

United States District Court,  
E.D. Pennsylvania.

**MCNEIL-PPC, INC,**  
Plaintiff and Counter-Defendant.

v.

**BAYER CORPORATION,**  
Defendant and Counter-Plaintiff.

**Nov. 8, 2000.**

Martin J. Black, Christopher J. Culleton, Dechert, Price & Rhoads, Phila., PA, Harry J. Roper, George S. Bosy, Sarah L. Taylor, Roper & Quigg, Chicago, IL, William P. Oberhardt, Chicago, IL, for McNeil-PPC, Inc., Plaintiff.

Albert G. Bixler, Eckert Seamans Cherin & Mellott, Phila., PA, Robert M. Isackson, Peter Bucci, Charles W. Bradley, Rodger A. Sadler, Orrick, Herrington & Sutcliffe LLP, New York, NY, for Bayer Corporation, Defendant.

### ***MEMORANDUM***

**TUCKER, J.**

This is an action for patent infringement. The parties conducted a *Markman* hearing before the Court on October 6, 2000 to present oral argument, expert testimony, and other evidence regarding the proper construction of certain language in Claim 1 of United States Patent No. 4,820,524 ("the '524 patent").

#### **I. BACKGROUND**

In 1987, Norbert I. Berta applied for a patent for gelcaps, a type of medicine manufactured by a process Berta had devised. The United States Patent and Trademark Office ("PTO") rejected the application at first, finding that the invention to which Berta sought exclusive rights was too close to an invention which had been patented by Richards in 1898. Berta revised the description of the invention, and the PTO granted the '524 patent for a "simulated, capsule-like medicament" in 1989, giving the patent holder the exclusive right to produce and offer for sale products covered by the patent for seventeen years.

Berta assigned his patent to McNeil, the manufacturers of Tylenol. Tylenol began producing gelcaps, claiming exclusive rights under the '524 patent. In the 1990s, Bayer Corporation began marketing its own line of gelcaps, and McNeil brought this lawsuit for patent infringement in 1999. Bayer argues that the '524 patent, as properly construed, does not apply to its gelcaps, and that therefore it has not infringed the patent. The scope of protection provided by a patent is determined by the language of the claims, the brief sentences or paragraphs which "particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention." 35 U.S.C. s. 112. The first step in determining the infringement of a patent is an

interpretation of the scope and meaning of the patent claims alleged to be infringed, and construction of those patent claims is a matter of law to be decided by the Court. *See Markman v. Westview Instruments Inc.*, 52 F.3d 967, 976, 979 (Fed.Cir.1995) ( *en banc* ), *aff'd* 517 U.S. 370 (1996). In order to aid the Court in this determination, the parties submitted written briefs and made presentations at a *Markman* hearing.

Plaintiff argues that the disputed terms have the following meanings:

1. "Simulated capsule-like medicament" means "a medicinal form that imitates, resembles, or suggests in form or appearance a gelatin shell enclosing medicine."
2. "Partially overlapping said first gelatinous coating and forming a seam" means "extending over and covering a part of, but not all of, the first gelatinous coating in a manner such that there is a resultant line of junction formed by the abutment (touching) of edges between the two gelatinous coatings."
3. "Generally cylindrical shape" means "shape formed, in a general manner, by a straight line moving parallel to a fixed line and intersecting a fixed curve."

Defendant, in response, argues that the disputed terms have the following meanings:

1. "Simulated capsule-like medicament" means "medicament made to simulate a hard gelatin capsule."
2. "Partially overlapping said first gelatinous coating and forming a seam" means "overlapping said first coating such that there is a visible transition in the thickness of the coating material in the central region of the medicament, and a thickened portion and a non-uniformity in the surface of the coated medicament, similar to that of a hard gelatin capsule."
3. "Generally cylindrical shape" means "shape having a body described by the rotation of a parallelogram around one of its sides and a generally circular cross-section, and not any other cross-sectional shape."

After a review of the legal standards for claim construction, the Court will discuss the parties' arguments regarding the three disputed phrases from the '524 patent's claims, and will conclude with the proper construction of these phrases.

## II. LEGAL STANDARD

A patent describes the scope and limits of an invention so as to alert the public to all that for which the patentee holds the exclusive rights, and all that which remains open to the public. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). A patent consists of the specification, which "should describe the invention in clear terms so that a person in the art of the patent may make and use the invention," as well as the claims, which "should 'particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention.'" *Katz v. AT & T Corp.*, 63 F.Supp.2d 583, 589 (E.D.Pa.1999) (quoting 35 U.S.C. s. 112). The public record of the patent before the Patent and Trademark Office ("PTO"), upon which the public is entitled to rely, also includes the prosecution history, which is the written record of the submissions of the patentee and the comments of the PTO. Together, the claims, specification, and prosecution history constitute the intrinsic evidence of the meaning of the claim terms, and as such are the most important sources for the meaning of claim terms. *See Vitronics Corporation v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582, 1583 (Fed.Cir.1996).

