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

ASTRAZENECA AB, Aktiebolaget Hassle and AstraZeneca LP, KBI Inc. and KBI-E, Inc,
Plaintiffs-Counterclaim Defendants.
v.
DR. REDDY'S LABORATORIES, LTD., and Dr. Reddy's Laboratories, Inc,
Defendants-Counterclaim Plaintiffs.

No. 07 Civ. 6790 (CM)(GWG)

March 10, 2009.

Background: Patent owner filed action against competitor alleging infringement of patent directed to highly crystalline form of omeprazole magnesium. Competitor filed motion for summary judgment.

Holdings: The District Court, McMahon, J., held that:
(1) additional discovery was not needed before considering whether to grant summary judgment to competitor;
(2) failure of patent owner to compel compliance with court order requiring competitor to produce knowledgeable corporate witness barred it from complaining at summary judgment stage about adequacy of testimony of that witness;
(3) phrase, "by the addition of water," meant that quantity of water that was not present during steps 1 and 2 of four step process had to be deliberately and affirmatively placed into mixture during step 3, the "crystallization" step, which took place following separation of organic salts from reaction mixture;
(4) phrase, "by the addition of water," could not be construed expansively to include water by extraction from solution's constituent raw materials or water by absorption from ambient air;
(5) prosecution history estoppel barred patentee from claiming that crystallization could be "facilitated" only by water that happened to be present;
(6) patent had not been literally infringed;
(7) accused product that had been made by evaporative process using aqueous alcohol solvent had not been made with process that infringed patent; and
(8) patented manufacturing process that began with active ingredient of omeprazole magnesium that was 70% or more crystalline had not been infringed by process for manufacturing accused omeprazole magnesium finished product that was not at least 70% crystalline.

Motion granted.

5,690,960, 5,900,424. Construed and Ruled Not Infringed by.

Claire Ann Gilmartin, John Michael Griem, Milbank, Tweed, Hadley & McCloy LLP, Los Angeles, CA, Errol Bancroft Taylor, Milbank, Tweed, Hadley & McCloy LLP, New York, NY, for Plaintiffs/Counter

Defendants.

Bruce D. Radin, Louis Harry Weinstein, Budd Larner Rosenbaum Greenberg & Sade, P.C., Short Hills, NJ, for Defendants.

DECISION AND ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

McMAHON**, District Judge:**

This is a Hatch-Waxman patent infringement ease. The product at issue is omeprazole magnesium, which is the active ingredient in the popular antacid that sells under the trade name Prilosec. Prilosec has been a highly successful drug for its creator, AstraZeneca, due to the ever-increasing girth of Americans and an apparently concomitant growth in gastro-intestinal reflux disorder (GIRD) and similar ailments of the digestive tract.

AstraZeneca and various of its corporate affiliates hold a number of patents listed in the Food and Drug Administration's Orange Book, including U.S. Patent No. 5,900,424 (the "'424 patent"), and U.S. Patent No. 5,690,960 (the "'960 patent"). These two patents cover Prilosec OTC, an over-the-counter version of the original Prilosec product (which was for years available only by prescription). The OTC product is distributed by Proctor & Gamble under license.

The inventions disclosed in the '424 and the '960 patents are directed to a highly crystalline form of omeprazole magnesium. AstraZeneca takes the position that only a highly crystalline form of omeprazole magnesium is maximally effective in treating the gastro-intestinal disorders that are susceptible to Prilosec. The patents in suit disclose a particular form of omeprazole magnesium-one that is at least 70% crystalline-and a "unique water-based process" that Plaintiff uses to make it. To quote from papers filed early in the case by AstraZeneca:

The [424] patent discloses that the new omeprazole magnesium salts exhibit more than 70% crystallinity ... the claims cover the product itself, methods of treatment antisecretory diseases using the claimed salts, and processes for preparing the claimed salts. The patent states that to obtain the desired product, it is significant that the product have a "[c]rystalline form, with a degree of crystallinity of not less than 70%, preferably higher than 75% as determined by x-ray powder diffraction."

[The '960 patent] claims, *inter alia,* final, stable dosage forms of the omeprazole salts described in the '424 patent.

(Weinstein Second Decl. Ex. 12 at 3 (citation omitted).) This summary of the invention is reflected in the claim language: Independent Claim 1 of the ' 424 patent and Independent Claims 1 and 22 of the '960 patent all require that the omeprazole magnesium in the claimed inventions exhibit at least 70% crystallinity in its structure as revealed by x-ray powder diffraction. It thus goes without saying that if x-ray powder diffraction of a competing product does not reveal more than 70% crystallinity in the structure of the omeprazole magnesium it incorporates, the competing product does not infringe the patent.

Defendants (or "DRL") have developed a different form of omeprazole magnesium (amorphous, with less than 1% crystallinity detectable), using a different manufacturing process (evaporation of an alcohol-based

solvent in a drier), which they hope to market in competition with Prilosec OTC. As is customary when a generic product is about to be introduced, AstraZeneca has filed suit, alleging infringement of its patents. It contends, albeit solely on information and belief, that the omeprazole magnesium capsules in DRL's abbreviated new drug application No. 78-878 infringe the '424 and '960 patents.

Defendants strenuously deny that their product infringes the patents in suit, because the product they hope to market does not contain omeprazole magnesium that is at least 70% crystalline in structure. Defendants also argue that their product is not made using an environmentally-friendly water-based process, which is a key aspect of the '424 patent.

Defendants have moved for summary judgment on the ground of noninfringement. The motion is granted and the complaint is dismissed.

Prior Proceedings

AstraZeneca has filed a Rule 56(f) affidavit, claiming that it cannot respond to the motion for summary judgment because it needs additional discovery. In support of that application, it complains that this Court has not followed the procedure used in many Hatch-Waxman cases to move this matter toward disposition.

The Court is not aware that it is required to follow any particular procedure in order to dispose of this case-there are no special rules of civil procedure for Hatch-Waxman cases-and the public's interest in getting lower cost medicines onto store shelves as quickly as possible makes it imperative that these matters move along as quickly as possible, even if they are complex (which, to tell the truth, this matter is not). This Court is always looking for ways to streamline patent matters, to narrow the issues and expedite resolution. I used such a method in this case. So that the reader might understand exactly what has happened, I set forth the procedural history in some detail.

The complaint was filed on July 27, 2007. A Rule 16 conference in this case was scheduled for September 21, 2007.

