IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

HOLLISTER INCORPORATED,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 10 C 6431**
	)	
CONVATEC INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Hollister Incorporated sued ConvaTec Inc. for patent infringement. ConvaTec asserted counterclaims of false patent marking, false advertising, and state law claims. In July 2011, the Court granted summary judgment in favor of ConvaTec on Hollister's infringement claim, but ConvaTec's counterclaims remain, including the false marking claim. The parties agree that this claim requires the Court to construe certain claims in Hollister's patents. The Court now rules on the construction of disputed terms in those patents.

Discussion

"[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Markman v. Westview Instruments*, 517 U.S. 370, 372 (1996). "[T]he words of a claim are generally given their ordinary and customary meaning," specifically, the meaning the words would have to a person of average skill in the relevant field in question at the time of the invention. *Phillips v.*

AWH Corp., 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

The words of a claim are read in the context of that claim and in the context of the patent as a whole. *Id.* at 1313. In construing the language of a claim, courts consider the language of the other claims, because terms used in multiple claims are presumed to be used in the same way, and differences among the claims can help define the meaning of particular terms. *Id.* at 1314–15.

Courts also consider the patent specification and the patent's prosecution history when determining the meaning of the claim language. *Id.* at 1313. Along with the claims, the specification and prosecution history are considered intrinsic evidence of the meaning of the language of the claims. The specification is an important basis for construing the claims, because federal law requires "that the specification describe the manner and process of making and using the patented invention." *Id.* at 1315 (internal quotation marks omitted). The specification must "describe the claimed invention in full, clear, concise, and exact terms." *Id.* at 1316 (internal quotation marks omitted). If the specification reveals that a word is being used in a way different from ordinary meaning, the specification's use controls. *Id.* Similarly, if the specification reveals that the inventor intended to disavow a certain scope regarding a claim, that disavowal is dispositive. *Id.*

Despite the importance of the specification, however, limitations in the specification or particular embodiments contained in the specification should not be read into the claims. *Id.* at 1323–24. The specification is a guide to reading the claims, but it does not trump the language of the claims unless the patentee intended the specification and claims to be strictly coextensive. *Id.* Thus, a patent can cover devices

that do not look like those shown in the specification. *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007). On the other hand, "a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever correct." *Id.* (alterations omitted).

Courts also consider the prosecution history of a patent when construing its terms. Generally, however, the prosecution history is not as clear or useful as the specification, because it represents a negotiation between the inventor and the patent office. *Phillips*, 415 F.3d at 1317. "[A]n applicant can make a binding disavowal of claim scope in the course of prosecuting the patent, through arguments made to distinguish prior art references. Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter." *Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008).

The court can also consider extrinsic evidence, including expert testimony, dictionaries, and treatises. *Phillips*, 415 F.3d at 1317. These sources are less useful, however, and should be used with caution, keeping in mind their flaws, and considering them in the context of the intrinsic evidence. *Id.* at 1318–19. In particular, the court can consult dictionaries, particularly technical dictionaries, to construe claim terms, but the dictionary definition cannot contradict any definition given or suggested by the patent itself. *Id.* at 1322–23. Additionally, courts may not begin with the dictionary definition of a term in the claims before examining the claims and specification themselves. *Id.* at 1321–22.

The parties dispute the meaning of terms in three patents: U.S. Patent No. 5,569,216 (216 patent), U.S. Patent No. 7,147,627 (627 patent), and U.S. Patent No.

7,722,583 (583 patent). The 583 patent is a continuation of the 627 patent, and they share the same specification. There are six disputed terms in the 216 patent and five in the 627 and 583 patents. The full text of all of the claims containing disputed terms is set out in the appendix to this decision.

A. 216 patent

The 216 patent claims a multipurpose colostomy device that can be inserted into the rectum or into surgically-created stomas (holes) in a patient's abdomen, although one of the disputed terms involves where the device can be used. There are two balloons on the patient proximal end of the device, that is, the end that goes inside the patient. The outer of the two balloons is inflated to keep the device in place. The inner balloon can be inflated or deflated to block off or open up a connecting tube. The connecting tube connects to a joint tube, which then connects to a drainage hose so that waste can flow out of the body.

The patent specification describes two embodiments of the invention. The first has an annular, ring-shaped, supporting plate that braces against the outside of the body to hold the device in place. It appears that this device is most suited for use in surgically-created stomas. The second embodiment is intended for use in the rectum and lacks a supporting plate.

1. "An enema fluid passage passed through said internal balloon"

Claims 1 and 7 of the patent state that the device contains a supply tube that "includ[es] an enema fluid passage passed through said internal balloon for communicating with the colon through an enema one-way valve." JA8 at 5:66–6:2, 6:59–61. The parties dispute the meaning of the term "passed through." ConvaTec

contends that this must mean that the fluid passage, a tube, "passes inside the internal balloon." Def. Br. at 7. Hollister contends that "passed through" means only that the fluid passage must "traverse the length of the internal balloon." *Id.*

The description and figures in the specification are unclear regarding whether the enema tube passes inside the internal balloon. The written description states that a supply tube "is passed through the internal balloon." JA7 at 3:12–13. The enema fluid passage is described only as "disposed in parallel with the supply tube." *Id.* at 3:17–18. The claim and the figures in the specification make clear that for at least part of its length, the enema tube is within the supply tube. JA4–5; JA8 at 5:66–67, 6:58–59. The supply tube also includes an air passage connecting to the inner balloon for inflation. JA8 at 5:63–66, 6:55–58.

Figures 1(A) and 1(B) of the patent show the enema valve, which is located on top of the enema fluid passage, coming out of the interior balloon; the position of the valve changes as the balloon is inflated or deflated. JA2; JA8 at 6:2–4, 6:61–63. Figure 2, a top-down view of the device, might show the enema tube lying on top of the internal balloon. JA2. Figure 3 shows the deflated internal balloon located on both sides of the enema tube and the supply tube in which part of the enema tube is contained. JA3. Hollister contends that Figure 3 shows that the enema tube does not pass inside the balloon and that the deflated balloon is just wrapped around the tube. The figure, however, could equally show the enema fluid passage going inside the balloon.

The patent specification also contains five cross-section figures, labeled figures 6(A) through 6(E). The first three cross-section figures show both the inner balloon and the enema tube. Figure 6(A) seems to show the enema tube passing out of the balloon,

but the other two show it in a position where it might be resting on the balloon. JA4–5. Hollister contends that figure 6(A) shows the inflated balloon bulging around the enema fluid passage, but there is nothing in the figure, such as a line drawn on the balloon, to indicate that the balloon is bulging around the tube, as opposed to the tube passing out of the balloon. The cross-section figures also show the supply tube, which contains the enema tube, and the air passage to the inner balloon. JA4. The figures could show the supply tube either lying on top of the inner balloon or located within it. *Id.* The air passage clearly opens into the inner balloon in figure 6(C). *Id.*

Hollister contends that the figures representing the second embodiment of the patent, figures 7(A)–(C), clearly show the enema tube on top of the balloon. JA5. Although they appear to do so, ConvaTec argues persuasively that the second embodiment described in the patent specification is excluded by the language of the claims. *See TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) (if claim language unambiguously does not include embodiment, court must follow claim language and exclude embodiment from patent protection).

Both of the independent claims in the 216 patent, claims 1 and 7, expressly require a connecting tube, a joint tube, an enema one-way valve, and a holder at the distal end of the supply tube. JA8 at 5:49–51, 5:60–61, 6:46–48, 6:52–53. The description in the specification of the second embodiment does not mention any joint tube, enema valve, or supply tube holder. *Id.* at 5:5–22. In addition, the claims require the joint tube to be disposed under the connecting tube, further away from the patient's body. *Id.* at 5:51, 5:48. The second embodiment, by contrast, states that the connecting tube connects directly to the drainage hose. *Id.* at 5:19–21; *see* JA5.

