United States District Court, D. Maryland.

D. HEMPHILL,

v.

JOHNSON & JOHNSON Consumer Companies, INC.

No. Civ.A. DKC 99-654

March 12, 2001.

Owner of patent for vaginal applicator brought infringement action against manufacturer of sanitary napkins. On manufacturer's motion for summary judgment, the District Court, Chasanow, J., construed terms of patent, and then held that accused products neither literally nor equivalently infringed patent.

Motion granted.

4,557,720. Not Infringed.

Allegra D. Hemphill, Rockville, MD, pro se.

George Pappas, Vicki Ann Margolis, Venable, Baetjer & Howard, LLP, Baltimore, MD, Davida H. Isaacs, Terri L. Turner, Venable, Baetjer Howard and Civiletti, LLP, Washington, DC, for defendant.

MEMORANDUM OPINION

CHASANOW, Judge.

Plaintiff Allegra Hemphill, proceeding *pro se*, alleges that Defendant Johnson & Johnson, Inc. ("Johnson and Johnson") manufactures and distributes products which infringe on her patent, U.S. Patent 4,557,720 ("the '720 patent"). FN1Presently pending and ready for resolution are three motions. Johnson & Johnson Consumer Companies, Inc. ("JJCCI") has filed a Motionfor Leave to Permissively Intervene. Defendant McNeil has filed both a Motion for Summary Judgment for Noninfringement and a Motion to Bifurcate.FN2 The issues are fully briefed and no hearing is deemed necessary. Local Rule 105.6. For the following reasons, the court shall deny JJCCI's Motion for Leave to Permissively Intervene and grant McNeil's Motion for Summary Judgment.FN3

FN1. On February 14, 2000, this court ordered that McNeil-PPC, Inc. ("McNeil") replace Johnson & Johnson as the party defendant because McNeil is the entity responsible for the manufacture and distribution of the Stayfree, Carefree, and Serenity products at issue in this case. Paper No. 36.

FN2. The issue of non-infringement is the sole issue in McNeil's summary judgment motion because Defendant does not argue the invalidity or unenforceability of Plaintiff's patent. Paper No. 57, 2 n. 2.

FN3. In light of this court's decision to grant McNeil's Motion for Summary Judgment, Defendant's Motion to Bifurcate is no longer applicable, and thus, the motion will be denied as moot.

I. Background

Ms. Hemphill filed her application for the '720 patent with the Patent and Trademark Office ("PTO") on June 11, 1984, and her patent was subsequently issued on December 10, 1985. Paper No. 46, Ex. D1. Bearing the title "Vaginal Applicator", the '720 patent describes a disposable vaginal swab or refresher meant either to cleanse or to treat the vaginal area with fragrances, medications, germicides, or deodorants. Id., Col. 1, lines 33-38. The '720 Patent has two independent claims, but only claim 2 is at issue in this litigation. Id., Ex. B, Deposition of Allegra Hemphill ("Hemphill Depo"), 10. The description contained in claim 2 of the Applicator is as follows:

a vaginal swab comprising an outer housing including an inner case member and an outer case member at least part of which is connected to and said overlies inner case member;

a core member, at least one layer of porous material secured to said core member, and housing means for both supporting and enclosing said core member, said core member being secured to said housing means, having at least two portions movable relative to one another between first and second positions for enclosing said core member when in said first position and for both, exposing said core member and the said porous padding secured thereto and for forming a handle for said swab when in said second position.

Id., Ex. D1, Col. 7-8, lines 1-10.

A. Prosecution of the '720 Patent

During the prosecution phase, Plaintiff narrowed her claims to distinguish her invention from prior art cited by the Examiner. For example, Plaintiff clarified the distinction between her invention and a patent awarded to M. Alvarez by explaining that:

[t]he Alvarez device does not allow for an elongated structure for the swabbing element to be introduced into the vaginal cavity nor does it provide a sufficient handle structure.

Id., Ex. D10, PTO 00313. She also differentiated between the porous material specified in the respective patents.