Prior to the conference, the Court received letters from the parties about the scope of litigation. DRL asserted that its product did not infringe the patents in suit and suggested that this matter could be resolved quickly. Specifically, DRL asserted that the patents in suit claimed a water-based process for manufacturing omeprazole magnesium that is more than 70% crystalline, and the use of a more than 70% crystalline form of omeprazole magnesium in a commercially available product. Defendants averred that the omeprazole magnesium in their finished capsules-the product DRL intends to sell in competition with Prilosec OTC-is not even close to 70% crystalline in structure, is not manufactured using a water-based process, and does not come within the terms of any other claims of the '424 and '960 patents. Counsel for DRL claimed that they had offered to provide AstraZeneca with samples of Defendants' product for testing in an effort to stave off litigation; they also provided Plaintiff with so-called independent expert testing that confirmed non-infringement. DRL asserted that Plaintiff was more interested in suing and obtaining a 30-month injunction against. FDA approval of DRL's product than in learning the truth.

In response, AstraZeneca offered the Court no concrete evidence of infringement. Indeed, the complaint avers that Plaintiff was bringing suit at least in part "to employ the judicial process and the aid of discovery" (Compl. para.para. 33, 53) in order to obtain information about DRL's product, presumably to see whether there actually was infringement. All AstraZeneca was able to say in its response to DRL's effort to

streamline the litigation was that it had a "reasonable belief" that DRL's product "would have the same or similar active ingredient as Prilosec OTC," which it identified as "omeprazole magnesium in a stable crystalline form." However, counsel for AstraZeneca represented to the Court that the company had no interest in pursuing litigation if in fact the DRL product did not infringe. I took counsel at his word.

[1] Infringement, of course, requires proof that each and every claim element is met by the accused product or process. Failure to meet even a single limitation in a patent is sufficient to negate infringement of the claim. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed.Cir.1991). It appeared to the Court, after listening to both sides make their presentations, that this action might well be resolved without years of contentious discovery. DRL contended that its product did not infringe at least one limitation in the patents in suit-the crystallinity of the omeprazole magnesium. That contention could be easily and quickly tested, using the very procedure that AstraZeneca specified in the patents-x-ray powder diffraction. If it were true that DRL's omeprazole magnesium was not 70% crystalline, the case would be over. The same would be true if DRL did not achieve whatever crystallization occurred by "the addition of water," which was an essential element of Plaintiff's patented process.

However, even though Metro. Life Ins. Co. v. Bancorp Servs., L.L.C., 527 F.3d 1330 (Fed.Cir.2008) had not yet been decided, the Court was leery of not giving AstraZeneca any discovery at all. I therefore ordered DRL to produce samples of its product so that AstraZeneca could test it. Defendants did so, providing a sample from the one and only batch of omeprazole magnesium that had been formulated into a sale-ready product, and also samples of various batches of the salt. I also ordered DRL to respond to ten interrogatories (including subparts). I directed AstraZeneca to report back after it had tested the samples and to advise the Court whether it wished to continue with the lawsuit or not.

On November 7, 2007, AstraZeneca reported to the Court that it had tested samples from one batch of DRL's product-the very same batch that had been submitted to the FDA (because it was the only extant batch of finished capsules)- *and the capsules did not infringe the patents in suit*. Rather, they incorporated an amorphous form of omeprazole magnesium that was less than 1% crystalline when examined by x-ray powder diffraction. Plaintiff also received sworn interrogatory answers from DRL, one of which revealed that x-ray powder diffraction tests of ten other batches of the salt, made in connection with its DMF and ANDA filings, revealedthat every batch exhibited no crystallinity above a 1% limit of detection. (Griem Decl. Ex. 16 at 8 (Response to Interrogatory No. 9).)

Nonetheless, Plaintiff insisted that it needed substantial additional discovery before it could decide whether to continue with the lawsuit.

In view of the results of the tests on the product, the Court was skeptical. Indeed, it appeared to me that AstraZeneca was a party in search of a theory on which to proceed. But I did not cut off discovery. Neither did I open the door to unlimited discovery, which is what AstraZeneca obviously wanted. Instead, I directed AstraZeneca to specify exactly what additional discovery it wanted on the issue of infringement, and to justify its requests "on a claim by claim basis." (Weinstein Second Decl. Ex. 14.)

On November 19, 2007, AstraZeneca provided Defendants and the Court with additional proposed interrogatories, a number of proposed document requests and a request for depositions covering eight specified topics. (Weinstein Second Decl. Ex. 12.) The requests were addressed to (1) whether the samples provided by Defendants for testing were in fact representative of the omeprazole that was to be used in the finished product, and (2) whether there were differences between the processes used to make the samples

and the process that would be used by DRL to make the finished product. In particular. AstraZeneca claimed that it was possible that DRL "may be using a crystalline form of omeprazole magnesium during its manufacturing process" and then converting it "into an amorphous form via the process disclosed in its patent application or another method." (*Id*. at 21.)

DRL responded within a week, objecting to the requests as not having been justified "on a claim by claim basis" (which they were not FN1), and as otherwise unnecessary to consideration of a motion for summary judgment. DRL argued that the requests were not directed to the issue of infringement-particularly whether the finished capsules (the product Defendants intended to sell to the public) infringed the patents. DRL pointed out that claims in the patents in suit relating specifically to Prilosec OTC-AstraZeneca's product-could only be infringed if DRL's ANDA product, in its finished and marketable form, contained omeprazole magnesium that was more than 70% crystalline. DRL asserted that none of Plaintiff's additional discovery requests would reasonably be expected to produce evidence that DRL's *finished product* contained the patented form of omeprazole magnesium. (Weinstein Second Decl. Ex. 13 at 7.) DRL also argued that the requests were not designed to reveal evidence about infringement in the process of manufacturing that finished product. (*Id*. at 8.)

FN1. "On a claim by claim basis" means that AstraZeneca was to identify how each discovery request was relevant to particular, identified claims in the patent in suit.

After reviewing these submissions, this Court concluded, "AstraZeneca's discovery requests smack of a fishing expedition." (Weinstein Second Decl. Ex. 14.) Nevertheless, the Court ordered DRL to produce portions of its ANDA and DMF, as filed with the FDA, and also to make available a witness with knowledge of DRL's process for manufacturing omeprazole magnesium. I ordered that this happen quickly. However, by agreement of the parties, the deadline for the deposition was extended from the end of December 2007 until May 23, 2008.

When the deposition was over, AstraZeneca protested that the witness was not prepared or able to answer certain questions.Allegedly for that reason, AstraZeneca-which still had no evidence that the ANDA product at any point contained high crystalline omeprazole magnesium-declined to withdraw the lawsuit. However, Plaintiff also did not seek additional discovery or bring a motion to compel compliance with this Court's order that a knowledgeable witness be produced. Instead, the parties finished briefing this motion for summary judgment.FN2

FN2. Actually, at the Rule 16 conference, the Court asked the parties to treat DRL's letters attempting to narrow the issues in suit as a motion for summary judgment on the issue of infringement. All subsequent papers have been filed in support of or in opposition to that motion. The last papers relating to the motion-and a motion to quash some of the evidence offered by AstraZeneca, which is denied-were filed in August 2008.