The parties have presented competing descriptions of the proper standard for construction of the language in patent claims. Plaintiff McNeil, which holds the interest in the '524 patent, argues that the Court need not look beyond the plain language and ordinary meaning of the terms in the clauses of Claim 1. Defendant Bayer counters that the Court must also consider the specification and the prosecution history when construing claim terms.

More specifically, both parties recognize that claim construction "begins and ends in all cases with the actual words of the claim," which, absent a special definition spelled out in the specification or prosecution history by the patent applicant, are given their "ordinary and accustomed meaning." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248, 1249 (Fed.Cir.1998). The 'ordinary' meaning is determined according to an objective standard: "The focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean." *Markman*, 52 F.3d at 986.

Both parties also recognize that the Court may need to look to sources outside of the claims themselves in order to understand the meaning of the claim terms. Plaintiff, however, argues that it is improper to enlarge, diminish, or vary the limitations in the claims by incorporating limitations from other sources, even from the specification or prosecution history. Defendant, meanwhile, argues that the Court must examine the prosecution history to see what the patent applicant gave up in order to win approval of the patent, and that the patent holder cannot claim rights to a claimed invention that was disclaimed or disavowed during the prosecution. As will be seen, both parties are correct.

Once the Court has determined the ordinary meaning of the claim terms, it must also consider the specification and, if it is in evidence, the prosecution history to determine whether the patentee provided a distinct definition for a term, or used any terms in a manner inconsistent with their ordinary meaning. *See Vitronics*, 90 F.3d at 1582. Claims can never be read in isolation, but rather "must be read in view of the specification, of which they are a part." *Markman*, 52 F.3d at 979. Nevertheless, while courts can look to the written descriptions in the specification to define a term already in a claim limitation, courts cannot read a limitation into a claim from the written description. *See Renishaw*, 158 F.3d at 1248 (Fed.Cir.1998). Courts should not narrow the meaning of the claim terms on the basis of the contents of the specification, by assigning a meaning to the claim terms other than their ordinary meaning, unless either the patentee has explicitly set forth a special, novel definition for a term, or else the "terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used." *Johnson Worldwide Associates, Inc. v. Zebco Corporation*, 175 F.3d 985, 990 (Fed.Cir.1999).

Courts should also consider the prosecution history, the record of correspondence and communications between the inventor and the PTO, which is kept on file at the PTO and made available for public inspection. "Although the prosecution history can and should be used to understand the language used in the claims, it too cannot 'enlarge, diminish, or vary' the limitations in the claims." *Markman*, 52 F.3d at 980 (citation omitted). "If a patentee takes a position before the PTO, such that a 'competitor would reasonably believe that the applicant had surrendered the relevant subject matter,' the patentee may be barred from asserting an inconsistent position on claim construction." *Katz v. AT & T Corp.*, 63 F.Supp.2d 583, 591 (E.D.Pa.1999) ( *citing* *Cyber Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1457 (Fed.Cir.1998)); *see also* *Cole v. Kimberly-Clark Corporation*, 102 F.3d 524, 531 (Fed.Cir.1996). It is well established, however, that " '[u]nless altering claim language to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage,' that is, by making a statement that concedes or

disclaims coverage of the claims at issue based on a piece of prior art." Katz, 63 F.Supp.2d at 591 ( *citing* York Products, Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed.Cir.1996)).

A court may consider evidence that is extrinsic to the public record of the patent as well, but it is entitled to very little weight. In most respects, the patent stands alone, and should be interpreted according to its own public record. The testimony and the intent of the inventor receives extremely little probative value in determining the scope of the claims, except to the extent that it is documented in the prosecution history. *See* Engel Industries, Inc. v. Lockformer Co., 96 F.3d 1398, 1405 (Fed.Cir.1996) ( *citing* Markman, 52 F.3d at 985). Other expert testimony, likewise, may not be used to vary or contradict claim language, and when patent documents are unambiguous, expert testimony regarding the construction of claim terms is entitled to no weight at all. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed.Cir.1996). The Federal Circuit has emphasized that, while district courts may rely on expert testimony for guidance in understanding the underlying technology, expert testimony "on the proper construction of a disputed claim term ... may only be relied upon if the patent documents, taken as a whole, are insufficient to enable the court to construe disputed claim terms. Such instances will rarely, if ever, occur." *Id.* at 1585. The chief reason for these limitations on the weight of extrinsic evidence is that the public is entitled to review the public record, apply the standard rules of claim construction, ascertain the scope of the claimed invention and then design around it, *see* Markman, 52 F.3d at 978-79, and "allowing the public record to be altered or changed by extrinsic evidence introduced at trial ... would make this right meaningless." Vitronics, 90 F.3d at 1583 (citation omitted).

