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

McNEIL-PPC, INC. et al,
Plaintiffs.
v.
PERRIGO COMPANY et al,
Defendants.

No. 05 Civ. 1321(WHP)

July 27, 2006.

Background: Patentee brought action against competitor, alleging that competitor infringed its patent for a tablet used to treat gastric disorders by filing an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA). Competitor moved for summary judgment on issues of infringement and invalidity, and for Rule 11 sanctions.

Holdings: The District Court, Pauley, J., held that:
(1) patent was broad enough to encompass both one-layer and two-layer coated granule tablets;
(2) willful infringement claim arising from competitor's abbreviated new drug application (ANDA) submission was not frivolous, so as to warrant Rule 11 sanctions; and
(3) genuine issues of material fact precluded summary judgment on issue of whether a patent was invalid as obvious.

Ordered accordingly.

5,817,340. Infringed.

Raymond N. Nimrod, Jenner & Block LLP, Chicago, IL, for Plaintiffs.

James A. Mitchell, Price, Heneveld, Cooper, DeWitt & Litton, LLP, Grand Rapids, MI, for Defendants.

MEMORANDUM AND ORDER

PAULEY**, District Judge.**

McNeill-PPC, Inc. ("McNeil"), Merck & Co., Inc. and Johnson & Johnson-> Merck Consumer Pharmaceuticals Co. (collectively, the "Plaintiffs") bring this action pursuant to the Hatch-Waxman Act, 35 U.S.C. s. 271(e)(2), against Perrigo Company, L. Perrigo Company and Perrigo Research & Development

Company (collectively, the "Defendants" or "Perrigo"). Plaintiffs accuse Perrigo of infringing U.S. Patent No. 5,817,340 (the "'340 patent") by filing Abbreviated New Drug Application ("ANDA") No. 77-355 with the United States Food and Drug Administration (the "FDA").

Defendants move under Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995), aff'd, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) and Fed.R.Civ.P. 56 for the Court to construe the relevant patent claims and for summary judgment dismissing the Complaint on grounds of non-infringement and invalidity. Defendants also seek sanctions under Fed.R.Civ.P. 11 for the inclusion of willful infringement allegations in the Complaint. For the reasons set forth below, Defendants' motions for summary judgment and Rule 11 sanctions are denied, and this Court grants summary judgment in favor of Plaintiffs on their claim of infringement.

BACKGROUND

The '340 patent pertains to a solid oral dosage of aluminum hydroxide or magnesium hydroxide (the "antacids") and famotidine. Famotidine is a guanidinothiazole compound that inhibits acid secretion in the stomach by interfering with histamine receptors in the stomach lining. (Declaration of Kristopher R. Kiel, dated Feb. 24, 2006 ("Kiel Decl."), Ex. 1: '340 Patent col. 51, ll. 31-32; Transcript of Proceedings, dated Apr. 25, 2006 ("Tr.") at 13-14.) Aluminum hydroxide and magnesium hydroxide neutralize acid already present in the stomach. (Tr. at 8-9.) When combined in a solid oral dosage, famotidine and antacids are used to treat gastric disorders arising from acid secretion, such as acid indigestion. McNeil markets this combined dosage as Pepcid Complete. (Declaration of James Gabriele, dated Dec. 30, 2005 ("Gabriele Decl.") para. 6; Tr. at 15.)

McNeil filed the '340 patent application on December 1, 1992 with Edward John Roche ("Roche"), Susan Decoteau and Eleanor Freeman as the named inventors. (Kiel Decl. Ex. 1: Paper No. 1.) FN1 These inventors discovered that famotidine degrades when exposed to antacids, yielding a therapeutically ineffective product with unknown properties. (Kiel Decl. Ex. 1: ' 340 Patent col. 1, ll. 26-30; col. 2, ll. 41-49; col. 2, ln. 61-col. 3, ln. 2.) The ' 340 patent teaches a method for preventing famotidine degradation.

FN1. Exhibit 2 to the Kiel Declaration contains the prosecution history of the '340 patent.

At issue are independent composition claim 1 and independent method claim 5 of the '340 patent. Claim 1 recites as follows:

1. A solid oral dosage form for the treatment of gastrointestinal disorders comprising a therapeutically effective amount of impermeably coated famotidine granules for the treatment of gastric disorders and pharmacologically acceptable salts thereof; and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide wherein the oral dosage form has said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other, but separated by said impermeable coating on the famotidine granules which is impermeable to the aluminum hydroxide or magnesium hydroxide.

('340 Patent col. 14, ll. 39-49.) Claim 5 recites as follows:

5. A method for manufacturing a solid oral dosage form comprising: a) forming granules containing

famotidine for the treatment of gastric disorder; b) coating the granules with a coating impermeable to aluminum hydroxide or magnesium hydroxide to form impermeably coated famotidine granules; c) mixing a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide with a therapeutically effective amount of impermeably coated famotidine granules and pharmaceutically acceptable excipients to form a compression mixture; then d) pressing the compression mixture to form a solid oral dosage form.

('340 Patent col. 15, ln. 6-col. 16, ln. 2.) The specification details several embodiments of the invention. In the preferred embodiment, granulated famotidine is coated with an impermeable material that protects the famotidine from the antacids. ('340 Patent col. 9, ll. 7-12.) The specification details two variations on this embodiment. In Examples I and V, the coated famotidine granules and the antacids are interspersed throughout a single-layer tablet. ('340 Patent col. 9, ln. 39-col. 10, ln. 60; col. 13, ln. 52-col. 14, ln. 37.) Examples II and III depict two-layer embodiments in which the coated famotidine granules comprise one layer and the antacids comprise the other layer.FN2 (' 340 Patent col. 10, ln. 63-col. 12, ln. 51.)

FN2. Example IV does not specify whether it embodies a one-layer tablet or a two-layer tablet. ('340 Patent col. 12, ln. 55-col. 13, ln. 48.)

The specification also presents three-layer embodiments in which a layer of impermeable film-forming polymer separates a layer of uncoated famotidine from a layer of antacids. ('340 Patent col. 3, ln. 14-col. 4, ln. 43.) There are two variations of this embodiment in the specification. In Figures 1 and 2, the uncoated famotidine is on top and the antacids are on the bottom, with a layer of impermeable material in between (the "barrier sandwich" embodiment). ('340 Patent col. 3, ll. 14-34.) Figures 3 and 4 depict an inner core of antacids encapsulated by the impermeable material, which is surrounded by an outer layer of uncoated famotidine (the "core" embodiment). ('340 Patent col. 3, ll. 35-65.)

The original '340 application encompassed all of the above-described embodiments (Kiel Decl. Ex. 2: Paper No. 1, at 5-8, 20-32.). The application purported to show that at 40 degrees Celcius and 75% humidity, uncoated guanidinothiazole exposed to aluminum hydroxide experienced 1.1% degradation by weight over the course of a month. (Kiel Decl. Ex. 2: Paper No. 1, Fig. 8.) Under the same conditions, coated famotidine experienced approximately 0.1-0.2% degradation by weight. (Kiel. Decl. Ex. 2: Paper No. 1, Fig. 9.) Thus, McNeil argued that the coating reduced the level of famotidine degradation.

The Patent Office repeatedly rejected McNeil's claims, primarily on grounds of obviousness. (*See* Kiel Decl. Ex. 2: Paper Nos. 5, 9, 16, 20, 29.) The examiner stated that primary references such as Boswell (Defendants' Summary Judgment Exhibit ("Defs.SJ.Ex.") C), Estevenel et al. (Defs. SJ Ex. D) and EP 294,933 (Defs. SJ Ex. E) use a coating material to prevent interaction between solid forms. (Kiel Decl. Ex. 2: Paper No. 16, at 3-4.) Plaintiffs also submitted to the examiner Roche's U.S. Patent No. 5,075,114 (the "'114 patent") which recited a method for masking the taste of famotidine granules with an impermeable coating material. (Defs.SJ.Ex. J.) According to the examiner, "granulated active ingredients coated with barrier materials are old and well known in the art." (Kiel Decl. Ex. 2: Paper No. 16, at 3.) The examiner determined that "the effect of combining histamine receptor antagonist compounds and antacids" is disclosed by the prior art. (Kiel Decl. Ex. 2: Paper No. 16, at 3-4.) Although none of the prior art disclosed famotidine degradation, published patent application WO 92/00102 by Davis et al. ("Davis") (Defs. SJ Ex. F) and Wolfe U.S. Patent No. 5,229,137 ("Wolfe") (Defs. SJ Ex. G) recited combinations of famotidine and antacids in a solid oral dosage. The examiner determined that the '340 patent application was obvious because, based on the prior art, one of ordinary skill would be motivated to use a barrier material to protect

famotidine from the antacids.

Further, because the examiner believed that "the stability problem with guanidinothizole compounds when administered with antacids was well known in the art," she determined that "the very small, approximately 1% difference in degradation ... between the uncoated and coated guanidinothizole compound is not seen to present unexpected results ..." (Kiel Decl. Ex. 2: Paper No. 20, at 3.) The examiner concluded that "[t]he evidence [of the 1% difference] is additionally questionable since there is no statistical evaluation to determine the significance of the results." (Kiel Decl. Ex. 2: Paper No. 20, at 3.)