DISCUSSION

A party is entitled to summary judgment when there is no "genuine issue of material fact" and the undisputed facts warrant judgment for the moving party as a matter of law. Fed.R.Civ.P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). In addressing a motion for

summary judgment, "the court must view the evidence in the light most favorable to the party against whom summary judgment is sought and must draw all reasonable inferences in [its] favor." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986).

Whether any disputed issue of fact exists is for the Court to determine. Balderman v. United States Veterans Admin., 870 F.2d 57, 60 (2d Cir.1989). The moving party has the initial burden of demonstrating the absence of a disputed issue of material fact. Celotex v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

Once the motion for summary judgment is properly made, the burden shifts to the non-moving party which "must set forth specific facts showing that there is a genuine issue for trial." Anderson, 477 U.S. at 250, 106 S.Ct. 2505 (*quoting* Fed.R.Civ.P. 56(e)). Because the District Court must determine "whether there is a need for trial-whether, in other words, there are any genuine factual issues that properly can be resolved ... in favor of either party," id., the non-moving party, in order to defeat the motion, must produce "sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party.... If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Id. at 249, 106 S.Ct. 2505 (citations omitted).

While the Court must view the record "in the light most favorable to the non-moving party," Leberman v. John Blair & Co., 880 F.2d 1555, 1559 (2d Cir.1989) (citations omitted), and "resolve all ambiguities and draw all reasonable inferences in favor of the party against whom summary judgment is sought," Heyman v. Commerce and Indus. Ins. Co., 524 F.2d 1317, 1320 (2d Cir.1975) (citations omitted), the non-moving party nevertheless "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec., 475 U.S. at 586, 106 S.Ct. 1348 (citations omitted). Not every disputed factual issue is material in light of the substantive law that governs the case. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude summary judgment." Anderson, 477 U.S. at 248, 106 S.Ct. 2505.

[2] Patent cases are amenable to summary judgment. Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd., 731 F.2d 831, 835 (Fed.Cir.1984). That is true even where the patent in suit is complex-but the patents here in suit are not particularly complex.

A. AstraZeneca's Request for Additional Discovery Is Denied

[3] The Court rejects the notion that AstraZeneca's Rule 56(f) discovery request should be allowed to take additional discovery before finally responding to this motion. While the Federal Circuit took a district court to task for not allowing adequate discovery in Metro. Life, that is not the case here. AstraZeneca has been permitted to take limited discovery that specifically relates to the issue of whether DRL's finished product or its process for manufacturing that product infringes the patents in suit in a particular way. No wider-ranging discovery is needed, since it is quite clear, as a matter of law, that unless DRL's finished product contains omeprazole magnesium that is 70% crystalline which highly crystalline salt is manufactured by the addition of water during a crystallization step-Defendants are entitled to prevail.

[4] Furthermore, if Plaintiff believed that DRL failed to comply with prior orders concerning discovery-specifically, the Court's order that it produce a knowledgeable witness who could testify pursuant to Federal Rule of Civil Procedure 30(b)(6)-it should have moved to compel compliance. Its failure to do so bars it from complaining about the adequacy of the witness' testimony at this point.

B. The Relevant Claims in the Patents in Suit

1. Product Claims

The '424 patent claims an omeprazole magnesium salt having a degree of crystallinity which is higher than 70% as determined by x-ray powder diffraction, together with variations on that salt that are not here relevant.

The '960 patent claims a stable oral pharmaceutical formulation containing the patented salt, a sub-coating layer and an enteric-coating layer sufficiently thin to permit the release of the salt into the small intestine.

Put colloquially, the '424 patent claims the highly crystalline form of omeprazole magnesium, and the '960 patent claims the pharmaceutical product that is sold as Prilosec OTC.

2. Process Claims

The '424 patent claim includes not only the salt, but also a process for manufacturing omeprazole magnesium of the desired crystallinity, consisting of four consecutive steps: (1) treating omeprazole or its salt with magnesium alcoholate in a solution; (2) separating the resulting inorganic salts from the reaction mixture; (3) crystallizing magnesium omeprazole by the addition or water, and (4) isolating the crystals so obtained. (Claim 11.) Several variations on this process are also claimed, but all variations require that the magnesium omeprazole be crystallized "by the addition of water." (Claims 12-19.) The amount of water to be used is not specified in the patent claims; the disclosures in the specification reveal that large quantities of water are put into the mixture at the third manufacturing step. In one variant on the process, the solvent to be used at the first step of the four-step process is specified to be methanol. Claim 20, which, according to a representation made by plaintiff to the Patent Examiner, corresponds to Claim 11, outlines a four-step process for manufacturing a "crystalline" salt, including a third step that "adds" water.

The '960 patent claims a process for manufacturing a pharmaceutical antacid containing the patented salt (Prilosec OTC). This process, too, involves four steps: (1) forming a core containing the patented salt; (2) applying at least one sub-coating layer onto that core in the presence of water: (3) further applying in the "presence of water" at least one enteric-coating layer onto the sub-coated core; and (4) drying the resulting product (Claim 10), and one variation on that process in which the sub-coating layer(s) is/are applied on the core material by a dry-coating process (Claim 11). Of critical importance, every claim in the '960 patent requires that the salt used in the pharmaceutical product be of the highly crystalline variety (more than 70% crystalline) that is the subject of the '424 patent.

C. Summary of The Relevant Prosecution History of the Patents in Suit

1. Product Claims

[5] During the prosecution of the applications for the patents in suit, AstraZeneca repeatedly argued that its claims were patentable because they were *limited* to a highly crystalline form of omeprazole magnesium-specifically, to a salt that was more than 70% crystalline. AstraZeneca insisted that, "There is no disclosure in the primary reference pertaining to magnesium omeprazole salt of degree of crystallinity of more than 70%," (Weinstein Second Decl. Ex. 4 at 3), and argued that the inherent advantage of its salt-the thing that represented an improvement over the prior art-was its extremely stable, highly crystalline structure.

(Weinstein Second Decl. Ex. 5 at 5-10.)

2. Process Claims

For the salt: During prosecution, AstraZeneca stated that "a further distinguishing feature of the claimed process is the use of an aqueous alcohol solvent, e.g., methanol, to put omeprazole in solution and the subsequent use of a different solvent, water, to recover the crystalline magnesium omeprazole sale from solution." (Weinstein Second Decl. Ex. 8 at 5.) The process being distinguished was found in an existing patent (the '974 patent), which relied on the evaporation of the organic solvent methanol to obtain omeprazole magnesium. (Id.) AstraZeneca described the use of two different solvents (methanol at the beginning, water at the end) as "an important contribution to the recovery of crystals of the claimed magnesium omeprazole salt that are suitable as pharmaceutical substances." (*Id*.) According to both Claim 11 and Claim 20 of the '424 patent, the inorganic salts are separated from the reaction mixture "prior to the crystallization step by the addition of water." (Weinstein Second Decl. Ex. 2 at 6:4-5.) In separate, recent briefs to the Court, the parties agreed that the phrase "by the addition of water" modifies the words "crystallization step," not the words "separating inorganic salts from the reaction mixture." (Pl. Br. Claim Constr. at 7; Def. Br. Claim Constr. at 8.)

