United States District Court,
M.D. North Carolina.

BANNER PHARMACAPS INC,
Plaintiff.
v.
PERRIGO COMPANY; L. Perrigo Company; and Perrigo Company of South Carolina,
Defendants.

No. 1:04CV492

Feb. 7, 2006.

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RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

WALLACE W. DIXON**, United States Magistrate Judge.**

This matter has been referred to the undersigned for construction of disputed terms of the claims in the patent at issue in this case. On January 26, 2006, a *Markman* hearing was held before the undersigned in which the parties presented their respective arguments over the disputed claim terms. For the reasons set forth below, it will be recommended that the court adopt Banner's proposed interpretations of the disputed claim terms in the '516 patent.

I. Background

Plaintiff Banner designs, manufactures, and sells pharmaceutical products, including over-the-counter medications for the treatment of cold, cough, flu, allergy, and other ailments. FN1 Banner employees conceived of a form of medication wherein a tablet, or "core," is enrobed in a gelatin covering formed by two layers of elastic gelatin film on opposite sides of the tablet. These products are commercially known as Banner's Softlet(R) products. In 2002, Banner obtained a patent on these products, Banner Patent 6,482,516 (the "'516 patent"). Defendant L. Perrigo Company ("L.Perrigo") is a pharmaceutical company which manufactures and sells lower-priced, store-brand alternatives to comparable brand over-the-counter pharmaceutical products. Banner is a vendor to pharmaceutical companies such as L. Perrigo, and for some time supplied to L. Perrigo its gelatin film-enrobed tablets in bulk quantities. Plaintiff has now sued L. Perrigo, its parent, and its sister company, accusing them of infringing the ' 516 patent.

II. The '516 patent

A. The Abstract to the '516 patent

The Abstract to the '516 patent describes a medicinal tablet that

is enrobed in a gelatin coating formed by application of respective layers of elastic gelatin film to opposite sides of the tablet. The applied gelatin layers conform tightly to the tablet surface, bond securely to the tablet, and are sealed together in essentially edge-to-edge manner at a seal line which extends around the tablet at a desired place on the tablet. The gelatin layers can be colored differently from the tablet and differently from each other. A range of formulations are described for film which can be peelable from a tablet or other product core, and for films which bond to the core. A presently preferred formulation for producing tablets having a bonded tamper-evident coating comprises a water-based gelatin preparation having about 45% gelatin and about 9% plasticizer (glycerin and/or sorbitol by weight).

Method and apparatus for producing such new products are also described. Product cores can be dispensed on a self-timed basis into essentially simultaneous contact with two enrobing films which are supported on locally recessed coacting rotary dies. The cores contact the films adjacent a nip between the dies at places on the films which overlie die recesses which are oversize relative to the cores. The films deform around each core and are sealed by the dies to each other before the dies coact to cut the enrobed cores from the films. A core feeding mechanism can include an alignment device which causes the cores to have a desired orientation as they are handled by the dies.

See Def.'s Ex. 2, attached to Def.'s Br. Supp. Mot. for Summ. J.

B. History of the '516 patent

On September 29, 1989, Banner filed a 76-page application (excluding drawings) which resulted in the '516 patent. The 1989 application, containing the written description of the invention at issue, included 85 claims directed to an article, a composition, a method, and an apparatus. Plaintiff prosecuted the application in three stages involving related "continuing" patent applications. The first stage resulted in U.S. Patent No. 5,146,730 (the '730 patent), for a method of enrobing tablets. The second stage resulted in U.S. Patent No. 5,459,983 (the '983 patent) for a tablet-enrobing apparatus. The third stage resulted in the '516 patent. The prosecution of the '516 patent involved an appeal to the Board of Patent Appeals and Interferences ("Board"). The ' 516 patent issued on November 19, 2002.

C. The Claims of the '516 patent

The '516 patent contains 24 claims. Claims 1, 8, 15, 22, 23, and 24 are independent claims. Claims 2-7 depend from Claim 1, Claims 9-14 depend from Claim 8, and Claims 16-21 depend from Claim 15. The claims are as follows:

1. An article of manufacture comprising a unitary article preform of selected shape and size and an enrobing covering fully enclosing the preform, the covering being comprised of two applied layers of preformed film material of selected thickness and composition which substantially conforms to the contours of the preform and which are sealed to each other in substantially edge to edge relation along a line which encircles the preform and which lies substantially in a common plane; wherein the covering adheres sufficiently tightly and securely to the preform that the covering cannot mechanically be removed from the preform without

removal of a part of the core.

2. The article of manufacture of claim 1 wherein the covering is thicker along the line sealing the two preformed films.

3. The article of manufacture of claim 1 wherein the thickness of covering is between and about 0.005 to 0.045 inches.

4. The article of manufacture of claim 1 wherein the thickness of covering is between and about 0.02 to 0.04 inches.

5. The article of manufacture of claim 1 wherein the covering is a different color than the preform.

6. The gelatin enrobed tablet of claim 1 wherein the shape of the preform has a major plane of symmetry that encompasses the maximum symmetrical cross-sectional area of the preform, and a secondary plane of symmetry that is perpendicular to the major plane of symmetry, wherein the covering seam line defines a plane that lies substantially within the secondary plane of symmetry of the preform.

7. The article of manufacture of claim 1 wherein the shape of the preform has a major plane of symmetry that encompasses the maximum symmetrical cross-sectional area of the preform, and wherein the covering seam line lies substantially within the major plane of symmetry of the preform.

8. A gelatin enrobed tablet comprising a tablet core and a gelatin covering enrobing the core, the covering being comprised of two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the covering being comprised of gelatin and a plasticizer present in a weight ratio of from about 3:1 to about 15:1.

9. A tablet according to claim 8 wherein the covering adheres sufficiently tightly and securely to the core that coating cannot mechanically be removed from the core without removal of a part of the core.

10. The gelatin enrobed tablet of claim 8 where the covering is comprised by weight of about 40 percent to 60 percent gelatin, and 5 percent to 12 percent plasticizer.

11. The gelatin enrobed tablet of claim 8 further comprising by weight 35 percent to 50 percent water and colorants and pigments in the range of 0.1 percent to 3 percent.

12. The gelatin enrobed tablet of claim 8 where the gelatin covering has a bloom value of between about 100 and 300.

13. The gelatin enrobed tablet of claim 8 where the gelatin covering has a bloom value of between about 120 and 250.

14. The gelatin enrobed tablet of claim 8 where the gelatin covering has a bloom value of between about 150 and 180.

15. A gelatin enrobed tablet comprising a tablet core and a gelatin covering enrobing the core, the covering being comprised of two layers of preformed gelatin film which are sealed together along and terminate at a

line encircling the core, the covering adhering to the core sufficiently tightly and securely that the covering cannot mechanically be removed from the core without removal of a part [o]f the core.

16. The gelatin enrobed tablet of claim 15 wherein the covering is thicker along the line sealing the two preformed films.

17. The gelatin enrobed tablet of claim 15 wherein the thickness of covering is between and about 0.005 to 0.045 inches.

18. The gelatin enrobed tablet of claim 15 wherein the thickness of covering is between and about 0.02 to 0.04 inches.

19. The gelatin enrobed tablet of claim 15 wherein the covering is a different color than the preform.

20. The gelatin enrobed tablet of claim 15 wherein the shape of the preform has a major plane of symmetry that encompasses the maximum symmetrical cross-sectional area of the preform, and a secondary plane of symmetry that is perpendicular to the major plane of symmetry, wherein the covering seam line defines a plane that lies substantially within the secondary plane of symmetry of the preform.