Hollister contends that the second embodiment has a joint tube, just one that is not described. The connecting tube attaches directly to the drainage hose in the second embodiment, however, so there is no place for a joint tube to go. Additionally, the description of the first embodiment in the specification does discuss the location of the joint tube, the enema valve, and the holder, making it less likely that the description of the second embodiment simply failed to mention a joint tube, enema valve, and holder even though they are present. JA7 at 3:1–30. Finally, in its brief, Hollister stated that the second embodiment had no joint tube, although it took a different position at the hearing once the potential exclusion of the second embodiment was raised. *See* Pl. Resp. at 15 (describing embodiment shown in figures 2, 3, and 5 as "the only described embodiments with a joint tube"). Although construing claims in a way that excludes embodiments contained in the specification is usually disfavored, the Court concludes that the express language of the claims excludes the second embodiment in the 216 patent. *See MBO Labs.*, 474 F.3d at 1333.

There is nothing in the written specification to suggest that the patentee used a specialized or idiosyncratic meaning of the word through, and the figures in the specification are ambiguous or contradictory. As such, it is appropriate to consult dictionary definitions. *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1328 (Fed. Cir. 2006) (using ordinary and customary meaning of annular when nothing in specification indicated differently); *Phillips*, 415 F.3d at 1314. ConvaTec states that a definition from Merriam-Webster defines the word through to mean "movement into at one side or point and out at another and especially the opposite side." Def. Ex. 1. Hollister argues that other definitions from Merriam-Webster

support its construction. It offers two definitions: "from one end or side to the other" and "extending from one surface to the other." *Id.* Neither of these definitions, however, supports Hollister's position that the word through can mean going around or over the top of an object. The Court concludes that the customary and ordinary meaning of through is going inside and then out of an object.

The Court construes the disputed claim language as advocated by ConvaTec: "The enema fluid passage passes inside the internal balloon." Def. Br. at 7.

2. "An enema one-way valve"

The term "an enema one-way valve" is contained in claims 1 and 7 of the patent. JA8. Hollister has agreed to ConvaTec's proposed construction: "A device that enables forward fluid flow but prevents backward fluid flow." Def. Br. at 10. The Court adopts the proposed construction.

3. "An enema fluid one-way valve located over said internal balloon and in the colon"

Claims 1 and 7 of the patent describe "an enema fluid one-way valve located over said internal balloon and in the colon." JA8. The parties disagree about whether the enema valve must extend past, and further into the patient's body than, all of the inner balloon. ConvaTec asserts the valve "extends axially beyond the internal balloon in both its deflated and inflated state, and into the colon." Def. Br. at 10. Hollister contends that the valve need only be "located at the patient proximal end of the internal balloon." *Id.*

Hollister concedes that the valve must be located over at least some part of the internal balloon, to convey enema fluid into the colon. When inflated, the balloon blocks

any liquid from traveling through the device. JA7 at 4:11–14. Thus the enema valve must be on the proximal side of the balloon to be of any use in conveying enema fluid into the patient. Hollister contends that there is no requirement, however, that the valve extend beyond the most proximal end of the fully inflated balloon. It could reach past some of the inner balloon, while not extending as far as all parts of the internal balloon.

As the claim language states, the valve must be located in the colon when the device is in use. JA8 at 6:4–5, 63. ConvaTec admitted during the hearing that the valve could be located in the patient's colon without extending past all of the balloon. Although excluded by the language of the claim, and apparently lacking an enema valve, the embodiment shown in figures 7(A) and 7(B) depicts the enema tube, on the top of which the enema valve should be located, extending past some but not all of the inflated inner balloon. JA5.

ConvaTec contends that the valve must extend beyond all of the inflated inner balloon based on language and figures in the specification. The specification states that the valve is on top of the enema tube, which "is higher than the internal balloon." JA7 at 3:16–20. The specification does not state, however, that the tube is higher than *all* of the internal balloon, so this language does not add much to the claim's requirement that the valve is over the inner balloon. Figures 1(A) and 1(B) appear to show the enema valve protruding beyond the inner balloon both when the balloon is inflated and when it is deflated. JA2. Figures 2, 3, and 5 also show the enema tube and valve extending beyond every part of the inner balloon. JA2–4. As ConvaTec recognizes, however, the mere fact that the only embodiment in the patent has an enema valve extending past all of the balloon does not mean that the claim language is limited to enema valves that

extend past all of the balloon. *See Phillips*, 415 F.3d at 1323 (claims are not be confined to embodiments contained in specifications). In light of the fact that the function of the enema valve does not require it to extend beyond all of the balloon, the fact that diagrams in the specification show the valve extending beyond the balloon (without explanation of this in the written specification) does not aid in interpreting the word over.

The Court concludes that Hollister's proposed construction is the proper construction of the disputed language and construes the language to mean "[t]he enema fluid one-way valve is located at the patient proximal end of the internal balloon." Def. Br. at 10. The customary and ordinary meaning of the phrase "over said internal balloon and in the colon" does not require the enema valve to extend past all of the internal balloon whether it is inflated or deflated. For the valve to be in the colon, it need only reach beyond some part of the inflated balloon. Unlike the word through from the first disputed term, ConvaTec does not suggest that the plain meaning of the word over requires that the valve extend past all of the inner balloon.

4. "An annular supporting plate upwardly disposed"

The term "an annular supporting plate upwardly disposed" appears in claim 1. JA8. The parties dispute whether the requirement that the plate is upwardly disposed refers to the location where it attaches to the device or to the plate's orientation. ConvaTec contends that the annular plate must be "angled toward the patient proximal end of the multipurpose colostomy device." Def. Br. at 11. Hollister argues that the term requires no construction and means only that the supporting plate is located "near the patient-proximal end of the colostomy device rather than the patient-distal end." Pl.

Resp. at 10.

The claim states that the device includes an "annular supporting plate upwardly disposed between said connecting tube and said joint tube." JA8 at 5:53–54. If the term upwardly disposed refers only to the location of the supporting plate, the claim includes redundant terms, because the plate's location is defined both by the phrase upwardly disposed and by locating it between the connecting and joint tubes. "[C]laims are interpreted with an eye toward giving effect to all terms in the claim." *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). Hollister acknowledges this redundancy but contends that the phrase upwardly disposed gives additional information. The claim language also states that the purpose of the plate is to "fix[ ] the multipurpose colostomy device to the abdominal wall." JA8 at 5:54–56. ConvaTec contends that if the supporting plate is for fixing or bracing the device against the abdomen, then logically, the plate should be oriented toward the body.

Hollister contends that the claims frequently uses the word disposed as a synonym for located, such as when the connecting tube is said to be "disposed under said internal and external balloons." JA8 at 5:49–50. Because "claim terms are normally used consistently throughout the patent," this might make it inappropriate to interpret disposed in the phrase at issue as referring to orientation. *See Phillips*, 415 F.3d at 1314. At times, however, the claims seem to use the word disposed to refer to orientation. Specifically, claims 1 and 7 refer to "a supply tube vertically disposed in said connecting tube and between said internal and said external balloons." JA8 at 5:57–58, 6:49–50.

The specification does not describe the orientation of the supporting plate,

although it does describe it as "disposed under the connecting tube," another usage of the word disposed to refer to location. JA7 at 3:1–2. The figures in the specification, however, show the supporting plate angled toward the patient's body. Specifically, figures 2, 3, and 5 show the plate angled toward the abdominal wall to accommodate a stoma that protrudes beyond the abdomen. JA2–3. As shown in the figures, any supporting plate would have to be angled upward to reach the abdominal wall around the protruding stoma. *See TIP Sys.*, 529 F.3d at 1373 (using depictions in patent diagrams to interpret claim language).

The parties dispute whether, according to the first embodiment shown in the specification, the supporting plate is really located in the patient proximal area of the device. Hollister suggests that the plate is proximally located compared to the drainage hose. As ConvaTec notes, however, the claim does not include a drainage hose. The specification discusses a drainage hose, but it also states that the hose can be detached and replaced with a plug. JA7 at 4:16–17, 4:57–64. ConvaTec contends that If there is no drainage hose, the supporting plate is closer to the distal end of the device than the proximal end. Figures 2 and 3 position the supporting plate in the middle of the device as shown, but Hollister contends that much more of device is not shown in these figures. JA2–3.