Alvarez teaches that a moisture **ab**sorbent layer is exposed after the protective covering is removed. There is a distinct difference between **Ab** sorbent and **Ad**sorbent, to *ab* as in Alvarez, absorb is to take in, suck up, swallow, engross wholly, to take up or receive by chemical or molecular actions as of gases or liquids, and to *ad* as in *Hemphill* to adsorb is to take up and hold, to gather gas or liquid or dissolved material on a surface.

Id., Ex. D6, PTO 00336 (emphasis added).

Additionally, Plaintiff distinguished the "housing" in her invention from the "housing" in the patent issued to Albert Gelardinfor a Cosmetic Holder. Plaintiff noted:

[t]he Hemphill device, after removing the outer housing serves as a handle structure, and still serves as a function for the device, unlike Gelardin that states that the cover is completely removed.

Id., Ex. D6, PTO 00342 (emphasis added).

B. Reexamination of the '720 Patent

On February 2, 1998, Plaintiff asked the PTO to re-examine her patent in light of the McNair patent ("McNair") for a Sanitary Napkin with wings. The description of the McNair patent states as follows:

The central element and side elements have fluid-impervious backing upon which is placed a thin layer adhesive which will not penetrate the absorbent materials placed thereon. The central element has a highly-absorptive pad means whereas the absorptive means on the side panels may be minimal. The backing element of the central portion of the invention contains a strip of adhesive covered by a protective tape until use.

Id., Ex. E2, AH 0222. Plaintiff differentiated her invention from McNair by stating that "Hemphill [vaginal swab] improves **ab**sorbing on the McNair cover sheet because of an **ad**sorbency characteristic." Id., Ex. E1, AH 0230. Thus, the McNair patent required an absorbent porous sheet, whereas Plaintiff's patent specified **ad**sorbent porous material.

Ultimately, the PTO denied Plaintiff's request for reexamination after finding that the McNair patent "did not raise a substantial new question of patentability.". Id., E4, AH 0227. Specifically, the PTO stated that the McNair patent "discloses none of the structural features recited [in Plaintiff's claims]" in light of Plaintiff's invention having a particular core member and housing. Id.

Plaintiff also applied for reexamination of her patent on May 20, 1998, this time over a patent held by Srinivasan, *et al.* Id., Ex. F2, U.S. Letters Patent No. 3,973,567 ("the Srinivasan patent"). The Srinivasan patent describes a "wrapped" sanitary napkin that includes plastic outer packaging and a napkin that affixes to an undergarment using an adhesive. The patent contains this description of the invention:

A sanitary napkin having an adhesive element thereon for attaching to an undergarment is provided with means for protecting the napkin and the adhesive element prior to use and for disposing of the napkin after use. The means comprise providing the napkin with a wrapper sheet of flexible material overlying one major surface, and the sides of the napkin and at least partially overlapping on the second major surface of the napkin. The sheet is releasably adhered to and held in place by the adhesive element.

Id., Ex. F1, PTO 00509.

The PTO granted Plaintiff's request for reexamination, finding that "[a] substantial new question of patentability affecting Claim 2" was raised by the Srinivasan patent. Id., Ex. F3, PTO 00481. Agreeing to compare claim 2 and the Srinivasan patent more closely, the PTO acknowledged the possibility that Srinivasan had the claimed structure, such as "a core member surrounded by a layer of porous material, an

outer housing, and housing means with 2 positions (one position that protects the core member and another position that exposes the core member for use)." Id.

In an effort to get her claim reissued, Plaintiff stated the Srinivasan patent lacked both the "housing means" and "a band" at the base of the core member, found in her invention. Id., Ex. F4, PTO 00484. Plaintiff emphasized that the missing band was particularly significant to her invention because "[t]he band is the means or intermediary in *both* positions from the closed location to the open state", Id., Ex. F4, PTO 00486 (emphasis in original), allowing users "to keep sticky fingers off the fibers." Id., Ex. F2, PTO 00447. Furthermore, Plaintiff distinguished her vaginal swab by stating: "[i]t should be well understood that **Hemphill does not behave, operate, or function like a sanitary napkin. Srinivasan does not have the components or parts to be vaginal swab.**" Id., Ex F2, PTO 00451 (emphasis in original).