21. The gelatin enrobed tablet of claim 15 wherein the shape of the preform has a major plane of symmetry that encompasses the maximum symmetrical cross-sectional area of the preform, and wherein the covering seam line lies substantially within the major plane of symmetry of the preform.

22. A gelatin enrobed tablet comprising a tablet core and a gelatin covering enrobing the core, the covering being comprised of two layers of preformed gelatin film which are sealed together along and terminate at a seam line encircling the core, the covering conforming to the core contours, having no opening in it, and adhering to the core; wherein the covering is comprised of gelatin and of a plasticizer present in a weight ratio in the range of from about 3:1 to about 15:1.

23. A gelatin enrobed tablet comprising a tablet core and a gelatin covering enrobing the core, the covering being comprised of two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the covering adhering to the core, the covering being nominally thicker along the seal line than elsewhere on the enrobed tablet; wherein the covering adheres sufficiently tightly and securely to the core that the covering cannot mechanically be removed from the core without removal of a part of the core.

24. A gelatin enrobed tablet comprising a tablet core and a gelatin covering enrobing the core, the covering being comprised of two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the covering adhering to the core, the covering being nominally thicker along the seal line than elsewhere on the enrobed tablet; wherein the covering is comprised of gelatin and of a plasticizer present in a weight ratio of from about 3:1 to 15:1.

III. Markman Analysis

A determination of patent infringement involves a two-step analysis. First, the court must determine the scope and meaning of the asserted claims. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed.Cir.1998) (citing Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d

577 (1996)). Next, the construed claims must be compared to the allegedly infringing device. *Id*. It is well settled that claim construction is a matter of law for the court to decide. *Id*. Moreover, "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.' " Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004)).

Words in a claim "are generally given their ordinary and customary meaning." Phillips, 415 F.3d at 1312 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996)). In arriving at the "ordinary and customary meaning" of a claim term, the central inquiry is what meaning "the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313. To understand that meaning, the court may rely on a variety of evidentiary sources, including intrinsic evidence, such as the patent's claims, specification, and prosecution history, and extrinsic evidence, such as inventor testimonies, expert testimony, dictionaries, and treatises. *See generally* Phillips, 415 F.3d at 1317-19. Sometimes the ordinary and customary meaning of a claim term will be readily understood, and the claim construction will involve "little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314 (citing Brown v. 3M, 265 F.3d 1349, 1352 (Fed.Cir.2001)). "In such circumstances, general purpose dictionaries may be helpful." *Id*. Many times, however, understanding the ordinary and customary meaning of the claim term in a field of art requires more elaborate interpretation. *Id*. In any event, in considering both intrinsic and extrinsic evidence, it does not matter which type of evidence the court examines first, as long as the court affords the appropriate weight to each evidentiary source to avoid misinterpreting a claim term. Phillips, 415 F.3d at 1324 ("The sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law.") Under this weighted-evidence approach, intrinsic evidence, particularly a patent's specification, is entitled to more weight than extrinsic evidence. *Id*.

With respect to a patent's specification, the Federal Circuit has stated that this source of intrinsic evidence is the "single best guide to the meaning of a disputed term." *Id*. at 1315. At the same time, the Federal Circuit has warned against the danger of importing limitations from a patent's specification into the claim terms. *Id*. at 1319-20. The Federal Circuit has further noted that such danger particularly exists when one attempts to confine the claims to specific embodiments of the invention as characterized in the specification. *Id*. at 1323. Indeed, "persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." *Id*. Accordingly, a patent's claims may embrace "different subject matter than is illustrated in specific embodiments in the specification." Nazomi Commc'ns, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1369 (Fed.Cir.2005).

The court may also consider the prosecution history of the patent to assist the court in interpreting the claims since this source of intrinsic evidence provides insight into how the inventor and the PTO understood the invention. Phillips, 415 F.3d at 1317. Nevertheless, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id*. This is particularly true when the prosecution history is ambiguous as to the meaning of a term. Inverness Med. Switzerland GmbH v. Warner Lambert Co., 309 F.3d 1373, 1380-82 (Fed.Cir.2002); *see also* Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325-26 (Fed.Cir.2003) (stating that for the prosecution history to be useful it must clearly and unmistakably disavow claim scope).

Finally, extrinsic evidence may also be considered to assist the court in understanding the underlying

technology as long as this evidence is weighted appropriately against intrinsic evidence. Phillips, 415 F.3d at 1317. For example, the Federal Circuit has made clear that dictionaries remain useful to "assist in understanding the commonly understood meaning of words." Id. at 1322. As the Federal Circuit reiterated in *Phillips:*

a judge who encounters a claim term while reading a patent might consult a general purpose or specialized dictionary to begin to understand the meaning of the term, before reviewing the remainder of the patent to determine how the patentee has used the term. The sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law.

Id. at 1324 (citing Vitronics, 90 F.3d at 1582). With these principles in mind, the court now turns to the parties' respective *Markman* arguments.

Person of Ordinary Skill In the Art

Since the court must construe the claims from the vantage point of a person of ordinary skill in the art, the court must first determine the level of ordinary skill in the art for purposes of construing the claims' terms. Phillips, 415 F.3d at 1313. At the *Markman* hearing, Banner took the position that a person of ordinary skill in the art has at least a bachelor's degree in the chemical arts and has some practical experience, either in chemical engineering, or in the processing of chemical formulations into various finished products, with some practical experience either in chemical engineering or in the chemistry of formulating materials. L. Perrigo did not object to Banner's proposed definition but added that the person would have some experience in the gelatin film-sealing field. For the purposes of construing the claims, the court should find that a person of ordinary skill in the art has at least a bachelor's degree in the chemical arts and has some practical experience, either in chemical engineering, or in the processing of chemical formulations into various finished products, with some practical experience either in chemical engineering or in the chemistry of formulating materials, and with some experience in the gelatin film-sealing field.

1. The phrase "sealed to each other in substantially edge to edge relation" in Claim 1

Claim One describes

[a]n article of manufacture comprising a unitary article preform of selected shape and size and an enrobing covering fully enclosing the preform, the covering being comprised of two applied layers of preformed film material of selected thickness and composition which substantially conforms to the contours of the preform and which are *sealed to each other in substantially edge to edge relation* along a line which encircles the preform and which lies substantially in a common plane; wherein the covering adheres sufficiently tightly and securely to the preform that the covering cannot mechanically be removed from the preform without removal of a part of the core.

The Parties' Proposed Constructions

The only disputed language in Claim 1 is the phrase "sealed to each other in substantially edge-to-edge relation." L. Perrigo would like for the court to construe this language to mean "the sealed relationship between the two applied layers of preformed film material after they have come together to form the covering, and after they have been cut where the two films come together." Banner would like for the court to construe this same language to mean "the sealed relationship between the two applied layers of preformed

film material after they come together to form the covering." For the following reasons, it is recommended that the court adopt Banner's proposed construction of the disputed language in Claim 1.

Analysis

Under Banner's interpretation of the above-disputed language, the "sealed edge to edge relation" describes the relationship of the two applied films of the enrobed product according to the ordinary meaning of the words in view of the written description provided in the '516 patent specification. In discussing Figures 1-4, which describe enrobed products, the specification explicitly states that the "[c]oating 12 is defined by layers 13 and 14 of soft elastic gelatin film which are applied to opposite sides of the core and which are sealed together, in an essentially edge-to-edge manner, along a seal line 15 which encircles the core." Col. 7, lines 1-5; *see also* Col. 8, lines 1-5 (discussing the sealed line); '516 Patent, Fig. 6, Item 15. By contrast, Perrigo's proposed claim construction attempts to add limitations into the terms of Claim 1. In particular, Perrigo attempts to add a "cutting" requirement to the "sealed edge-to-edge" language. No such cutting step is involved, however, with any reasonable interpretation of the words "substantially edge to edge relation." Of course, cutting the films at the seal line is one embodiment of the method described in the patent specification. The specific language in Claim 1, however, does not require cutting as the means for separating the two films so that they become sealed together in substantially edge-to-edge relation. As Banner noted at the *Markman* hearing, it is conceivable that the films could be separated by some method other than cutting, so construing Claim 1 to require cutting as the means for separation unnecessarily narrows the language of Claim 1. FN2

In any event, as Banner further pointed out in the *Markman* hearing, L. Perrigo has already admitted in discovery that it imports products comprising a unitary article preform of selected shape and size and an enrobing covering fully enclosing the preform wherein the covering is comprised of two applied layers of preformed film material of selected thickness and composition which substantially conforms to the contours of the preform and "which are sealed to each other in substantially edge to edge relation." FN3 *See* L. Perrigo's Admissions No. 30. Therefore, the court agrees with Banner that there should be no dispute over the interpretation of the above-cited terms in Claim 1. For these reasons, it is recommended that the court adopt Banner's proposed construction of the above-disputed language in Claim 1.

2. The phrase "sealed together along and terminate at a line" in Claim 8

Claim 8 describes

A gelatin enrobed tablet comprising a tablet core and a gelatin covering enrobing the core, the covering being comprised of two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the covering being comprised of gelatin and a plasticizer present in a weight ratio of from about 3:1 to about 15:1.

The Parties' Proposed Constructions

The disputed language in Claim 8 involves the phrase "sealed together along and terminate at a line." The parties do not dispute that this phrase "describes the sealed relationship between the two films after they come together to form the covering." Additionally, the parties do not dispute that the juncture of the two films forms a line that "encircles the tablet core." The parties do dispute, however, whether this phrase requires an additional limitation that the line encircling the core exists as a result of the two films being "cut" where the two films come together. L. Perrigo would like for the court to construe the phrase "sealed

together along and terminate at a line" to mean "the sealed relationship between the two films after they come together to form the covering, *and have been cut* where the two films come together to form a line that encircles the tablet core." Banner, on the other hand, would like for the court to construe this phrase to mean "the sealed relationship between the two films after they come together to form the covering, forming a line that encircles the tablet core." For the following reasons, it is recommended that the court adopt Banner's proposed construction of the disputed language in Claim 8.

Analysis

Here, the parties' dispute over the construction of the phrase "sealed together along and terminate at a line" mirrors their dispute over the "sealed to each other in substantially edge to edge relation" language of Claim 1. In other words, L. Perrigo would like for the court to read into this language a prerequisite "cutting" requirement. For the same reasons given as to Claim 1, the court should not construe the language in Claim 8 to require this additional cutting step. Here, as Banner noted in the *Markman* hearing, the "sealed together along and terminate at a line" phrase describes the relationship of the two applied films of the enrobed product according to the ordinary meaning of the words in view of the written description provided in the '516 patent specification, and L. Perrigo's interpretation unnecessarily narrows the scope of the claim by adding a cutting step as a limitation. As with the language in Claim 1, while "cutting" the films at the seal line is one embodiment of the method described in the patent specification, there is no justification for adding such a method limitation to product Claim 8.

Furthermore, L. Perrigo admitted in discovery that it imports a gelatin-enrobed tablet comprising a tablet core and a gelatin covering enrobing the core wherein the covering is comprised of two layers of preformed gelatin film which are "sealed together along and terminate at a line encircling the core." See Ex. 4, L. Perrigo, Admission Nos. 15, 16. 17, 44, and 53. Additionally, in a previous summary judgment motion, L. Perrigo has already conceded that, to the extent that the patent is valid, its products made with a gelatin-to-plasticizer ratio of 4.8:1 literally infringe Claim 8. *See* Banner Pharmacaps Inc. v. Perrigo Co., No. 1:04CV492, 2005 WL 2136927, at *2-3 (M.D.N.C. Aug.1, 2005). Therefore, the court agrees with Banner that there should be no dispute over the interpretation of the terms in Claim 8. For all these reasons, it is recommended that the court adopt Banner's proposed construction of the above-disputed language in Claim 8.

3. The phrase "the covering adheres sufficiently tightly and securely to the preform [or to the core] that the covering cannot mechanically be removed from the preform [or from the core] without removal of a part of the core" in Claims 1, 9, 15, and 23

The next disputed language involves the following phrase, found in Claims 1, 9, 15, and 23: "The covering adheres sufficiently tightly and securely to the preform [or to the core] that the covering cannot mechanically be removed from the preform [or from the core] without removal of a part of the core."

The Parties' Proposed Constructions

L. Perrigo would like for the court to construe the above-cited language to mean that

the covering adheres tenaciously to the core, such that in all tablets made in accordance with the teaching of the patent, the covering cannot under any conditions be mechanically removed from the core without removal of a part of the core. "Removal of a part of the core" refers to removal of a sufficiently large amount of the core that a typical customer can tell by looking at the core with a typical customer's usual

degree of care that the core has been substantially damaged. The damage must be the result of the tenacious adherence between the covering and the core, rather than from other factors. The terms "core" and "preform" mean the same thing. The [term] "core" means the entirety of the object that is enrobed by the layers of film. The term "core" would encompass any surface coatings such as HPMC or carnauba wax.

Banner, on the other hand, would like for the court to construe the above-cited language to mean that

the covering adheres to the core in a sufficiently tight and secure manner such that one cannot physically remove the covering without removing a part of the core. Visible indications of efforts to remove the covering might exist on the core's surface itself or on the undersurface of at least a portion of a removed covering or on both surfaces. The terms "core" and "preform" mean the same thing. The [term] "core" means the entirety of the object (including the "dosage formulation") that is enrobed by the layers of film. The term "core" would encompass any surface coatings such as HPMC or carnauba wax.

In construing the above-cited language from Claims 1, 9, 15, and 23, the parties' proposed interpretations of the words "core" and "preform" are not significantly different. The heart of the dispute between the parties, rather, is directed to the degree of adherence that is required by the words "sufficiently tightly and securely to the preform [or to the core] that the covering cannot mechanically be removed from the preform [or from the core] without removal of a part of the core." For instance, L. Perrigo argues that the court must construe the phrase "removal of a part of the core" as meaning "removal of a sufficiently large amount of the core that a typical customer can tell by looking at the core with a typical customer's usual degree of care that the core has been substantially damaged." L. Perrigo would also like to incorporate the descriptive term "tenacious" into the language "adheres to the core in a sufficiently tight and secure manner such that one cannot physically remove the covering without removing a part of the core." For the following reasons, it is recommended that the court adopt Banner's proposed construction of the disputed language in Claims 1, 9, 15, and 23.

Analysis

The court first notes that the parties have already disputed the meaning of the language in Claims 1, 9, 15, and 23 in a previous summary judgment motion in the context of L. Perrigo's invalidity argument, and the court has already interpreted some of the language in these claims. As the undersigned noted in an earlier Recommendation that has since been adopted by the court, the specification to the '516 patent describes varying degrees of "adherence," and there is nothing in the patent specification to indicate that the words "tightly" and "securely" must be afforded some special definition, such as "tenacious" or "tamper-evident." *See* Recommendation, p. 8-10, 19-22, 1:04CV492 (M.D.N.C. Nov. 7 2005), adopted Jan. 4, 2006. Moreover, as Banner has pointed out, although L. Perrigo argues that the degree of adhesion is "tenacious," nowhere in either the specification or the file history is the term "tenacious" ever used to describe the claimed invention. By contrast, the specification contains several instances where the terms "tightly" or "securely" are used to describe the several embodiments of a gelatin-enrobed tablet claimed in the specification for the '516 patent. For instance, in Col. 4, lines 49-57, the specification states:

The film material applied in tablet-enrobing manner to the tablet is a gelatin-base film so formulated that, as applied to and sealed around the tablet, it conforms tightly to the tablet contours and bonds securely to the tablet surfaces, is colored differently from the tablet, and dries to a hard state. The resulting product is stronger than the preform itself and provides a readily visible indication of efforts to remove the enrobing film from the tablet, whereby the enrobed tablet is tamper-evident.

Further explaining this embodiment, in Col. 20, lines 42-46, the specification states:

The other aspect of film adhesion is relevant during the product drying process where the applied gelatin layers forming the gelatin coating around the enrobed product *becomes an integral part of the finished product and cannot, as presently preferred, be physically removed without damaging the core*.

Col. 20, lines 42-46 (emphasis added). In another embodiment, at Col. 7, lines 7-9, the specification states:

After being applied to and sealed together around the core, layers 13 and 14 dry to a hard, glass-like state, *in which the coating is securely bonded* to the core.

Col. 7, lines 7-9 (emphasis added). Finally, at Col. 24, lines 49-53, the specification states:

The presently preferred product of this invention, as noted above, is a medicine tablet to which the applied-film enrobing coating *conforms in an air-tight manner* and to which that coating *tightly adheres upon curing (drying) to a hard glass-like state*.

Col. 24, lines 49-53 (emphases added). Fundamental to claim construction is reading the claims in light of the specification. Here, Banner's requested interpretation, including that "one cannot physically remove the covering without some disruption of the core" is consistent with the plain meaning of the words used in Claims 1, 9, 15, and 23 and with the manner in which those words are described in the specification. By contrast, Perrigo's proposed construction imports the limitations "sufficiently large amount of the core," "typical consumer can tell by looking at the core," "customer's usual degree of care," "substantially damaged," and 19 "damage must be the result of the tenacious adherence." L. Perrigo offers no sound explanation for why the court should import these additional words into Claims 1, 9, 15, and 23. As already noted, the specification does not contain the word "tenacious." Furthermore, while being "tamper-evident" is certainly a touted feature of the tablet described in the '516 patent, there is no need to import this word into the disputed claim terms themselves.

Finally, introducing the additional words requested by L. Perrigo merely invites further interpretation. For instance, construing the language of the claims to include terms such as "typical customer" and the typical customer's "usual degree of care" would require the court to identify the "typical customer" as well as the "usual degree of care." For example, is the "typical customer" using their "usual degree of care" a person with 20/20 vision who routinely and carefully inspects the coverings of medicine tablets before ingesting them to make sure that they have not been tampered with? Or, rather, is the "typical customer" using their "usual degree of care" a person who has less than perfect eyesight and who does not think to inspect the covering of a medicine tablet before ingesting it? As these examples demonstrate, L. Perrigo's proposed interpretation of the disputed claims language opens up a whole new "can of worms" and is simply not supported by the plain meaning of words in the claims and the specification. In sum, the court agrees with Banner that there is no justification for L. Perrigo's narrow reading of the terms in Claims 1, 9, 15, and 23. For these reasons, it is recommended that the court adopt Banner's proposed construction of the above-disputed language in Claims 1, 9, 15, and 23.

4. The phrase "the covering is thicker along the line sealing the two preformed films" in Claims 2 and 16

Claim 2 describes "an article of manufacture of claim 1 wherein the covering is thicker along the line sealing

the two preformed films." Claim 16 describes "[t]he gelatin enrobed tablet of claim 15 wherein the covering is thicker along the line sealing the two preformed films." The parties dispute the meaning of the phrase "wherein the covering is thicker along the line sealing the two preformed films" in these two claims.

The Parties' Proposed Constructions

L. Perrigo would like for the court to interpret the above-cited language to mean that "there is a very slight thickening along the seal or seam line which is a characteristic signature of the enrobing process." Banner would like for the court to interpret this language to mean that "along the line at which the two preformed films are sealed together, the depth of covering, as measured from the outer surface of the covering to the inner surface of the covering contacting the preform, is greater than the depth of covering elsewhere." For the following reasons, it is recommended that the court adopt Banner's proposed construction of the disputed language in Claims 2 and 16.

Analysis

The court first looks at the plain meaning of the claims' terms. The term "thick" means "having or being of relatively great depth or extent from one surface to its opposite surface." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 1225 (10th ed.1998). As Banner notes, because of this commonly known and understood meaning, the '516 patent uses the term "thick" or variations of the word, such as "thickness" and "thickening," numerous times throughout the specification to describe various embodiments of the enrobed product and processes for making the enrobed product. It is also commonly known and understood that the term "thicker" is a relative term, meaning that something has a greater depth at one area or region relative to another area or region. The court agrees with Banner that, by relying on these commonly understood meanings of "thick" and "thicker," Claims 2 and 16 use the term "thicker" to describe the depth of the gelatin films at the seam line where the two films of the enrobed product are sealed together and to compare that thickness to the thickness of other regions of the gelatin film. Thus, as Claims 2 and 16 read, the meaning is clear that the depth of the films at the seam line is greater than the depth of the films elsewhere, as measured from the surface of the covering to the inner surface of the covering.

Here, L. Perrigo attempts to narrow the scope of the term "thicker" as used in Claims 2 and 16 to a "very slight" thickening. As a purported basis for this narrowed interpretation, L. Perrigo points to Column 8, lines 27-31 of the patent specification, where the specification describes enrobed tablets that are produced by a preferred rotary die process as having a "characteristic signature" of a "very slight thickening of [the] coating ... along [the] seam line...." L. Perrigo further notes that the embodiment of the invention described at Column 8, lines 27-31 of the specification is the subject of Claims 23 and 24, which refer to a covering that is "nominally thicker along the seal line." L. Perrigo contends that since Banner and Perrigo have agreed that the language "nominally thicker" in Claims 23 and 24 should be interpreted to mean "very slight thickening," then the same interpretation should be applied to the term "thicker" as it appears in Claims 2 and 16. For the following reasons, the court should reject both of L. Perrigo's arguments.

First, the enrobed tablet with a "very slight thickening" along the seam line that is described in Column 8, lines 27-31 is merely a preferred embodiment of the more broadly described gelatin-enrobed tablet having a cover that is "thicker" along the seam line. Moreover, the patent specification neither states nor suggests that the two terms "thicker" and "nominally thicker" are of equal scope. Indeed, the two terms are of plainly different scope due to the presence of the adjective "nominally." L. Perrigo gives no justification for ignoring the ordinary and customary meanings of such terms to define "thicker" and "nominally thicker" as being of equal scope. Finally, as Banner notes, L. Perrigo has already admitted in discovery that it imports

articles of manufacture and gelatin-enrobed tablets in which the covering is "thicker" along the line sealing the two preformed films. *See* L. Perrigo's Admissions Nos. 32 and 41. The court, therefore, agrees with Banner that the meaning of the word "thicker" in Claims 2 and 16 should not be in dispute. For these reasons, it is recommended that the court adopt Banner's proposed construction of the above-disputed language in Claims 2 and 16.

5. The phrase "a gelatin enrobed tablet comprising a tablet core and gelatin covering enrobing the core" as found in Claims 8, 15, 22, 23, and 24

The parties dispute the meaning of the phrase "a gelatin enrobed tablet comprising a tablet core and gelatin covering enrobing the core" as found in Claims 8, 15, 22, 23, and 24.

The Parties' Proposed Constructions

L. Perrigo would like for this court to construe the phrase "a gelatin enrobed tablet comprising a tablet core and gelatin covering enrobing the core" as meaning that the "covering is made of a material containing gelatin, and enrobes the core, though as to claims 8, 15, 23, and 24, not necessarily 'fully,' or 'having no opening in it' as is specifically required by claim 1 and claim 22, respectively." Banner, on the other hand, would like for the court to construe the phrase as meaning the "covering is made of a material containing gelatin, and the covering enrobes the core." For the following reasons, it is recommended that the court adopt Banner's proposed construction of the above-disputed language in Claims 8, 15, 22, 23, and 24.

Analysis

Here, the dispute is over whether the phrase "a gelatin enrobed tablet comprising a tablet core and gelatin covering enrobing the core" should be interpreted to mean that the covering that enrobes the core does not necessarily enrobe the core fully-in other words, the covering may have holes in it. The specification explicitly defines the terms "covering" and "enrobe" to mean an "enclosing layer ... around" the core. In particular, Col. 4, lines 1-11 of the specification state:

The following description of this invention and the appended claims use the terms "coat," "coating," "enrobe," and "covering" to refer to and to describe the enclosing layer which the practice of this invention provides *around* a medicine tablet, for example. In that context, unless the specific usage indicates otherwise, the words "coat" and "coating" are used in the same sense and meaning as "cover" and "covering" and not in the sense of an outer tablet layer which is formed incrementally over some period of time on a tablet core by techniques known in the pharmaceutical industry as "pan coating" or their equivalents.

Col. 4, lines 1-11 (emphasis added). Moreover, the specification teaches broadly that the "enrobed product" has a "hermetically sealed applied-film coating around the tablet or other solid core." Col. 6, lines 48-50. According to its dictionary definition, "hermetically" means "airtight" and "impervious to external influence." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 543 (10th ed.1998). "Sealed" means "to close or make secure against access, leakage, or passage by a fastening or coating." *Id*. at 1052. Finally, the specification also describes the film coating as "continuous," meaning that no holes or openings would exist. Col. 6, line 51.

Despite the plain language of the specification, L. Perrigo contends that Claims 8, 15, 23, and 24 should be interpreted to encompass a covering that does not fully enrobe the core or a covering that includes openings.

Under L. Perrigo's construction, the covering described in Claims 8, 15, 23, and 24 might have holes, whereas the covering of Claims 1 and 22 would cover the entirety of the core surface. There is no support for such a distinction anywhere in the specification. Indeed, the only justification that L. Perrigo gives for assigning such a narrow meaning to the terms used in Claims 8, 15, 22, 23, and 24 is the fact that Claims 1 and 22 specifically describe a covering that "fully" encloses the core and that "have[ ] no opening." L. Perrigo asserts that since Claims 8, 15, 22, 23, and 24 do not also contain this language, then by negative implication Claims 8, 15, 22, 23, and 24 must allow for openings. The court does not agree and finds that, rather than limiting the meaning of the language in Claims, the terms "fully" and "having no opening" as used in Claims 1 and 22 further define the coverings described in Claims 8, 15, 22, 23, and 24 as an enclosing layer around the core that is continuous and impervious to external influence (i.e., has no openings). FN4 For these reasons, it is recommended that the court adopt Banner's proposed construction of the above-disputed language in Claims 8, 15, 22, 23, and 24.

6. The phrase "gelatin and a plasticizer present in a weight ratio of from about 3:1 to (about) 15:1" as used in Claims 8, 22, and 24

The parties next dispute the meaning of the phrase "gelatin and a plasticizer present in a weight ratio of from about 3:1 to (about) 15:1" in Claims 8, 22, and 24.

The Parties' Proposed Constructions

L. Perrigo would like for the court to construe the above-stated language in Claims 8, 22, and 24 in the following manner: that " 'about 3:1 to about 15:1,' or 'about 3:1 to 15:1' means '3:1 to 15:1,' as stated in the application as originally filed." L. Perrigo proposes, alternatively, that the court construe the claims to mean that the phrase "about 3:1" means "no less than 2.95 to 1 ." FN5 Banner, on the other hand, would like for the court to construe the disputed language so that the

term "about" means approximately and is an indicator that an exact limit is not claimed and that variation is expected. The phrase "gelatin and a plasticizer present in a weight ratio of from about 3:1 to about 15:1" and other similar language means that the range of gelatin to plasticizer ratios is inexact and thereby could fall somewhat outside of the range of 3:1 to 15:1. When determining whether a particular ratio for gelatin to plasticizer is within the range of about 3:1 to 15:1, all the attributes and properties of covering materials as identified in the patent specification, the prosecution history, and the prior art, should be considered.

For the following reasons, it is recommended that the court adopt Banner's proposed construction of the above-disputed language in Claims 8, 22, and 24.

Analysis

Here, Banner argues that the term "about" in the phrase "about 3:1 to about 15:1" means "approximately" and is an indicator that an exact limit is not claimed. L. Perrigo argues, on the other hand, that "about 3:1 to about 15:1" or "about 3:1 to 15:1" means "exactly 3:1 to 15:1" as stated in the application as originally filed. Alternatively, L. Perrigo would like for the court to construe "about 3:1" to mean no less than 2.95:1. According to L. Perrigo, this alternative construction is appropriate because during prosecution of the patent Banner specifically abandoned any gelatin-to-plasticizer ratios falling below 2.94:1 in order to avoid the prior art.

First, as for the meaning of the term "about" in Claims 8, 22, and 24, the court need not spend too much

time on this issue because the court has already construed this term when addressing L. Perrigo's invalidity argument in a prior summary judgment motion. It is well settled that claims construed for the purpose of determining validity must be construed the same way for the purpose of determining infringement. *See* W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1279 (Fed.Cir.1988). In L. Perrigo's prior summary judgment motion, L. Perrigo argued that the '516 patent was invalid for lack of enablement. The court found that the patent was not invalid for lack of enablement. As the court explained, because of the nature of the invention, some variation of gelatin-to-plasticizer ratios must be expected; therefore, it would be impossible to give an exact ratio, and failure to do so did not render the patent non-enabling. The court further noted that, while some experimentation would be necessary to achieve a gelatin-to-plasticizer ratio with the desired adherence, L. Perrigo had not shown that the teaching of the patent was so vague that "undue experimentation" was required to achieve the patented result. In holding this way, the court proceeded on the assumption that the word "about" indicated an approximation, so that ranges below 3:1 and ranges above 15:1 were included in the claim terms. Indeed, L. Perrigo proceeded on this same assumption, arguing that because an approximate range was given the patent did not teach one skilled in the art how to make the invention over the full scope of the claims.FN6 Thus, although it was in the context of addressing L. Perrigo's invalidity argument, the court has already construed the word "about" to mean "approximate." Having construed the claims one way for determining their validity, "it is axiomatic that the claims must be construed in the same way for infringement." W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1279 (Fed.Cir.1988) (citing Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1449 (Fed.Cir.1984)).

In any event, to the extent that the court did not explicitly state its reasons for interpreting the term "about" in its earlier summary judgment ruling to mean "approximately," and for clarification, the court will do so now. The court first looks to the plain meaning of the word "about." The relevant dictionary definition of the term "about" indicates that the common usage of the term means "approximately," "almost," or "nearly." WEBSTER'S NEW INTERNATIONAL DICTIONARY 5 (3d ed.1993).

Consistent with this dictionary definition, the Federal Circuit has recently confirmed that the word "about" should usually be given its ordinary meaning of "approximately." Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1369 (Fed.Cir.2005); *see also* In re Indep. Serv. Orgs. Antitrust Litig., 85 F.Supp.2d 1130, 1165 (D.Kan.2000) (stating that "about" means "reasonably close to"); Minn. Mining & Mfg. Co. v. Beautone Specialties Co., Ltd., 117 F.Supp.2d 72, 88 (D.Mass.1999) (stating that "the term 'about' suggests that there is some degree of flexibility"); Evans Med. Ltd. v. American Cyanamid Co., 11 F.Supp.2d 338, 353 (S.D.N.Y.1998) (determining that a ratio does not have to be exact). In discussing use of the word "about" in patent claims, the Federal Circuit has further stated that:

[s]uch broadening usages as "about" must be given reasonable scope; they must be viewed by the decisionmaker as they would be understood by persons experienced in the field of the invention. Although it is rarely feasible to attach a precise limit to "about," the usage can usually be understood in light of the technology embodied in the invention. When the claims are applied to an accused device, it is a question of technological fact whether the accused device meets a reasonable meeting of "about" in the particular circumstances.

Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1554 (Fed.Cir.1996) (citations omitted).

Here, there is nothing in the written description of the '516 patent or the claim terms themselves to indicate

that the patentee intended to redefine or use the term "about" in a manner different from its ordinary meaning. Indeed, L. Perrigo's preferred interpretation of "about" would render this language in the patent redundant and therefore meaningless. That is, if "from about 3:1 to about 15:1" means "from exactly 3:1 to exactly 15:1," then the word "about" in the patent claims is entirely meaningless. *Accord* Sunny Fresh Foods, Inc. v. Michael Foods, Inc., 205 F.Supp.2d 1077, 1091 (D.Minn.2002) (construing the words "about 8 weeks to about 36 weeks" to mean "approximately 8 weeks to approximately 36 weeks," where an alternative construction would have rendered the word "about" meaningless).

Furthermore, and as the court stated in the earlier summary judgment motion addressing the validity of the '516 patent, the language of the patent's specification supports the interpretation of the word "about" to mean "approximately." The specification makes clear that the gelatin-to-plasticizer ratio necessary to achieve the desired adherence will depend on numerous variables, such as the attributes and properties of the covering materials and the type of core that is being covered. As noted in the specification, several features of the gelatin, for example, including gelatin, gelatin type, source, and formula impact the film's "elasticity, the ability of the films to adhere to cores dispensed to the films, and adhesion of the films to the dies." Col. 20, lines 30-38. Similarly, the gelatin bloom value can affect the physical and mechanical properties of the gelatin. Id. Because these different gel components all affect the physical behaviors of the gelatin film, it is logical that a range of gelatinto-plasticizer ratios is necessary to encompass film compositions compatible with the enrobed tablet invention as claimed. *See, e.g.,* Chemical Separation Tech., Inc. v. United States, 51 Fed. Cl. 771, 782 (Fed.Cl.2002) (stating that "the usage [of the word 'about'] can usually be understood in light of the technology embodied in the invention") (quoting ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT s. 5.6(b), at 251 (5th ed.2001)). In fact, the written description in the '516 patent specification includes the use of relative terms such as "low ratios" and "high ratios" to describe the amounts of gelatin to plasticizer that are compatible with the invention as claimed. Col. 20, lines 54-57. The specification also states that " *most* tablet cores" will fall within the 3:1 to 15:1 range, acknowledging that some film compositions expressly outside this range will function within the ambit of the invention. As stated in the earlier recommendation on summary judgment:

approximate chemical ratios such as the one in the '516 patent comprise a continuum reflected by the word 'about.' In other words, [t]here is no clear line of delineation whereby something works at a ratio of 3.0:1 but fails entirely at 2.9:1.

See p. 32, Recommendation, 1:04CV492 (M.D.N.C. Nov. 7, 2005) (docket no. 101), adopted Jan. 4, 2006 (docket no. 145). Thus, this court has already found that the word "about" as used in the phrase "about 3:1 to about 15:1" means "approximately."

L. Perrigo argues, nevertheless, that during prosecution Banner specifically abandoned all gelatin-to-plasticizer ratios falling below 2.95:1 to avoid prior art. L. Perrigo notes that the application as filed included claims directed to a method of enrobing the films using one of either of two different formulas. One of the formulas included a .9:1 to 2.94:1 range, and another formula included a 3.33:1 to 12:1 range. L. Perrigo argues that in a preliminary amendment, however, Banner cancelled both of these claims and reinserted a claim of about 3:1 to about 15:1. L. Perrigo argues that Banner prosecuted the "about 3:1 to about 15:1" claim through to the Board's decision, and the Board indicated the allowability of such claims. Banner then added back a product claim that included a gelatin-to-plasticizer range of 3.33:1 to 12:1, which is Claim 10 of the '516 patent. L. Perrigo points out that Banner did not add back a gelatin-to-plasticizer range of .9:1 to 2.94:1. According to L. Perrigo, Banner dropped the .9:1 to 2.94:1 ratio specifically to avoid the prior art of the Italian patent. L. Perrigo argues, therefore, that the gelatin-to-plasticizer ratios of

Banner's claimed invention may not go below 2.95:1 because Banner has expressly relinquished claims within the .9:1 to 2.94:1 range in order to avoid prior art. For the following reasons, the court does not agree.

The Italian Patent

Before delving into whether Banner expressly abandoned all gelatin-to-plasticizer ratios falling below 2.95:1, it is important to first understand the background of the Italian patent and its role in the prosecution history of the '516 patent. Like the '516 patent, the Italian patent generally describes a medicinal tablet that is enrobed in a coating formed by application of respective layers of elastic film to opposite sides of the tablet.FN7 The Italian patent was not in the initial disclosures for the ' 516 patent, but was discovered during prosecution.FN8 Banner was allowed to refile the application to address issues raised by the Italian patent.FN9 DX8, PER 002384. During prosecution of the ' 516 patent, the examiner informed Banner that its claimed invention was not allowable in light of the Italian patent. Banner, in turn, argued that the Italian patent did not bar the claimed invention because the Italian patent did not disclose effectively operable procedures or equipment for making the product it purported to disclose; therefore, the Italian patent was a "non-enabling disclosure." FN10 *See* DX8, PER 002340 to PER 2363. Banner pointed out, for instance, that the failure rate for the Italian patent was as high as 20%.FN11 *See* DX8, PER 002344. The examiner rejected Banner's non-enabling disclosure argument, finding that the fact that the Italian patent had a relatively high failure rate did not render it a non-enabling disclosure. The examiner, therefore, rejected the claimed invention as anticipated by the Italian patent. DX8, PER 002385.

Banner appealed the examiner's rejection and presented the non-enabling disclosure argument to the Board of Appeals. *See* DX8, PER 002377 to PER 002410. The Board of Appeals also rejected Banner's non-enabling disclosure argument. The Board of Appeals further observed, however, that the claimed invention and the Italian patent differed in the following two ways:

1. The Italian patent did not contain language stating that "the gelatin film enrobing the tablet core adheres so tightly to the core that it cannot be removed without removing part of the core"; and

2. The Italian patent did not specifically say that the gelatin-to-plasticizer range used in the enrobing gelatin film was from "about 3:1 to about 15:1" as set forth in Banner's claims.

See DX8, PER 002534 to PER 002536. With regard to the second factor, the Board of Appeals noted, in fact, that the Italian patent did not include any gelatin-to-plasticizer ratios at all. For this very reason, the Board specifically reversed the examiner's finding of unpatentability on Banner's claims directed to gelatin-enrobed tablet coverings comprised of gelatin-to-plasticizer ratios of from "about 3:1 to about 15:1." *See* DX8, PER 002534.

In accordance with the Board's decision on appeal, Banner then amended its claims accordingly in order to obtain allowance of the patent. In July 2002, the examiner allowed the amendments for the following stated reasons:

As decided by the Board of Appeals and Interference, the Italian patent does not teach or suggest a gelatin enrobed tablet comprising: (1) a weight ratio of the gelatin-to-plasticizer in the covering film of from about 3:1 to from 15:1; and (2) a bond between the covering and the core that is sufficiently tight [ ] and secure[ ] that the covering cannot mechanically be removed from the core without removing part of the core.

DX 8, PER002512. Thus, the patent office allowed the '516 patent claims over the Italian patent for the following two reasons: (1) the '516 patent claims contained specific ratios of "about 3:1 to about 15:1," whereas the Italian patent did not contain any ratios at all, and (2) the '516 patent described a degree of adherence in which the covering adheres sufficiently tightly and securely to the core that the covering cannot mechanically be removed from the core without removal of a part of the core, whereas the Italian patent did not specify this degree of adherence.

The prosecution history for a patent may indicate that a patentee has unambiguously abandoned or disavowed a claim construction in a claim amendment or argument during prosecution to avoid prior art and to, therefore, obtain claim allowance. *See, e.g.,* Schreiber Foods, Inc. v. Saputo Cheese USA Inc., 83 F.Supp.2d 942, 949 (N.D.Ill.2000) (stating that where the patentee expressly abandoned its claim to "about 20%" in an earlier application to avoid prior art, the words "about 25%" in the patent could not encompass "21.25%"). For abandonment to attach, however, Federal Circuit precedent "requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325-26 (Fed.Cir.2003); *see also* Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 986-87 (Fed.Cir.1989). Here, based on the prosecution history surrounding the Italian patent, the court does not agree with L. Perrigo that Banner expressly abandoned all claims having gelatin-to-plasticizer ratios below 2.95:1 so as to avoid the prior art of the Italian patent. First, as noted above, the Italian patent did not even contain any specific gelatin-to-plasticizer ratios. Therefore, contrary to L. Perrigo's argument, there is nothing to indicate that the Italian patent covers *all* gelatin-to-plasticizer ratios up to 2.95:1, but that it covers none below that level. In other words, the noted difference between the Italian patent and Banner's claimed invention was *not* that the '516 patent included gelatin-to-plasticizer ratios *different* from gelatin-to-plasticizer ratios disclosed by the Italian patent, but that the Italian patent disclosed no specific ratios *at all*. Thus, there is simply no evidence in the prosecution history that the Italian patent disclosed all claims with a gelatin-to-plasticizer ratio of 2.95:1 or below, or that Banner abandoned such ratios to avoid the Italian patent as prior art. As the court has already discussed in depth, the nature of the invention is such that the claimed adherence cannot be found at only one precise ratio. Therefore, if a person can create a tablet with a gelatin-to-plasticizer ratio below 2.94:1, and which has an adherence in which the covering cannot mechanically be removed from the core without a removal of a part of the core, then infringement has been established, even though the gelatin-to-plasticizer ratio is not the ratio *most likely* to create such adherence. Therefore, the court should reject L. Perrigo's argument that the claims in the '516 patent contain a specific floor of gelatin-to-plasticizer ratio of 2.95:1.

Furthermore, Banner has given a reasonable explanation for why it did not add the specific ratio of ".9 to 2.94:1" of its original application back into the claims as allowed. As Banner explained at the *Markman* hearing, the original patent application described a claim for four subjects-a method, an apparatus, a tablet product, and a composition. The patent office responded with a restriction, finding that Banner had described four different subjects and that Banner had to, therefore, submit a separate application for each subject. Banner retained the original patent application directed to the method. Claims 23 and 24 are the method claims in the original patent application, and they include the gelatin-to-plasticizer ratio ranges of .9:1 to 2.94:1 and 3.3:1 to 12:1. When that first application was chosen to become the method patent, those claims remained in the application and subsequently issued as Claims 2 and 3 of the method patent. Banner next filed the application for an apparatus. In accordance with patent office procedures, Banner took a photocopy of the original application and submitted it as an original application for the apparatus. Banner then changed the claims to conform to the apparatus subject matter. When the apparatus application was nearing completion, Banner then decided to pursue the tablet patent subject matter application. Again, in

accordance with the patent office procedures, Banner took the original patent application and submitted its application for the tablet patent claims. Simultaneously with the filing of that tablet patent application, the claims to the tablet patents were then substituted into the applications, and in those claims Banner added the language of "about 3:1 to about 15:1."

Banner explained at the *Markman* hearing that it did not pursue the method claim of .9:1 to 2.94:1 in the tablet patent application because that claim had already been issued in the method patent. Banner explained that since the ratio was already covered in the method patent, it would have been "double patenting" and therefore improper for Banner to continue the prosecution of the .9:1 to 2.94:1 in the tablet patent application, when that claim was already in the method patent.FN12 Banner argues, therefore, that there was no express abandonment of any ratios falling below 2.95:1. Banner further explained at the *Markman* hearing that it did not include an exact ratio of 2.95:1 in the ' 516 patent because the use of the word "about 3:1" was specifically designed to cover that range below 3 that would normally be covered under the plain meaning of "about," which is "approximately." Banner submits, therefore, that there is nothing to indicate that there is some artificial limit to the language "about 3:1."

This court finds that Banner has shown that it did not expressly abandon all gelatin-to-plasticizer ratios falling below 2.95:1. First, Banner has offered a reasonable explanation for why the ratio of ".9:1 to 2.94:1" was included in the original application but not in the amendments that led to the '516 patent.FN13 Furthermore, there is simply nothing to show that the Italian patent specifically covered all ratios of below 2.95:1. Certainly, if Plaintiff's retention of the .9 to 2.94:1 ratio would have prevented allowability in light of the Italian patent, then Banner would be estopped from arguing now that the "about 3:1" language includes ratios below 2.95:1. Substantive changes to a claim that *clearly* respond to an examiner's rejection of that claim as unpatentable over prior art give rise to prosecution history estoppel. *See* Bai v. L & L Wings, Inc., 160 F.3d 1350, 1355 (Fed.Cir.1998). Here, however, the allowability of the ' 516 patent over the Italian patent did not rise or fall with the addition or deletion of any *particular* gelatin-to-plasticizer ratio. In other words, the outcome would be different if the Board of Appeals had stated during prosecution that the ' 516 patent was not allowable over the Italian patent because the Italian patent specifically teaches a gelatin-enrobed tablet comprising a weight ratio of the gelatin-to-plasticizer in the covering film of "2.94:1 and below." If this were the case, then it would seem that "about 3:1" would have to be limited to 2.95:1 or above in order for the ' 516 patent to avoid the prior art of the Italian patent. That is not what the Italian patent specifically teaches, however, nor did the Board interpret the Italian patent as teaching this specific ratio.

Finally, although the court cannot assign any artificial floor to "about 3:1," it is recommended that the court find that this floor may include a gelatin-to-plasticizer ratio of 2.85:1.FN14 For these reasons, it is recommended that the court adopt Banner's proposed construction of the above-disputed language in Claims 8, 22, and 24, and that the court further find that the "about 3:1" language in these claims can encompass a gelatin-to-plasticizer ratio of 2.85:1.

IV. Conclusion

For the reasons stated herein, it is **RECOMMENDED** that the court adopt Banner's proposed interpretations of the disputed claim terms in the '516 patent.

FN1. The background information set forth here is taken substantially from an earlier Recommendation by the undersigned on a previous summary judgment motion. The court notes that there have been two prior

summary judgment motions filed in this case. The ruling in the first motion addressed, among other things, L. Perrigo's literal infringement of some of the patent claims. *See* Banner Pharmacaps Inc. v. Perrigo Co., No. 1:04CV492, 2005 WL 2136927, at *2-3 (M.D.N.C. Aug.1, 2005) (docket no. 62), adopted Sept. 6, 2005 (docket no. 78). The second summary judgment ruling addressed, among other things, L. Perrigo's invalidity argument. *See* Recommendation, 1:04CV492 (M.D.N.C. Nov. 7, 2005) (docket no. 101), adopted Jan. 4, 2006 (docket no. 145).

FN2. Moreover, as Banner further noted in the *Markman* hearing, Claim 1 is specifically directed to and concerned with a product, whereas the "cutting" requirement involves a process.

FN3. Additionally, in a previous summary judgment motion, L. Perrigo has already conceded that its products made with a gelatin-to-plasticizer ratio of 4.8:1 literally infringe Claim 8. *See* discussion of Claim 8, *infra*. Claim 8 contains substantially similar language to the "sealed to each other in substantially edge to edge relation" language in Claim 1. *See* Banner Pharmacaps Inc. v. Perrigo Co., No. 1:04CV492, 2005 WL 2136927, at *2-3 (M.D.N.C. Aug.1, 2005).

FN4. The court recognizes that the doctrine of claim differentiation "create[s] a presumption that each claim in a patent has a different scope," Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed.Cir.1998), and that the difference in meaning and scope between claims is presumed to be significant "[t]o the extent that the absence of such difference in meaning and scope would make a claim superfluous." Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed.Cir.1987). Nevertheless, the presumption is not a hard and fast rule of construction and will be overcome by a contrary construction dictated by the written description or prosecution history. Kraft Foods, Inc. v. International Trading Co., 203 F.3d 1362, 1368 (Fed.Cir.2000). Here, the presumption in this case is clearly overcome by the construction dictated by the patent's written description, which shows that the language of Claims 8, 15, 22, 23, and 24 does not allow for openings between the covering and the core.

FN5. In support of this alternative construction, L. Perrigo states that "[t]he meaning of about 15:1 covers a higher ratio than 15:1, but the amount higher is not at issue in this case."

FN6. Indeed, in asserting this invalidity argument in its prior motion for summary judgment, L. Perrigo took the opposite position that it takes now regarding the meaning of the word "about." That is, here L. Perrigo insists that the word "about" does *not* mean "approximately," whereas before L. Perrigo argued that the word "about" *did* mean "approximately," and therefore the patent was invalid for lack of enablement.

FN7. The patent referred to as "Italian Patent No. 538,281" was published in 1956 and was granted to the R.P. Scherer Corporation. *See* DX 8, PER00234.

FN8. L. Perrigo stated in the *Markman* hearing that Banner initially represented to the patent office that it was the first to claim a gelatin-enrobed tablet, but during prosecution Banner "ran into" the Italian patent,

which also claimed a gelatin-enrobed tablet. L. Perrigo explained that Banner then had to "back off" and abandon those claimed embodiments already covered by the Italian patent.

FN9. For simplicity's sake, the court is using Banner's name when discussing the prosecution history.

FN10. A disclosure which suggests a product but does not teach how to make it is referred to as a "non-enabling disclosure," since it does not enable one of ordinary skill in the art to make the product. *See* 35 U.S.C. s. 112.

FN11. Banner asserted that this failure rate was due to the fact that under the drop-metered approach of the Italian patent, the enrobed tablets were not fed effectively and reliably to the converging films in the correct timed relation to the die cavity positions behind the converging films. *See* DX8, PER 002350 to PER 002361 (Dietel Decl.); DX8, PER 001970 to PER 002402; DX8, PER 002377 to PER 002402. As Banner explained, if a tablet core is not engaged with the converging films in the proper positional relation of the core to the die cavities, the core can become "nipped" or "mashed" by the dies between or at the ends of the cavities as the dies mate at the nip between them. DX8, PER 002388. If, however, a core is engaged with the films in the proper positional relation to the die cavities, the core properly extends into the cavities, causing the films to be stretched around and to conform to the core so that the films are properly sealed together and separated from the surrounding film web as desired. Banner explained that in its initial attempt to obtain effective dispensing of the tablets, it used the same "drop-metered approach" that had been used in the Italian patent. Despite extended efforts to make that approach work, however, Banner found that the drop-metered approach of the Italian patent had a success rate of only 60-80% under the best of short-term conditions. DX8, PER 002390. Banner further explained that after more experimentation it developed its own unique process for tablet enrobing-that is, an enrobing process that was different from the failed, metered-drop approach of the Italian patent and which resulted in an efficient and reliable arrangement and procedure for engaging tablet cores with the converging films at a high success rate.

FN12. The "double patenting" doctrine generally prevents a patentee from receiving two patents for the same invention. Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed.Cir.2005).

FN13. As for the "3.3:1 to 12:1" ratio, Banner states that this ratio was added back into the tablet patent because the entire ratio is clearly encompassed within the claimed "about 3:1 to 15:1" ratio of the '516 patent.

FN14. It is recommended that the court make this determination now because L. Perrigo is currently using a 2.85:1 ratio in its products. Since interpreting the meaning of claims is the court's obligation, the court must determine whether the "about 3:1" language encompasses 2.85:1 before submitting the question of infringement to the fact-finder. Of course, at some point the gelatin-to-plasticizer ratio will reach a point where the patented degree of adherence cannot be achieved, and there are ratios that are clearly not within the "about 3:1" range. *See, e.g.,* Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1562 (Fed.Cir.1994) (where the court found that there was "simply no basis" for interpreting the phrase "about 40:1" to

encompass a 162.9:1 ratio, noting that this would imply an expansion of the term "about" to encompass over a fourfold increase in the specified numerical ratio and thus would ignore the ordinary meaning of that term).

M.D.N.C.,2006.
Banner Pharmacaps Inc. v. Perrigo Co.

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