The Court adopts the construction proposed by ConvaTec: "An annular plate angled toward the patient proximal end of the multipurpose colostomy device." Def. Br. at 11. ConvaTec's construction avoids any redundancy in the claim language, because the position of the supporting plate is fixed by reference to the plate being located between the connecting and joint tubes and the phrase upwardly disposed refers to its

orientation. The same structure and usage of the term is employed later in claim 1 and in claim 7 to describe the orientation and position of the supply tube. The term "upwardly disposed" also seems most naturally to refer to orientation, not position. The embodiment shown in the specification figures confirms this interpretation by displaying a supporting plate that is oriented towards the patient's abdomen, as indeed it must be to accommodate the stoma.

Hollister argues that ConvaTec's interpretation improperly reads restrictions in the specification into the claim, because "even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words of expressions of manifest exclusion or restriction." *Arlington Indus. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254 (Fed. Cir. 2011). The Court adopts ConvaTec's construction, however, because it best represents the ordinary meaning of the claim language to a person with average skill in the field. The fact that the specification supports the proposed construction is an aid to interpreting the claim, which confirms the interpretation otherwise suggested by the claim language.

5. "For fixing the multipurpose colostomy device to the abdominal wall of the stoma"

The phrase "an annular supporting plate upwardly disposed between said connecting tube and said joint tube, *for fixing the multipurpose colostomy device to the abdominal wall of the stoma*" appears in claim 1. JA8 (emphasis added). The parties dispute what constitutes a stoma. ConvaTec argues that a stoma is only "a surgically constructed opening connected to the colon or ileum," the last part of the small intestine.

Def. Br. at 12. Hollister argues that a stoma is any opening the body, natural or artificial, including the rectum.

Claim 1 covers "[a] multipurpose colostomy device for fixing in the stoma or the rectum of the human body." JA8 at 5:44–45. ConvaTec contends that this phrase supports its interpretation of the word stoma, because Hollister's definition would improperly make the claim's use of the word rectum redundant. *Bicon, Inc.*, 441 F.3d at 950; *see Schumer v. Lab. Computer Sys.*, 308 F.3d 1304, 1311 (Fed. Cir. 2002) ("We have consistently interpreted the word 'or' to mean that items in the sequence are alternatives to each other."). Additionally, the disputed language states that the supporting plate is "for fixing the multipurpose colostomy device to the abdominal wall of the stoma." JA8 at 54–56. ConvaTec contends that only surgical stomata will be surrounded by abdominal walls to which to attach the device; rectums and other natural orifices do not.

Hollister argues that the disputed claim language, which is found in the preamble to the claim, uses stoma as a general term and lists rectum as an important example. It also notes that claim 6, which is dependent on claim 1, refers specifically to using the device in the rectum. JA8 at 6:40. Hollister relies on this to argue that claim 1 must encompass devices used in the rectum. Of course, because the language in claim 1 specifically refers to a device used in the rectum, there is no doubt that claim 1 covers such a device. The question here is whether the word stoma encompasses the rectum.

The language of claim 7 may also help in interpreting the meaning of the word stoma. That claim describes a device "for fixing in the rectum of a human body." *Id.* at 6:41–42. The claim later says, however, that the balloons of the device "can effectively

close the stoma." *Id.* at 6:66–67. If stoma is understood to refer to rectum in claim 7, defining the term in claim 1 to include the rectum would mean that the term is defined consistently.

The specification's uses of the word stoma point in different directions from a definitional standpoint. The written specification refers to fixing the device "in the stoma of patients with colostomy or ileostomy . . . and the rectum of the patient who cannot control his bowel movements." JA6 at 1:34–39. This suggests that stoma, as used in the patent, refers only to the abdominal opening in patients with a colostomy or an ileostomy, not the rectum. On the other hand, the specification states that the device has "an external balloon fitted around the stoma for preventing liquid from leaking through the anal canal." JA6 at 1:65–67; *accord id.* at 1:14–17. A surgically created stoma would not be anywhere near the anal canal, so the reference to liquid leaking from the stoma to the anal canal suggests that this particular use of the word stoma must refer to the rectum.

ConvaTec contends that evidence from the prosecution of the patent shows that the patentee understood that the rectum is not included in the definition of stoma. Initially, claim 1 of the application only described a "device for fixing in the stoma of a human body." JA36. Later, the claim was amended to read "device for fixing in the stoma or the rectum of a human body." JA73. This suggests that the patentee thought the word rectum in claim 1 was of independent significance, and not a mere illustration of one type of stoma that the patent already claimed.

Hollister contends that a separate aspect of the patent prosecution shows that the word stoma as used in the patent includes the rectum. Initially, in the description of

the second embodiment, the specification used the phrase "[w]hen the stool is to discharge from the stoma." JA35. At the request of the patent applicant, the specification was amended to state "[w]hen the stool is to discharge from the rectum." *Id.*; JA73. The parts of the specification dealing with the second embodiment, however, are of lesser weight: as noted earlier, the express language of the claim excludes that embodiment because it lacks a joint tube, a one-way enema valve, and a supply tube holder. Furthermore, the fact that the patentee thought it necessary to replace the word stoma with rectum does not suggest that the two have the same meaning. In fact, it suggests that their meanings are different.

Both parties cite to dictionaries to support their respective proposed constructions. ConvaTec cites to two medical dictionaries, Black's and Stedman's, which define a stoma as an artificial or constructed opening. Def. Exs. 2, 3. Hollister cites to two other medical dictionaries, Medical Meanings and the Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, that define a stoma as simply a mouth-like opening. Pl. Exs. A (referring to stomata as "mouth-like openings" and discussing "surgical stomas [sic]" separately), B. The conflicting dictionary definitions illustrate a weakness of using this sort of extrinsic evidence to construe claim terms. Specifically, the parties are likely to cite the evidence that supports their position from the "virtually unbounded universe of potential extrinsic evidence of some marginal relevance." *Phillips*, 415 F.3d at 1318. Perhaps more important than any dictionary definition, however, is the fact that Hollister's own website also defines a stoma as a surgically created opening. Def. Ex. 9.

The Court adopts the construction offered by ConvaTec: "The annular

supporting plate attaches the multipurpose colostomy device to the abdomen wall surrounding a surgically constructed opening connected to the colon or ileum." Def. Br. at 12. The language of claim 1 indicates that the supporting plate fixes the device to the abdominal wall around the stoma, and there is no abdominal wall around the rectum. Further, the use of the phrase "the stoma or the rectum" in the claim suggests that the term stoma does not include the rectum. This is particularly so when the patent's prosecution history shows that the word rectum was added to the claim later in the process, in a way that suggests that the applicant thought that the word stoma did not cover use of the device in the rectum. The specification is ambiguous on this point, and on the whole it does not provide useful guidance for interpreting the meaning of the word stoma in claim 1.

Hollister contends that claim 7 may be rendered meaningless by this construction, because claim 7 describes a device that is used in the rectum but refers to the device closing the stoma. As an initial matter, the Court notes that the parties have not asked the Court to interpret the meaning of the word stoma in claim 7. The construction of the word stoma as used in claim 1 does not necessarily render claim 7 meaningless, because claim terms are only "*normally* used consistently throughout the patent." *Phillips*, 415 F.3d at 1314 (emphasis added). In other words, the word stoma may mean something different as it is used in claim 7. More importantly, even if the Court's construction might be said to render claim 7 nonsensical, that is permissible if the plain meaning of the language requires it. *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 782–83 (Fed. Cir. 2010). Here, the plain meaning of the term stoma in claim 1 does not include the rectum, for the reasons the Court has discussed.

A court cannot "redraft claims to contradict their plain language in order to avoid a nonsensical result." *Id.* at 782.

6. "A joint tube disposed under said connecting tube"

The language "a joint tube disposed under said connecting tube" appears in claims 1 and 7. JA8. The parties disagree about whether the language requires the joint tube to be a separate piece from the connecting tube, or whether they can be two portions of the same tube. ConvaTec contends that "[t]he joint tube is separate from the connecting tube and the annular support plate." Def. Br. at 14. Hollister contends that the joint tube may be a "tube portion disposed under the connecting tube," and that effectively the joint tube and connecting tube may be distinguishable parts of the same tube. *Id.*

The language of claims 1 and 7 states that the joint tube is "disposed under said connecting tube." JA8 at 5:52, 6:48. Claim 1 also states that the supporting plate is located between the connecting tube and the joint, suggesting that the two tubes are separate pieces. JA8 at 5:53–54. ConvaTec asserts that "[w]here a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components of the patented invention." *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010). In *Becton*, the court required a spring to be a "separate structural component of the patented invention" when it was listed separately from the other parts of the invention but sequentially to them. *Id.* at 1254–55. But although the court required the spring to be "a distinct structural element," it did not require the spring to be wholly separate from the hinged arm to which it was connected. *Id.* at 1253–54. Similarly, in this case the joint tube

might be a separate structural component from the connecting tube without being an entirely separate tube.