From the initial submission of the '340 application to September 1997, the examiner consistently rejected McNeil's arguments regarding the obviousness of the invention. (*See* Kiel Decl. Ex. 2: Paper Nos. 5, 9, 16, 20, 29.) On September 18, 1997, Roche submitted a declaration to the examiner setting forth the results of a test he had conducted. (Kiel Decl., Ex. 2: Paper Nos. 31-32.) By combining 10mg of uncoated famotidine granules with 200mg of aluminum hydroxide or magnesium hydroxide in a single layer tablet, Roche observed a 25-70% degradation in the famotidine. When impermeably coated famotidine granules were substituted for the uncoated granules, approximately 2% degradation occurred. (Kiel Decl., Ex. 2: Paper No. 32, Figs. 4-5; Defendants' Claim Interpretation Brief, dated Feb. 24, 2006, at 9.) Roche did not test the effect of impermeable coating in a two-layer coated granule embodiment.

The Patent Office deemed the Roche declaration "persuasive as to unexpected results in stability over the prior art for the dosage form tested therein, i.e., coated granule solid oral dosage form containing famotidine and aluminum or magnesium hydroxide." (Kiel Decl. Ex. 2: Paper No. 33, at 2.) Based on these results, the Patent Office allowed originally filed claims 9, 10 and 27. FN3 (Kiel Decl. Ex. 2: Paper No. 33, at 2-3.) The examiner stated, "All other claims herein remain obvious in view of the cited prior art since nothing unexpected has been adequately demonstrated for any other aspects of applicants' invention." (Kiel Decl. Ex. 2: Paper No. 33, at 3.)

FN3. Originally filed claims 9 and 10 were included in McNeil's initial submission to the Patent Office dated December 1, 1992. (Kiel Decl. Ex. 2: Paper No. 1, at 35.) Claim 27 was added to the '340 application by submission to the Patent Office dated June 22, 1994. (Kiel Decl. Ex. 2: Paper No. 13, at 2.)

Originally filed claim 9 depended from originally filed claim 1. Originally filed claim 1 states:

An oral dosage form for the treatment of gastrointestinal disorders comprising a therapeutically effective amount of a guanidinothiazole compound suitable for the treatment of gastric disorders ... and a therapeutically effective amount of an antacid wherein the oral dosage form has a first portion containing the antacid and a second portion containing the guanidinothiazole compound suitable for the treatment of gastric disorders wherein the first and second portions are in contact with and separated by a barrier which is substantially impermeable to the antacid.

(Kiel Decl. Ex. 2: Paper No. 1, at 33.) It is undisputed that this claim covered all of the embodiments detailed in Figures 1-4 and Examples I-V. Originally filed claim 9 provides for a coated granule embodiment "wherein the guanidinothiazole is famotidine." (Kiel Decl. Ex. 2: Paper No. 1, at 35.) Originally filed claim 10 provides for the same tablet form as originally filed claim 9, but specifies the particular amounts of famotidine, excipient and coating to be used. (Kiel Decl. Ex. 2: Paper No. 1, at 35.)

Originally filed claim 27 depended from originally filed independent claim 24. Claim 24 recited "[a]n oral dosage form ... comprising: a first portion containing a therapeutically effective amount of famotidine; a second portion containing a therapeutically effective amount of antacid; and barrier means between said first and second portions for preventing the antacid from substantially degrading the famotidine." (Kiel Decl. Ex 2: Paper No. 13, at 1.) Claim 27 specifies coated granules as the barrier means to be utilized. (Kiel Decl. Ex. 2: Paper No. 13, at 2.)

After application claims 9, 10 and 27 were allowed, McNeil submitted several new and revised claims. Some of these embodied the coated granule methods, some embodied the barrier sandwich and core methods, and others broadly covered all methods. (Kiel Decl. Ex. 2, Paper No. 34.) After the Patent Office rejected any claim potentially involving the barrier sandwich and core methods (Kiel Decl. Ex. 2: Paper No. 36), McNeil cancelled all such claims (Kiel Decl. Ex. 2: Paper No. 37, at 1-2). The '340 patent issued on October 6, 1998.

On October 29, 2004, Perrigo filed ANDA No. 77-355 to obtain permission from the FDA to market a generic tablet containing 10mg of coated famotidine in one layer and 165mg of magnesium hydroxide in a separate layer. (Defendants' Tutorial Presentation, dated Apr. 25, 2006, at 2.) Perrigo certified to the FDA that the '340 patent was invalid and would not be infringed by Perrigo's proposed tablet. On February 3, 2005, Plaintiffs filed this action alleging that the ANDA willfully infringes the '340 patent and requesting attorneys' fees pursuant to 35 U.S.C. s. 285. Defendants now move for summary judgment on grounds of non-infringement and invalidity. Defendants also seek sanctions pursuant to Fed.R.Civ.P. 11 based on Plaintiffs' allegations of willfulness.

DISCUSSION

I. ***Summary Judgment Standard***

Summary judgment is warranted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c); *see also* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). The materiality of disputed facts is determined by the governing substantive law. Dister v. Cont'l Group, Inc., 859 F.2d 1108, 1114 (2d Cir.1988). Material facts are those that "affect the outcome of the suit under the governing law [while] an issue of fact is 'genuine' if the evidence is such that a reasonable jury could return a verdict for the non-moving party." Shade v. Hous. Auth. of New Haven, 251 F.3d 307, 314 (2d Cir.2001). The burden of demonstrating the absence of any genuine dispute as to a material fact rests with the moving party. Adickes v. S.H. Kress & Co., 398 U.S. 144, 157, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970); Grady v. Affiliated Cent., Inc., 130 F.3d 553, 559 (2d Cir.1997). In determining whether there is a genuine issue as to any material fact, "the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." Liberty Lobby, 477 U.S. at 255, 106 S.Ct. 2505.

If the moving party meets its initial burden, the non-moving party must then come forward with "specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(c); Carlton v. Mystic Transp., Inc., 202 F.3d 129, 133 (2d Cir.2000). The non-moving party must "do more than simply show there is some metaphysical doubt as to the material facts," Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986), and "may not rely on conclusory allegations or unsubstantiated speculation," Scotto v. Almenas, 143 F.3d 105, 114 (2d Cir.1998). "The mere existence of a

scintilla of evidence in support of the [non-movant's] position will be insufficient." Liberty Lobby, 477 U.S. at 248, 106 S.Ct. 2505. Instead, the non-movant must offer "concrete evidence from which a reasonable juror could return a verdict in [its] favor." Liberty Lobby, 477 U.S. at 252, 106 S.Ct. 2505. Where it is apparent that no rational finder of fact "could find in favor of the non-moving part[ies] because the evidence to support [their] case is so slight," summary judgment should be granted. Gallo v. Prudential Residential Servs., Ltd., 22 F.3d 1219, 1223 (2d Cir.1994).

II. ***Infringement***

[1] When a party moves for summary judgment of non-infringement, the court must first determine the meaning and scope of the claims as a matter of law and then compare the construed claims to the allegedly infringing product. See Markman, 52 F.3d at 976, *aff'd,* 517 U.S. at 376, 116 S.Ct. 1384. On April 25, 2006, this Court conducted a *Markman* hearing to determine the scope of the '340 patent's claims. The parties dispute the construction of the following claim terms: (1) "mixing" and "compression mixture"; (2) "in contact with"; (3) "therapeutically effective amount"; and (4) "impermeable" and "impermeably coated famotidine granules." The first three claim construction disputes concern whether the '340 patent broadly encompasses both one-layer and two-layer coated granule embodiments, or whether the claims are instead limited to a one-layer embodiment. The parties agree that claim construction is the sole determinant of infringement in this case. (Tr. at 118.) In other words, once this Court defines the claims, there will be no disputed issues of law or fact as to whether the '340 patent has been infringed.

A. ***Canons of Claim Construction***

[2] [3] [4] "It is the *claims* that measure the invention." SRI Intern. v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed.Cir.1985) (en banc) (emphasis in original). Claim construction "is a question of law, to be determined by the court, construing the letters-patent, and the description of the invention and specification of claim annexed to them." Markman, 517 U.S. at 384, 116 S.Ct. 1384; Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451 (Fed.Cir.1998) (en banc). Claim construction requires a district court to determine "what the words in the claim mean." Markman, 517 U.S. at 374, 116 S.Ct. 1384. However, a court must construe "only those [claim] terms ... that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Techs., Inc. v. Am. Science & Eng'g, Inc., 200 F.3d 795, 803 (Fed.Cir.1999).

[5] [6] To determine the proper meaning of claim elements, a court must first consider the intrinsic evidence, i.e., "the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). With this understanding, "the patent is [regarded as] an integrated document, with the claims 'pointing out and distinctly claiming,' 35 U.S.C. s. 112, the invention described in the rest of the specification." Astrazeneca AB v. Mutual Pharm. Co., 384 F.3d 1333, 1337 (Fed.Cir.2004). Courts look to the intrinsic evidence because it comprises the public record, and public policy mandates that competitors be able to ascertain the metes and bounds of patent claims by reviewing the public record. See Vitronics, 90 F.3d at 1583.

