

Abstract

Attempting to invalidate Plaintiff's patents, Defendant asserted Plaintiff failed to disclose the 'best mode' in their U.S. application, as required under U.S. law. Defendant supplied as support Plaintiff's PCT application, which disclosed a mode different from the U.S. application mode, and the fact that the PCT application mode was better than the U.S. application mode. The court held that, because of the "stringent" requirements of the 'best mode' doctrine and Applicant's statement in the PCT application that the disclosed mode was 'another method', non-inclusion of the PCT application mode in the U.S. application was not a violation of the 'best mode' doctrine.

ABBOTT LABORATORIES, an Illinois corporation, Plaintiff, v. ALRA LABORATORIES, INC., an Illinois corporation, Defendant.

92 C 5806

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

October 20, 1997, Decided  
October 24, 1997, Docketed

**COUNSEL:** For ABBOTT LABORATORIES, plaintiff: Mark E. Barmak, Catherine A. Sazdanoff, Abbott Laboratories, Abbott Park, IL.

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For ALRA LABS INC, defendant: Russell W. Pyle, Juettner, Pyle & Lloyd, Chicago, IL.

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For ABBOTT LABORATORIES, counter-defendant: Daniel E. Reidy, James R. Daly, Lester Julian Savit, Robert C. Micheletto, Jones, Day, Reavis & Pogue, Chicago IL.

**JUDGES:** James B. Zagel, United States District Judge.

**OPINIONBY:** James B. Zagel

**OPINION:** MEMORANDUM OPINION and ORDER

Abbott Laboratories has sued Alra Laboratories for infringement of two of its patents covering divalproex sodium. Abbott and Alra have filed cross motions for summary judgment on the infringement issue.

Background The two patents at issue, the '731 and '326 patents, are entitled "Sodium Hydrogen Divalproate Oligomer," another name for divalproex sodium. Divalproex sodium was originally identified as useful to treat epileptic seizures or convulsions. More recently, divalproex sodium has been approved for treatment of bipolar disease and migraine headaches. The active ingredient in divalproex sodium is valproic acid. Valproic acid was first synthesized in the 1890's. In the early 1960's, it was discovered that valproic acid and its various salts, including sodium valproate, could be administered to prevent or minimize epileptic seizures or convulsions. Patents on the use of valproic acid and its salts as a drug expired in the late 1970,'s. Valproic acid is a liquid and as such is less desirable for preparing an oral dosage form. Sodium valproate is a solid that has poor stability characteristics partially due to a pronounced tendency to absorb moisture from the air. Thus, both drugs have drawbacks when used alone.

Divalproex sodium is a compound made from equal parts of valproic acid and sodium valproate. This new compound is a highly stable, nonhydroscopic, solid entity. As such, it has greater stability factors in a solid drug form than either of its parts when used alone, but it provides the same pharmacological properties.

Depakote is the trademark for Abbott's anti-convulsant drug that contains divalproex sodium as its active ingredient. Alra has produced a generic version of Depakote which is called DepaTab. Abbott contends that DepaTab infringes on its patents. Alra claims that neither Depakote nor DepaTab are covered by either the '731 or '326 patents because the chemical structures of the commercial versions are distinct from the patented invention. In the alternative, Alra argues that the patents are invalid due to obviousness and failure to disclose the Best Mode.

## Discussion

Summary judgment should be granted when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986). A genuine issue of material fact exists if there is sufficient evidence for a jury to return a verdict in favor of the non-moving party on the particular issue. *Methodist Medical Center of Illinois v. American Medical Sec. Inc.*, 38 F.3d 316, 319 (7th Cir. 1994). The court must draw all justifiable inferences in the light most favorable to the opposing party and must resolve any doubt against the moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

The patent infringement analysis involves two steps. First, the claim must be properly construed to determine its scope and meaning. This is a question of law. Then, the claim, as properly construed, must be compared to the accused device or process. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581-82 (Fed. Cir. 1996).

The first step, claim construction, involves ascertaining the true meaning and scope of each claim. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). To determine the proper construction of a claim, the court should first look to the intrinsic evidence of record, the patent itself, including the claims, the specifications and, if in evidence, the prosecution history. *Vitronics*, 90 F.3d at 1582. Extrinsic evidence, such as expert testimony, should not be relied upon unless an analysis of the intrinsic evidence alone will not resolve all the ambiguity in a disputed claim term. *Id.* at 1583.