On January 26, 1999, the PTO issued a reexamination certificate for the '720 Patent over Srinivasan for the following reasons:

Claim 1 of the patent to Hemphill (4557720) is considered patentable over the patent to Srinivasan, et al. (3973567) because Srinivasan simply does not disclose the claimed structure, such as an open end opposite a closed end, an annular band, and frangible seams.

Claim 2 of the patent to Hemphill (4557720) is considered patentable over the patent to Srinivasan, et al., (3973567) because Srinivasan does not disclose the housing means of Hemphill and does not disclose a structure that could be considered equivalent to the housing means of Hemphill.

Id., Ex. F6, PTO 00490.

According to Defendant, beginning in 1994 and continuing for the next four years, Plaintiff sent letters to Johnson & Johnson executives alleging that the company's sanitary and adult napkins incorporate her patented technology. Specifically, Plaintiff has alleged that the Stayfree sanitary napkin, Carefree sanitary napkin, and Serenity adult napkin product lines infringe upon her patent.FN4 Moreover, Plaintiff testified that she considers these respective product lines to be structurally equivalent to each other. Id., Ex. B, 363, 368, 372-74, 376-77.

FN4. Although Plaintiff mentions in her deposition testimony that Band Aid brand adhesive bandage products also infringe upon her patent, she never actually argues this contention. This court construes Plaintiff's complaint as limited to products from the Stayfree, Carefree, and Serenity product lines.

Defendant agrees that the three different product lines are nearly identical in design. Id., Ex. A, McCoy Decl., para. 5. Defendant has provided the following undisputed description of these products:

The Accused Napkins are sold in multiple units in large plastic bags, inside of which are individual napkins packaged in plastic wrappers. (Ex. A, McCoy Decl., para. 6). Each of these individual units is composed of absorbent material with a flexible thin porous membrane that is attached on one side to a flexible plastic sheet that has an adhesive on the other side. Id., para. 7. In its packaging, the side of the plastic sheet containing the adhesive is attached to a thin paper sheet. Id., para. 7. In order to use the napkin, the consumer removes the plastic packaging, and peels off the thin paper sheet. Id., para. 9. Then, the consumer presses the side with the adhesive to the undergarment in order to attach the napkin to the undergarment. Id.

The napkin is intended to passively collect fluid during use. Id., para. 10. After use, the consumer pulls on the napkin to peel it off of the undergarment, and then discards it, either directly or by first inserting the napkin into the plastic wrapper of the next napkin. Id., para. 11. The Accused Napkins are not designed to be used or placed internally in the vagina. Id., para. 12. They do not have handles, and do not have adsorbent material. Id., para. 13.

Paper No. 46, 5.

II. Motion To Intervene

JJCCI has filed a motion for leave to permissively intervene pursuant to Rule 24(b). *See* Fed.R.Civ.P. 24(b). In October 1999 at her deposition, Plaintiff suggested that Band-Aid brand adhesive bandage products may also infringe upon her patent. These bandages are manufactured and/or distributed by JJCCI, another subsidiary of Johnson & Johnson, not by McNeil-the current party Defendant.

A. JJCCI's Motion for Leave to Permissively Intervene

[1] Rule 24(b)(2) provides, in pertinent part:

Upon timely application anyone may be permitted to intervene in an action ... when an applicant's claim or defense and the main action have a question of law or fact in common ... In exercising its discretion, the court shall consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties.

Fed.R.Civ.P. 24(b)(2). Thus, permissive intervention is appropriate in circumstances in which 1) the application is timely; 2) the moving party's claim or defense and the main action have a common question of law or fact; and 3) the proposed intervention will not unduly delay or prejudice the adjudication of the original parties' rights. Hill v. W. Electric Co., 672 F.2d 381, 386 (4th Cir.1982); 6 James Wm. Moore et al., *Moore's Federal Practice* s. 24.10 (3d ed.1997).