The Federal Circuit has noted that technical treatises and dictionaries, even though technically forms of extrinsic evidence, are worthy of special note. Vitronics, 90 F.3d at 1584, n. 6. Unlike expert testimony offered after the fact, such standard reference works are equally available to the public as the prosecution history to assist in understanding the claim terms and the scope of the claimed invention. Thus, "[j]udges are free to consult such resources at any time ... and may also 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." *Id.*

### **III. CLAIM CONSTRUCTION**

The parties disagree about the proper construction of certain phrases in subparagraphs 1(a) and 1(c) in Claim 1 of the '524 patent. Claim 1 generally describes the basic physical structure of the medicament, or solid-form medicine, that is covered by the patent. The contested language refers to an observer's overall impression of the medicament's appearance, its geometrical shape, and its surface texture and appearance. The phrases at issue are: "simulated capsule-like medicament", "generally cylindrical shape", and "partially overlapping said first gelatinous coating and forming a seam".

#### **A. "Simulated Capsule-Like Medicament"**

This phrase appears at the beginning and the end of Claim 1, and is used the same way in each instance. The parties are essentially in agreement that the ordinary meaning of this phrase is "a medicinal form that imitates, resembles, or suggests in form or appearance a gelatin shell containing medicine." This is essentially the definition derived from *Webster's Third New International Dictionary* (1961), an extrinsic source to which the Court may properly turn.

Defendant argues, however, that "capsule-like" is effectively defined in the specification and the prosecution history of the '524 patent as meaning "similar to a hard gelatin capsule". Defendant's sole argument with

regard to the specification is that "the only capsules disclosed or referred to in the '524 patent are hard gelatin capsules with overlapping separable halves ... [having] an overlap where the one capsule half fits inside the other, and a visible raised portion" (Defendant Bayer Corporation's *Markman* Brief at 25-26), so that when the phrase "capsule-like" appears in the '524 patent, it must mean "similar to a hard gelatin capsule".

Defendant would have the Court place too much weight on indirect references in the specification to "hard gelatin capsules". The claims do not specifically state that the claimed medicament is intended to simulate a "hard gelatin capsule," and the specification does not do so either. "Capsule" has a clear, ordinary meaning, as the parties agree, so that there is no automatic need to turn to the specification for clarity, and therefore the '524 patentee could not have assigned a different meaning to the term unless he had explicitly set out a special definition in the specification. *See Johnson Worldwide*, 175 F.3d at 990.

The two distinct references to hard gelatin capsules in the specification, when read carefully in context, do not purport to use that phrase as a definition for the term "capsule." The narrative description of the background of the invention mentions "hard gelatin capsules" as a means of encapsulating medicine that was popular and widespread until the mid-1980's, when a need arose to replace the capsules with products such as the medicament claimed in the '524 patent, and the detailed description of the invention in the '524 patent mentions the particular use of hard gelatin capsule-producing machinery as instruments which may be converted to the production of the "simulated capsule-like medicaments" claimed in the patent. In neither case does the patent define "hard gelatin capsules" as the only type of capsules used in this industry; indeed, the phrase "hard gelatin capsule" is not set out in the specification as a definition at all—it is merely a type of capsule to which the specification happens to make reference, and a mere reference to this type of capsule in the specification cannot serve to define "capsule" as meaning specifically "hard gelatin capsule" for purposes of the claims. The finished product resulting from the process described in Claim 1 may very broadly resemble a hard gelatin capsule, as a cylindrical caplet is coated with gelatin layers of different colors, but the claim terms and the specification do not define the specific phrase "simulated capsule-like" to mean only medicaments that simulate the hard gelatin capsules to which the specification makes reference.

Defendant argues that "capsule" is given a particular definition by the prosecution history. The first application by the patentee of the '524 patent, Mr. Berta, was rejected by the PTO, and in order to escape rejection, he filed an amended version of his claims, along with remarks explaining the changes and the manner in which they distinguished this patent from the 1898 Richards patent and thus warranted granting of this patent; these remarks are now part of the prosecution history. In these remarks, the patentee states that "the change in thickness at the end of the outer gelatinous coating accompanied by the changing color makes it appear that rather than a coated caplet, the medicament is actually a hollow, hard gelatin capsule."

This phrasing in the prosecution history is not enough to limit the construction of the disputed terms in the claims, however, because, under clear Federal Circuit precedent, the prosecution history cannot be used to enlarge, vary, or diminish the limitations in the claim language, unless the patentee has disclaimed or disavowed a certain scope or definition for the purpose of escaping rejection by the PTO. In this case, the phrase "simulated capsule-like medicament" appears in both the original application by the patentee and the amended application, and the remarks in the amended application state that it is the new language, regarding the color dichotomy and the seam resulting from the overlapping of the layers of gelatin, that has been added in order to avoid rejection. The patentee did not amend the wording of the phrase "simulated capsule-like medicament."