First, we look to the words of the claims themselves to define the scope of the patented invention. *Id.* at 1582. A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." *Hoechst Celanese Corp. v. BP Chemicals Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir.), *cert. denied*, 136 L. Ed. 2d 198, 117 S. Ct. 275 (1996). Thus, a patentee may choose to use terms in a manner other than their ordinary meaning, so long as the special definition of the term is clearly stated in the patent specification or file history. *Vitronics*, 90 F.3d at 1582.

Second, it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. *Id.* The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication. *Id.* citing

Markman, 52 F.3d at 979. The specification is the single best guide to the meaning of a disputed term. Vitronics, 90 F.3d at 1582.

Third, the court may also consider the prosecution history, if in evidence, as it is here. The prosecution history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. *Id.* "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

### Construction of the '731 and '326 patents

The '731 patent has two claims. The first claim recites the following four features:

- (i) An oligomer
- (ii) having a 1:1 molar ratio of sodium valproate and valproic acid
- (iii) of the unit formula,  
 $(\text{CH}_3\text{CH}_2\text{CH}_2)_2\text{CHCO}_2\text{Na}/(\text{CH}_3\text{CH}_2\text{CH}_2)_2\text{CHCO}_2\text{H}$ ,  
and
- (iv) containing about 4 such units.

The second claim covers an oral pharmaceutical dosage form for treating the symptoms of epileptic seizures or convulsions containing as the active principal the compound recited in claim one.

The '326 patent has five claims. The first and second claims are the same as the '731 patent except the '326 patent recites the fourth feature as having "about 4 to 6 such units." The third and fourth claims of the '326 patent recite the fourth feature as "about 6 such units." The fifth claim does not recite any specific number of units, but lists the following physical/chemical properties:

- a. stable, white crystalline powder;
- b. melting point of 98 [degrees] -100 [degrees] C; and
- c. an infrared spectrum having strong absorption bands at about 2957, 2872, 2932, 1685, 2932, 1685, 1555 and 1370  $\text{cm}^{-1}$ .

There are two main disputes regarding the scope and meaning of these patents. First, the parties dispute the meaning of the term oligomer. Second, the parties dispute the number of repeating units.

There is no dispute that the term "oligomer" is the patentable element of this invention. The oligomeric structure is what distinguishes the invention from a simple mixture of valproic acid and sodium valproate. The combination of the two chemicals results in a compound that has different physical characteristics from either of the starting materials. As stated in both patents, the new compound represents a single chemical molecule which does not have the detrimental physical characteristics of either of the two starting materials, rather it is a crystalline, stable solid. The term oligomer appears in every claim of the '731 and '326 patents, but it is not defined in the claims. The generally accepted definition of oligomer among chemists is a composition made up of a relatively small number identical repeating units joined end to end. Maitland Jones, Jr., *Organic Chemistry*, 821 (1997). Abbott seeks to have this definition represent the complete meaning of the term oligomer as used in the patents. Abbott asserts that the claims, specifications and patent history do not limit the oligomer to a joining of the units in any particular manner. Alra asserts the term oligomer must be given a more narrow definition in relation to the patents because Abbott specifically narrowed the definition to exclude the possibility that the oligomer could contain ionic bonds or be a salt.

A technical term, such as oligomer, is generally interpreted to have the meaning that it would be given by persons experienced in the field of the invention. However, if it is apparent from the patent and prosecution history that the inventor used the term with a different meaning then the term is defined in this manner. *Hoechst*, 78 F.3d at 1578. Abbott admits that it added the term oligomer to the claims as a shorthand to describe the structure of the compound which is described and pictured in the specifications. So we must carefully examine the specifications and prosecution history to determine if there is a special meaning Abbott attributed to the term "oligomer," including any meanings that may have been excluded in the prosecution history.

There is no question that the basic definition of an oligomer applies here. The patented invention is made up of a relatively small number of identical repeating units joined end to end. At issue is whether Abbott narrowed the definition to explain how the units that make up the oligomer are joined together. Alra asserts that the patent specifically excludes any possibility that units can be joined by ionic bonds<sup>1</sup>, and claims the oligomer is restricted to covalent<sup>2</sup> or coordinate

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<sup>1</sup> Ionic bonds are the simplest type of chemical bond in which an electron is transferred from one neutral atom to another, and the resulting charged species are held together by electrostatic attraction. 3 *Encyclopedia Britannica Micropaedia* 154 (Gwinn 1990).

bonds<sup>3</sup> only and the new chemical composition is not a salt. We look first to the specifications for guidance. The specifications of the '731 and '326 patents state:

the compound consists of one molecule each of valproic acid or diethylacetic acid and sodium valproate...the molecules are distributed as an ionic oligomer rather than as a dimer as originally believed.

emphasis added.