B. Analysis

[2] Although Plaintiff identified Band Aid brand adhesive bandages at her deposition taken October 18, 1999 as a product line allegedly infringing upon her patent, she never made this assertion again. Paper No. 53, Exhibit A, Hemphill Depo., 375-376. In fact, both Plaintiff's response to JJCCI's motion for leave to permissively intervene and her opposition memorandum to McNeil's motion for summary judgment contain assertions that Stayfree, Carefree, and Serenity product lines are the sole product lines she is litigating in this lawsuit. Paper No. 48 at 5, Paper No. 55 at 1. Plaintiff does not assert that Band Aid products are within the identified accused products in her complaint or in any of her papers, thus, this court will not force her to litigate an issue she has not asserted.

Moreover, JJCCI provides absolutely no explanation for the eight month time lapse between receiving notice through Plaintiff's deposition testimony in October 1999 and filing this motion in May 2000. Plaintiff also asserts that JJCCI's motion is untimely, particularly, in light of discovery closing on March 13, 2000. Thus, the court shall deny JJCCI's motion for leave to permissively intervene.

III. McNeil's Motion for Summary Judgment

A. Summary Judgment Standard

In patent cases, as well as in other cases, a motion for summary judgment will be granted only if there exists no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); Clark v. Alexander, 85 F.3d 146, 150 (4th Cir.1996). The moving party bears the burden of showing that there is no genuine issue of material fact. Fed.R.Civ.P. 56(c); *Pulliam*, 810 F.2d at 1286 (citing Charbonnages de France v. Smith, 597 F.2d 406, 414 (4th Cir.1979)).

When ruling on a motion for summary judgment, the court must draw all reasonable inferences in favor of and construe the facts in the light most favorable to the non-moving party. Tinsley v. First Union Nat'l Bank, 155 F.3d 435, 437 (4th Cir.1998). A properly supported motion for summary judgment may not be defeated by "the mere existence of some alleged factual dispute between the parties." Anderson, 477 U.S. at 247-48, 106 S.Ct. 2505. Further, while the court is charged with liberally construing a complaint filed by a pro se litigant to allow the development of a potentially meritorious case, the requirement of liberal construction does not mean that the court can assume the existence of a genuine issue of material fact where none exists. Weller v. Dep't of Social Services, 901 F.2d 387, 391 (4th Cir.1990); Beaudett v. City of Hampton, 775 F.2d 1274, 1277 (4th Cir.1985).

[3] Although an infringement analysis usually involves both questions of fact and law, summary judgment of noninfringement may still be proper. Nike, Inc. v. Wolverine World Wide, Inc., 43 F.3d 644, 646 (Fed.Cir.1994); Chemical Eng'g Corp. v. Essef Indus. Inc., 795 F.2d 1565, 1571 (Fed.Cir.1986). A good faith dispute about the meaning and scope of asserted claims does not, in and of itself, create a genuine dispute to preclude summary judgment in patent cases. Lantech, Inc. v. Keip Mach. Co., 32 F.3d 542, 546 (Fed.Cir.1994).

B. Analysis

Plaintiff alleges that McNeil's Stayfree, Carefree, and Serenity product lines literally infringe her '720 patent. Defendant objects to this characterization by stating that the original design for these products existed prior to Hemphill's patent and that these products vary in both design and purpose compared to Hemphill's vaginal applicator.FN5

FN5. Defendant asserts that all of the accused products arise from a Stayfree sanitary napkin sold in 1981, prior to the existence of the '720 patent. *See* Paper No. 46, Exhibit L, Stayfree Sanitary Napkin Manufacturing Specifications. Plaintiff, however, contends that the design of these accused products changed after she sent samples of her patented invention to Defendant's parent company in an attempt to distribute her product commercially. Without reaching the question of whether the accused products were sold in the same form prior to the filing of the '720 patent, this court will analyze whether the products in their present form infringe Plaintiff's '720 patent.

[4] [5] [6] In order to assess this motion, the court must engage in a two-step infringement analysis. "The first step is determining the meaning and the scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995) (*en banc*), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Claim construction is correctly a matter of law for the court to decide. *Id*. When

construing a claim, a court should look to the intrinsic evidence, *i.e.*, the patent itself, its claims, written description, and the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Additionally, statements made during the reissue [reexamination] proceeding "are relevant prosecution history when interpreting claims." E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1439 (Fed.Cir.1988).