The specification does not describe the connecting tube and joint tube as totally separate. The written specification states that the connecting tube is elastic and the joint tube is resilient, suggesting that they are made of different materials. JA7 at 5:5–8. Hollister contends, however, that this connotes different thicknesses, not different materials. It states that the connecting tube is thinner, making it more elastic than the joint tube, which is more resilient because it is thicker. Of course, even if the specification indicated that the connecting tube and joint tube are made of different materials, that limitation would not necessarily be applied to the claims. The claims themselves do not discuss the elasticity, resiliency, or material of the connecting and joint tubes.

The figures illustrating the first embodiment of the patent do not show the two tubes as separate. *See In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1325 (Fed. Cir. 2011) (interpreting two numbers discussed in patent as distinct when separate fields for each were shown in patent figure). Figures 2, 3, and 5 do not show any physical distinction or separation between the connecting tube and the joint tube on the left side each figure, the side that is labeled to indicate the joint and connecting tubes. JA2–4. On the right side of the figures, however, there is a line, indistinct in figures 2 and 5 but clear in figure 3, that may indicate some separation between the tubes. *Id.* It is difficult to tell what the line is intended to convey, because the side of the figures on which it appears is not labeled to show the joint and connecting tubes. By contrast, the supporting plate, which is located in the same area

as the two tubes, is clearly separate from the two tubes and also drawn with diagonal lines to make it more distinct from the two tubes. *Id.*

The Court adopts the construction proposed by Hollister: "A tube portion disposed under the connecting tube and used to connect to a drainage hose or a collecting container." Def. Br. at 14. The claim language requires the joint and connecting tubes to be distinct, and the lack of a joint tube is part of why the second embodiment described in the specification is excluded by the claim language. Nevertheless, nothing in the claims requires them to be physically separate, as opposed to distinct portions of the same continuous tube. The specification likewise does not require the tubes to be physically separate, and indeed the figures illustrating the first embodiment show the two tubes as continuous. Furthermore, it is obvious that the connecting tube and joint tube are attached to each other when the device described in the claims is assembled, so it is difficult to understand the requirement of ConvaTec's proposed construction that they must be separate tubes.

Accepting ConvaTec's construction might also result in excluding the first embodiment which, as discussed above, is generally disfavored. Although the Court determined that the language of the claims excludes the second embodiment of the specification, in that case the language was entirely clear. The claims require a joint tube, an enema one-way valve, and a supply tube holder, none of which were included in the second embodiment. Here, by contrast, the claims only state that the joint tube is located under the connected tube. The language does not clearly require the tubes to be separate, as opposed to distinct portions of a tube, and so the Court will not conclude that the tubes must be separate at the expense of excluding the first

embodiment in the specification.

ConvaTec argues that, by accepting Hollister's construction and calling the joint tube a tube portion, the Court is improperly adding the word portion to the claim. ConvaTec notes that the word portion is never used in reference to the joint tube and that portion is otherwise used in claims 1 and 7 when appropriate. JA8 at 5:61, 6:53. Portion is also used in the specification. *E.g.*, JA7 at 3:23, 3:32. ConvaTec is incorrect, however, when it contends that a construction of a claim cannot employ words not used in the claim. A court cannot rewrite claims, but "in clarifying the meaning of claim terms, courts are free to use words that do not appear in the claim so long as the resulting claim interpretation accords with the words chosen by the patentee to stake out the boundary of the claimed property." *Pause Tech. LLC v. TiVo Inc.*, 419 F.3d 1326, 1333 (Fed. Cir. 2005) (ellipses and internal quotation marks omitted). The use of the word portion in the Court's construction in meant to indicate only that nothing in the claim language requires the joint tube to be a separate tube from the connecting tube.

B. 627 and 583 patents

The 627 and 583 patents describe a bowel management system and methods for use of that system. The bowel management system includes a catheter with at least two parts. The first part is placed in the patient's rectum and is relatively hard, so that it always remains open. The second part is located in the patient's anus and is less hard so that it does not cause discomfort. The system also has a balloon attached to the first part of the catheter, which is inflated to hold the device in place in the rectum. The device can also have an intraluminal balloon that when inflated would block the catheter, or a third section of catheter located distally from the patient. Some of the

claims include one or more lumened members, or tubes, for inflating the balloons or delivering medication into the patient's rectum. The device can also have a flush/sampling port, although the parties dispute the uses of the port.

1. "The proximal-most end of the retention balloon is coincident to the proximal-most first end of the patient proximal first section of the waste catheter"

"The balloon having a proximal-most end coincident to a proximal-most first end of the first catheter section"

The parties agree that the terms "the proximal-most end of the retention balloon is coincident to the proximal-most first end of the patient proximal first section of the waste catheter" and "the balloon having a proximal-most end coincident to a proximal-most first end of the first catheter section" should be interpreted in the same way. The first of the disputed terms is contained in the 627 patent in claims 1, 21, 22, 25, and 33. JA165–67. The second version appears in the 583 patent in claims 1 and 13. JA441.

The parties disagree about the meaning of the word coincident. ConvaTec contends that coincident means that the first section of the catheter and the retention balloon must extend to exactly the same point in the patient's rectum and that "neither of the proximal-most ends extend axially beyond the other." Def. Br. at 17. Hollister argues that the front ends of the balloon and catheter need only "occupy[ ] the same area in space." *Id.*

Neither party contends that the language of the claims can offer assistance in interpreting the term coincident. The specification of each patent requires only that the ends of the retention balloon and catheter be "substantially flush (or at least closely adjacent to) with one another." JA162 at 5:61–65; JA438 at 5:54–58. In both patents,

figure 7 shows the catheter extending beyond the exterior retention balloon, so that the only embodiment in each patent would be excluded by ConvaTec's proposed construction. JA154, 430. "Such an interpretation is rarely, if ever, correct and would require highly persuasive evidentiary support." *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

ConvaTec argues, however, that during prosecution of the 583 patent, Hollister made an express disavowal that its claims covered anything but balloons and catheters that ended at exactly the same point. ConvaTec implies that the prosecution history of the 583 patent governs the interpretation of claim language in the 627 patent as well. Although the 583 patent is a continuation of the 627 patent and was issued after the 627 patent, Hollister does not contend that the prosecution history of the 583 patent cannot be used as a guide to interpreting the claims of the 627 patent (even though it notes that such use amounts to retroactive application of the 583 patent's prosecution history).

In the initial application for the 583 patent, claims 51 and 81 (which ConvaTec asserts and Hollister concedes correspond to claims 1 and 13 in the issued patent), did not include any language describing the point to which the proximal ends of the balloon and catheter extended. JA585–86, 592. The Patent and Trademark Office (PTO) rejected claims 51 and 81. It concluded that claim 51 was anticipated by U.S. Patent No. 4,676,778 (the Nelson patent) and that claim 81 was obvious based on the Nelson patent. JA673, 675–77.

In response, Hollister amended the rejected claims to add language stating that balloon would have "a proximal-most end coincident to a proximal-most first end of the first catheter section." JA697, 699–700. Hollister also argued to the PTO that its

balloon and catheter were coincident at their proximal ends but that "[i]n [the Nelson patent], the region of the tube indicated as the downstream end extends axially beyond the balloon, so it is respectfully submitted that the proximal, or downstream end of the catheter of [the Nelson patent] is not coincident to a proximal-most end of the balloon." JA707 (figure numbers omitted). In effect, according to ConvaTec, Hollister distinguished Nelson by noting that the catheter in Nelson extended beyond the forward end of the balloon and therefore was not coincident. For this reason, ConvaTec argues, the word coincident must mean that neither the catheter or the retention balloon extends beyond the other, even if this would exclude the embodiments described in the specifications of the 627 and 583 patents.