For the pharmaceutical product containing the salt: In prosecuting the ' 960 patent, AstraZeneca claimed that its water-based process was both "novel" and "environmentally friendly through the absence of organic solvents" in the production of the sub-coating layer. (Weinstein Second Decl. Ex. 5 at 6-7.)

D. Claim Construction

1. "By the addition of water"

As previously stated, the patents in suit are easy to understand. They use plain language to describe common concepts and familiar products, However, AstraZeneca argued that summary judgment would be premature because there has been no Markman hearing to construe disputed claims.

Defendants not surprisingly viewed this as another stalling tactic by Plaintiff. There is nothing particularly complicated about a phrase like "70% crystalline." However, AstraZeneca insisted that the phrase "by the addition of water" required construction.

Exercising my authority to handle Markman issues at any point in the lawsuit and in any way that seems best suited to disposing of them, I decided to hold a Markman hearing "on papers" after I became apprised of this dispute. In accordance with my customary procedure, which is to address the issue of claim construction only considering intrinsic evidence as a first step, I directed counsel to point me to any intrinsic evidence that would support a construction broader than the normal and natural construction of the words "by the addition of water." (*See* Docket No. 53.)

The parties submitted concise briefs that (to borrow a salient word) "crystallized" their dispute over the meaning of the phrase "by the addition of water." After considering both sides' submissions, I agree with DRL that that AstraZeneca's proposed interpretation of that phrase-aside from making absolutely no sense-represents a desperate attempt to extend its patents by stretching the concept of "adding" water to incorporate the natural and perpetually ongoing process of atmospheric evaporation and absorption. I therefore reject it in favor of Defendants' sensible construction of the phrase. I see no need for any second Markman phase, which would involve the submission of extrinsic evidence.

The plain meaning of the phrase "crystallizing magnesium omeprazole by the addition of water" is "turning magnesium omeprazole into crystalline form by affirmatively putting extra water into" whatever mixture or substance contains the omeprazole magnesium. There is a strong presumption that the words used in a claim take on their ordinary and customary meaning to those of ordinary skill in the art (not just their ordinary and customary meaning), but there is no evidence that the phrase "addition of water" is a term of art. Rather, the words chosen by the patentee are simple and easily understood-even by those of us who are not skilled in the art of crystallizing salts, but who are skilled in the "art" of adding water to something (such as a pot of tea or a box of cake mix).

AstraZeneca argues, however, that the phrase should be construed to mean "by the use of water in sufficient proportion to other solvents to facilitate crystallization." (PI. Br. Claim Constr., at 1.) It contends that the specification-which of course provides texture and context to the claims, thereby allowing one skilled in the art to understand the invention, *see* Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996)-necessitates this broad reading of the word "addition."

Some background is in order. As the reader is by now aware, the claimed invention is a salt that is first treated with magnesium and then rendered highly crystalline "by the addition of water" (which facilitates crystallization) to the mixture in which the treated salt is present. In its interrogatory answers, DRL revealed that a certain amount of water was present in each of the batches of omeprazole magnesium that it manufactured-between 6.5% and 9.1% by weight. (Griem Decl. Ex. 16 at 6 (Response to Interrogatory No. 7).). In its brief opposing summary judgment, AstraZeneca noted that the highly crystalline salts manufactured using AstraZeneca's "novel, water-based" process had between 5 and 10% water by weight, and argued that this coincidence created a genuine issue of fact concerning whether DRL's manufacturing process infringed on the patented process by "adding water."

The problem with this argument is that DRL had responded fully to an interrogatoryasking it to describe the process by which it manufactured omeprazole magnesium. (*Id*. at 13-14 (Response to Interrogatory No. 10).) Nowhere in the process described was any water added to anything.

Recognizing this, and having no evidence to contradict it, AstraZeneca does not argue that DRL affirmatively pours new water into a mixture or solution containing omeprazole magnesium prior to evaporating that solution in a Agitated Thin Film Drier (which is how DRL creates its finished salt). Rather, Plaintiff suggested that water could have been introduced into the process at some point, either via the raw materials that were used to make the salt (some of which might have contained miniscule portions of water), or by absorption from the atmosphere. (Pl Opp'n at 12.) While conceding that water was added as a "separate solvent" in the embodiment set forth in the patent specification-thereby admitting that the specification did not reveal any example in which water that was merely present in either the ingredients or in the atmosphere precipitated the requisite crystallization-AstraZeneca contended, "[T]he claims do not require that the water be added as a separate solvent. Water can be added to the process through other means as well, so long as the water is added in some way, whether through solvent, *atmosphere,* and is present in sufficient amounts when needed." (*Id*. at 6) (emphasis added.)

The clear import of AstraZeneca's argument is that any batch of omeprazole salt that contains water will somehow infringe the patents in suit-even if additional quantities of water were not deliberately added to the salt (or to any solution containing the salt) during the manufacturing process, but were instead absorbed

into the mixture from the surrounding air. AstraZeneca effectively says as much in its Claim Construction Brief; it argues that the phrase "by the addition of water" should be read as equivalent to "in the presences of water"-specifically, in the presence of enough water to facilitate crystallization of a salt. (It is for that reason that AstraZeneca equates "addition" with "use" in its proposed definition).

To support this strained (to say the least) reading of the phrase "by the *addition* of water," Plaintiff focuses on the following language from the specification: "The process for manufacturing the new form of magnesium omeprazole differs from the earlier known processes in that the product is recovered after a controlled crystallization step in aqueous alcohol, preferably methanol ..." (Griem Decl. Ex. 1 at 3:14-15.) From this, AstraZeneca says, one skilled in the art would deduce that "water is clearly present during the crystallization step." (Pl. Br. Claim Constr. at 2.) Plaintiff notes that crystallization is facilitated when water "is added to the methanol solvent ... so that its proportion increases" relative to its prior concentration in what is clearly described as an "aqueous" (i.e., water-based or water-containing) alcohol solvent. (*Id*.) Plaintiff argues that one skilled in the art would understand that, "the essential aspect of the addition of water in the specification is that when the proportion of water is increased relative to the methanol in the process, crystallization is facilitated ...." (*id*. at 3) and asserts that, "Any process that 'adds water' relative to the amount of other solvents to facilitate crystallization meets the literal terms of Claims 11 and 20 in this regard." (*Id*.)