1. Claim Construction

[7] [8] Claim construction begins with the words of the claim. Bell Comm. Research, Inc. v. Vitalink Comm. Corp., 55 F.3d 615, 619-620 (Fed.Cir.1995). Moreover, claim terms are given their plain meaning unless the inventor, "choosing to be his or her own lexicographer," uses terms in a manner other than their ordinary meaning and clearly discloses these special or alternative meanings in the patent specification or file history. Vitronics, 90 F.3d at 1582; Beachcombers v. WildeWood Creative Products, Inc., 31 F.3d 1154, 1158 (Fed.Cir.1994). Courts may rely on dictionary definitions when construing claim terms "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Vitronics, 90 F.3d at 1582.

The parties agree that only claim 2 of the '720 patent is at issue. Claim 2 provides in pertinent part as follows:

A vaginal swab comprising an outer housing including an inner case member and an outer case member at least part of which is connected to and overlies said inner case member;

a core member, at least one layer of porous material secured to said core member, and housing means for supporting and enclosing said core member, said core member being secured to said housing means, having at least two portions movable relative to one another between first and second positions for enclosing said core member when in said first position and for both exposing said core member and the said porous padding secured thereto and form forming a handle for said swab when in said second position.

Plaintiff has specifically identified the four component parts to the vaginal swab as: 1) outer housing; 2) core member; 3) at least one layer of porous material; and 4) a housing means. Paper No. 46, Ex. G.

a. Vaginal Swab

[9] Plaintiff asserts that the term "vaginal" refers to the outer housing as the cover or sheath, and "swab" refers to the unit being used as either a swab to dry or absorb or an applicator to hold or apply treatment. Paper No. 55, 3. By contrast, Defendant offers a narrower definition that a "vaginal swab" is a stick or wire with a small piece of absorbent material attached to the end of it, which is of a size and structure for cleansing or applying medicine within the vaginal canal.

While the claim provides little guidance as to the terms "vaginal" and "swab", the '720 patent specification clarifies that Plaintiff designed the "vaginal swab" to enter into the vaginal cavity. For example, the specification defines the purpose of the invention as "a truly portable, convenient, and disposable internal vaginal cleaning device or refresher." Paper No. 46, Exhibit F1, Col. 1, lines 46-48. Moreover, the invention in the '720 patent "is designed to dry or absorb material in the internal vaginal area." Id., Col. 3, lines 5-6. In fact, the length of the average vaginal cavity establishes the approximate length of the swab, including the core and gauze material. Id., Col. 3, lines 50-54. From the prosecution history, Plaintiff also distinguished her invention from prior art on this particular point by stating that the invention (Alvarez) lacked "an

elongated structure for the swabbing element to be introduced into the vaginal cavity." Id., Ex. D10, PTO 00313.

In the face of all of this evidence, Plaintiff will not be allowed to claim that her invention is not meant to enter into the vaginal cavity. After all, "a patentee may not construe a claim term one way during prosecution in order to obtain allowance of the patent and then in a different way during litigation in order to obtain a finding of infringement." Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 133 F.Supp.2d 833, ----, 2001 WL 179815, at (E.D.Va.2001) (citing Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed.Cir.1995)). Thus, the '720 patent limits the term "vaginal" to a swab entering into the vaginal canal.

[10] As for "swab", the '720 Patent states that a vaginal swab should preferably be "comprised of fairly rigid core member, constructed either in segments or as a one piece unit, over which a thick, gauze type adsorbent pad or layer is secured." Paper No. 46, Ex. D1, Col. 2, lines 5-9. The plain meaning of the term "swab" is "a small piece of absorbent material attached to the end of a stick or wire and used for cleansing or applying medicine." *American Heritage Dictionary* 1810 (3d ed.1992); *Dorland's Medical Dictionary* 1617 (28th ed.1994).

