavailing and may work against its argument. ConMed cites to patent no. 3,989,035 ("the '035 patent") which has a "disposable pre-gelled medical electrode ... wherein said carrier sheet is formed of *a multiply sheet of*

polypropylene." (ConMed Mem. of Law at 8 (emphasis added).) According to ConMed, "this reference for a disposable medical electrode expressly identifies a single 'sheet' as having multiple layers." (Id.) This argument is unpersuasive because, in the '035 patent, the patentee expressly defined the term sheet to be "multi-ply." The term "ply" means "one thickness or layer." Random House Dict. at 1108. The prefix "multi" means "many." Id. at 939. Thus, the '035 patentee ensured that his use of the term "sheet" included multiple layers. The converse of this is that the term "sheet" does not ordinarily encompass multiple layers. Cartmell made no effort to define the term sheet to include multiple layers.

[5] As ConMed points out, there is a rule of patent construction that "an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.' " KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed.Cir.2000). Applying this rule of claim construction, ConMed's patent can be interpreted as follows: one or more sheets of flexible material and one or more conductive paints adhered to one face of said sheet ... and wherein said electrode further comprises one or more layers of patient adhesive means on said one face of said sheet. (*See* Powers Aff., Ex. A, col. 16.) The problem with applying this rule here is that the claim requires, among other things, that "a conductive paint [be] adhered to *one face of said sheet* " and that a "layer of patient adhesive means [be applied] on said *one face of said sheet*." (*Id*. (emphasis added).) This part of the claim does not contemplate the plural form of sheet, but, rather, refers only to the singular form. Thus, the parts of the claim limiting application of the adhesive and conductive paint to "one face of said sheet" suggest only one sheet. Even if the claim contemplates multiple layers of flexible material as comprising the sheet, the claim still requires that both the conductive paint and the patient adhesive be applied to "one face of said sheet." (*Id*.)

B. ***Whether the 210 Infringes*** The '511 Patent

1. ***Literal Infringement***

[6] As previously noted, "[l]iteral infringement of a claim exists when each of the claim limitations 'reads on,' or in other words is found in, the accused device." Allen Eng'g Corp., 299 F.3d 1336, 1345 (Fed.Cir.2002). The '511 patent requires, among other things, that: (1) the conductive paint be "adhered to one face of said sheet;" and (2) the patient adhesive also be "on said one face of said sheet." The 210 contains a sheet of flexible material (the backer) with patient adhesive on it. Thus, the 210 implicates the '511 patent insofar as the conductive paint is adhered to one face of the sheet. A sheet of polyester is then applied to the backer. There is no patient adhesive on the polyester sheet. The polyester sheet is smaller in size than the underlying flexible backer. As discussed, the backer loses its characteristic as a sheet when the dimensionally different polyester sheet is affixed thereto. The conductive paint is applied to one face of the polyester layer. The conductive paint is not applied to the flexible backer. Because the conductive paint is applied to the face of the sheet of polyester rather than to the sheet of flexible backer, it does not fall within the '511 patent's claim requirement that the patient adhesive and conductive paint both be applied to "one face" of the "sheet of flexible material." Stated otherwise, the '511 patent requires that the conductive paint and the patient adhesive be applied to the same face of the same sheet of flexible material. In the 210, the patient adhesive is applied to one sheet of flexible material (the backer) while the conductive paint is applied to a different sheet of flexible material (the polyester layer). Accordingly, no fair-minded trier of fact could reasonably conclude that the 210 literally infringes the '511 patent.

2. ***The Doctrine of Equivalents***

[7] The next question is whether the 210 is an equivalent of the '511 patent such that it may be found to infringe upon the '511 patent's monopoly. Under the doctrine of equivalents, "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo,* 122 S.Ct. at 1837. "The doctrine of equivalents is premised on language's inability to capture the essence of innovation." *Id*. at 1839. "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original claim but which could be created through trivial changes." *Id*. at 1838. The essential objective inquiry for infringement under the doctrine of equivalents is "does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?" *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 117 S.Ct. 1040, 1052, 137 L.Ed.2d 146 (1997). Factors to be considered in determining equivalence include assessing whether a person of ordinary skill in the art would have recognized the interchangeability of the elements of the 210 electrode with those described in the 511 patent. *See* id. at 1047.

The scope of equivalents embraced by a claim limitation is dependent on the description in the supporting specification. *See* Manual of Patent Examining Procedures ("MPEP") s. 2184 (8th ed.2001). Here, in the '511 patent, the text in column 16 line 7 states

Paper and polyethelene terephthalate have been mentioned as suitable materials for the substrates or carrier sheets to which the conductive paint is applied.... Other materials which are flexible and substantially dimensionally stable in sheet form could be used.