In addition, the seven pages of remarks accompanying the newly worded claims describe how the claim terms, as amended, disclose an invention which is different than the invention disclosed in the Richards patent. The remarks specifically emphasize a change in color and a change in thickness as elements which set the claimed invention off from the older patent, but they do not state that the claimed invention is distinct from the Richards patent by virtue of resembling a "hard gelatin capsule." The description quoted by defendant is made in passing, in a single place in the remarks. Elsewhere in the remarks, the patentee says simply that the appearance of the medicament provides an "illusion that the medicament is actually a capsule," and that it "would fool the viewer into believing that it was, in fact, a capsule." The patentee did not disclaim or disavow other possible types of capsules by making a single reference to a "hollow, hard gelatin capsule," given that in several other places the patentee represented that the general illusion of a "capsule" was sufficient to achieve the effect required for his claimed invention. Since the patentee did not endeavor to escape rejection by arguing to the PTO that his invention was limited to a medicament specifically simulating a "hard gelatin capsule," and he did not 'clearly disavow' coverage of simulated capsules other than simulated hard gelatin capsules, he did not limit the '524 patent to such type of medicament, and the Court will not read that limitation into the claims from the prosecution history. *See, e.g., York Products*, 99 F.3d at 1572. The phrase "simulated capsule-like medicament" will be construed to have its ordinary meaning.

In this case, where the term has a clear ordinary meaning, the specification does not provide an explicit alternative definition, and the prosecution history does not require such a definition, the Court would only apply a different definition for the term if there were clear evidence that the term would have a meaning other than the ordinary meaning for one skilled in the art of the patent. Here, defendant offers expert testimony as extrinsic evidence that "capsule-like" would be understood by an ordinary person skilled in the art of pharmaceuticals to mean "like a hard gelatin capsule." Defendant's witness, Dr. Gilbert Banker, did not provide an interpretation of the term "capsule" from the perspective of pharmaceuticals, however. Rather, Banker offered his own opinion of how one skilled in the art would understand the phrase "simulated capsule-like medicament" in light of the other remarks in the specification and the prosecution history. Asked to give his understanding of the phrase, Banker remarked, "[W]e have a hard gelatin capsule. There are, by the way, soft gelatin capsules, but they are not at issue here. This patent is clearly related to hard gelatin capsules ... It was made clear in the specification that we were dealing with hard gelatin capsules." *Markman* Hearing on Patent Claim Construction, transcript at 148-149.

Having testified that hard gelatin capsules have strictly circular cross-sections, Banker then also testified that the United States Pharmacopeia, a standard reference work in the field, refers to flat, pancake-shaped caplets as "capsule-shapes." *Id.* at 205. He agreed that this definition is "a general definition ... that people use," *id.* Having defined "cylindrical" as meaning "shaped like a hard gelatin capsule," Banker was asked, "[C]apsule-shaped then does not necessarily mean cylindrical?", and he replied, "That's right." *Id.* at 210. Banker thus conceded that there are other common capsule forms aside from hard gelatin capsules, and that the phrase "capsule-shaped" is commonly used to refer to a shape other than that of a hard gelatin capsule. The expert testimony was therefore not conclusive on whether "simulated capsule-like" would be understood by one of ordinary skill in the art of pharmaceuticals to mean "like a hard gelatin capsule." Banker thus did not offer expert testimony as to how the term "capsule" is understood by one skilled in the art of pharmaceuticals, but rather offered his own construction of the term based upon limitations that he perceived as implicit in the intrinsic evidence of the '524 patent. As a matter of law, claim construction is the duty of the court. Here, the Court does not agree with Banker's assessment that the patent, using the regular rules of claim construction, is "clearly" limited to hard gelatin capsules. The disputed phrase is not ambiguous in the claim, the specification does not lay out a particular definition for the phrase, and the prosecution history

does not indicate that the patentee disavowed claims to medicaments defined by the phrase as commonly understood. Therefore, the Court will assign the plain, ordinary meaning to the phrase "simulated capsule-like." FN1

FN1. It may be that the '524 patent, read as a whole, discloses only medicaments that turn out to resemble hard gelatin capsules, but that fact would not, by itself, mean that the specific phrase "simulated capsule-like medicament" is limited to such a narrow definition.

## **B. "Partially Overlapping Said First Gelatinous Coating And Forming A Seam"**

The parties are essentially in agreement about the meaning of the phrase "partially overlapping said first gelatinous coating"; their proffered definitions differ only in choice of words, not in any substantive sense. With regard to the meaning of "seam", however, defendant argues that the patentee disavowed coverage of any surface feature other than "a visible transition" consisting of "a thickened portion and a non-uniformity in the surface".