b. Outer Housing & a Housing Means

[11] Plaintiff asserts that "outer housing" is the "packaging" that protects [the swab] from danger, risk or loss in an enclosing or protecting relationship and the "housing means" is a part of the "outer housing". Paper No. 55, 2. In claim 2, she states that the outer housing must have "an inner case member and an outer case member," must be secured to the core member and must have "at least two portions movable relative to one another." Paper No. 46, D1, Col. 7-8, lines 1-10. Moreover, the '720 patent specification states that the "outer housing" is comprised of "an exterior cover, an internal tubular member, and rotatable base." Id., Col. 1, lines 19-22. During the prosecution process, Plaintiff further clarified the housing structure in order to distinguish her invention from Gelardin's patent. She explained:

[t]he Hemphill device, after removing the outer housing serves as a handle structure, and still serves as a function for the device, *unlike Gelardin* ... that states that the cover is completely removed.

Thus, the outer housing is not designed to be removed and thrown away but actually functions as a handle for the use of the swab. Plaintiff's suggestion that the outer housing is only equivalent to protective packaging is clearly at odds with both the terms of the patent as well as the Plaintiff's own assertions during the prosecution phase.

c. Core Member

[12] Plaintiff claims that having an accused device with a core member, whether flexible or rigid, is enough to infringe upon her patent. However, according to the '720 patent specifications, the core member should be "fairly rigid", Id., Col. 7, line 10, and have an "annular band or ring" at the base, Id., Col. 5, lines 31-33. Furthermore, the core member is secured to the outer housing and "can be formed either as a solid structure or preferably with a hollow interior." Id., Col. 5, lines 33-35. The purpose of the "annular band" is twofold: 1) "to keep sticky fingers off the fibers," Id., Ex. F2, PTO 00447, and 2) to possess "an outer diameter which is at least equal to the inner diameter" of the band attached to the outer housing, "so that the two can fit thereby allowing the core to be secured within the band by a suitable adhesive." Id., Ex. D1, Col. 5, lines 45-48. Thus, consistent with the patent specifications, claim 2 requires a fairly rigid core member with an

annular band or ring at its base that can fit into the band or ring of the outer housing.

d. Layer of porous material

[13] Plaintiff identified the layer of porous material as a critical element of her invention. Paper No. 46, Exhibit G. In prior documentation, including the patent itself, Plaintiff provided a much more specific definition for the layer of porous material. In fact, the '720 patent specification dictates that the porous material should be "secured about the exterior surface of [the] core." Id., Ex. D1, Col. 5, lines 35-37. Moreover, the porous material should be a "thick gauze type adsorbent pad or layer." Id., Col. 2, lines 7-8. During the reexamination proceedings, Plaintiff emphasized that the **ad**sorbency of her invention distinguished it from McNair's **ab**sorbent invention. Id., Ex. E1, AH 0229 ("Hemphill improves absorbing on the McNair cover sheet because of an **ad**sorbency characteristic"). According to the patent specifications and Plaintiff's previous assertions, the porous material should be secured to the exterior surface of the core member and be composed of **ad**sorbent material.

2. Comparison to Accused Devices

After the claims are properly construed, then the terms "must be compared to the accused device or process." Carroll Touch, Inc. v. Electro Mechanical Systems, Inc., 15 F.3d 1573, 1576 (Fed.Cir.1993). "In order for there to be infringement, each and every limitation set forth in a patent claim must be found in the accused device, either literally or under the doctrine of equivalents." Bell Atlantic Network Services, Inc. v. Covad Comm. Group, Inc., 92 F.Supp.2d 483, 498 (E.D.Va.2000) (citing Lemelson v. United States, 752 F.2d 1538, 1551 (Fed.Cir.1985)).

a. Literal Infringement

[14] Plaintiff offers an advertisement for the accused devices as evidence that Defendant has literally infringed her patent. The advertisement contains these assertions: 1) "an absorbent core pulls fluid in and locks it away", and 2) "the silky clean cover draws fluid away and helps keep it below the surface to help you feel clean and dry." Paper No. 52, Ex 2. Despite Plaintiff's attempt to portray the elements of her invention in a manner similar to the quoted advertisement, she is unable to prove that each element of her patented invention can be found in the accused devices. A claim of literal infringement requires proof that the accused devices meet every limitation of the properly construed claims, Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1476 (Fed.Cir.1998) "If even one limitation is missing or not met as claimed, there is no literal infringement." Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed.Cir.1998).