The specifications clearly state that the compound contains ionic bonds. This reference to an ionic oligomer thus clearly refutes Alra's claim that the patent excludes the presence of ionic bonds and restricts the invention to units joined together by covalent bonds. The specifications also contain a diagram of the invention and describe its structure as follows:

one mole each of the valproic acid moieties form coordinate bonds with the sodium of the sodium valproate molecule, and the valproate ion is ionically bonded to the sodium atom.

emphasis added. This language again refutes Alra's claim that the patent rejected the possibility of the compound being bound solely by covalent bonds and not by any ionic bonds.

Alra maintains that the ionic bonds referred to in the specifications have no consequence to the oligomeric structure because it refers to the bonding within the divalproex sodium molecule of the valproic ion of valproic acid and the sodium ion of sodium valproate. Alra maintains that the bond of significance to this patent is between the divalproex sodium molecules which are held together by covalent bonds.

The diagram and wording of the specifications are definitive on the structure of the molecule here. The specifications indicate that several pairs of sodium valproate and valproic acid are held together through ionic interactions, but you cannot tell much more about the structure from the specifications than that. Abbott makes a distinction in the specifications between the way valproate binds to sodium and the way valproic acid binds to sodium, but this is not related to the way in which each divalproex sodium molecule is joined to the next as Alra suggests. In fact, Abbott does not explain how each divalproex sodium molecule is joined together in the specifications or the prosecution history, likely because

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<sup>2</sup> Covalent bonds are the most common type of bond; they share electrons between atoms. Id. at 154 & 156.

<sup>3</sup> Coordinate bonds are not typically covalent because the electrons are donated by only one of the atoms involved. Id. at 156

it did not know at the time. What Abbott did know, and I read into the claims, is that sodium hydrogen divalproate oligomer contained ionic bonds which made this new compound unique, but the location of those bonds was not relevant to the patent.

Alra further contends that the prosecution history clearly estopps Abbott from claiming the compound is a salt or acid salt because Abbott specifically rejected any description of the compound as a salt in the prosecution history. In 1979, in the original patent application, Abbott described the new compound as salts of valproic acid. In 1987, Abbott filed an amended application and replaced the description of "salts" of valproic acid with "sodium hydrogen divalproate oligomer." Along with this change, Abbott deleted the sentence, "it is possible that two molecules bind to one another in some other fashion."

While Abbott did change the name of the compound and deleted the use of the term salt, I do not find Abbott abandoned the use of the term salt to describe its invention. A salt is "a chemical compound created when the 'parent' substance reacts with another chemical. A salt is 'formed when the hydrogen of an acid is replaced by a metal or its equivalent.'" *Abbott Laboratories v. Young*, 287 U.S. App. D.C. 190, 920 F.2d 984, 986 (D.C. Cir. 1990). Ionic bonds are specifically referenced in the specifications. If Abbott abandoned a salt in the prosecution history, the specifications would not now refer to ionic bonds. Alra's argument implies that an oligomer, as the term is used in the patent, is mutually exclusive of a salt.

This reading ignores the fact that the specifications clearly refer to the inventive compound as a salt. The '731 patent first states that "this invention relates to salts of valproic acid." And, just above the diagram of the molecular structure, it states "the sodium salt may be illustrated:..."

The second dispute involves the number of repeating units that make up the oligomer. All the claims of the '731 and '326 patents claim either "about 4," "about 4 to 6" or "about 6" units, except claim number 5 of the '326 patent. Alra argues that claim number 5 must also be construed to contain about 4 to 6 units since Abbott only submitted data to the patent office that supported an oligomer length of 4 to 6 units.

Comparison to Accused Device There is no dispute that Abbott's commercial product Depakote and Alra's product DepaTab have the same structure. The issue, however, is not whether Alra's product is the same as Abbott's commercial product, but whether Alra's product infringes the patent as properly construed. In this case, because the parties admit that Depakote and DepaTab are identical, we

need only determine whether the patent covers either one of the commercial embodiments.

Alra admits that both its and Abbott's commercial products have a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula stated in the claims, but assert that neither product is an oligomer and that neither has about 4, 4 to 6, or 6 repeating units.