Defendant argues that the specification in the '524 patent assigns this narrow definition to the term "seam," but the specification simply does not disclose any such definition. Rather, the specification uses "seam" simply to refer to a surface feature of the medicament, without clearly setting out any particular description of the physical appearance of that feature. The specification does note that several drawings set out in the accompanying sheets of illustrations display a "seam", but the indicated drawings simply display a region on the medicament where the seam is located. Defendant argues that the drawings display a visible raised portion in the region of the seam, but any such elevation in the surface area is extremely slight, possibly an accidental by-product of the drafter's effort to set off the seam in order to indicate its location on the surface. Nothing in the language of the specification mentions a "visible raised portion" as a surface feature, or mentions such a feature as something worth noting in the drawings.

Defendant also argues that the prosecution history reveals that the patentee disclaimed any meaning of "seam" other than "a visible transition in the thickness of the coating material ... [consisting of] a thickened portion and a non-uniformity in the surface." (Defendant's *Markman* Brief at 30) Plaintiff responds that "seam" does not refer to thickness, but rather means a "line of junction formed by the abutment (touching) of edges between the two gelatinous coatings." Plaintiff argues that the patentee "did not amend the language of the claims to include a limitation relating to gelcaps having different gelatin thicknesses." (Plaintiff McNeil's Responsive Pre- *Markman* Hearing Brief at 25) The remarks accompanying the amended claims in the prosecution history of the '524 patent make plain, however, that the patentee was revising the language of the claims to emphasize the seam in order to distinguish the claimed medicament from the older patent, by Richards, and thereby escape rejection by the PTO, and that plaintiff's revised language did indeed define "seam" to refer to a transition in the thickness of the coating material.

The original patent application had been rejected because the claimed structure was too similar to an invention patented earlier by Richards. The original '524 patent application had described "first and second gelatinous coatings substantially covering said caplet to form a simulated capsule-like medicament with a seam." This original description did not indicate that that seam resulted from the overlap of the coatings; rather, it simply stated that the medicament featured a "seam", which might have been a gap, an abutment, an overlap, or something else. In the amended claim, the patentee specifically altered this language to describe "[a] second gelatinous coating ... partially overlapping said first gelatinous coating and forming a

seam." The patentee stated that he had "amended the claims to more clearly state the structure of the coated caplet as having an overlapping seam of gelatin. Therefore, the ... rejection should be withdrawn."

The remarks consistently emphasize two features that set the claimed invention apart from the medicament described by Richards: different colors on either end of the medicament, and a "thickened portion" formed by the overlap of the two gelatin coatings at the midsection of the medicament. The remarks declare that the separate colors provide an illusion that the medicament is, in fact, a capsule. The remarks go on to stress that

[f]urther enhancing the illusion, is the specifically claimed structure ... calling for a seam .... provided by the overlapping of the two gelatinous coatings which form a thickened portion at the overlap. The change in thickness accompanied by the changing color makes it appear that ... the medicament is actually a ... capsule. These features and structural limitations ... are clearly not disclosed by, or inherent in Richards.

These comments leave no doubt that the "seam" is a "thickened portion" of the surface at the location of the transition in color, i.e. the point where the two differently colored gelatinous coatings meet. The comments make it clear that, for the purpose of escaping rejection and distinguishing the claimed invention from Richards, the patentee disavowed any type of seam other than an overlap of two coatings resulting in a 'change in thickness.'

This interpretation is confirmed by the comment later in the remarks that "what Richards is attempting to provide is a smooth continuous coating about the entire pill.... [The '524 a]pplicant's claimed structure, however, actually ... requires non-uniformity in its surface. The transition of color, the transition of thickness, the clear demarcation between the two gelatinous coatings are not disclosed or inherent from Richards." From the repetition of this point, and the explicit insistence that the "transition in thickness" is one of the crucial elements entitling the patentee to escape rejection, any competitors reading the prosecution history would reasonably believe that the patentee had surrendered any claim to a "seam" other than one consisting of a "transition in thickness." Contrary to plaintiff's arguments, the patentee did indeed amend the language of the claim and place the word "seam" in a different context for the specific purpose of escaping rejection. Having done so, the patentee went on, in remarks which are recorded in the prosecution history, to emphasize that "seam" had a specific definition: a feature consisting of a transition in thickness at the location of the transition in color. Plaintiff is therefore barred from asserting an inconsistent position on claim construction, and the Court will apply the definition of "seam" that the patentee assigned in the prosecution history.