Hollister notes that the Nelson patent described a catheter that extended far beyond the balloon, providing enough space for two aspirating openings located after the balloon and before the end of the catheter. *See* Def. Ex. 4, figure 1; *id.* at 4:17–47. Hollister claims that by contrast, its patents described a balloon and catheter that end closely adjacent to each other, even if they do not extend to exactly the same point in the patient's rectum.

There is some additional evidence that the patent examiner understood the word coincident to exclude instances where the catheter and balloon were only closely adjacent or substantially flush. *See ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1079 (Fed. Cir. 2003) (what patent examiner and applicant understood at the time is relevant to interpretation, although statement of reasons for allowance does not necessarily limit a claim). In his reasons for allowance, the examiner stated that none of the references submitted by Hollister had balloons that were coincident to the

catheter. JA803. Yet among the cited references in Hollister's supplemental disclosures were three patents, U.S. Patent No. 3,802,418, WO Pub. No. 03/086507, and FR. Pat. No. 2,326,208, that have balloons and catheters that are closely adjacent even though they do not extend to the same proximal-most point. JA773, 777; Def. Ex. 11. The figures in the three patents are thus similar to the embodiments in the 627 and 583 patents that show the retention balloon and catheter ending close to each other, but not at exactly the same point. Although there is no scale provided in any of the figures, the figures in the three patents included among the supplemental disclosures appear to have the balloon and the catheter ending much closer to one another than they do in the Nelson patent. Def. Exs. 4, 11.

As Hollister notes, however, the supplemental disclosures submitted with the application that eventually resulted in issuance of the 583 patent cite more than sixty U.S. patents and thirty-five foreign patents. Accordingly, a general statement by the patent examiner, to which Hollister was not obliged to respond, may not say much about the examiner's understanding of small details in the three referenced patents in question. *ACCO Brands*, 346 F.3d at 1079. In addition, the examiner noted a second reason for allowance, specifically that the second section of the catheter was collapsible, and he used that aspect of Hollister's application to distinguish a foreign patent. JA803. The collapsible catheter section thus may have been a more important consideration for both the examiner and Hollister at the time.

Despite the language in the specifications of Hollister's patents, the Court adopts ConvaTec's proposed construction:

The proximal-most end of the retention balloon closest to the patient and

> the proximal-most end of the first catheter section closest to the patient occupy the same plane in space that is perpendicular to the longitudinal axis of the waste collection catheter, and neither of the proximal-most ends extend[s] axially beyond the other.

Def. Br. at 17. As discussed above, "an applicant can make a binding disavowal of claim scope in the course of prosecuting the patent, through arguments made to distinguish prior art references. Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter." *Cordis Corp.*, 511 F.3d at 1177.

Hollister sought to save its claims after they had been rejected on the ground that they were anticipated by and obvious based on the Nelson patent. In doing so, Hollister added the word coincident to its claims and distinguished the Nelson patent as lacking coincident ends of its balloon and catheter, because the catheter in the Nelson patent extended beyond the balloon. Hollister did not argue that the Nelson patent's balloon and catheter were not coincident because the tube extended *far* beyond the balloon or because there was enough space for two aspirating openings between them. Rather, it argued that the Nelson patent was distinguishable simply because the tube extended beyond the balloon. Although the patent examiner's reasons for allowance are not accorded much weight for the reasons discussed above, they provide additional support to ConvaTec's construction.

ConvaTec's construction is correct, even though it will result in the exclusion of the only embodiment in both of the patents. *See Elekta Instrument S.A. v. O.U.R. Sci. Int'l*, 214 F.3d 1302, 1308 (Fed. Cir. 2000) (even though it is rarely appropriate to interpret a claim to exclude the only embodiment, court adopted claim construction

doing so when prosecution history was unambiguous).

2. "Having an inflated size so as to be sufficiently large enough to retain the patient proximal end of the catheter into the patient's rectum"

"Securing the waste collection catheter in the position to which it has been inserted so that the catheter does not become separated from the patient during an extended period of time"

"For selective inflation and deflation of the retention balloon as necessary for . . . retention"

"Having an inflated size sufficiently large so as to prevent migration of the first catheter section out of the patient's rectum through the patient's anal canal"

The parties agree that these four terms should be construed together. The term "having an inflated size so as to be sufficiently large enough to retain the patient proximal end of the catheter into the patient's rectum" appears in the 627 patent in claims 1, 21, 22, 25, and 33. JA165–68. The term "securing the waste collection catheter in the position to which it has been inserted so that the catheter does not become separated from the patient during an extended period of time" appears in the 627 patent in claims 21 and 22. JA166. The term "for selective inflation and deflation of the retention balloon as necessary for . . . retention" appears in the 627 patent in claim 33. JA168. The term "having an inflated size sufficiently large so as to prevent migration of the first catheter section out of the patient's rectum through the patient's anal canal" appears in the 583 patent in claim 1. JA441.

ConvaTec contends that these claim terms require the balloon to be inflated to at least 44 cc. Hollister contends that the terms are clear and need no construction. Hollister also argues that no size restriction need be read into the claims and that if one

is, the inflated size of the balloon should include the volume of the rectal tube located in the balloon.

The plain language of the claims does not suggest that they have a numerical limitation or that the limitation is 44 cc. None of the six claims containing the disputed terms includes any numerical limitation on the size of the retention balloon or the amount of liquid with which it is to be filled. Furthermore, there are dependent claims that include specific limitations regarding the volume of the retention balloon. In the 627 patent, claim 4, dependent on claim 1, and claim 35, dependent on claim 33, specifically mention that the balloon should be inflated to a volume of 44 to 59 cc. JA165 at 12:9–10; JA168 at 17:25–26. "[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1315.

ConvaTec argues that the principle of claim differentiation does not apply to claims 4 and 35 because both claims also specify "an inflated length-to-diameter ratio" for the retention balloon. JA165 at 12:8; JA168 at 17:25. It cites *Vizio, Inc. v. Int'l Trade Comm'n*, 605 F.3d 1330 (Fed. Cir. 2010), for the proposition that if a dependent claim includes a different limitation, the principle of claim differentiation does not apply. *Id.* at 1337–38. *Vizio*, however, dealt with whether a function called "channel map information must replicate . . . four data fields," one of which was PCR_PID. *Id.* at 1336. The court concluded that channel map information did have to replicate the four data fields. The appellants argued that claim differentiation dictated a different result, because a claim that was dependent on the one related to channel map information referred to associating a program with a PCR value. *Id.* at 1337. The court concluded that PCR

and PCR_PID were different things, and the fact that the principle of claim differentiation suggested that the independent claim did not involve PCR did not mean that it did not involve PCR_PID. *Id.* at 1337–38.

Vizio does not stand for a general principle that claim differentiation does not apply when the dependent claim has additional limitations. Such a principle would make no sense, because claim differentiation *requires* that the "dependent claim . . . add[ ] a particular limitation." *Phillips*, 415 F.3d at 1315. Logically, if claims 4 and 35 add limitations concerning both inflated length-to-diameter ratios and volumes to the retention balloons, then neither of those limitations is contained in the independent claims. ConvaTec's argument would suggest that both of the additional limitations could be part of the independent claims.

The specifications of the patents do suggest that generally the balloon must be at least 44 cc in volume. They state that the ideal size for the balloon is 44 to 69 cc in a normal adult patient, JA163 at 7:7; JA438 at 6:64, and they describe the 44 cc volume as the minimum volume. JA163 at 7:11; JA438–439. In addition, the specifications make it clear that the size of the inflated balloon is critical to prevent leaks and keep the system inside the patient's rectum. JA163 at 7:4–6; JA438 at 6:61–63. The specifications, however, also make it clear that the normal sizes for the retention balloon "are for an average adult patient and can be adjusted proportionally for other non-average patients." JA163 at 7:18–20; JA439 at 7:8–10.

The Court accepts Hollister's argument that the disputed claim language does not require any additional construction and also declines to add precise numerical limitations to the claims at issue. The claims in which the disputed language is located

lack numerical limitations, whereas claims that depend from some of the claims containing the disputed language include exact volume limitations. Although the specifications suggest that 44 cc is often, but not always, the minimum volume for the retention balloon, it is improper to read that limitation into the claims. *Phillips*, 415 F.3d at 1323.