[15] First, and foremost, Plaintiff herself has stated that her vaginal swab does not resemble, behave, or function like a sanitary napkin. Each of the accused products is a type of sanitary napkin which lacks the rigid core required in a swab and is not designed for use within the vaginal canal. The accused products are designed "to cover a substantial portion of an undergarment in order to passively collect fluid that flows onto them." Paper No. 46, Ex. B, para. 12.

Second, the structure of Plaintiff's invention differs vastly from the accused devices on each element. Plaintiff's vaginal swab is comprised of a outer housing structure that encloses a core member in first position and exposes the core member and forms a handle for the swab in the second position. The accused devices have an outer wrapping that is discarded once the sanitary napkin is utilized. At most, the discarded wrapper covers the used and soon-to-be discarded napkin. The protective packaging of the accused devices is in no way equivalent to the handle function of the "outer housing" in Plaintiff's invention. Moreover, Plaintiff asserts that because the accused products have a core pad, they infringe upon her invention. However, the '720 patent clearly specifies that the core member be "fairly rigid" and have an annular band at its base that can fit into the band of the outer housing. The accused products do not have such a structure.

Finally, Plaintiff went to great lengths during the reexamination phase to distinguish the **ad**sorbency characteristic of the porous material used in her invention versus the **ab**sorbency characteristic of the McNair patent. Plaintiff, herself, asserts that McNeil's products have an **ab**sorbent core, yet, offers absolutely no explanation as to how the porous material can possibly be the same between Plaintiff's invention and the accused devices. Accordingly, Plaintiff has failed to establish that the accused products literally infringe upon her '720 patent.

b. Doctrine of Equivalents

[16] [17] Under this doctrine, a product which does not literally infringe upon the express terms of a patent may nonetheless infringe if there is "equivalence" between the elements of the accused products and the claimed elements of the patent. Zelinski v. Brunswick Corp., 185 F.3d 1311, 1316 (Fed.Cir.1999) (citing Warner-Jenkinson, Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 21, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997)). Infringement occurs under this doctrine or equivalents if the difference between the particular element and the claim limitation are "insubstantial." *Id.* A test to determine "insubstantiality" is whether "the element performs substantially the same function in substantially the same way to obtain substantially the same result as the claim limitation." Id. at 1316-17 (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, 70 S.Ct. 854, 94 L.Ed. 1097 (1950)).

[18] Once again, Plaintiff has admitted that her invention, a vaginal swab, "does not look or behave like a sanitary napkin" or even "function like a sanitary napkin" Paper No. 46, Ex. E3, AH 0245. Moreover, Plaintiff has failed to offer a single assertion illustrating that the difference between the elements of her invention and the accused devices is only insubstantial. Rather, the evidence establishes the difference is vast. Accordingly, the court shall find that no reasonable jury could find there to be equivalence between the elements of Plaintiff's invention and the accused devices.

IV. Conclusion

For the foregoing reasons, this court shall GRANT McNeil's Motion for Summary Judgment for Noninfringement.

A separate Order will be entered.

ORDER

For the reasons stated in the foregoing Memorandum Opinion, it is this _____ day of March, 2001, by the United States District Court for the District of Maryland, ORDERED that:

1. Johnson & Johnson Consumer Companies, Inc.'s Motion for Leave to Permissively Intervene BE, and the same hereby IS, DENIED;

2. McNeil-PPC, Inc.'s Motion for Summary Judgment BE, and the same hereby IS, GRANTED;

3. McNeil-PPC, Inc.'s Motion to Bifurcate BE, and the same hereby IS, DENIED AS MOOT;

4. JUDGMENT BE, and the same hereby IS, ENTERED in favor of Defendant, McNeil-PPC, Inc., and against Plaintiff, Allegra Hemphill; and

5. The Clerk will transmit copies of the Memorandum Opinion and this Order to Magistrate Judge Day, to Plaintiff, and to counsel for the Defendant and proposed intervenor and CLOSE this case.

D.Md.,2001. Hemphill v. McNeil-PPC, Inc.

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