[7] [8] A court's "analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.' " Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. s. 112); *accord* Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 326 F.3d 1215, 1220 (Fed.Cir.2003); *Digital Biometrics,* 149 F.3d at 1344. "[A] court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give

full effect to the ordinary and accustomed meaning of claim terms." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999); *accord* Brookhill-Wilk, 326 F.3d at 1220; Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed.Cir.2002). Next, "[t]he written description is considered, in particular to determine if the patentee acted as his own lexicographer, as our law permits, and ascribed a certain meaning to those claim terms." *Digital Biometrics,* 149 F.3d at 1344. Finally, courts may consider a patent's prosecution history when reviewing the intrinsic evidence. See Vitronics, 90 F.3d at 1582.

[9] "[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." Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed.Cir.2005). Dictionary definitions may be used to assist in understanding the commonly understood meaning of words "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Phillips, 415 F.3d at 1322-23 (quoting Vitronics, 90 F.3d at 1584). The "adoption of a dictionary definition entirely divorced from the context of the written description" is improper. Phillips, 415 F.3d at 1321.

[10] [11] The specification is the "single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). A patentee may assign a novel or special meaning to a term in the specification. *See, e.g.,* Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1366 (Fed.Cir.2001). While "a patentee is free to be his or her own lexicographer and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings," the patentee must clearly state the special definition of the term in the patent specification or prosecution history. Vitronics, 90 F.3d at 1582; *accord* Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed.Cir.1996).

[12] [13] [14] Because the specification is an important part of the intrinsic evidence, claims are construed in light of the specification of which they are a part. *See, e.g.,* ATD Corp. v. Lydall, Inc., 159 F.3d 534, 540 (Fed.Cir.1998). However, particular embodiments or examples appearing in the specification may not be read to limit the claim. See Johnson Worldwide, 175 F.3d at 992 ("[M]ere inferences drawn from the description of an embodiment of the invention cannot limit claim terms."); Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1572 (Fed.Cir.1988) ("[P]articular embodiments and examples appearing in the specification will not generally be read into the claims."); *accord* Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1338-39 (Fed.Cir.2001); Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1277 (Fed.Cir.1995). Functional limitations expressed in the specification but not in the claim may not be read into the claim. See Interactive Gift Express, 256 F.3d at 1331; Transmatic, 53 F.3d at 1278; Ecolab, 264 F.3d at 1367. At the same time, a patentee may expressly limit the scope of the claims to the embodiment described in the specification. Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1314 (Fed.Cir.2006). An embodiment may be disclaimed if it is "demeaned" in the written description. Honeywell Int'l, 452 F.3d 1312, 1314.

[15] Finally, as noted above, a patent's prosecution history may be examined when reviewing the intrinsic evidence. See Vitronics, 90 F.3d at 1582. "The prosecution history is relevant because it may contain contemporaneous exchanges between the patent applicant and the [Patent Office] about what the claims mean." *Digital Biometrics,* 149 F.3d at 1344. Yet where the written description clearly identifies the invention, "an expression by a patentee during prosecution that he intends his claims to cover more than what his specification discloses is entitled to little weight." Honeywell Int'l, 452 F.3d 1312, 1314.

[16] When "intrinsic evidence is insufficient to enable the court to determine the meaning of the asserted

claims," a court may rely on extrinsic evidence. Vitronics, 90 F.3d at 1584; *see also* Interactive Gift Express, 256 F.3d at 1332 ("Relying on extrinsic evidence to construe a claim is 'proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence.' " *(quoting* Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed.Cir.1997))). Extrinsic evidence is helpful to the extent "it 'can shed useful light on the relevant art and thus better allow a court to place itself in the shoes of a person of ordinary skill in the art' reading the claims alongside the rest of the specification." Astrazeneca AB, 384 F.3d at 1337 *(quoting* Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed.Cir.2004)).

B. "*Mixing" and "Compression mixture"*

[17] Claim 5 recites the method of:

c) *mixing* a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide with a therapeutically effective amount of impermeably coated famotidine granules and pharmaceutically acceptable excipients to form a *compression mixture;* then d) pressing the *compression mixture* to form a solid oral dosage form.

(Emphasis added.) Plaintiffs define "mixing" as "combining two or more ingredients into one mass," and "compression mixture" as "one mass containing two or more ingredients that are compressed into a tablet." Plaintiffs' construction of these terms is sufficiently broad to encompass both one-layer and two-layer coated granule tablets. Defendants propose the following alternative construction of "mixing" and "compression mixture": "Effecting a *uniform dispersion* of liquid, semi-solid or solid ingredients of a mixture by means of a mechanical agitation." (Emphasis added.) Defendants' construction would purportedly encompass only a one-layer tablet because the famotidine and antacids would not be "uniformly dispersed" if they are separated into two layers.

This Court must "determine the ordinary and customary meaning, if any, that would be attributed to the term[s] by those skilled in the art." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1346 (Fed.Cir.2003). None of the parties have submitted a proposal for the qualifications and experience required of a person skilled in the art. Nevertheless, this Court concludes that one of skill in the art would have a Ph.D in chemistry, organic chemistry, pharmaceutics or pharmaceutical microbiology, or a B.S. or M.S. with several years of work experience in pharmaceutics or pharmaceutical microbiology, or an M.D. with several years of clinical experience in administering H_2 blockers or antacids. *See, e.g.,* Astrazeneca Pharms., LP v. Mayne Pharma (USA) Inc., 352 F.Supp.2d 403, 411-12 (S.D.N.Y.2004); Bayer AG v. Carlsbad Tech., Inc., No. 01 Civ. 867(LSP), 2001 WL 34125673, at (S.D.Cal. Oct.24, 2001).

1. *Specification*

[18] This Court must examine the specification to determine a construction that is consistent with the spirit of the claimed invention. Phillips, 415 F.3d at 1315-17. The specification favors Plaintiffs' broad construction of "mix" and "compression mixture" in two ways. First, Examples II and III each contemplate a dual-layer coated granule tablet. ('340 Patent col. 10, ln. 63-col. 12, ln. 51.) Example II requires that the "famotidine [be] layered on top of [the] antacid blend" and compressed into a bilayer tablet. ('340 Patent col. 11, ln. 39.) Likewise, Example III expressly involves a "bilayer tablet." ('340 Patent col. 11, ln. 58.) "[I]t is ... well established that a claim construction that excludes a preferred embodiment is 'rarely, if ever, correct.' " Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1378 (Fed.Cir.2001) (quoting Vitronics,

90 F.3d at 1583); *see also* Burke, Inc. v. Bruno Ind. Living Aids, Inc., 183 F.3d 1334, 1341 (Fed.Cir.1999) (holding that a claim interpretation excluding the preferred embodiment was improper). This is because "it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way." Hoechst Celanese Corp., 78 F.3d at 1581.

Second, Example II describes a two-layer tablet comprised of "coated famotidine granules *admixed* with granules of an antacid and formed into a solid oral dosage form." ('340 Patent col. 10, ll. 63-66 (emphasis added).) Defendants concede that the term "admixed" means "to mix with." (Kiel Decl. Ex. 11 para.para. 64-65.) Thus, Example II implicitly defines "mix" to include a dual-layer embodiment. Phillips, 415 F.3d at 1321 (the specification "acts as a dictionary when it ... defines terms by implication").

Perrigo responds by contending that portions of Example II were copied from McNeil's United States Patent 5,679,376 (the "'376 patent"), which claims a single-layer tablet comprised of loperamide and simethicone. (Defendants' Claim Construction Exhibit ("Defs. Cl. Constr. Ex." H: '376 Patent col. 10, ln. 40-col. 11, ln. 55.) According to Defendants, the word "admixed" was mistakenly used in Example II because of this copying error, and for that reason should not be considered in connection with the two-layer embodiment. This Court disagrees. Extrinsic evidence such as the '376 patent cannot be used to contradict the unambiguous intrinsic evidence. See Vitronics Corp., 90 F.3d at 1584. Moreover, the relevant language of the '376 patent is different from its alleged counterpart in the '340 patent. Defendants offer no testimonial or documentary evidence demonstrating that the latter is derived from the former. Finally, Plaintiffs' proposed constructions of "mixing" and "compression mixture" broadly cover both a one-layer and a two-layer coated granule embodiment. (Tr. at 49, 88.) These constructions are entirely consistent with Plaintiff's use of the term "admixed" to describe a one-layer embodiment in the '376 patent and, later, a two-layer embodiment in the ' 340 patent.