DRL argues that AstraZeneca's proposed construction of the phrase "by the addition of water" is unwarranted for a number of reasons.

First, Defendants note that the claims in suit describe a process comprising four sequential steps, Sequential steps bear a temporal relationship to each other, with one taking place prior to the next. The third of these consecutive steps-and claim 11 explicitly requires " *consecutive* steps" (Weinstein Second Decl. Ex. 2 at 4:53 (emphasis added))-is "crystallizing omeprazole magnesium by the addition of water." (*Id*. at 4:57-8.) This step comes after step one (treating the omeprazole in an aqueous solution containing magnesium) and step two (separating the inorganic salts from the resulting mixture). (*Id*. at 4:54-56.) Likewise, claim 20 explicitly requires the separation of inorganic salts " *prior* to the crystallization step by the addition of water." (*Id*. at 6:4-5 (emphasis added).)

The plain meaning of adding water to something is affirmatively and deliberately putting water into that something. In the context of this patent-adding water *in a deliberately sequential crystallization step*-the word "adding" can only mean putting water that was not present in the mixture during steps 1 and 2 into the mixture at step 3. DRL's proposed construction flows naturally from the language of the claims; Plaintiff's does not.

Second, DRL urges that the specification-far from supporting AstraZeneca's broad reading of the word "addition"-actually supports the more literal construction it espouses. The specification describes a process in which a lot of water is added in order to induce crystallization of omeprazole magnesium from solution. The specification's generalized process describes a crystallization step that follows the step of separating the inorganic salts: the solution is seeded and, "An amount of water, which is approximately equal to the volume of the solution, is *added* to start the crystallization." (*Id*. at 3:3-6) (emphasis added.) As Plaintiff itself notes (*see* Pl. Br. Claim Constr. at 2), this suggests that a very generous amount of water is put into an existing solution (which already contains water, since it is an aqueous solution)-an amount of water so great that it literally doubles the volume of the mixture, giving the new water and the old mixture a 1:1 ratio (as Plaintiff concedes in its Claim Construction Brief). Thus, the embodiment described in the specification

plainly calls for affirmatively putting in water that was not already there. Water in such a volume could not be "added" during a manufacturing process by extraction from the solution's constituent raw materials (which water would not be "added," since it would already be present). Nor could it occur by absorption from the ambient air.

Underscoring that the addition of a large amount of water is anticipated, the lone example of the process given in the specification describes a process in which the liquid that remained following the separation of inorganic salts "was seeded with magnesium omeprazole crystals *whereafter* the magnesium omeprazole was precipitated by *addition* of 900 [liters] of water." (Weinstein Second Decl. at 3:42-45 (emphasis added).) This embodiment, which refers to putting more than 237 gallons of water into a pre-existing liquid, can likewise only be understood to contemplate putting in water that was not already present.

[6] Not surprisingly, Plaintiff contends that Defendants are trying to limit the scope of the claim language to the preferred embodiment. But if there were any doubt that the specification undermines rather than supports AstraZeneca's proposed definition, it was put to rest in the recent case of Netcraft Corp. v. eBay, Inc., 549 F.3d 1394, 1399 (Fed.Cir.2008). In that case, the Federal Circuit squarely held that where no language (much less express language) in the specification indicated that a disputed term was meant to disclose an alternative embodiment, the specification would be deemed not to includeadditional embodiments. In other words, courts should not construe claims expansively if no disclosure in the specification supports a broad construction.

[7] Nothing in the specification of AstraZeneca's patents (particularly the '424 patent) supports the notion that an increase in the amount of water in a mixture containing omeprazole by virtue of some naturally-occurring process (like absorption) would embody the claimed invention. Therefore, applying Netcraft, the disputed term cannot be read so broadly.

Third, DRL contends that the prosecution history supports its literal reading of the disputed phrase. It notes that AstraZeneca amended all the process claims to include "by the addition of water" as a claim limitation. In an amendment filed on July 31, 1998, Plaintiff inserted the term "by the addition of water" into the crystallization step of pending claim 9 (which eventually became claim 11 in the '424 patent). (Choi Decl. Ex. 23 at 2 (the underscoring in the amendment shows the words being added).) AstraZeneca told the Examiner that this amendment put the limitation of pending dependent claim 12 (Choi Decl. Ex. 33 at 9:17-18 ("the crystallization is accomplished by addition of water")) into pending independent claim 9. (Choi Decl, Ex. 23 at 4.) Because pending claim 9 was the only pending independent process claim, this amendment necessarily added the limitation "by the addition of water" into the crystallization step of each and every pending process claim.

The same amendment also added new claim 36, which became issued claim 20 in the '424 patent. (Id. at 3.) AstraZeneca specifically averred that new claim 36 corresponded to original claim 9. (Id. at 4.) New claim 36 stated, as does claim 20 of the issued patent, that "the improved process comprises separating inorganic salts from the reaction mixture *prior* to the crystallization step by the addition of water." (Id. at 3 (emphasis added).)

As a result of the amendment, all of the process claims were limited to crystallizing by the "addition" of water in some sort of clearly sequenced series of steps.

After amending the claims in this manner, AstraZeneca filed a Supplemental Amendment on October 1,

1998, (Weinstein Second Decl. Ex. 8), in which it told the Examiner that its basic invention resided in a *controlled* crystallization step, where water is added to form crystals of omeprazole magnesium *after* the step of separating inorganic salts:

Advantageously, the inventors of the subject invention discovered that a magnesium omeprazole salt having a high degree of crystallinity could be recovered after a controlled crystallization step in aqueous alcohol and this salt was more suitable and, hence, preferred for use in full scale production (Lindberg Declaration, para. 6). ***Specifically,*** inorganic salts are separated from the mother liquor ***prior to the addition of water*** to form crystals of magnesium omeprazole (*See,* amended claim 9).

(Id. at 4-5 (emphasis added).) Logic dictates that if the separation of inorganic salts is *prior* to "the addition of water" the "addition of water" must come *after*. In this context, the addition of water must mean putting water into the mixture that was not there when the salts were separated from the mother liquor. The water cannot be part of the ingredients in the salt's raw materials, because that water would be part of the mixture before the second (separation) step. And the new, additional water cannot come from the air, because there is no telling when it was absorbed-certainly not limited to a discrete third step.

The argument in the Supplemental Amendment that "the addition of water" comes *after* separating inorganic salts was not a mere slip of the pen by AstraZeneca's patent attorney, according to DRL. Rather, it is confirmed by Dr. Per Lindberg, the Head of the Preclinical Alliances Group of Astra Hassle AB. (Choi Decl. Ex, 21 at para. 1.) AstraZeneca submitted his Declaration to the Examiner to support the patentability of the claims over the prior art. Dr. Lindberg twice declared, under penalty of perjury, that the water used to form the crystals is added *after* the step of separating inorganic salts.