Plaintiff attempts to argue that the definition of "seam" suggested by defendant would constitute a 'limitation' on that claim term, and that courts are prohibited from reading limitations from prosecution history into claims which do not contain those limitations, citing *Intervet America, Inc. v. Kee-Vet Labs, Inc.*, 887 F.2d 1050, 1054 (Fed.Cir.1989). *Intervet* can be distinguished from the present case, however. There, the prosecution history included a statement by the attorney that all seven claims under consideration would, in the future, prior to issuance of the patent, be amended specifically to include a numerical limitation on the frequency of administration of an action. In fact, only four of the seven claims were actually amended to include the limitation that the attorney had described, and the court held that it was erroneous to read that specific, discrete, numerical limitation into the three claims which did not contain it. When an attorney's erroneous remark tending to ascribe a limitation to the claims which is not present there, the court held, the claim language controls. *See id.* at 1053-1054. In the present case, there was no erroneous remark in the prosecution history. The term "seam" appears in the claim, and the prosecution history allows the public to understand the meaning of that term as it is used in the '524 patent. *See Markman*, 52 F.3d at

980 ("The court has broad power to look as a matter of law to the prosecution history of the patent in order to ascertain the true meaning of language used in the patent claims."). The explanation in the prosecution history of what is meant by a seam is properly read, not as a diminishment or variation of the limitations in the claims, but rather as a definition of the term "seam." The Federal Circuit has made it clear that the prosecution history cannot be used to enlarge, diminish, or vary the limitations in the claims, so that when the claims contain limitations, the prosecution history cannot contradict those limitations. *See id.* The prosecution history can, however, serve effectively to limit the meaning of terms used in the claims by providing a definition of terms as they are used in that patent, as the amendment remarks do here.

Plaintiff's contention that "it is impossible to specially define a claim term in the file history" (Plaintiff's Responsive Brief at 24) is broadly correct as a statement of law, but is irrelevant to the present case. The Federal Circuit has held that when the patentee wishes to serve as his or her own lexicographer and provide an 'uncommon' definition, one which "differs from the conventional definition," that special definition must be clearly set out in the specification. *See Beachcombers Int'l, Inc. v. Wildewood Creative Products, Inc.*, 31 F.3d 1154, 1158 (Fed.Cir.1994); *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388 (Fed.Cir.1992).FN2 In the present case, the prosecution history does not provide a special, novel, unconventional definition for the word "seam," but simply one particular understanding of a word which could have numerous potential meanings in the context of a medicament. Both in the claims and in the prosecution history, the "seam" is the feature of the medicament where the edges of the two gelatinous coatings are in proximity, just as a seam on a garment is the feature where two pieces of fabric are connected. The '524 patent's prosecution history does not provide a novel definition in contradiction of the common understanding, but rather limits the definition to a particular type of seam, in accordance with the claimed structure that is described and the possible alternatives, such as a line of abutment, which are disavowed. The definition in the prosecution history is thus not a "special" definition, which can only appear in the specification, but is rather an explanation of "the true meaning of language used in the patent claims," which is a proper purpose for it to serve under *Markman*, 52 F.3d at 980.

FN2. "Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning." *York Products*, 99 F.3d at 1572.

Defendant has also argued that the prosecution history limits plaintiff to a definition of "seam" which provides that the transition in thickness is "visible." The patentee asserted at one point in the amendment remarks that the amended claims call for "a visible seam, something which is unwanted in the Richards process." The claim language was not amended to add any mention of visibility of the seam, however, and the remarks do not consistently and specifically emphasize visibility as an element of the seam which separates the claimed invention from the medicament described in Richards. Where the remarks do discuss visibility, they generally describe it as a function of the seam generally, and not as a specific result of the transition in thickness.

The remarks, such as the sentence quoted by defendant regarding a "visible seam", place great stress on the fact that the claimed medicament has a bifurcated color structure, which Richards does not, and that the seam is the feature that occurs at the location of the transition in color, i.e. the juncture of the two gelatinous coatings. The remarks do suggest that the seam is visible, but since they do not describe visibility as a specific result of the transition in thickness, it is doubtful from the remarks that the 'visibility' of the seam results from the transition in thickness. Reading the remarks in context, they suggest that the seam's visibility is due to the transition in color which occurs at the point of the seam. The sentence quoted by

defendant, referring to a "visible seam", appears in the context of a discussion of the process for drying the gelatinous coatings. The patentee states that in Richards, the coatings might be blurred, which is adequate for Richards because in that patent "no color difference is disclosed." In the '524 patent, by contrast, the patentee explains, the gelatin sets quickly, which "prevents undesirable blurring between the colors. It is clear [the remarks continue] that Applicant's structure calls for a visible seam." In that context, the reference to the visibility of the seam appears to refer to the transition in color and not the transition in thickness.

In addition, one aspect of the remarks suggests that the change in thickness is not itself visible at all. The remarks state that the contrast of the colors gives "the illusion of different sizes to the two ends" of the medicament. The fact that the appearance that the two ends of the medicament are of different sizes is only an illusion strongly suggests that any appearance of a 'change in thickness' is also an illusion, and that, even though there may in fact be a change in thickness, no such change is actually visible to the ordinary viewer. The remarks do not establish with any certainty that the change in thickness is not, in fact, visible, but the failure of the remarks to address this point consistently and directly, and the ambiguity of the references to the visibility of features on the surface of the medicament, prevent the prosecution history from serving to clarify whether the "change in thickness" is to be understood as visible or non-visible. The amendment remarks therefore do not limit the construction of the claim term "seam" to a transition of thickness which is actually visible.