ConvaTec contends that in other cases, the Federal Circuit has read numerical limitations from the specification into the claims. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239–41 (Fed. Cir. 2003) (claim language "consisting essentially of aluminum" permitted no more than 0.5% silicon, in light of specification language that material should be no more than 0.5% silicon); *Amazin' Raisins Int'l, Inc. v. Ocean Spray Cranberries, Inc.*, 306 F. App'x 553, 556–57 (Fed. Cir. 2008) (unpublished) (constructing term dried fruit to mean fruit with 10 to 18% moisture remaining, in light of specification language that only fruit with those moisture levels could be used in the process). Both of these cases are distinguishable from the current case. *AK Steel* used a term in its claims, "consisting essentially of aluminum," that required some numerical definition to determine how pure the aluminum had to be in order for the process to work. *AK Steel*, 344 F.3d at 1239. The parties disagreed about what percentage of silicon was allowable in the aluminum, and the specification was a logical place to look for guidance. The case does not justify imposing a numerical limitation here, when the claims in question do not require one. In *Amazin' Raisins*, the court was required to define the claim term "dried fruit" and looked to the specification to help define the term. *Amazin' Raisins*, 306 F. App'x at 556–57. The specification stated that only dried fruit with a particular moisture content would suffice. *Id.* Again, however, there is no term in

the disputed language in the present case that requires definition, and certainly not one that demands a numerical definition.

3. "So that the catheter patient proximal section . . . is soft and pliable enough to permit folding longitudinally for ease of insertion into the rectum of the patient"

The term "so that the catheter patient proximal section . . . is soft and pliable enough to permit folding longitudinally for ease of insertion into the rectum of the patient" appears in the 627 patent in claims 1, 14, 21, 22, 25, and 33. JA165–67. The parties disagree about what the phrase "for ease of insertion" means. ConvaTec contends that ease of insertion requires that "longitudinally folding the catheter patient proximal section facilitates insertion into the patient's rectum without any difficulty." Def. Br. at 21. Hollister asserts that the term does not need any additional definition.

The parties agree that the claim language in unambiguous and that the specification does not discuss what ease of insertion means. ConvaTec nevertheless contends that dictionary definitions support its proposed construction. It cites a definition from the Oxford English Dictionary defining ease as "absence of difficulty or effort." Def. Ex. 5. It also cites Merriam-Webster defining ease as "freedom from labor or difficulty." Def. Ex. 6. These definitions, ConvaTec argues, mean that folding the catheter must permit the device to be inserted without any difficulty. As Hollister notes, however, both dictionaries include other definitions for ease that would not require there to be no difficulty inserting the catheter. Merriam-Webster includes the definitions "freedom from pain or discomfort" and "relief from discomfort or obligation." Def. Ex. 6. The Oxford English Dictionary defines ease as a verb to mean "facilitate." Def. Ex. 5. These conflicting definitions do not support ConvaTec's conventions and demonstrate

again that in many cases such extrinsic evidence is weak, because it is easily marshaled to support either party's contentions. *See Phillips*, 415 F.3d at 1318. These conflicting dictionary definitions do not suggest that the common and ordinary meaning of the word ease to one skilled in the field is freedom from any difficulty, as opposed to reducing difficulty or making insertion easier.

ConvaTec also contends that if ease of insertion simply means to make insertion easier, the claim would be indefinite. "A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003) (citing 35 U.S.C. § 112). Here, the claim language encompasses a catheter section that can be folded to make insertion into the rectum easier. No person of ordinary skill in the field would have difficulty understanding whether this aspect of the claim reads on a given device. ConvaTec argues that the claim must indicate that folding makes insertion easier than something else and cannot merely be construed to mean easier. The claim language makes clear, however, that folding is "for ease of insertion." Therefore, folding must make insertion easier than it would be with the unfolded catheter.

ConvaTec argues finally that if the claim refers to a catheter that is easier to insert when folded than when not folded, the claim is contradicted by the specification. The specification states that the intraluminal balloon facilitates insertion when it is inflated. JA162 at 5–6; JA164 at 9:51–54. Of course, limitations in the specification should not be read into the claims, and of the six claims containing the disputed language, only claim 22 discusses inflating the intraluminal balloon to ease insertion.

JA166 at 14:36–41; *see Phillips*, 415 F.3d at 1323. Claim 22 does not state that the first catheter section cannot be folded at the same time as the intraluminal balloon is inflated. Another one of the claims, claim 21, does not require an intraluminal balloon at all and specifically mentions folding the first section of catheter prior to inserting it into the rectum. *Id.* at 13:63–66. Furthermore, the specification states that the intraluminal balloon is optional, and there is nothing in the specification to suggest that the catheter could not simultaneous be folded longitudinally and have the intraluminal balloon inflated. JA162 at 5–6.

The Court agrees with Hollister that the disputed claim language does not require additional construction. Ease of insertion means only making insertion easier than it might otherwise be. The claim language does not require that insertion into the patient's rectum occur with no difficulty at all.

4. "The first catheter section being sufficiently pliable to permit folding for insertion into a patient's rectum"

The phrase "the first catheter section being sufficiently pliable to permit folding for insertion into a patient's rectum" appears in the 583 patent in claim 1. JA441. The parties disagree about the manner in which the tube can be folded. ConvaTec contends that the claim language refers only to folding the catheter longitudinally, along its axis. Hollister contends that the language needs no additional construction because its meaning is unambiguous and that it is not limited to a single method of folding as ConvaTec argues.

The parties agree that there is nothing in the claim language or specification to help interpret the term folding for insertion. ConvaTec argues that construction of the

claim language to cover only folding longitudinally is consistent with the language of the claim. Presumably, however, a catheter that folded in any direction would be consistent with language that states only that the catheter is foldable.

ConvaTec contends that during the prosecution, Hollister expressly disavowed any other sort of folding. As discussed above, the application claim that became claim 1 of the 583 patent was initially rejected as anticipated by the Nelson patent. JA673. To distinguish the Nelson patent, Hollister noted that its catheter was sufficiently pliable for folding, whereas the Nelson patent did not claim that. JA707–08. Hollister stated, "[The Nelson patent] does not disclose a device having a catheter section sufficiently pliable to permit folding for insertion." *Id.* Hollister argued that the Nelson patent's catheter had to be rigid enough to resist kinking in the small intestine and that, because it was used for aspiration, it had to be used with suction. JA708. Hollister noted that if a foldable catheter was used with suction, it would quickly collapse. Based on this, Hollister argued, the Nelson patent's catheter could not be foldable. *Id.* Hollister also stated that "the nasogastric intestinal catheter of [the Nelson patent] is not folded along its axis in order to give it a smaller profile to facilitate insertion, and has an inherent rigidity that would prevent it from being so folded." *Id.*

ConvaTec argues that this final sentence, noting that the Nelson patent catheter could not fold axially, means that Hollister has expressly disavowed that its own catheter can fold in any other way. Hollister contends that the Nelson catheter was not foldable in *any* direction, because it had to resist kinking, and that not folding longitudinally was just an example of what the Nelson catheter could not do. As ConvaTec notes, however, figures in the Nelson patent show the catheter bent, and

indeed it must bend to some extent to extend from the nose all the way into the small intestine. Def. Ex. 4 at Figure 1.

The Court agrees with Hollister that the disputed claim language requires no construction and that it should not be construed to encompass only longitudinal folding. Although Hollister distinguished the Nelson patent in part by noting that it could not fold longitudinally, it also stated that the Nelson patent did not claim that its device could be folded for insertion at all. JA707–08. In fact, Hollister noted that because the Nelson patent's device used suction, it could not fold because the suction would cause a foldable section to collapse. Although it appears that the Nelson patent's device could at least bend somewhat, there is nothing to show that the device could be folded in any manner for insertion.

As discussed above, disavowal during the prosecution process must be a clear and unmistakable surrender of subject matter. *Cordis*, 511 F.3d at 1177. Hollister discussed one way in which its device was different from that of the Nelson patent, but it did not clearly disavow all other types of folding for its catheter. The construction of this disputed language is different from that involving the term coincident discussed earlier, because there the prosecution history clearly showed that Hollister and the patent examiner defined and understood the term coincident to mean in the same plane and not merely closely adjacent.