Specifically, in paragraph 14 of his declaration Dr. Lindberg declares that "Inorganic salts are separated from the mother liquor *prior* to the addition of water to crystallize magnesium omeprazole." (Id. at para. 34 (emphasis added).) In paragraph 6 of his Declaration Dr. Lindberg is even more explicit about the criticality of adding the water *after* the separation of the inorganic salts:

According to the invention, inorganic salts are separated from the mother liquor *prior* to the addition of water to form crystals of magnesium omeprazole.

(Id. at para. 6 (emphasis added).) Far from suggesting that water from the ambient air can enter the product at any point, Dr. Lindberg's declaration demonstrates that the needed water must be deliberately put into the mixture *during a crystallization step that comes after separating the inorganic salts*.

The Examiner accepted this argument. In the Notice of Allowability the Examiner stated under the heading " ***Reasons for Allowance*** " that it was the *step* of adding water to crystallize the product that made the process claims patentable:

The process claims are patentable *because of the step of adding water* to crystallize the claimed product.

(Choi Decl. Ex. 34 at 2 (emphasis added).) FN3

FN3. The Examiner's use of this formulation gives the lie to AstraZeneca's argument, made at page 6 of its Claim Construction Brief, that the only thing that has to happen at the third step is crystallization-not the addition of water.

Having made this statement, the Examiner invited AstraZeneca to submit any comments it considered necessary. (Id.) No comments were submitted-certainly not any comments suggesting that the patent claims as amended contain "no restriction on when or how water is added to the process," rather than requiring that it be added as part of a properly sequenced, separate and identifiable step. For Plaintiff now to argue otherwise, DRL urges, is wrong.

The Court agrees. AstraZeneca's construction disregards the simple, plain and easily understood words of the claim ("by the addition of water") in favor of a construction ("the use of water in sufficient proportion to other solvents to facilitate crystallization") that is litigation-driven and overly complex. Plaintiff takes the clear words of the claims and renders them far less comprehensible to a trier of fact. At no point in the patent prosecution did Plaintiff so much as suggest that the word "addition" had anything other than its ordinary and commonly understood meaning, or that it ought to be construed as some sort of term of art. Indeed, the meaning of the words "addition" and "adding" is so obvious that AstraZeneca did not define it, but simply used it, over and over again, in its submissions to the Patent Office-which indicates that the term, far from requiring explanation, defines itself. AstraZeneca even continues to refer to "the addition of water" in a self-defining way in its Claim Construction Brief.

In the end, AstraZeneca's proposed construction cannot be accepted because it is inherently self-contradictory. It reads out of the patent the patentee's own descriptionof the way that extra water (over and above that which is already present in the aqueous solution) gets into the mixture-via a discrete and sequenced *step* that facilitates *controlled* crystallization. If, as Plaintiff here maintains, there is "no restriction on when or how water is added to the processes," then the crystallization *step* is not really a step at all, let alone one that occurs at a specific point in the manufacturing process, after the inorganic salts are separated from the mother mixture. And if water that is present in the raw materials used to create the mixture, or that is absorbed into the mixture from the ambient air, causes the crystallization, then crystallization *is not controlled*-it occurs at whatever rate, and to whatever degree, the naturally-occurring water allows it to occur!

Thus, AstraZeneca's proposed construction does violence to its own carefully-crafted description of its invention. While I think DRL guess too far when it describes Plaintiffs AstraZeneca's proposed construction as "shockingly Orwellian," it is clearly beyond the pale.

[8] Finally, Plaintiff's proposed claim construction is barred by law. During prosecution all of the process claims were repeatedly rejected and no process claims were allowed until AstraZeneca added the words "by the addition of water" to the crystallization step. Plaintiff argued that the "addition" of the water in a discrete step that took place *after* separating the inorganic salts was the basis of the invention. As a result, AstraZeneca cannot obtain the much broader construction it now seeks.FN4

FN4. DRL exhibits 33, 35, 4, 38, 39 and 23 (listed in date order) (attached to Choi Decl.), show the status of the claims during prosecution and DRL exhibits 36, 37 and 22 (listed in date order) (attached to Choi Decl.) show the three rejections that issued on August 9, 1996, April 22, 1997, and January 27, 1998, respectively. DRL exhibits 8 and 21 (attached to Choi Decl.) show the argument AstraZeneca made to obtain allowance of the claims.

Under Supreme Court precedent, AstraZeneca's amendment of the crystallization step to include "by the addition of water," after the repeated rejection of claims that did not have that limitation, absolutely prohibits it from obtaining a construction that would cover what it gave up. *See* Smith v. Magic City Kennel Club, Inc., 282 U.S. 784, 790, 51 S.Ct. 291, 75 L.Ed. 707 (1931) ("limitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected, *must be strictly construed against the inventor* and looked upon as disclaimers.") (emphasis added); *accord* Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1334 (Fed.Cir.2003) (quoting Smith and affirming a summary judgment of no infringement).

By contrast, in Carboline Co. v. Mobil Oil Corp., 301 F.Supp. 141 (N.D.Ill.1969), the case on which Plaintiff relies, the claim at issue (unlike the claims here) was not a process claim with recited steps. Id. at 143 n. 2. Carboline's holding of infringement was under the doctrine of equivalents, and the court did not construe what the claims literally meant. Id. at 152 (applying the function, way, result test). Most importantly, the court found that there was nothing in the prosecution history of that patent to indicate that the patentees "intended to restrict themselves" to any particular process for making the claimed product. Id. at 152-53. Here that cannot be said.

Claim 20

[9] While the parties have agreed that the claim limitation "by the addition of water" in claim 20 modifies the words "crystallization step" and not "separating inorganic salts from the reaction mixture," AstraZeneca nevertheless seeks to read the limitation out of the claim. Claim 20 does not need a separate construction. Rather, claim 20 claims the same process as claim 11, and its construction is controlled by the same intrinsic evidence.

The plain language of claim 20 states that the improvement over the prior art process is "separating inorganic salts from the reaction mixture prior to the crystallization step by the addition of water." (Choi Decl. Ex. 23 at 3.) This plain language makes clear that the crystallization step (1) follows the step of separating inorganic salts, and (2) is performed by putting water into the mixture during that step.

The claim that became claim 20 was added in the July 31, 1998 Amendment, in which AstraZeneca explained that the added claim corresponded to the claim that became claim 11 in the issued patent, but that it was being written in different form to highlight the claimed invention. (*Id*. at 4 ("which have been written in Jepson form to clearly recite the improvement vis-a-vis the prior art").) There is nothing in the prosecution history to support a conclusion that "by the addition of water" in claim 20 should be interpreted differently from "by the addition of water" in claim 11.