### C. "Generally Cylindrical Shape"

The parties also offer competing definitions of the term "cylindrical," and of the resultant meaning of the phrase "generally cylindrical." The Court "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 1584, n. 6. Defendant argues that "cylinder" means "a solid body described by the rotation of a parallelogram round one of its sides [such that] the ends of [the body] are equal and parallel circles." (Defendants' *Markman* Brief at 14) That definition is derived from a non-authoritative dictionary, however, published by Dorset & Baber. At oral argument, defendant did not contest plaintiff's assertion that a respected authority on dictionaries, Kenneth Kister, has dismissed defendant's chosen dictionary as a mediocre, inferior work which is especially shallow on technical terms. ( *See* Appendix to Plaintiff McNeil's Pre- *Markman* Hearing Responsive Brief at A855-A857)

Plaintiff cites a definition derived from Webster's Third New International Dictionary (1961), published by Merriam-Webster. Kister states that it is "a great dictionary," and that its "coverage of the vocabulary of modern science is one of the dictionary's most impressive strengths." (App. Pl. Brief at A861) The definition given by Webster's Third New International is "the surface traced by any straight line moving parallel to a fixed line and intersecting a fixed curve." Webster's at 565. Unlike defendant's proffered definition, plaintiff's definition would not limit the term to objects with curving sides and perfectly circular cross-sections; rather, objects under this definition could have rectangular cross-sections, and curved or straight sides that were conjoined at angles. *See Markman* Hearing on Patent Claim Construction, testimony of Dr. Larry Augsburger, transcript at 85-86. The Court recognizes the authoritative status of this dictionary, and accepts this definition as the plain, ordinary meaning of the term "cylinder."

Unlike the term "seam," "cylinder" is not given a particular definition or limitation in the specification or the prosecution history. Defendant argues that the specification does not disclose any shape other than an oblong tube with a circular cross-section as being appropriate for the medicament or the retaining mechanism for preparing the medicament. Defendant also draws the Court's attention to the patent drawings

depicting an uncoated caplet which is used for the medicaments, and which is described as having a "cylindrical" center portion. *See* '524 patent, Figures 9 and 10.

The drawings in the patent reveal that a circular cross-section is one possible form for a cylinder, as that term is used in the patent, but neither the drawings nor the specification actually define "cylindrical" in a particular manner, or limit the term to the particular form that is used as an example in the drawings. "Where a specification does not require a limitation, that limitation should not be read from the specification into the claims ." *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed.Cir.1988) ( *citing* *Lemelson v. United States*, 752 F.2d 1538, 1551-52 (Fed.Cir.1985)).

At the *Markman* hearing in this case, defendant also offered, as extrinsic evidence, the testimony of Dr. Banker in support of its definition of "cylindrical." Banker testified that someone of ordinary skill in the pharmaceutical arts would understand the term "cylindrical" to refer to an object that is shaped like a right cylinder, i.e. a tube with a perfectly circular cross-section. Banker testified that such persons would analogize the right cylinders found in a typical pharmaceutical laboratory to the medicament claimed in the '524 patent, and, conforming to their understanding of the "capsule" shape that is being simulated, would therefore believe that the medicament claimed in the '524 patent must have a perfectly or nearly circular cross-section.

The Court may rely on expert testimony in order to come to a proper understanding of the meaning of technical or specialized terms in the claims. *See Vitronics*, 90 F.3d at 1584. In this case, the word "cylindrical" is not an unambiguous word in everyday speech, but rather a technical term from geometry, and Dr. Banker's testimony is helpful to the Court in understanding what a person of ordinary skill in the art of pharmaceuticals would understand the term "cylindrical" to mean. Claim 1 does not disclose a strictly cylindrical shape, however-it discloses a caplet with a "generally cylindrical shape." Unlike "cylindrical," "generally" is not a technical term of art for which the Court must seek the guidance of extrinsic evidence. Defendant argues that, in its ordinary meaning, "generally" means "reproducing the details of the model almost, but not quite, perfectly", so that a medicament with a "generally cylindrical shape" must have a "circular, although perhaps not perfectly circular, cross-section." Defendant argues that any shape which does not have an almost perfectly cross-section cannot be "generally cylindrical" because it is, by definition, "distinctly non-cylindrical."

Defendant's argument places too limited a gloss on the word "generally," which, according to Webster's Third New International Dictionary, means "in a general manner; in a reasonably inclusive manner: in disregard of specific instances and with regard to an overall picture; on the whole." Webster's at 945. "Generally" cannot be limited to mean "almost perfectly," as defendant would have the Court read it.