2. *Prosecution History*

[19] [20] [21] The prosecution history also supports Plaintiffs' construction. A court must consider the prosecution history of the patent "to determine whether the applicant clearly and unambiguously 'disclaimed or disavowed [any interpretation] during prosecution in order to obtain a claim allowance.' " Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed.Cir.2002) (quoting Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed.Cir.1985)) (alteration in original). Disclaimer during prosecution of the patent may include instances where "the patentee distinguished [a] term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67 (Fed.Cir.2002). Prosecution disclaimer must be narrowly tailored, however, to exclude only claim scope that has been "clearly and unmistakably" disclaimed. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324-26 (Fed.Cir.2003) ("[F]or prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable."); *accord* Sunrace Roots Enter., Co. v. SRAM Corp., 336 F.3d 1298, 1306-07 (Fed.Cir.2003). "[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of surrender." Omega Eng'g, 334 F.3d at 1324; *accord* Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1310 (Fed.Cir.2003).

[22] Significantly, Perrigo identifies no statement made by McNeil disclaiming the dual-layer coated granule

embodiment. Perrigo instead asserts that the scope of claims allowed on the basis of unexpected results cannot exceed the parameters of those results, and therefore, the '340 claims must be limited to the single-layer tablets tested by Roche. It is true that a patent applicant using unexpected results to show non-obviousness must provide data commensurate in scope with the claims which the evidence is offered to support. See In re Grasselli, 713 F.2d 731, 743 (Fed.Cir.1983); In re Tiffin, 58 C.C.P.A. 1420, 448 F.2d 791, 792 (1971). However, that does not mean that courts mechanically import limitations from the test results into the claims. See, *e.g.,* In re Cescon, 474 F.2d 1331, 1334 (C.C.P.A.1973) (allowing "broadly drawn" claims even though "[n]ot all compounds encompassed by the claims [were] tested"). Moreover, the Federal Circuit has held that claims allowed based on "surprising results" may be construed more broadly that the results themselves. Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1135-37 (Fed.Cir.2006). In *Purdue Pharma,* Plaintiff Purdue Pharma ("Purdue") alleged that Defendant Endo Pharmaceuticals Inc. ("Endo") infringed various Purdue patents by filing an ANDA for a generic version of Purdue's OxyContin, a pain relief tablet comprised of a controlled release oxycodone product. After the examiner rejected the OxyContin patents as obvious, Purdue distinguished the prior art using "surprising results" allegedly observed in a specific dosage range of oxycodone. Purdue Pharma, 438 F.3d at 1130. Thereafter, Purdue relied on these "surprising results" as a "prominent, and at times, the only, argument in favor of patentability before the PTO, resulting in allowance of the claims." Purdue Pharma, 438 F.3d at 1130 (internal quotations omitted). Construing the term "controlled release," the district court found a prosecution disclaimer of claims to oxycodone outside the range detailed in the extraordinary results.

Sitting *en banc,* the Federal Circuit reversed the district court's construction of the claim. Purdue Pharma, 438 F.3d at 1135-37. The panel:

agree[d] with Purdue that it made no such disclaimer or disavowal ... While it is true that Purdue relied on its 'discovery' of the ... dosage range to distinguish its claimed oxycodone formulations from other prior art ..., Purdue's statements do not amount to a clear disavowal of claim scope.

438 F.3d at 1136. By restricting the claims in accord with the alleged test results, "the trial court [had] impermissibly imported a limitation [from the prosecution history] into the claims." Purdue Pharma, 438 F.3d at 1136-37. Perrigo urges this Court to make precisely the same error of law. *See also* Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1220 (Fed.Cir.1996) (refusing to import limitations from the prosecution history into the claims). The submission of extraordinary results that are narrower in scope than the claims does not, by itself, impose a limitation on the construction of the claims.

Absent evidence of a clear disavowal in the prosecution history, this Court will not deviate from the claim meanings compelled by the remainder of the intrinsic evidence. See, *e.g.,* Playtex Prods., Inc. v. Procter & Gamble Co., 400 F.3d 901, 908 (Fed.Cir.2005); Cordis Corp. v. Medtronic Ave, Inc., 339 F.3d 1352, 1359-62 (Fed.Cir.2003). Here, there is no incontrovertible evidence that McNeil disavowed the two-layer embodiment during the prosecution of the '340 patent. McNeil's initial claims were rejected by the Patent Office. Following the submission of the Roche declaration, the examiner found McNeil's claims "persuasive as to unexpected results ... over the prior art for the dosage form tested therein, i.e. coated granule solid dosage form." The Patent Office accepted application claims 9, 10 and 27, each of which was sufficiently broad to encompass a dual-layer coated granule embodiment.

Again, there is no record evidence of an express disclaimer of the dual-layer coated granule embodiment. Purdue Pharma, 438 F.3d at 1135-37. Perrigo focuses on statements made by the examiner following the submission of the Roche declaration. As an initial matter, "unilateral statements by an examiner do not give

rise to a clear disavowal of claim scope by an applicant." Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1347-48 (Fed.Cir.2005). To the extent the examiner's statements are relevant, they are, at most, ambiguous. After McNeil submitted the Roche declaration, the examiner noted that the unexpected results were sufficient to allow the "dosage form tested therein." (Kiel Decl. Ex 2: Paper No. 33, at 2.) Perrigo asserts that the singular "form" refers only to the single-layer embodiment tested by Roche. Yet the examiner explained that the phrase "dosage form tested therein" broadly referred to the "coated granule solid dosage form." (Kiel. Decl. Ex. 2: Paper No. 33, at 2.) Having failed to distinguish between one-layer and two-layer embodiments, the examiner apparently was persuaded as to all coated granule embodiments. This interpretation of the examiner's statement is consistent with the specification's description of the preferred embodiment, in which the singular "form" expressly refers to both one-layer and two-layer tablets. ('340 Patent col. 9, ll. 12-14.)

Likewise, in explaining her reasons for allowing claims 9, 10 and 27, the examiner expressed her approval of claims that "limit[ed] allowed claims to coated granules. Other barrier means, e.g., the barrier sandwich, have not been allowed." (Kiel Decl., Ex. 2: Paper No. 36.) Defendants contend that the dual-layer coated granule embodiment is one of the "other barrier means" that, in addition to the barrier sandwich, was disallowed. Yet the quoted passage does not distinguish between one-layer and two-layer coated granule embodiments in describing the allowed application claims. The better reading of the passage is that both one-layer and two-layer coated granule embodiments were allowed, and the remaining embodiments-the barrier sandwich and the core embodiments-were rejected. At the very least, the examiner's statement is open to more than one reasonable interpretation, meaning there has been no demonstration of a "clear and unmistakable" disclaimer. SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1287 (Fed.Cir.2005); Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1332 (Fed.Cir.2004).

Perrigo's contentions are further weakened by the nature of the unexpected results. Perrigo asserts that its proposed constructions are necessary because the 25-70% degradation Roche observed in uncoated famotidine can be achieved only by mixing the ingredients into a single layer coated granule tablet. But Perrigo offers no evidence demonstrating that the same results would not be achieved using a two-layer tablet. Perrigo admits that the examiner did not review the results of a test exploring the degradation in a two-layer embodiment. (Tr. at 65.) Nor can Perrigo identify *any* such test that was completed prior to the allowance of the '340 patent. (Tr. at 66.) Regardless, there is no record evidence showing that either the examiner or McNeil viewed the unexpected results as narrowly as the Defendants submit.

Perrigo also notes that the examiner rejected application claim 24. (Kiel Decl. Ex. 2: Paper No. 36.) That claim, as amended February 27, 1998, recites:

An oral dosage form ... comprising: a first portion containing a therapeutically effective amount of famotidine granules; a second portion containing a therapeutically effective amount of [antacid]; and barrier means between said first and second portions for separating the [antacid] from the famotidine, wherein the barrier means is a coating disposed on the famotidine granules which prevents the famotidine from degrading more than an additional 1% by weight of the famotidine as compared to an identically formulated dosage form not containing an antacid ...

(Kiel Decl. Ex. 2: Paper No. 34, at 3.) Defendants contend that this claim was rejected because it encompassed a two-layer coated granule embodiment. However, the examiner explained her rejection of this claim as follows: "[C]laim 24 is indefinite as to how the absence of 'an antacid' broadly ... would be relevant to the construction of the dosage form." (Kiel Decl. Ex. 2: Paper No. 36, at 1.) This explanation has nothing

to do with the inclusion of a two-layer embodiment in the claim. Application claim 24 also contains the quoted "1% by weight" language which is irrelevant to the number of layers in the tablet and which references the data the examiner had found to be insufficient on several occasions during the prosecution history.FN4 (Kiel Decl. Ex. 2: Paper Nos. 16, at 6; 20, at 3; 29, at 4.) No clear disavowal arose from the rejection of application claim 24.

FN4. The inclusion of the "1% by weight" language in application claim 32 would explain why the examiner rejected that claim as well.

3. *Other Evidence*

As a final matter, this Court may consult dictionaries, encyclopedias and treatises to develop an understanding of the disputed terms. Phillips, 415 F.3d at 1324. Here, the dictionary definitions of the word "mix" are inconclusive. *Webster's Third New International Dictionary,* at 448 (3d ed.1986), provides a variety of definitions. One is "to stir, shake, or otherwise bring together (different substances) with a loss of separateness of identity" and to "cause to be scattered or diffused throughout." This definition supports Defendants' proposed construction. However, *Webster's* also defines "mix" to mean: (1) to "combine ... in one mass," (2) to "put as an ingredient," (3) to "bring together in ... close association," and (4) to "combine with or introduce into a mass already formed." These constructions are sufficiently broad to encompass a two-layer tablet.

Technical dictionaries can also assist claim construction by showing how persons skilled in the art define a particular term. Dow Chem., 257 F.3d at 1375. Defendants cite the portion of *Hawley's Condensed Chemical Dictionary* that defines "mixing" as "[e]ffecting a uniform dispersion of liquid, semi-solid or solid ingredients of a mixture by means of a mechanical agitation." However, an alternative definition in *Hawley's* also supports Plaintiff's construction: "A heterogeneous association of substances which cannot be represented by a chemical formula. Its components may or may not be uniformly dispersed ..." These conflicting dictionary definitions do not aid this Court's construction of the claims.

Based on the intrinsic evidence, this Court adopts McNeil's proposed definitions and construes "mixing" to mean "combining two or more ingredients into one mass," and "compression mixture" to mean "one mass containing two or more ingredients that are compressed into a tablet."

C. "*in contact with*"

[23] Claim 1 recites a tablet with:

said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide *in contact with* each other, but separated by said impermeable coating on the famotidine granules ...

(Emphasis added.) Plaintiffs urge this Court to construe "in contact with" to mean "a union or junction of body surfaces, a touching or meeting," which would be broad enough to encompass both a one-layer and a two-layer embodiment. Defendants propose the following construction: "The coated famotidine granules and the magnesium or aluminum hydroxide have been mixed together and then pressed together in a solid oral dosage form, such that a therapeutically effective amount of the famotidine and magnesium or aluminum hydroxide are in contact with each other in the solid oral dosage form." According to Defendants, this definition would cover only a one-layer tablet because the full therapeutically effective amount of the

famotidine granules would not be in contact with the antacid inside a two-layer tablet.

Only Plaintiffs' proposed construction is consistent with this Court's construction of the terms "mixing" and "compression mixture." Indeed, the evidence from the specification and prosecution history discussed above supports McNeil's construction of "in contact with." Defendants argue that a 1998 revision to the claims compels a narrower construction. When the examiner rejected several of McNeil's proposed claims following the submission of the Roche declaration, McNeil amended the claims further to recite for all composition claims:

1. [A] therapeutically effective amount of coated famotidine granules suitable for the treatment of gastric disorders and pharmacologically acceptable acid addition salts thereof; and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide ... [and]

2. [W]herein the oral dosage form has the coated famotidine granules and the aluminum hydroxide or magnesium hydroxide *in contact with each other,* but separated by the coating on the famotidine granules which is substantially impermeable to the aluminum hydroxide or magnesium hydroxide.

(Kiel Decl. Ex. 2: Paper No. 37, at 1-2 (emphasis added).) The examiner required the highlighted word "the" in the quoted claim proposal to be replaced with the word "said." (Kiel Decl. Ex. 2: Paper No. 39, at 2.) As issued, the '340 patent recites:

1. [A] therapeutically effective amount of impermeably coated famotidine granules for the treatment of gastric disorders and pharmacologically acceptable salts thereof; and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide ...

2. [W]herein the oral dosage form has said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide *in contact with each other,* but separated by said impermeable coating on the famotidine granules which is impermeable to the aluminum hydroxide or magnesium hydroxide.

(Emphasis added.) Because "said" coated famotidine granules refer to "a therapeutically effective amount of famotidine granules," Defendants claim that the examiner required a therapeutically effective number of famotidine granules to be in contact with the antacids. According to Defendants,this can only be achieved in a single-layer tablet.

The prosecution history does not support Perrigo's contentions. When the proposed claim recited "the coated famotidine granules," the word "the" clearly referred to the previous recital of "therapeutically effective amount of coated famotidine." The language required by the examiner-"said coated famotidine granules"-makes precisely the same reference back to the "therapeutically effective" language. The amendment, therefore, did not affect the meaning of the proposed claims. Indeed, the examiner explicitly regarded the amendment as a "matter[ ] relating only to the form of the claims and not the substance ..." (Kiel Decl. Ex. 2: Paper Nos. 38-39.)

Regardless, Defendants implicitly argue that unless the claims require only "some of the coated famotidine granules" to be in contact with the aluminum or magnesium hydroxide, every granule of therapeutically effective famotidine must touch the antacid. This argument is unavailing. The amended language ("said coated famotidine granules") could refer to a singular *group* of therapeutically effective famotidine granules, requiring only some portion of that group to be in contact with the antacids. This Court cannot

conclude that McNeil "clearly and unambiguously" disclaimed the two-layer coated granule embodiment. SanDisk, 415 F.3d at 1287.

Finally, the dictionary definition of "contact" undisputedly supports McNeil's construction. *Webster's* defines "contact" as a "union or junction of body surfaces: a touching or meeting." *Webster's,* at 490. In a two-layer coated granule tablet, the coated famotidine granules and the aluminum hydroxide or magnesium hydroxide are in contact when they touch or meet at the interface of the layers. Defendants offer no competing definition from a dictionary, treatise or encyclopedia. In light of the above, this Court construes the term "in contact with" in claim 1 to mean "a union or junction of body surfaces, a touching or meeting."

D. "*therapeutically effective amount*"

Claim 1 recites:

A solid oral dosage form for the treatment of gastrointestinal disorders comprising a *therapeutically effective amount* of impermeably coated famotidine granules for the treatment of gastric disorders ... and a *therapeutically effective amount* of aluminum hydroxide or magnesium hydroxide wherein the oral dosage form has said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other ...

(Emphasis added.) Plaintiffs construe "therapeutically effective amount" to mean "an amount appropriate for the treatment of gastrointestinal disorders." Defendants construe the term to mean at least 5mg of famotidine, at least 145.7mg of magnesium hydroxide and at least 130mg of aluminum hydroxide.

In view of the claim language this Court has already construed, it is unnecessary for the Court construe the term "therapeutically effective amount." The tablet envisioned by Perrigo's ANDA would contain 10mg of famotidine and 165mg of magnesium hydroxide. This tablet would infringe the ' 340 patent even if the Court were to adopt Defendants' proposed construction. Vivid Techs., Inc., 200 F.3d at 803 (stating that a court must construe "only those [claim] terms ... that are in controversy, and only to the extent necessary to resolve the controversy"). Presumably, Defendants dispute the construction of this term to bolster the argument that claim 1 requires each of the therapeutically effective famotidine granules to be in contact with the antacid. The Court has rejected that argument, thereby mooting the construction of "therapeutically effective amount."

E. "*impermeable*" *and* "*impermeably coated famotidine granules*"

[24] Claim 1 recites the following composition:

A solid oral dosage form for the treatment of gastrointestinal disorders comprising a therapeutically effective amount of *impermeably coated* famotidine *granules* [and antacids] ... separated by said *impermeable* coating on the famotidine granules which is *impermeable* to the aluminum hydroxide or magnesium hydroxide.

Claim 5 recites the following method:

b) coating the granules with a coating *impermeable* to aluminum hydroxide or magnesium hydroxide to form *impermeably coated* famotidine *granules;* c) mixing a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide with a therapeutically effective amount of *impermeably coated*

famotidine *granules* and pharmaceutically acceptable excipients to form a compression mixture ...

(Emphasis added.) According to Plaintiffs, "impermeable" refers to "a coating material that does not permit the passage of aluminum hydroxide or magnesium hydroxide," and "impermeably coated famotidine granules" means "famotidine granules that are coated with a material that is impermeable to the aluminum hydroxide or magnesium hydroxide." Plaintiffs' construction does not require that the impermeable coating cover the entire surface area of the granules, and instead describes a property of the coating material itself.

Perrigo contends that "impermeable" and "impermeably coated famotidine granules" refer to granules with coating that is "completely impermeable to the antacid and prevents any contact or interaction between any of the famotidine and any of the antacid." According to Perrigo, this construction would include only granules whose surface area is completely coated by the impermeable material.

The plain language of the claim is ambiguous. Some of the claim language focuses on the nature of the coating material. Claim 1 recites "*impermeable coating* on the famotidine granules which is impermeable to the aluminum hydroxide or magnesium hydroxide." (Emphasis added.) Likewise, claim 5 recites a method of "coating the granules with *a coating impermeable to aluminum hydroxide or magnesium hydroxide*." (Emphasis added.) At the same time, claims 1 and 5 each refer to "impermeably coated famotidine granules." This language arguably indicates that not only must the coating material be impermeable, but also that each famotidine granule must be completely encapsulated by the material.

The ambiguity arising from the claim language is resolved by the intrinsic evidence. The specification reveals that the inventors contemplated at least some interaction between the famotidine and the antacids. Famotidine degrades in small amounts even when isolated from the antacids. ('340 Patent, Fig. 5.) According to the specification, combining the "impermeably" coated famotidine with antacid could result in "an additional 1% by weight" degradation. ('340 Patent col. 4, ll. 5-14.) The "additional" degradation is caused by interaction between the famotidine and the antacids. Thus, "[t]he examples in the patents demonstrate that the inventors did not contemplate that each and every particle of [famotidine] must be enclosed perfectly ..." Astra Aktiebolag v. Andrx Pharm., Inc., 222 F.Supp.2d 423, 461 (S.D.N.Y.2002) (rejecting a claim constructionthat would disallow any imperfection in the coating of omeprazole particles).

Perrigo's proposed construction also contradicts the principle that claims be construed in the way that one of ordinary skill in the art would understand them. At the *Markman* hearing, Plaintiffs asserted, without objection from Defendants, that the coating procedures identified by the parties cannot achieve 100% coating on each famotidine granule. (Tr. at 30, 33-34.) "[O]ne of ordinary skill in the art would understand the terms ['impermable' and 'impermeably coated famotidine'] to include not only the perfect manifestations of these terms, but also objects that are as close to perfection as available technology can reasonably achieve." John Mezzalingua Assocs. v. Arris Int'l, Inc., No. 03 Civ. 353, 2003 WL 23282752, at (W.D.Wisc. Nov. 14, 2003). To require perfectly coated famotidine granules would be "inconsistent with the intrinsic evidence and the real world ..." Astra Aktiebolag, 222 F.Supp.2d at 471.

Defendants rely on statements in the examiner's Notice of Allowability to support their position. (Kiel Decl. Ex. 2: Paper No. 39, at 3-4.) There, the examiner required that claim 1 be edited to remove the term "substantially" from the phrase "coating on the famotidine granules which is *substantially* impermeable to the aluminum hydroxide or magnesium hydroxide." (Kiel Decl. Ex. 2: Paper No. 39, at 2.) Yet, as noted above, the quoted language refers to a property of the coating material, not the extent of coverage on the granule. Therefore, the removal of the word "substantially" is consistent with McNeil's view that only the

coating material need be completely impermeable.

Defendants also highlight the examiner's amendment changing the phrase "coated famotidine granules" to "impermeably coated famotidine granules." (Kiel. Decl. Ex. 2: Paper No. 39, at 2.) However, this amendment was adopted to eliminate a potential indefiniteness problem under 35 U.S.C. s. 112. As the examiner explained:

The instant claims have been amended to recite an "impermeable coating" or "impermeably coated" granules so that inconsistently narrow and broad references in the claims to what is apparently the same coating would be eliminated and a rejection under 35 U.S.C. 112 ... would thereby be avoided.

(Kiel Decl. Ex. 2: Paper No. 39, at 4.) Prior to the examiner's revision, the claims merely recited "coated famotidine granules" without explaining what material would be used for the coating.

Indeed, the prosecution history-and the Roche declaration in particular-supports Plaintiffs' construction of the terms. The examiner found the results of the Roche test sufficiently convincing to allow certain of McNeil's original claims. Yet it is undisputed that the *coated* famotidine in the Roche test experienced approximately 2% degradation, at least part of which resulted from interaction with the antacids. (Kiel Decl., Ex. 2: Paper No. 32, Figs. 4-5; Defendants' Claim Interpretation Brief, dated Feb. 24, 2006, at 9.) In other words, the coating used by Roche could not have precluded all interaction between the famotidine and the antacids because the coated famotidine experienced degradation that could only have been caused by the antacids. Defendants' papers rely heavily on the Roche test, but that test demonstrates that a person of ordinary skill would reject their proposed constructions of "impermeable" and "impermeably coated famotidine granules."

Finally, the sole dictionary definition of "impermeable" provided by the parties is: "not permeable: not permitting passage (as of a fluid) through its substance." *Webster's,* at 1133. This definition indicatesthat the word "impermeable" relates to the property of a substance, rather than the application of that substance to a surface.

This Court construes "impermeable" to refer to "a coating material that does not permit the passage of aluminum hydroxide or magnesium hydroxide," and "impermeably coated famotidine granules" to refer to "famotidine granules that are coated with a material that is impermeable to the aluminum or magnesium hydroxide, using Wurster coating, rotocoating or another coating process acceptable to a person of ordinary skill in the art."

F. ***Summary Judgment***

"Whoever without authorization makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore [directly] infringes the patent." 35 U.S.C. s. 271(a). It is undisputed that Perrigo's ANDA presents an oral dosage tablet with two layers, one consisting of 10mg of coated famotidine granules and the other consisting of 165mg of magnesium hydroxide. (Defendants' Tutorial Presentation, dated Apr. 25, 2006, at 2; Tr. at 35-36.) Claim 1 of the '340 patent recites a "solid oral dosage form ... comprising a therapeutically effective amount of impermeably coated famotidine granules ... and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide wherein the oral dosage form has said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other, but separated by

said impermeable coating ..." Claim 5 recites a method for manufacturing the solid oral dosage described in claim 1. This Court has construed claims 1 and 5 to encompass a bilayer tablet consisting of coated famotidine and magnesium or aluminum hydroxide. Perrigo concedes that 10mg is a "therapeutically effective amount" of famotidine and that 165mg is a "therapeutically effective amount" of magnesium hydroxide. (Defendants' Claim Interpretation Brief, dated Feb. 24, 2006, at 16.) Thus, Perrigo further concedes that if claims 1 and 5 include a bilayer dosage form, they encompass the ANDA's two-layer coated granule embodiment. The '340 patent reads directly on the ANDA and therefore, Perrigo has infringed on the '340 patent. Although Plaintiffs have not moved for summary judgment on their infringement claim, this Court is entitled to search the record and determine the motion in Plaintiffs' favor. See Coach Leatherware Co. v. AnnTaylor, Inc., 933 F.2d 162, 167 (2d Cir.1991) (holding that district court's sua sponte grant of summary judgment to non-moving party is "an accepted method of expediting litigation"); Korea Life Ins. Co. v. Morgan Guar. Trust Co. of New York, 269 F.Supp.2d 424, 435 n. 7 (S.D.N.Y.2003) (same).

III. Rule 11 ***Sanctions***

[25] Defendants assert that Plaintiffs violated Rule 11 by seeking attorneys' fees based on a claim of willful infringement. This Court disagrees.

[26] Under the Hatch-Waxman Act, "a court may award attorney fees under section 285" when an ANDA filer has infringed on a patent. 35 U.S.C. s. 271(e)(4). Title 35 U.S.C. s. 285 provides: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." Accordingly, attorneys' fees are awardable for infringement by an ANDA filing only in exceptional cases, which include "offensive litigation tactics, vexatious or unjustified litigation, or frivolous filings." Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1346-47 (Fed.Cir.2000). McNeil's infringement claims are predicated on the submission of ANDA 77-355 to the FDA. In paragraph 23 of the Complaint, Plaintiffs allege that "Perrigo's infringement of the '340 patent was and is willful," and paragraph 25 alleges that "[t]his case is in an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. s. 285."

In *Glaxo Group Ltd. v. Apotex, Inc.,* the Federal Circuit held that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees ..." Glaxo, 376 F.3d 1339, 1350-51 (Fed.Cir.2004); *see also* Astrazeneca Pharms. LP v. Mayne Pharma (USA) Inc., No. 02 Civ. 7936(WHP), 2005 WL 2864666, at (S.D.N.Y. Nov.2, 2005). According to Perrigo, the *Glaxo* opinion foreclosed recovery under s. 285 for willful infringement claims arising from an ANDA submission and therefore, McNeil had no basis for alleging willful infringement.

[27] Rule 11 sanctions for advancing a frivolous legal argument are only warranted where "under an objective standard of reasonableness, it is clear ... there is no chance of success and no reasonable argument to extend, modify or reverse the law as it stands." Morley v. Ciba-Geigy Corp., 66 F.3d 21, 25 (2d Cir.1995). McNeil had an objectively reasonable basis for its willful infringement claims. In certifications provided to the FDA, ANDA applicants explain why the FDA should approve the ANDA despite the existence of any patents that cover the drug for which approval is sought. Here, Perrigo submitted a "Paragraph IV" certification, whose purpose is to demonstrate that the '340 patent "is invalid or will not be infringed by the manufacture, use or sale of [Perrigo's] drug ..." 21 U.S.C. s. 355(j)(2)(A)(vii)(IV).

In *Glaxo,* the defendant's ANDA was "atypical in that it did not contain a certification pursuant to 21 U.S.C. s. 355(j)(2)(A)." Glaxo, 376 F.3d at 1344. In support of its holding that the "mere filing of an ANDA

[cannot] form the basis of a willful infringement finding," *Glaxo* noted that the defendant "did not file a paragraph IV certification of any kind, let alone one that made baseless accusations of invalidity ..." Glaxo, 376 F.3d at 1351. Therefore, McNeil argues that the holding in *Glaxo* was based in part on the absence of a Paragraph IV certification. Because Perrigo submitted a certification which, according to McNeil, contains baseless accusations of invalidity, McNeil argues that the present case is distinguishable from *Glaxo*.