Plaintiff asserts, at page 8 of its Claim Construction Brief, that "there can be no suggestion that the term 'by the addition of water' has to require that the water be added only at the time of crystallization." Having told the Examiner it was using the same words in a different form to claim the same process in order to obtain allowance of the claims, it is improper for AstraZeneca to argue now that the different form of the same words means something else.

I therefore conclude that the phrase "by the addition of water," as used throughout the '424 patent-in every claim in which it appears-means that a quantity of water that was not present during steps 1 and 2 of the four step process must be deliberately and affirmatively placed into the mixture during step 3 (the "crystallization" step), which takes place following the separation of organic salts from the reaction mixture.

I agree with Defendants that there is no basis in the intrinsic evidence to suggest AstraZeneca's construction that the crystallization need only be "facilitated" by water that happens to be present, rather than being deliberately put into the process.

E. DRL's Motion for Summary Judgment on the Product Claims is Granted

[10] With the Markman issue out of the way, it is clear that no dispute of material fact prevents the Court from granting Defendants' motion for summary judgment dismissing AstraZeneca's claim that DRL's finished product infringes the two patents in suit.

Independent Claim 1 in each patent plainly discloses an invention consisting of or incorporating omeprazole magnesium at a crystallinity of 70% or more as revealed by x-ray diffraction. For the product claims, the issue is whether DRL's finished capsules-not any intermediate product that may be temporarily formed during the manufacturing process-contain omeprazole magnesium that is at least 70% crystalline. *See* Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527-28, 92 S.Ct. 1700, 32 L.Ed.2d 273 (1972); Zoltek Corp. v. United States, 442 F.3d 1345, 1359 (Fed.Cir.2006) (noting that an "accused product infringes a patent claim only if each and every limitation in the claim appears in the accused product") (*citing* V-Formation, Inc. v. Benetton Group SpA, 401 F.3d 1307, 1312 (Fed.Cir.2005).) The very same finished product that was sent to the FDA for clearance-Batch EC6319-was also given to AstraZeneca, which tested the sample using x-ray diffraction. The test did not reveal 70% crystallinity, which is the touchstone of the patented salt. Instead, it revealed an amorphous (non-crystalline) product with no crystallinity above 1% limit of detection. Similarly, not a single batch of product-ready salt (i.e., magnesium omeprazole that had been manufactured but not yet incorporated into ready-for-sale capsules) was 70% crystalline. The tests run by DRL showed no crystallinity above a 1% limit of detection (Griem Decl. Ex. 16 at 8 (Response to Interrogatory No. 9))-well below the extraordinarily high level of crystallinity that characterizes the patented salt.

Thus, there is simply no evidence that DRL's finished product infringes on Claim 1 of either patent. In fact, all the evidence, including tests run using the detection process specified in the patent, is to the contrary.

All of the product claims of the '424 patent are dependent on, and import the limitations of, Claim 1 of that patent-that is to say, all of the product claims in the '424 patent explicitly require that the omeprazole magnesium mentioned in that claim be more than 70% crystalline in structure. Similarly, all of the product claims in the '960 patent are likewise dependent on Claim 1 of that patent, which is for a stable oral formulation comprising, *inter alia,* a core containing magnesium omeprazole that is crystalline at more than 70%. Since there is no evidence whatever that DRL makes or uses a salt with the requisite degree of crystallinity, there is no need for detailed discussion of any other product-based claims: none is infringed.

In its response to the motion for summary judgment on the product claims, AstraZeneca argues that x-ray diffraction testing on DRL's finished product "may be difficult or impossible" and that there may be "other methods that might be used to measure crystallinity." (Pl. Opp'n at 21.) But AstraZeneca was the master of its own patent application, and the patents in suit *require* that the necessary degree of crystallinity be visible using x-ray powder diffraction. The fact that DRL's finished product (a tablet) must be crushed in order to run the test is irrelevant-especially since AstraZeneca has not explained why any other method of testing for crystallinity (and none is identified) would uncover what the method specified in its patent claims failed to find. Nor do AstraZeneca's experts suggest any reason why the process and apparatus used by DRL would result in a finished product containing 70%-or-more crystalline omeprazole magnesium. Absent such

evidence, AstraZeneca has not raised any genuine issue of material fact that would defeat DRL's motion for summary judgment on the product claims.

AstraZeneca also notes that the last step in DRL's manufacturing process involves micronizing its omeprazole magnesium, and argues that the omeprazole magnesium might well have been crystalline prior to micronization. The problem with this argument is that the micronized salt-which is not 70% crystalline-is used in DRL's finished product. That is the end of any argument that the finished ANDA product infringes.

Unable to adduce any evidence that the finished DRL product contains salt of the requisite crystallinity. AstraZeneca is reduced to arguing that DRL's product "probably" contains highly crystalline omeprazole magnesium, because the use of any other type of omeprazole "is less attractive in full scale production." (Luk Dec. para. 5.) Put otherwise, Plaintiffs expert opines that use of the amorphous substance revealed by AstraZeneca's own tests will result in an inferior product.

But as DRL points out, a competitor wishing to introduce a lower cost competingproduct would be likely to design the product around the patent, even if the patented product is in some respects clinically superior. And since the principal and central claim of the patents in suit is *highly crystalline* omeprazole magnesium, the logical step for a competitor who wishes to use omeprazole in its antacid is to use a salt that is *not* highly crystalline! AstraZeneca may well be right that Prilosec OTC is superior to DRL's, but that battle will be fought in the marketplace; it is for consumers to decide whether they can obtain sufficient relief-gastric and otherwise-using DRL's "inferior" but less expensive product.

For these reasons, DRL's product does not literally infringe Independent Claim 1 in either patent in suit, or any claim that depends thereon.

[11] And so we come to the doctrine of equivalents-an issue that is simply disposed of. Because AstraZeneca argued to the USPTO that its patented product could be distinguished from other products because it was more than 70% crystalline, it cannot now argue that a product less than 70% crystalline infringes under the doctrine of equivalents. Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 995 (Fed.Cir.2003).

Therefore, Defendants are entitled to summary judgment dismissing the claim that their finished product infringes the '424 and '960 patents. FN5

FN5. All the discovery in the world would not give AstraZeneca a stronger argument against dismissal, because the use of a highly crystalline form of omeprazole magnesium as revealed by x-ray diffraction in the finished pharmaceutical product is the *sine qua non* of the patents in suit.

F. DRL's Motion for Summary Judgment on the Process Claims is Granted

[12] 35 U.S.C. s. 271(g) makes it an infringement to import a product that does not infringe any product claim if the product was made overseas using an infringing process:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale or use of the product occurs during the term of such patent ...