ConvaTec cites the case of *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366 (Fed. Cir. 2008), as an example of a case in which prosecution disavowals led to certain limitations being imposed on the claims. That case, however, is distinguishable. The patentee made a clear statement during the prosecution that the

invention did not include certain parts. The invention was a portable microprocessor, and the prosecution history noted the advantages it gained by not including a built-in keyboard and display. *Id.* at 1376–77. Based on this, the court concluded that the claims were limited to devices lacking a built-in keyboard or display, and so laptops were not within the claims. *Id.* The situation in the current case is different, because Hollister did not note the advantages its catheter gained from only being able to fold longitudinally. Instead, it said that an earlier patented invention was different because it was rigid and could not fold, and in particular it could not fold in a certain way.

5. "Wherein the third section of the catheter has a flush port to thereby permit the infusion of sufficiently large volumes of fluid into the system to permit irrigation of the patient's bowel"

The phrase "wherein the third section of the catheter has a flush port to thereby permit the infusion of sufficiently large volumes of fluid into the system to permit irrigation of the patient's bowel" appears in the 627 patent in claim 14. JA166. The parties disagree about the uses to which the flush port can be put. ConvaTec contends that the flush port must be "used to supply fluid to the patient's bowel for irrigation." Def. Br. at 22. Hollister contends that the language requires no construction, and that the term "permit" only requires the flush port to allow irrigation, without necessarily being used for that purpose.

The parties agree that the claim language is unambiguous, but there is contradictory language in the specification. Although the claim language refers to the flush port being large enough for irrigation, the specification states that the flush port is used to take fecal samples and flush the catheter. JA163 at 8:33–39. The specification discusses irrigation of the bowel occurring through an entirely different process not

involving the flush port. JA164 at 10. ConvaTec argues that the patent claim might be poorly or mistakenly drafted, but its language still controls over the contrary language in the specification. *Elekta Instruments*, 214 F.3d at 1307–08; *see Chief Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374–75 (Fed. Cir. 2004) (construing claim to state a process that would result in ruined baked goods, when the claim language unambiguously required that dough be heated to 400 degrees).

The Court agrees with Hollister that the disputed language requires no construction and does not mean that the flush port must be used to irrigate the bowel. The disputed language only requires that the flush port allow irrigation or make it possible, not that the part normally be used for this purpose.

ConvaTec argues that the Federal Circuit has interpreted language stating that a pin was "for extending into said security slot" as a functional limitation on the pin. *Acco Brands*, 346 F.3d at 1077–78 (internal quotation marks omitted). To say that a claim limitation is for a particular purpose, however, is more restrictive language than to say that the claim limitation permits or allows something. Furthermore, in *Acco Brands* the prosecution history showed that the patentee had argued that the pin had a functional limitation based on the "for extending" language. *Id.* at 1078–79. ConvaTec has not pointed to any similar language in the prosecution history of the 627 patent.

Conclusion

The Court construes the disputed terms as discussed above for the reasons stated above. The case is set for a status hearing on August 30, 2012 at 9:30 a.m. to

set a schedule for further proceedings.

_____
MATTHEW F. KENNELLY
United States District Judge

Date: August 18, 2012

Appendix

Disputed claim language appears in claims 1 and 7 of the 216 patent; claims 1, 14, 21, 22, 25, and 33 of the 627 patent; and claims 1 and 13 of the 583 patent.

A. 216 patent claim 1

> **1.** A multipurpose colostomy device for fixing in the stoma or rectum of a human body, said colostomy device comprising:
>
> an internal balloon;
>
> an external balloon surrounding said internal balloon;
>
> a connecting tube disposed under said internal and external balloons;
>
> a joint tube disposed under said connecting tube;
>
> an annular supporting plate upwardly disposed between said connecting tube and said joint tube, for fixing the multipurpose colostomy device to the abdominal wall of the stoma;
>
> a supply tube vertically disposed in said connecting tube and between said internal and external balloons for communicating with the connecting tube and the internal and external balloons, said supply tube having a holder disposed at an end of a bending portion thereof, for assembling with a socket connected to a fluid tank and an air pump wherein said supply tube includes a pair of air passages communicating with said internal and external balloons through a first air opening and a second air opening, respectively, said supply tube further including an enema fluid passage passed through said internal balloon for communicating with the colon through an enema one-way valve, and wherein said enema fluid passage includes an enema fluid one-way valve located over said internal balloon and in the colon; and
>
> means for inflating and deflating the internal and external balloons and supplying enema irrigating fluid, such that the multipurpose colostomy device can effectively close the stoma, prevent leakage, particularly liquids and gases, discharge the stool, wash the contaminated connecting tube after discharge of stool, and irrigate the colon with enema fluid.

JA8.

B. 216 patent claim 7

7. A multipurpose colostomy device for fixing in the rectum of a human body, said colostomy device comprising:

an internal balloon;

an external balloon surrounding said internal balloon;

a connecting tube disposed under said internal and external balloons;

a joint tube disposed under said connecting tube;

a supply tube vertically disposed in said connecting tube and between said internal and external balloons for communicating with the connecting tube and the internal and external balloons, said supply tube having a holder disposed at an end of a bending portion thereof, for assembling with a socket connected to a fluid tank and an air pump, wherein said supply tube includes a pair of air passages communicating with said internal and external balloons through a first air opening and a second air opening, respectively, said supply tube further including an enema fluid passage passed through said internal balloon for communicating with the colon through an enema one-way valve, wherein said enema fluid passage includes an enema fluid one-way valve located over said internal balloon and in the colon; and

means for inflating and deflating the internal and external balloons and supplying enema irrigating fluid, such that the multipurpose colostomy device can effectively close the stoma, prevent leakage, particularly liquids and gases, discharge the stool, wash the contaminated connecting tube after discharge of stool, and irrigate the colon with enema fluid.

JA8–9.

C. 627 patent claim 1

1. A bowel management system for use in a patient comprising: a waist collection catheter having at least two distinct sections of varying durometer hardness including: a first section which is patient proximal and which is disposed in the patient's rectum in normal use position, having a first end and a second end, and a durometer hardness in the range of about 50A to about 90A, so that the catheter patient proximal section is stiff enough to automatically maintain an open position for free flow of bowel waste when in normal use position with a retention balloon inflated, yet is soft and pliable enough to permit folding longitudinally for

ease of insertion into the rectum of the patient; a second section having a first end connected to the second end of the patient proximal section, and a second end, and a durometer hardness in the range of about 5A to about 49A, so that the second section can be positioned and retained in the anal canal of the patient for extended periods without distending the sphincters or causing discomfort; and a selectively collapsible, substantially spherical retention balloon attached coaxially and exterior of the patient proximal first catheter section such that the proximal-most end of the retention balloon is coincident to the proximal-most first end of the patient proximal first section of the waste collection catheter, the substantially spherical retention balloon having an inflated size so as to be sufficiently large enough to retain the patient proximal end of the catheter in the patient's rectum without being so large as to trigger a defecatory response.

JA165.

D. 627 patent claim 14

14. A bowel management system for use in a patient comprising: a waste collection catheter having at least two distinct sections of varying durometer hardness including: a first section which is patient proximal and which is disposed in the patient's rectum in normal use position, having a first end and a second end, and a durometer hardness in the range of about 50A to about 90A, so that the catheter patient proximal section is stiff enough to automatically maintain an open position for free flow of bowel waste when in normal use position with a retention balloon inflated, yet is soft and pliable enough to permit folding longitudinally for ease of insertion into the rectum of the patient; a second section having a first end connected to the second end of the patient proximal section, and a second end, and a durometer hardness in the range of about 5A to about 49A, so that the second section can be positioned and retained in the anal canal of the patient for extended periods without distending the sphincters or causing discomfort; and a third section of the waste collection catheter, which is positioned patient distal in normal use, wherein the third section of the catheter has a flush port to thereby permit the infusion of sufficiently large volumes of fluid into the system to permit irrigation of the patient's bowel.

JA165–66.