Therefore, the potential range of equivalents encompassed by the language in the patent is broad and appears to include the addition of a polyester layer. Defendant's expert states that "the use of the intermediate polyester layer as a substrate for the conductive paint has several manufacturing and functional advantages of the claimed structure." (*See* Griem Aff. Ex. 2, at 23.) According to defendants, the use of a polyester layer provides two advantages: (1) it can better tolerate the heat and process needed to properly apply the conductive paint; and (2) "it is smoother and less porous than the foam substrate, suggesting the need for much less coating of the conductive paint." (Griem Aff., Ex. 2, para. 74.) These minor alterations serve only to assist in the production process. They do not add to the value of the invention as a medical electrode. Thus, it appears that the addition of the polyester layer is a relatively insubstantial, trivial change, thereby implicating the doctrine of equivalents. *Festo,* 122 S.Ct. at 1838.

[8] ConMed may not, however, rely on the doctrine of equivalents under the facts and circumstances of this case because the countervailing doctrine of prosecution history estoppel bars ConMed from claiming infringement. "Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the USPTO during the application process. Estoppel is a 'rule of patent construction' that ensures that claims are interpreted by reference to those 'that have been canceled or rejected.' " *Id*. at 1838 (quoting Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 220-21, 312 U.S. 654, 61 S.Ct. 235, 85 L.Ed. 132 (1940)). "When ... the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Id*. at 1838.

[9] The analysis starts with "the presumption that prosecution history estoppel bars a finding of equivalence." *Festo,* 122 S.Ct. at 1842. "[T]he patentee bears the burden[s] of proving that an amendment was not made for reason that would give rise to an estoppel ... [and that] the amendment does not surrender the particular equivalent in question." *Id*. Cartmell amended claim 1 to avoid the prior art cited by the

USPTO in the rejection. In the prior art, although there are other differences in the inventions' designs, the patient adhesive is separate and apart from the conductor. The amendment language narrowed the scope of the claim and added the disputed phrase a "sheet of flexible material" and the requirements that the patient adhesive and conductive paint be adhered to one face of the sheet of flexible material. FN12 In his response to the USPTO's rejection, Cartmell stated:

FN12. *See supra* at n. 6.

[C]laim 1 is amended to recite that the conductor comprises a sheet of flexible material and conductive paint adhered to one face of said sheet, that the conductive adhesive forms a layer engaging said sheet in overlying relationship to at least a portion of said paint, and that the patient adhesive means is a layer on said one face of said sheet. *This structure is in clear contrast to the prior art relied upon by the [PTO] in which, with the exception of Anderson et al '215, the patient adhesive is on a piece of tape or the like separate from the conductor* .... [T]he Engel patent is most similar in appearance. However, its backing 20 and adhesive coating 22 are clearly on the side of the plate 12 opposite its skin-contacting face.
(Griem Aff., Ex. D, at 115) (emphasis added). With this amendment to his patent application, Cartmell explicitly distinguished his invention from the prior art by applying the conductive paint, the conductive adhesive and the patient adhesive directly to one side of the flexible backer. By narrowing the application in this regard, Cartmell gave up the broader, unamended claim that permitted the flexible backer to be separate from the conductive paint. ConMed has not come forward with any affirmative evidence suggesting that this amendment was not made for a reason that would give rise to an estoppel or that the amendment did not surrender the particular equivalent in question. *See Festo,* 122 S.Ct. at 1842. "When the patentee is unable to explain the reason for amendment, estoppel not only applies but also 'bar[s] the application of the doctrine of equivalents as to that element.' " *Id*. (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 33, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997)). Therefore, the doctrine of equivalents does not apply to the element at issue and ConMed, as the successor in interest to the '511 patent, is estopped from claiming that a "sheet" as used in the 511 patent can consist of a layer of some other material between the flexible backer and the conductive paint. *See* id. at 1840.
This conclusion is supported by the USPTO's restriction requirement. As is discussed more fully *supra* at section II(A), Cartmell was forced to choose a single species of claims for prosecution on the merits. (*See* Griem Aff., Ex. D at 104-05.) Cartmell traversed the restriction requirement "to the extent that election is sought as between the species of FIGS. 15-16 and FIGS. 17-18" and elected to proceed with the species contained in figures 15 and 16. (Id. at 108) Finding the disclosed embodiments to be patentably distinct, the USPTO made the restriction requirement final. (*See* Griem Aff., Ex. D at 110). Based on the record presented, Cartmell did not file a divisional application, file a new patent application or otherwise challenge the restriction requirement. *See* 37 C.F.R. s. 1.144 ("After a final requirement for restriction, the applicant ... may petition the Commissioner to review the requirement. Petition ... must be filed not later than appeal.").FN13 By failing to challenge the restriction requirement or attempting to patent the distinct invention identified in embodiment 8 (which is depicted in Figs. 17 and 18), Cartmell gave up that subject matter. *See* In re Weiler, 790 F.2d 1576, 1582 (Fed.Cir.1986) ("By acquiescing in the examiner's restriction requirement, and failing to file divisional applications on the subject matter of non-elected claims, [the patentee has] foreclosed ... his right to claim that subject matter."); *see also Festo,* 122 S.Ct. at 1838 ("While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim."); Merck & Co., Inc. v. Mylan Pharmaceuticals, Inc., 190 F.3d 1335, 1340 (Fed.Cir.1999) ("[T]he controlling fact is that [the patentee] no longer sought to claim [the broader claims]."); In re Watkinson, 900 F.2d 230, 232