A product which is made by a patented process will, for purposes of this title, not be considered to be so made after-

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

For purposes of summary judgment only, the Court assumes that the statutory predicates for this section are met. DRL does not contest the issue at this stage, but has announced that it will do so if the Court does not grant summary judgment on the process claims.

AstraZeneca's argument is that, somewhere in the course of manufacturing a product that does not infringe its patents, DRL must create a product that *does* infringe-namely, a salt that is at least 70% crystalline-and must do so by the addition of water, as required by the patented process.FN6

FN6. A 70% crystalline salt that is not created by "the addition of water" at the third step in a four step process would not infringe.

The two processes-one for manufacturing omeprazole magnesium and one for manufacturing the pharmaceutical end product-are described above. I will deal first with the process for making the active ingredient, the salt omeprazole magnesium.

Claim 11 of the '424 patent is directed to a process for the manufacture of the patented salt. The process requires that the omeprazole be treated with magnesium in the presence of an organic solvent (such as methanol, which is specified in Dependent Claim 13). Then the treated salt must be recovered (separated) from the reaction mixture. At the third step, the resulting compound must be crystallized "by the addition of water." Absorption is nowhere mentioned in Claim 11, or anywhere else in the patented process.

The undisputed evidence demonstrates that DRL prepares the highly amorphous, virtually non-crystalline omeprazole magnesium that is found in its finished product by using an organic solvent to treat the omeprazole with magnesium and then evaporating the solvent in a device called an Agitated Thin Film Drier. There is no evidence that DRL adds water to the mixture after separating out the treated salt. Indeed, at no point in the manufacture of DRL's salt is additional water (over and above whatever may be present in the solvent) deliberately added to the solution containing the omeprazole and magnesium. As noted above, the Court declines to interpret the phrase "by the addition of water" to encompass situations in which some amount of water is present, either because water is found in some raw material or because of the natural process of absorption from the ambient air.

DRL freely admits that its process is similar to the prior art process that AstraZeneca distinguished in order to obtain the '424 patent. The Examiner originally rejected the '424 patent as obvious over U.S. Patent 4,738,974 (the '974 patent). AstraZeneca addressed this rejection in a Supplemental Amendment dated October 1, 1998. (Weinstein Second Decl. Ex. 8.) It specifically represented that its process was different from the process disclosed in the '974 patent because, after "an aqueous alcohol solvent, e.g. methanol" is used to put omeprazole in solution, there followed "the subsequent use of a different solvent, i.e., water, to recover the crystalline magnesium omeprazole salt from solution." (*Id*. at 5.) The '974 patent, by contrast,

used methanol at both steps: first dissolving the omeprazole salt into methanol, and then evaporating it away to obtain a crystal. AstraZeneca specifically stated that the use of two different solvents at two different times "is an important contribution to the recovery of crystals .... that are suitable as pharmaceutical substances." (*Id*.) This critical difference between the process used by DRL to retrieve its salt from solution and the patented process makes literal infringement impossible as a matter of law.

AstraZeneca responds by noting that DRL admits (1) that the various batches of omeprazole magnesium it has produced contain a certain amount of water-between 6.5% and 9.1% water by weight-both after drying and after micronization (*see* Griem Decl. Ex. 16 at 6 (Response to Interrogatory 7)); and (2) the presence of water (humidity) can cause a substance to become more crystalline. (*Id*. at 7 (Response to Interrogatory 8).) Since the amount of water present in the aqueous methanol solvent used at the outset of DRL's manufacture is (admittedly) insufficient to account for the water content of the batches, AstraZeneca argues that water may be introduced into the process via raw materials (sugar spheres, for example) or absorbed from the atmosphere, and thereafter concentrated during the evaporation of the methanol in the Agitated Thin Film Drier. Plaintiff notes that its patented omeprazole magnesium contains between 5% and 10% water, and argues that this raises a genuine issue of fact concerning process infringement.

This argument was addressed and effectively rebutted in the Markman phase of this decision. The patent in suit does not claim crystallization "in the presence of water" or even crystallization "by the use of water." Rather, an infringing manufacturer would have to induce crystallization by taking the affirmative step of adding water to the omeprazole salt that has been (1) treated with magnesium and (2) subsequently separated. DRL's evaporative process does not "add" water in the sense of deliberately putting new water (water not previously present) into the mixture. There is no dispute about this. Neither is there any dispute that water is present-in the air, in the solution-resulting in a certain amount of water by weight in the active ingredient that DRL manufactures. Astra Zeneca argues that this means DRL "adds" water during the manufacturing process, as required by Claims 11 and 20. But DRL does not "add" the water from the humidity in the air to the mix; it does not deliberately put water into the process. Since there is water in the air everywhere (even in the desert), all pharmaceuticals are subject to having water "added" by operation of Mother Nature. The Court has already rejected any such definition of the phrase "by the addition of water;" that means Defendants do not infringe the '424 patent.FN7

FN7. In a footnote at page 8 of its Claim Construction Brief, AstraZeneca asserts that Claim 20 of the '424 patent "does not require that the resulting magnesium omeprazole salt be highly crystalline." And indeed, Claim 20 (which is for a process for the manufacture of a magnesium salt) speaks only of a "crystalline magnesium salt" rather than a "highly crystalline" salt. However, there is still no question of infringement, because Claim 20 requires "the addition of water" at a discrete third step of the process for manufacturing the "crystalline" salt of which it speaks. Therefore, it is not necessary to discuss whether DRL's process for manufacturing an amorphous, non-crystalline salt could possibly infringe Claim 20 of the '424 patent.

[13] As for the '960 patent: this is the patent that discloses the process for using the salt that is the subject of the '424 patent to manufacture the commercial product Prilosec OTC (the product disclosed in Claim 1). It is beyond peradventure that Claim 10 (the independent process claim), and every claim that derives therefrom, requires that the manufacturing process begin with an active ingredient that is 70% or more crystalline. When dealing with the '960 patent, it is irrelevant whether or not DRL's omeprazole magnesium might achieve such a high level of crystallinity at some point during the manufacturing process of the salt, because the starting point is the finished salt, and there is no genuine issue that the omeprazole magnesium being

used by DRL in its capsules is not at least 70% crystalline. Therefore, DRL's process for manufacturing its finished product cannot possibly infringe any claim in the '960 patent.

Again, and for the reason articulated above (see p. 613, supra), the doctrine of equivalents is of no help to AstraZeneca.

CONCLUSION

Defendants are entitled to summary judgment dismissing Plaintiffs complaint. Defendants' motion to strike certain submissions (Docket No. 47) is denied (*see supra* note 2, at page 602) and any other motion that may be pending should be denied as moot and marked off calendar. The Clerk of the Court is directed to enter judgment for Defendants and to close the file.

S.D.N.Y.,2009.
AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd.