EXHIBIT 2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC, Plaintiff, v. NOVEL LABORATORIES, INC., Defendant.	Civil Action No.: 11-1341(PGS) **MEMORANDUM AND ORDER**

SHERIDAN, U.S.D.J.

This matter comes before the Court in order to construct four claim terms. See, *Markman v. Westview Instruments*, 517 U.S. 370 (1996). The claim terms in dispute are a) purgation; b) clinically significant electrolyte shifts; c) aqueous hypertonic solution; and d) effective amount. Before addressing the construction of each, some background information at the standard for claim construction is set forth.

Background

Braintree is a small pharmaceutical company that manufactures colon preparation products. Such products became more prevalent in the sixties when the colonoscope was invented. The colonoscope allows a physician to examine the bowel of the colon to determine whether polyps or cancerous lesions appear. The colon needs to be visually clear in order to successfully perform a colonoscopy; and the usage of the colonoscope was initially stymied by large amount of fecal matter which clouded the pictures being observed on the colonoscope. As a result, the preparation for the colonoscopy required that the colon would be cleared. This preparation included drinking liters of

a solution which caused diarrhea. Through the diarrhetic reaction, the colon was sufficiently cleared to allow a doctor to satisfactorily examine inside the colon. Since most patients disliked the taste and the large quantity of the solution imbibed, there was significant non-compliance with the preparation protocol. Due to the non-compliance, doctors often found that the colon was not clear enough to successfully perform the colonoscopy.

At the end of the nineties, a phospho soda solution was invented which substantially reduced the quantity of solution necessary to prepare the colon. Unfortunately, this product caused electrolyte abnormalities which resulted in unexpected dangerous side effects including heart and kidney failure as well as death in certain cases. As a result, the FDA required warnings to doctors. Due to the dangerous side effects, in the early 2000's, it was apparent that a new preparatory product was needed.

During that period of time, inventors Cleveland and Fordtran designed a reduced volume colonic purgative formulation that avoids the dangerous side effects and electrolyte imbalances. On September 5, 2005, U.S. Patent No. 6,946,149 (the '149 Patent) was granted to Braintree. Later, on June 30, 2009, an ex parte reexamination certificate was issued[1].

The claims in dispute are claims 15 and 18. They state:

> 15. A composition for inducing purgation of the colon of a patient, the composition comprising about 100 ml to about 500 ml of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.
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> * * *

[1] Throughout this opinion, the Court refers to the ex parte certificate in examining the disputed claim terms presented in this case.

> 18. A composition for inducing purgation of the colon of a patient comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution consisting essentially of an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

The Court held a Markman Hearing on June 15 and 18, 2012, in which David A. Peura, M.D., John F. Johanson, M.D., and David Goldfarb, M.D. testified. Each disputed term is discussed after the standard for claim construction is set forth.

I. STANDARDS FOR CLAIM CONSTRUCTION

There is a two-step analysis for determining patent infringement: "first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007) (citation omitted). When the court engages in claim construction to determine the meaning of disputed claim terms, it is decided as a matter of law. *Markman v. Westview Instruments*, 517 U.S. 370, 372 (1996). It is well established that "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Id.*

When construing claims, the court must focus on the claim language. As explained by the Federal Circuit:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to particularly point out and distinctly claim the subject matter which the patentee regards as his invention.

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-16 (Fed. Cir. 2004)

(citations omitted). When looking at the words of a claim, the words "are generally given their ordinary and customary meaning," which has been defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

The Federal Circuit has counseled:

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning usage in the field. The inventor's words that are used to describe the invention—the inventor's lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decision making process by reviewing the same resources as would that person, viz., the patent specification and prosecution history.

Id. at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). Those resources, called intrinsic evidence, include the claim language, the specification, and the prosecution history. *See id.* at 1314.

However, when intrinsic evidence alone does not resolve the ambiguities in a disputed claim term, extrinsic evidence—evidence that is outside the patent and prosecution history—may also be used to construe a claim. *See id.* at 1317; *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996). "[E]xtrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art" may be consulted; for example, expert testimony, dictionaries, and treatises. *Id.* at 1314. However, when a court relies on extrinsic evidence to construe a claim, the court should be guided by the principle that extrinsic evidence may never

conflict with intrinsic evidence, because courts "have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.* at 1319. Thus, a court should take care to "attach the appropriate weight to be assigned to those sources." *Id.* at 1322-24.

II. THE DISPUTED CLAIM TERMS- '149 PATENT

Purgation

The key dispute was the definition of the word "purgation." Braintree argues that "Purgation is an evacuation of a copious amount of stool from the bowels after oral administration of the solution." Braintree posits that purgation is a method for ridding fecal matter from the colon; and as a result of purgation, cleansing of the colon may occur. Novel, on the other hand, contends that purgation means cleaning.

Novel argues that Braintree acted as its own lexicographer by defining colonic purgation as synonymous with colon cleansing. See *Philips v. AWH Corp.*, 415 F. 3d 1303, 1313 (Fed. Cir. 2001). As such, Novel rephrases purgation to be defined as:

> Allowing the administered composition to induce colonic purgation: Permitting the administered composition having an effect amount of Na_2SO, an effective amount of $MgSO_4$, an effective amount of K_2SO_4, and a volume from about 100 ml to about 500 ml to cleanse the colon in preparation for surgical or diagnostic procedures.

Novel's argument that "purgation" means "cleansing" has some merit. For instance, in the "background" section of the '149 Patent it states that "the colon must be thoroughly purged and cleansed" (Col. 1, L 17-18), and there are other areas of the specification that reference a "colon cleaning catharsis" (Col. 3, L. 34), "cleaning the colon" (Col. 4, 7-8), and the "quality of colon cleansing." (Col. 11, 47). At first blush, these references indicate that "purgation" is synonymous

with "cleansing". However, the term "cleanse" is never used in the language of claims 15 and 18. Both claim 15 and 18 begin with the phrase "a composition for inducing purgation of the colon." Hence, when enumerating the claims, the inventors were being more precise with their use of "purgation." The witnesses noted the distinctions between the claim and the specifications. Dr. Peura described purgation "as a result water comes in, and an osmotic diarrhea, a purgation is caused, by these poorly absorbable sulphate salts, and -- which has resulted from water being pulled into the lumen of the intestine and this results in a large amount of diarrhea, a copious amount." (T. 32, 1-10) and T. 34, 16-20). Dr. Fordtran, a co-inventor, stated that the colon must be "clear" of fecal matter, and this could be very different from the colon being "cleansed". (T. 15, 14-15). Even Dr. Johanson, an expert for Novel, indicated that he had to see "90% of the lining of the colon" in order to perform a colonoscopy successfully (T. 84, 5-10); and that "as much fecal matter as possible be removed to permit adequate visualization." (T. 88, 7-10). Hence, Dr. Johanson does not suggest a cleansing of the colon is necessary, rather it is removal of fecal matter in order to increase visibility. As such, purgation as set forth in the claim is different from cleansing. Although cleansing is a term used in the specification of the '149 Patent, claims 15 and 18 clearly adopt purgation as the methodology to improve visualization of the colon.

In addition to the intrinsic references to the term purgation, there is some extrinsic evidence as well. For instance, in *Stedman's* Medical Dictionary (126th Ed., p. 1469), purgation is defined as an "evacuation of the bowels with the aid of a purgative or cathartic." Or, as Dr. Peura indicated, purgation means "an evacuation of a copious amount of stool from the bowels after oral administration of the solution." The Peura definition gives the fact finder a more precise understanding of what purgation is; as opposed to "cleansing" which may connote a different image

of the process to the factfinder.

Aqueous Hypertonic Solution

Claims 15 and 18 adopt the term "aqueous hypertonic solution". Braintree defines aqueous hypertonic solution as:

> Aqueous hypertonic solution: a water-based mixture of poorly absorbable sulfate salts that creates an osmotic pressure gradient between the bowel and bodily fluids large enough to induce the movement of water from the body into the bowel and thereby produce a purgation.

Novel's definition of aqueous hypertonic solution is not as complex as Braintree's definition. It reads:

> From about 100 ml to about 500 ml of an aqueous hypertonic solution means approximately 100 - 500 ml of a water based mixture of electrolytes present in a concentration higher than in the human body.

Both Novel and Braintree agree that "aqueous" means "a water based mixture" so the word "aqueous" will be constructed as "water based mixture." Braintree's definition relies upon the explanation of Dr. Peura. Dr. Peura testified that the solution contains a concentration of sulphate salts, and these

> . . . are poorly absorbed. And these poorly absorbed sulphate salts remain in the intestine when they're ingested, and they create a difference in osmotic pressure, a pressure gradient across the semipermeable membrane, which in this case is the intestinal lining or the lining of the intestine.
>
> So as a result water comes in, and an osmotic diarrhea, a purgation is caused, by these poorly absorbable sulphate salts, and -- which has resulted from water being pulled into the lumen of the intestine . . . when that water is pulled in, diarrhea occurs; a large amount of diarrhea, a copious amount.

(T. 31, 20 through T. 32, 5).

More simply put, Dr. Peura summarized "water is pulled in, diarrhea occurs." Dr. Johanson,

Novel's expert, agreed with Dr. Peura's analysis. When asked about Dr. Peura's and Braintree's definition, Dr. Johanson concluded "yeah it seems reasonable." (T. 132, 23-25). Although Braintree's construction is somewhat complex, Novel's definition is so basic that it does not assist the fact finder in analyzing the claim. Accordingly, the specifications are consistent with Braintree's construction wherein it explains "the aqueous phosphate salt concentrate produces a tremendous osmotic effect on the intra-luminal contents of the bowel, and therefore evacuation of the bowel occurs a large influx of water and electrolyte into the colon from the body." (Col. 2, 21-28). Based on Dr. Peura's testimony and Dr. Johanson's concurrence, the Braintree construction is the better construction of the term.

Effective Amount

Claims 15 and 18 include the term "effective amount" three times within each claim. The claims use the phrase "an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$ and an effective amount of K_2SO_4". Braintree constructs "an effective amount" as:

> The amount and combination of salts necessary to produce a colonic purgation, while not producing clinically significant electrolyte shifts.

Novel's constructs "effective amount" in two ways.

> An amount of $Na_2SO_4/MgSO_4/K_2SO_4$ sufficient on its own to cleanse the colon in preparation for surgical or diagnostic procedures; or
>
> An effective amount of the composition: from about 100 ml to about 500 ml of a composition, administration or which is sufficient to cleanse the colon in preparation for surgical or diagnostic procedures.

Dr. Peura testified that Braintree's construction of "an effective amount" has two components. First, it must produce purgation, and second it must prohibit any clinically significant electrolyte shifts. (T. 53, 13 through T. 44, 5). According to Dr. Peura, Novel's construction misses the mark for several reasons. First, it fails to address the requirement of "not producing clinically significant electrolyte shifts." (T. 44, 24-25). As such, Dr. Peura noted that if there was excessive potassium sulphate in the solution, as Novel's construction could allow, it could "lead to a fatal complication." (T. 45, 18-22) (T. 46, 14-18). And finally, Dr. Peura notes that claim 23 requires two doses of the solution to be administered. A single dose' is not sufficient. (T. 47, 10-15). As such, "an effective amount" contemplates two doses over a period of time to prevent any clinically significant electrolyte shift which is not provided in the Novel construction.

In conclusion, Novel's construction is unacceptable for two reasons. First, the '149 Patent does not state that "an amount of the salts sufficient on its own." The '149 Patent appears to "balance" the salts in a "mixture"; and the specifications indicate that "one or more sulfate salts" may be used (Col. 3, 52-55) which indicates that a combination of the sulfate salts may be in the solution. (Col. 4, 58-67). Secondly, the Novel construction relies on "cleansing the colon", but, as stated above, "cleansing" is at odds with the construction of the word purgation. There is no reason to introduce the term "cleansing" here in light of the construction of purgation above.

As such, Braintree's construction is adopted.

Clinically Significant Electrolyte Shifts

Claims 15 and 18 include the term "any clinically significant electrolyte shifts." Braintree constructs the term as "alterations in electrolyte chemistry outside the upper or lower limit of a normal range, which are produced by ingestion of the solution and have an adverse effect on the health of a

subject, as determined by a medical professional." Novel constructs the term differently:

> "Wherein the composition having an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, and a volume from about 100 ml to 500 ml does not, when administered to any patient, increase or decrease blood chemistry values outside the normal upper or lower limits of their normal range indicate that any electrolyte shift has occurred."

From reading the specification, it also provides a definition of "the terms clinically significant." According to the specification, it is meant to "convey alterations in blood chemistry that are outside the normal upper or lower limits of their normal range or other untoward effects. These solutions are hyperosmotic, that is, the electrolyte concentration of the solution is much higher than the electrolyte concentration in the human body." (Col. 2, 47-53).

Since the term "other untoward effects" is ambiguous in the specification, it appears Braintree changed the term to "adverse effect on the health." Novel's expert, Dr. Goldfarb indicated that Braintree's insertion of a medical physician to determine the "adverse effect on the health of a subject" is unreasonable because each doctor may evaluate health needs differently. As such, it is indefinite. The constructions proposed by Braintree and Novel do not clarify the term much. It appears that "untoward effects" may refer to those fatal side effects of the phospho soda solution because such side effects are referred to in the specification. Hence the definition in the specification is more precise than the construction of the parties, and is adopted.

ORDER

IT IS on this 19th day of September, 2012

ORDERED that the following terms are constructed as set forth below.

1. Purgation is an evacuation of a copious amount of stool from the bowels after oral administration of the solution.

2. Aqueous hypertonic solution is a water based mixture of poorly absorbable sulfate salts that creates an osmotic pressure gradient between the bowel and body fluids large enough to induce the movement of water from the body into the bowel and thereby produce a purgation.

3. Effective amount is the amount and combination of salts necessary to produce a colonic purgation, while not producing clinically significant electrolyte shifts.

4. Clinically significant electrolyte shifts is meant to convey alterations and blood chemistry that are outside the normal upper or lower limits of their range or other untoward effects.

s/Peter G. Sheridan
PETER G. SHERIDAN, U.S.D.J.

September 19, 2012