(Fed.Cir.1990) ("[A]fter acquiescing in the restriction requirement, canceling the nonelected claim and allowing the .. patent to issue, [the patentee] has lost her opportunity to challenge the propriety of the restriction requirement."); In re Cornell, 32 C.C.P.A. 1251, 150 F.2d 702, 704 (Cust. & Pat.App.1945); In re Smyser, 30 C.C.P.A. 1093, 135 F.2d 747, 751 (Cust. & Pat.App.1943).

FN13. Claims restricted from a patent application can be prosecuted at the USPTO separately in a divisional or separate patent application. *See* MPEP s. 821.

[10] Through restriction practice, Cartmell essentially was required to narrow the scope of his application. Accordingly, estoppel applies to the restriction. *Festo,* 122 S.Ct. at 1839 (noting that prosecution history estoppel is not limited to amendments made to avoid prior art and may be invoked any time "an amendment is made to secure the patent and the amendment narrows the patent's scope."). Furthermore, it is well-established that "subject matter disclosed but not claimed in a patent application is dedicated to the public." Maxwell v. J. Baker Inc., 86 F.3d 1098, 1106 (Fed.Cir.1996) (citing Unique Concepts, Inc. v. Brown, 939 F.2d 1558 (Fed.Cir.1991)), *cert. denied,* 520 U.S. 1115, 117 S.Ct. 1244, 137 L.Ed.2d 327 (1997); *see also* Genentech, Inc. v. Wellcome Found., Ltd., 29 F.3d 1555, 1564 (Fed.Cir.1994) ("An applicant should not be able deliberately to narrow the scope of examination to avoid during prosecution scrutiny by the USPTO of subject matter ... and then, obtain in court, either literally or under the doctrine of equivalents, a scope of protection which encompasses that subject matter."); International Visual Corp. v. Crown Metal Mfg. Co., 991 F.2d 768, 775 (Fed.Cir.1993) (doctrine of equivalents should not extend to disclosed, but unexamined, subject matter) (Lourie, J., concurring). Here, Cartmell's failure to prosecute the restricted embodiments resulted in the dedication of those disclosed embodiments to the public.

This is particularly significant here because, like the 210, embodiment 8 describes a device whereby there is a layer of material between the backer containing the patient adhesive and the conductive paint. Embodiment 8 specifically described and claimed a configuration literally equivalent to the configuration of the 210 electrode. (*See* Griem Aff. Ex. C, at drawing sheet 6 of 7.) In light of the language of the restricted out matters, ConMed is unable to "show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo,* 122 S.Ct. at 1842. This analysis leads to the conclusion that the 210 electrode is not the equivalent of the electrode described in the '511 patent because the '511 patent was restricted to the prosecution of a singular embodiment,FN14 embodiment 8 was held by the USPTO to be separately patentable subject matter, and one skilled in the art could reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent. ConMed, as Cartmell's patent assignee, should be estopped from arguing that the '511 patent includes that subject matter. *See Festo,* 122 S.Ct. at 1839-40.

FN14. Cartmell elected embodiment 7.

V. *CONCLUSION*

A sheet of flexible material, as used in the '511 patent, does not encompass a multi-layer configuration of different materials that are dimensionally diverse. While the '511 patent may allow for multiple sheets of flexible material, its claims require that the patient adhesive and the conductive paint both be adhered to one face of the sheet of flexible material. The 210 does not literally infringe the '511 patent because the conductive paint is affixed to one face of a polyester layer while the patient adhesive is affixed to one face

of the substrate and these two elements, therefore, are not both on one face of the sheet of flexible material. ConMed cannot avail itself of the doctrine of equivalents because it gave up the subject matter of the alleged infringing element through the restriction, and it has otherwise failed to sustain its burdens of demonstrating that the amendment was made for a reason that would not give rise to estoppel and that the amendment did not surrender the particular equivalent in question. Having found that the 210 does not infringe upon the '511 patent, it is unnecessary to consider Ludlow's argument that the '511 patent is invalid.

Accordingly, it is

ORDERED, that

1. Ludlow's motion for declaratory judgment of non-infringement is GRANTED;

2. The Kendall Care 210 Resting ECG Electrode does not infringe upon U.S. Patent No. 4,674,511.

3. Ludlow's motion for a declaratory judgment that the U.S. Patent No. 4,674,511 is invalid is DENIED as moot; and

4. ConMed's motion for summary judgment is DENIED.

The clerk is directed to enter judgment accordingly and close the file.

IT IS SO ORDERED.

N.D.N.Y.,2002.
Conmed Corp. v. Ludlow Corp.