Whether McNeil's argument is persuasive is irrelevant for purposes of deciding a Rule 11 motion. McNeil's willful infringement claims were not frivolous, and Perrigo's motion for Rule 11 sanctions is therefore denied.FN5

FN5. The issue of willful infringement is absent from Perrigo's motion for summary judgment on infringement and invalidity, filed on December 2, 2005. In the Rule 11 motion and accompanying papers, filed on March 3, 2006, Perrigo requests summary judgment on willful infringement as an alternative remedy to sanctions. This request violates Rule 11's requirement that a "motion for sanctions ... be made separately from other motions or requests." Fed.R.Civ.P. 11(c). Additionally, Perrigo's motion for summary judgment on willful infringement was unaccompanied by a statement of undisputed facts, in contravention of the Local Civil Rules. See Local Civil Rules of the United States District Courts for the Southern and Eastern Districts of New York, 56.1(a). For these reasons, this Court declines to consider that application.

VI. ***Invalidity***

[28] Perrigo also moves for summary judgment on grounds of invalidity, claimingthat the '340 patent is obvious in light of the prior art. For the reasons set forth below, Perrigo's motion is denied.FN6

FN6. Indeed, during oral argument, Perrigo's counsel conceded at various points that a trial appeared necessary to resolve issues of material fact. (Tr. at 37-38, 40, 45.)

[29] A patent claim is invalid if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. s. 103(a); Merck v. Teva, 395 F.3d 1364, 1372-78 (Fed.Cir.2005); Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 716 (Fed.Cir.1991). An obviousness inquiry involves examining the combination of elements in multiple prior art references. The ultimate determination of obviousness is a question of law that turns on the underlying facts. Sandt Tech. Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1354 (Fed.Cir.2001). In determining obviousness, the fact finder must consider the following "Graham factors": "1) the scope and content of the prior art; 2) the differences between the prior art devices and the claimed invention; 3) the level of ordinary skill in the art; and 4) objective considerations, such as commercial success, long felt need, failure of others, and copying." Sandt, 264 F.3d at 1354 (*citing* Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966)); Yamanouchi, 231 F.3d at 1343; Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1371 (Fed.Cir.2000).

[30] For a patent to be invalid for obviousness based "on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references." In re Rouffet, 149 F.3d 1350, 1355 (Fed.Cir.1998) (citing In re Geiger, 815 F.2d 686, 688 (Fed.Cir.1987)); ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed.Cir.1984). Such motivation must be established by clear and convincing

evidence. In re Dembiczak, 175 F.3d 994, 999 (Fed.Cir.1999); In re Rouffet, 149 F.3d at 1357-58. The Federal Circuit has pointed out that meeting this "burden is especially difficult when the asserted prior art was before the PTO examiner during the prosecution of the application." *Al-* Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 1323 (Fed.Cir.1999). The suggestion to combine references may flow from the problem itself, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573 (Fed.Cir.1996), or from "teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In re Rouffet, 149 F.3d at 1357. Thus, "when determining the patentability of a claimed invention which combines two known elements, 'the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.' " In re Beattie, 974 F.2d 1309, 1311-12 (Fed.Cir.1992) (quoting Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1462 (Fed.Cir.1984)).

[31] [32] [33] 35 U.S.C. s. 102, as limited by 35 U.S.C. s. 103(c), defines prior art for purposes of an obviousness analysis. Only "analogous art" may be considered. See Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 864 (Fed.Cir.1993); In re Clay, 966 F.2d 656, 658-59 (Fed.Cir.1992). The claimed invention as a whole must be compared to the prior art as a whole, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383 (Fed.Cir.1986); Hodosh v. Block Drug Co., 786 F.2d 1136, 1143 n. 5 (Fed.Cir.1986), and courts must avoid aggregating pieces of prior art through hindsight which would not have been combined absent the inventors' insight. *See* Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 880 (Fed.Cir.1998); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1552-53 (Fed.Cir.1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."). As a further check against hindsight analysis, the Court must consider "secondary considerations" of nonobviousness. Ruiz v. A.B. Chance Co., 234 F.3d 654, 662-63, 667 (Fed.Cir.2000); Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579 (Fed.Cir.1997). These considerations include evidence of commercial success and unexpected results. Dann v. Johnston, 425 U.S. 219, 230 n. 4, 96 S.Ct. 1393, 47 L.Ed.2d 692 (1976); Graham, 383 U.S. at 17-18, 86 S.Ct. 684; Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1378 (Fed.Cir.2005).

A. ***Scope and Content of the Prior Art***

In addressing the question of obviousness, this Court must determine the scope of the prior art. The Davis patent application WO 92/00102 and Wolfe U.S. Patent No. 5,229,137 are prior art reciting the combination of uncoated famotidine and magnesium or aluminum hydroxide in a solid oral dosage. (*See* Defs. SJ Exs. F-G.) The Davis application was based on the purported surprising result that antacids increase the bioavailability of histamine H_2-receptor antagonists. (Defs. SJ Ex. F at 3.) Thus, Davis "provides the use of an orally administrable pharmaceutical composition comprising a histamine H_2-receptor antagonist and an antacid for the manufacture of a medicament for the treatment of gastric disorders." (Defs. SJ Ex. F at 3.) Famotidine and aluminum hydroxide and magnesium hydroxide were among the H_2-blockers and antacids, respectively, recited by Davis. (Defs. SJ Ex. F at 4, 13-14.) Absent from Davis is any mention of impermeable coating for the H_2-blockers. Davis provides that "[c]ompositions may be formulated for oral administration in solid or liquid form, for example as tablets, capsules, powders, suspensions or dispersions." (Defs. SJ Ex. F at 7.) The H_2-blockers in the tablet formations may be "blended along with conventional tabletting aids, fillers and palatability aids" such as "flavoring agents." (Defs. SJ Ex. F at 7-8.)

Similarly, Wolfe claims a method of "orally administering ... together or substantially together an antacid in

an amount effective to substantially neutralize gastric acid and a histamine H_2-receptor antagonist ..." (Wolfe col. 7, ll. 27-30.) The claim "is based upon the unexpected realization that antacids and histamine H_2-receptor antagonists can be effectively administered together or substantially together to achieve continuous relief from pain, discomfort and/or symptoms associated with episodic heartburn ..." (Wolfe col. 2, ll. 2-7.) The invention encompasses famotidine, aluminum hydroxide and magnesium hydroxide. (Wolfe col. 7, ll. 49-52.) The modes of oral administration include "tablets, lozenges, aqueous or oily suspensions, dispersible powders or granules, emulsions, hard or soft capsules, syrups or elixirs." (Wolfe col. 4, ll. 34-37.) These compositions may contain "one or more agents such as, for example, sweetening agents, flavoring agents, coloring agents and the like, in order to provide a pharmaceutically elegant and palatable preparation." (Wolfe col. 4, ll. 40-43.) Wolfe does not recite the coating of H_2-blocker granules.

Additionally, the '114 patent teaches a method for coating granulated medicaments to mask the taste of active ingredients in chewable tablets.FN7 (See Defs. SJ Ex. J.) Although ibuprofen is the medicament included in the preferred embodiment of the invention, the '114 specification provides details for the coating of numerous additional medications, including famotidine. (' 114 Patent col. 2, ll. 53-57; col. 6, ll. 17-18; col. 7, ll. 35-42.) The coatings recited by the ' 114 patent are a blend of cellulose acetate, cellulose acetate butyrate and hyroxypropylcellulose (' 114 Patent col. 2, ll. 21-24), with a preferred coating weight of 7-15% of the total coated granule weight (' 114 Patent col. 7, ln. 41). The ' 340 patent recites the same coating materials at a similar coating weight. (' 340 Patent at col. 7, ln. 58-col. 8, ln. 27.)

FN7. Perrigo also cites Australian patent application AU-B-77234/91, which is identical to the '114 patent in all material respects.

Thus, it is undisputed that all relevant limitations of the '340 patent-the combination of famotidine and antacids, and use of the impermeable coating-appear in the prior art. Defendants contend that in light of Davis, Wolfe and the '114 patent, it would have been obvious to a person of ordinary skill in the art to combine impermeably coated famotidine granules with aluminum hydroxide or magnesium hydroxide in a solid oral dosage.

McNeil questions whether one of ordinary skill would have combined the cited references to form the chewable tablet taught by the '340 patent, as opposed to some other dosage form. Although the prior art does teach multiple embodiments, each reference cited by Defendants contemplates use of the tablet form. (See Wolfe col. 4, ll. 33-34 ("The pharmaceutical compositions may be in a form suitable for oral use, for example, as tablets ..."); Davis at 7, ll. 12-14 ("Compositions may be formulated for oral administration in solid or liquid form, for example as tablets ..."); '114 Patent col. 1, ln. 6-col. 2, ln. 19 ("This invention relates to tablets ...").) Therefore, the prior art presented the respective medications in the same form as the '340 Patent.

This Court must therefore consider the remaining *Graham* factors-and particularly, the differences between the prior art devices and the claimed invention, and objective considerations FN8-to determine whether the ' 340 patent is valid.