E. 627 patent claim 21

21. A method for inserting a bowel management system into a patient, the method comprising: (a) providing a bowel management

system, the system having: a waste collection catheter having at least two distinct sections of varying durometer hardness including: a first section which is patient proximal and which is disposed in the patient's rectum in normal use position, having a first end and a second end, and a durometer hardness in the range of about 50A to about 90A, so that the catheter patient proximal section is stiff enough to automatically maintain an open position for free flow of bowel waste when in normal use position with retention balloon inflated, yet is soft and pliable enough to permit folding longitudinally for ease of insertion into the rectum of a patient; a second section having a first end connected to the second end of the patient proximal section, and a second end, and a durometer hardness in the range of about 5A to about 49A, so that the second section can be positioned and retained in the anal canal of the patient for extended periods without distending the sphincters or causing discomfort; and a selectively collapsible, substantially spherical retention balloon attached coaxially and exterior of the patient proximal first catheter section such that the proximal-most end of the retention balloon is coincident to the proximal-most first end of the patient proximal first section of the waste collection catheter, the substantially spherical retention balloon having an inflated size so as to be sufficiently large enough to retain the patient proximal end of the catheter in the patient's rectum without being so large as to trigger a defecatory response in the patient; (b) folding the patient proximal first end of the waste collection catheter longitudinally; (c) inserting the folded patient proximal first end of the waste collection catheter into the patient's rectum sufficiently far that the selectively collapsible, substantially spherical retention balloon is entirely within the patient's rectum; and d) securing the waste collection catheter in the position to which it has been inserted so that the catheter does not become separated from the patient during an extended period of time, in the range of hours, while the patient's body waste is permitted to drain out of the patient's body through the waste collection catheter.

JA166.

F. 627 patent claim 22

22. A method for inserting a bowel management system into a patient, the method comprising: (a) providing a bowel management system, the system having: a waste collection catheter having at least two distinct sections of varying durometer hardness including: a first section which is patient proximal and which is disposed in the patient's rectum in normal use position, having a first end and a second end, and a durometer hardness in the range of about 50A to about 90A, so that the catheter patient proximal section is stiff enough to automatically maintain an open position for free flow of bowel waste when in normal use position with

retention balloon inflated, yet is soft and pliable enough to permit folding longitudinally for ease of insertion into the rectum of a patient; a second section having a first end connected to the second end of the patient proximal section, and a second end, and a durometer hardness in the range of about 5A to about 49A, so that the second section can be positioned and retained in the anal canal of the patient for extended periods without distending the sphincters or causing discomfort; and a selectively collapsible, substantially spherical retention balloon attached coaxially and exterior of the patient proximal first catheter section such that the proximal-most end of the retention balloon is coincident to the proximal-most first end of the patient proximal first section of the waste collection catheter, the substantially spherical retention balloon having an inflated size so as to be sufficiently large enough to retain the patient proximal end of the catheter in the patient's rectum without being so large as to trigger a defecatory response in the patient; b) inflating an intralumenal balloon in the patient proximal end of the waste collection catheter to the extent that the intralumenal balloon extends slightly beyond the proximal-most end of the catheter, to thereby provide a curved tip for ease of introduction of the catheter into the patient's rectum (c) inserting the patient proximal first end of the waste collection catheter into the patient's rectum sufficiently far that the selectively collapsible, substantially spherical retention balloon is entirely within the patient's rectum; and (d) securing the waste collection catheter in the position to which it has been inserted so that the catheter does not become separated from the patient during an extended period of time, in the range of hours, while the patient's body waste is permitted to drain out of the patient's body through the waste collection catheter; and (e) deflating the intralumenal balloon in the patient proximal end of the waste collection catheter to permit free flow of body wastes from the patient.

Id.

G. 627 patent claim 25

25. A method for managing an incontinent patient's bowel, the method comprising: (a) providing a bowel management system, the system having: a waste collection catheter having at least two distinct sections of varying durometer hardness including: a first section which is patient proximal and which is disposed in the patient's rectum in range of about 50A to about 90A, so that the catheter patient proximal section is stiff normal use position, having a first end and a second end, and a durometer hardness in the enough to automatically maintain an open position for free flow of bowel waste when in normal use position with retention balloon inflated, yet is soft and pliable enough to permit folding longitudinally for ease of insertion into the rectum of a patient; a second

section having a first end connected to the second end of the patient proximal section, and a second end, and a durometer hardness in the range of about 5A to about 49A, so that the second section can be positioned and retained in the anal canal of the patient for extended periods without distending the sphincters or causing discomfort; and a selectively collapsible, substantially spherical retention balloon attached coaxially and exterior of the patient proximal first catheter section such that the proximal-most end of the retention balloon is coincident to the proximal-most first end of the patient proximal first section of the waste collection catheter, the substantially spherical retention balloon having an inflated size so as to be sufficiently large enough to retain the patient proximal end of the catheter in the patient's rectum without being so large as to trigger a defecatory response in the patient; (b) inserting the first section of the waste collection catheter into the patient's rectum; (c) connecting an end opposite the first section of the waste collection catheter to a waste collection vessel; (d) confirming patentcy of the waste collection catheter; (e) permitting body wastes to flow through the waste collection catheter into the waste collection container; (f) emptying the waste collection container from time to time as necessary when the waste collection container becomes filled.

JA166–67.

H. 627 patent claim 33

33. A bowel management system for use in a patient comprising: a waste collection catheter having at least two distinct sections of varying durometer hardness including: a first section which is patient proximal and which is disposed in the patient's rectum in normal use position, having a first end and a second end, and a durometer hardness in the range of about 50A to about 90A, so that the catheter patient proximal section is stiff enough to automatically maintain an open position for free flow of bowel waste when in normal use position with a retention balloon inflated, yet is soft and pliable enough to permit folding longitudinally for ease of insertion into the rectum of the patient; a second section having a first end connected to the second end of the patient proximal section, and a second end, and a durometer hardness in the range of about 5A to about 49A, so that the second section can be positioned and retained in the anal canal of the patient for extended periods without distending the sphincters or causing discomfort; and a selectively collapsible, substantially spherical retention balloon attached coaxially and exterior of the patient proximal first catheter section such that the proximal-most end of the retention balloon is coincident to the proximal-most first end of the patient proximal first section of the waste collection catheter, the substantially spherical retention balloon having an inflated size so as to be sufficiently large

enough to retain the patient proximal end of the catheter in the patient's rectum without being so large as to trigger a defecatory response in the patient, and further comprising a lumened member which is substantially smaller in diameter than the waste collection catheter and which has a first end and a second end, the first end of the lumened member being connected to the patient proximal first section of the waste collection catheter and being in fluid communication with the selectively collapsible retention balloon, and wherein the second end of the lumened member is connectable to a port for introduction or removal of fluid from the retention balloon, for selective inflation and deflation of the retention balloon as necessary for insertion, retention or removal of the rectal catheter patient proximal segment to or from the patient's rectum.

JA167–68.

I. 583 patent claim 1

1. A bowel management system comprising:
a rectally inserted catheter having a first catheter section having a patient proximal opening that, when in position for normal use, is in a patient's rectum to receive bowel waste, and a second catheter section located distal to the first section that, when in position for normal use, can be collapsed by a patient's anal sphincter muscles;
the first catheter section being sufficiently pliable to permit folding for insertion into a patient's rectum but following insertion permits flow of bowel waste through the patient proximal opening;
the second catheter section permitting passage of bowel waste from the patient and being sufficiently soft to permit retention within a patient's anal canal for extended periods of time; and
a balloon coaxial with, and extending radially outward relative to, the patient proximal opening of the first catheter section for retaining the patient proximal opening in a position for normal use where it opens into the rectum of the patient, and the balloon having a proximal-most end coincident to a proximal-most first end of the first catheter section, the balloon having an inflated size sufficiently large so as to prevent migration of the first catheter section out of the patient's rectum through the patient's anal canal without being so large as to trigger a defecatory response in the patient.

JA441.

J. 583 patent claim 13

13. A bowel management system for use in a patient comprising:
a waste collection catheter having a first catheter section which is patient

proximal and which is disposed in the patient's rectum in a normal use position;

the waste collection catheter also having a second catheter section which is positioned patient distal in normal use, the second catheter section being coated at least one of internally with a substance to facilitate flow-through of waste matter from the patient or externally with a substance to facilitate milking of the waste collection catheter by a caretaker for the patient; and

a selectively collapsible retention balloon attached coaxially and exterior of the patient proximal first section, the balloon having a proximal-most end coincident to a proximal-most first end of the first catheter section.

Id.