Dr. Banker suggested in his testimony that, in the context of the '524 patent, the phrase "generally cylindrical" follows defendant's proposed definition and means, in essence, "having a circular cross-section". *Markman* Hearing, transcript at 153, 165-166. The Court notes that Banker premised this definition on his understanding that a person skilled in the art would read that phrase together with the phrase "simulated capsule-like medicament" and would, therefore, understand that the thing being imitated was a capsule, which Banker took to mean a medicament with a perfectly circular cross-section. Banker appears not to have offered a definition of the phrase "generally cylindrical" in isolation, but rather to have limited it to the implication drawn from another phrase in the claims.FN3 The phrase "simulated capsule-like medicament" has its own definition, however, and the word "generally" does not take on a different meaning merely by virtue of appearing in the same claim as a separate phrase describing the same medicament. "Generally" is

not defined in the specification or the prosecution history to mean anything other than "generally", and so it does not mean "almost perfectly"-it means "generally," as defined by Webster's.

FN3. In other words, Banker seems not to have actually been addressing the specific meaning of the phrase "generally cylindrical" when he was asked about that particular phrase-his answer reflected his view that the phrase was, as he put it, "defined" by, and interchangeable with, the phrase "simulated capsule-like medicament." *Markman* Hearing, transcript at 153.

The Court notes that Banker testified that something which was "generally cylindrical" would have to be "something that, if not 100 percent cylindrical, be very close to a cylinder." *Markman* hearing, transcript at 153. To the extent that Dr. Banker's testimony would conflict with the broader understanding of the phrase "generally cylindrical," the Court notes that when patent documents are unambiguous, expert testimony regarding the construction of claim terms is entitled to no weight at all, *see* *Vitronics*, 90 F.3d at 1584, and that expert testimony "on the proper construction of a disputed claim term ... may only be relied upon if the patent documents, taken as a whole, are insufficient to enable the court to construe disputed claim terms. Such instances will rarely, if ever, occur." *Id.* at 1585. In this case, the term "generally" is unambiguous, and the Court will not give any weight to Banker's contradictory testimony.FN4

FN4. Moreover, plaintiff presented the testimony of Dr. Augsburger, who stated that in his view, based upon nearly forty years of experience, the phrase "generally cylindrical shape" would be understood by an ordinary person in the field of pharmaceuticals to have the broader meaning ascribed by plaintiff. *See Markman* Hearing, transcript at 82-83. Given that the expert testimony is inconsistent, the Court will accept the view that accords with its understanding of the meaning of the modifier "generally."

The Court agrees with defendant that "generally cylindrical" cannot be defined so broadly as to include shapes that are distinctly non-cylindrical, but at the least, shapes which are generally cylindrical must include shapes which are within the plain, ordinary, dictionary definition of the term "cylinder." Even accepting Dr. Banker's definition of the term "cylindrical" to mean a right cylinder for the purposes of the '524 patent, the addition of the modifier "generally" cannot limit the phrase to objects which have almost perfectly circular cross-sections. A generally cylindrical object resembles a cylinder "in a general manner; in disregard of specific[s] ... and with regard to the whole picture; on the whole." Plaintiff's proffered definition of "cylinder" would encompass defendant's definition, but would also include objects with elliptical or parabolic cross-sections. These latter shapes would resemble a right cylinder on the whole, in disregard of the specific nature of the curve of the exterior surface of the medicament, and without almost perfectly imitating that curve. In light of Banker's testimony about the proper understanding of the term "cylindrical," therefore, the Court will accept plaintiff's proffered definition of the term "cylinder" as the correct construction of the phrase "generally cylindrical shape" for purpose of Claim 1.

#### **IV. CONCLUSION**

The Court concludes that the disputed terms have the following meanings:

1. "Simulated capsule-like medicament" shall mean "a medicinal form that imitates, resembles, or suggests in form or appearance a gelatin shell enclosing medicine."

2. "Partially overlapping said first gelatinous coating and forming a seam" shall mean "extending over and covering part of, but not all of, the first gelatinous coating in a manner such that there is a transition of color and a transition of thickness."

3. "Generally cylindrical shape" shall mean "shape formed by a straight line moving parallel to a fixed line and intersecting a fixed curve."

An appropriate order follows.

### ***ORDER***

AND NOW, this 7<sup>th</sup> day of November, 2000, upon consideration of the briefs and materials submitted by the parties, and after a *Markman* hearing on patent claim construction, it is hereby ORDERED that the following terms in the claims of United States Patent No. 4,820,524 shall be construed to have the definitions herein assigned to them:

1. "Simulated capsule-like medicament" shall mean "a medicinal form that imitates, resembles, or suggests in form or appearance a gelatin shell enclosing medicine."

2. "Partially overlapping said first gelatinous coating and forming a seam" shall mean "extending over and covering part of, but not all of, the first gelatinous coating in a manner such that there is a transition of color and a transition of thickness."

3. "Generally cylindrical shape" shall mean "shape formed by a straight line moving parallel to a fixed line and intersecting a fixed curve."

E.D.Pa.,2000.

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