FN8. As in the infringement context, the parties do not discuss the issue of ordinary skill in the art. Therefore, this Court applies the same definition of ordinary skill described *supra*.

B. ***Differences Between Claimed Invention and Prior Art***

Again, there is no dispute that every limitation of the '340 patent is present in the cited references. Yet "[v]irtually all [inventions] are combinations of old elements." Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 698 (Fed.Cir.1983). "If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue." In re Rouffet, 149 F.3d at 1357. When the elements of the present invention exist in the prior art, this Court must inquire as to "whether there is something in the prior art as a whole to suggest the *desirability* ... of making the combination." In re Beattie, 974 F.2d at 1311. Defendants do not claim that prior art discloses famotidine degradation and, therefore, the motivation to combine the prior art cannot be to protect famotidine from the antacids. Rather, the purported motivation to combine the prior art was to mask famotidine's allegedly bitter taste. This is because Wolfe and Davis disclose combining uncoated famotidine and antacids, and the '114 patent teaches coating famotidine *for the purpose of taste-masking*.

Perrigo has failed to demonstrate by clear and convincing evidence that one of ordinary skill in the art would have been motivated to combine the prior art for the purpose of taste-masking famotidine. In re Dembiczak, 175 F.3d at 1000. In determining whether summary judgment should be granted to Perrigo on the issue of validity, this Court must view the evidence in a light most favorable to McNeil. This Court cannot conclude at summary judgment that (1) famotidine necessarily has a bitter taste, or (2) if it does, whether one of ordinary skill in the art would be motivated to mask famotidine's taste using an impermeable coating, as opposed to some other method of taste-masking. First, Perrigo is correct in asserting that a reasonable factfinder could infer famotidine's lack of palatability based on the inclusion of famotidine as an example in the '114 specification ('114 Patent col. 6, ll. 17-18; col. 7, ll. 35-42). See Fed.R.Evid. 401. Yet a reasonable factfinder need not make that inference. The '114 specification contains no discussion whatsoever about famotidine's taste. Rather, it merely describes a method of coating in the event that famotidine does have a bitter taste. Indeed, neither Wolfe nor Davis utilizes granule coating even though the '114 patent predates each of those references. The absence of coating in Wolfe and Davis tends to show that one of ordinary skill in the art would not be motivated to coat famotidine in order to mask famotidine's taste.

Moreover, viewing the evidence in a light most favorable to Plaintiffs, this Court cannot conclude that one of ordinary skill in the art would choose granule coating over the other methods of taste-masking disclosed in the prior art. Wolfe teaches the inclusion of "sweetening agents" and "flavoring agents" to provide for a "palatable preparation" of its famotidine and antacid tablets. (Wolfe col. 4, ll. 41-43.) Davis also teaches the use of "flavoring agents" and "palatability aids." (Davis at p. 7, ln. 19; p. 8, ln. 6.) Wolfe and Davis therefore offer a taste-masking solution that does not involve-and may in fact be superior to-coating the famotidine granules. The '114 patent itself concedes the availability of alternatives to impermeable coating, stating that "[i]n some cases, the taste of the active medicament in a tablet can be overpowered by adding flavoring ingredients to the tablet ..." ('114 Patent col. 1, ll. 49-51.)

[34] "When resolving an obviousness issue, the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." Grain Processing Corp. v. Am. Maize-Prods. Co., 840 F.2d 902, 907 (Fed.Cir.1988) (internal quotation omitted). It may be that famotidine has a pleasant taste. If it does not, but impermeable coating is unnecessary when sweeteners or flavors are used with famotidine, then one of ordinary skill would not have been motivated to combine Wolfe and Davis with the '114 patent, because the impermeable coating would have been superfluous. See Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1349 (Fed.Cir.2000) (affirming the district court's ruling that no motivation to combine the prior art was found in the "nature of the problem" because "no

'problem' was perceived"); *see also* In re Kotzab, 217 F.3d 1365, 1371 (Fed.Cir.2000) (holding that "particular findings must be made as to the reason the skilled artisan ... would have selected these components for combination in the manner claimed"). There is no record evidence showing that impermeable coating would adequately replace sweeteners and flavors to mask the taste of the famotidine. Nor is there evidence that the addition of coating to a sweetened and flavored tablet would improve the tablet's taste. Perrigo may demonstrate at trial that impermeable coating is useful when applied to sweetened and flavored famotidine. Nevertheless, Perrigo has failed to overcome its burden on summary judgment to show the absence of a genuine factual dispute. Ryko Mfg. Co., 950 F.2d at 716 (a motion for summary judgment on invalidity should be granted only "when the factual inquiries into obviousness present no genuine issue of material facts").

C. *Secondary Considerations*

"[I]t may be legal error for a district court to presuppose that all evidence relating to secondary considerations, when considered with the other *Graham* indicia relating to the obviousness/nonobviousness issue, cannot be of sufficient probative value to elevate the subject matter of the claimed invention to the level of patentable invention." Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 306 (Fed.Cir.1985). Assuming Perrigo had established a motivation to combine the prior art, the secondary considerations identified by McNeil would still preclude summary judgment. See Tec Air, Inc. v. Denso Mfg. Mich., Inc., 192 F.3d 1353, 1361 (Fed.Cir.1999) (holding that regardless of whether defendant had shown a motivation to combine the prior art, the showing could be rebutted by evidence of commercial success); Pro-Mold & Tool Co., 75 F.3d at 1574-75 ("Pro-Mold's evidence of commercial success ... created genuine issues of material fact precluding summary judgment."); Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1273 (Fed.Cir.1991) (denying summary judgment when "the factual issues surrounding the objective indicia were disputed, and material").

[35] First, "[c]ommercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." Merck, 395 F.3d at 1376. "When a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention." J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed.Cir.1997); Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed.Cir.1988) ("A prima facie case ... is generally made out when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent.")

NcNeil markets a chewable tablet containing coated famotadine and antacids as "Pepcid Complete." (Gabriele Decl. para. 6; Tr. at 15.) Defendants concede that Pepcid Complete embodies the features claimed in the '340 patent. (Defendants' Reply Brief in Support of Their Motion for Summary Judgment, dated Jan. 11, 2006 ("Defs. SJ Reply Br."), at 8.) Defendants also accept for the purposes of this motion that Pepcid Complete has enjoyed commercial success, with U.S. sales likely totaling over $200 million since the product's launch in December 2000. (Gabriel Decl. para. 7; Tr. at 121.) Perrigo "adduced no evidence to show that [Pepcid Complete's] commercial success was due to any factor other than its patented structure." Demaco, 851 F.2d at 1394. Absent such evidence,the financial success enjoyed by Pepcid Complete "strongly suggests that [McNeil] had created a new product." Pfizer Inc. v. Perrigo Co., 988 F.Supp. 686, 693 (S.D.N.Y.1997) (finding non-obviousness based in part on the invention's achieving "hundreds of millions of dollars in sales").

Likewise, it is undisputed for purposes of this motion that the Roche declaration submitted to the examiner during prosecution of the '340 patent contained unexpected results as to the prevention of famotidine degradation. (Defs. SJ Reply Br. at 8.) Perrigo argues that regardless of McNeil's showing of surprising results, its purported prima facie case of obviousness is sufficient to overcome them. This Court disagrees. "If the evidence used to establish the prima facie case were necessarily sufficient to overcome rebuttal of that case [by a showing of unexpected results], rebuttal would be impossible." Kao Corp. v. Unilever United States, Inc., 441 F.3d 963 (Fed.Cir.2006); see also In re De Blauwe, 736 F.2d 699, 706 n. 8 (Fed.Cir.1984) (stating that "[a] proper showing of unexpected results will rebut a prima facie case of obviousness"). "The basic principle behind this [ruling] is straightforward-that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." In re Mayne, 104 F.3d 1339, 1343 (Fed.Cir.1997). Based on the above, the secondary considerations weigh in favor of non-obviousness. *See* Rockwell Int'l Corp. v. United States, 147 F.3d 1358, 1366-67 (Fed.Cir.1998) (reversing district court's grant of summary judgment to defendants in part because of secondary considerations).

After consideration of the *Graham* factors, this Court concludes that Perrigo has failed to demonstrate by clear and convincing evidence that the ' 340 claims would have been obvious to a person of ordinary skill in art. There is no material dispute regarding the scope and content of the prior art or the level of ordinary skill in the art. However, the disputed factual issues regarding motivation to combine the prior art and the secondary considerations are sufficient to defeat Perrigo's motion. Medinol Ltd. v. Guidant Corp., 412 F.Supp.2d 301, 327 (S.D.N.Y.2005) (denying summary judgment when "disputed issues of material fact exist[ed] regarding the last two *Graham* factors: differences between the prior art and the claimed invention, and secondary considerations").

CONCLUSION

For the foregoing reasons, Defendants' motions for summary judgment on infringement and invalidity and for Rule 11 sanctions are denied. Summary judgment is awarded to Plaintiffs on their infringement claim.

SO ORDERED.