Alra claims its product is not an oligomer because it contains ionic bonds, and the patent disclaims the presence of ionic bonds. It is clear at this point, however, that the term oligomer has been construed to contain ionic bonds. Thus, Alra's product does infringe this first claim.

Alra next argues that neither commercial product has about 4 to 6 repeating units based on the results of x-ray diffraction tests conducted on Depakote and DepaTab. Rather, Alra claims they have 7 repeating units. Abbott asserts that x-ray diffraction tests cannot be used to determine the number of repeating units because the techniques used to develop the model used in the tests were not available at the time the invention was made and thus cannot be used now. Instead, Abbott claims the techniques described in the prosecution history to determine molecular weight should be used to determine the number of repeating units.

It is well established that a party cannot avoid a finding of infringement by relying on tests not known to the art at the time of the application for the patent or that were not generally used at the time. *Raybestos-Manhattan, Inc. v. Texon Inc.*, 268 F.2d 839, 842 (1st Cir. 1959); *Swift Chemical Co. v. Usamex Fertilizers, Inc.*, 490 F. Supp. 1343, 1354 (E.D. La. 1980), *aff'd*, 646 F.2d 1121 (5th Cir. 1981). If new tests were allowed, it would "cause the patent to mean one thing at the time of its issuance and another at some later date upon the discovery of a more accurate test." *Raybestos*, 268 F.2d at 842. Thus, infringement is determined by the methods generally used by those skilled in the art at the time the patent application was filed. *Id.*

Both patents specifically refer to x-ray diffraction tests as the specifications state: "the new compound represents a single chemical molecule as can be determined by . . . x-ray diffraction." Alra claims this phrase justifies the use of x-ray diffraction to determine the number of repeating units in the compound. It is clear that x-ray diffraction was used at the time of the patent application by those skilled in the art as the test is referred to in the specifications, but it is not clear what those skilled in the art actually used the test for. The specifications only state that x-ray diffraction can be used to determine whether the compound is a "single chemical molecule." Determining whether a compound is a single



molecule and how many repeating units the molecule has are distinct questions and cannot necessarily be determined using the same techniques.

X-ray diffraction is a test that is conducted to determine the structure of a compound. In order to conduct this test a crystal must be grown. Growing a good crystal is an art. Whether x-ray diffraction is able to determine the structure of the compound with specificity depends on the crystals available at the time. The size and quality of the crystal as well as the nature of the material all affect the growth of the crystal. Thus, it is not the state of the technology of x-ray diffraction that determines whether the test can be used, but the nature of the crystal. While a particular crystal may be clear enough to determine that the compound is a single chemical molecule, it may not be clear enough to determine the more specific properties of the structure such as how many repeating units are in the structure. George L. Clark, *The Encyclopedia of Chemistry*, 665-66 (2d ed. 1966).

There is no evidence that Abbott or anyone else successfully utilized single crystal x-ray diffraction to determine the structure of divalproex sodium until 1996 when Alra's expert performed her study. Further, there is no evidence that any scientist had successfully postulated a structure for divalproex sodium based on a single crystal x-ray study. These facts suggest that a crystal could not be grown at the time that was suitable for x-ray diffraction. Without a suitable crystal, the x-ray diffraction test would not have given clear results as to the number of repeating units in divalproex sodium.

Thus, the issue is not whether x-ray diffraction was generally in use by those skilled in the art at the time the patent application was filed, but whether one skilled in the art at the time would have been able to grow a suitable crystal in order to successfully use x-ray diffraction to determine the specific structure of divalproex sodium, including the number of repeating units and type of bonds. I find, based on the evidence before me, that while x-ray diffraction was used at the time, the nature of the crystal probably did not permit obtaining a clear picture of the structure, and thus this test cannot be used now to determine infringement. *Mobil Oil Corp. v. Amoco Chemicals Corp.*, 779 F. Supp. 1429, 1447 (D. Del. 1991), *aff'd*, 980 F.2d 742 (Fed. Cir. 1992) (often advances occur in chemical analysis that allow us to detect certain things that were not detectable previously).

Even assuming we could use x-ray diffraction to determine infringement, the results reveal that Depakote and DepaTab have exactly 7 repeating units. The '731 patent claims "about 4" units and the '326 patent claims "about 4 to 6" and "about 6" units. There is no question that 7 units is about 6 or about 4 to 6 units. Thus, under Alra's theory of the case, it still infringes the '326 patent.

However, we cannot use x-ray diffraction to determine infringement here, so we must look to the tests that were used by those skilled in the art at the time of the patent application. Three methods were identified in the prosecution history: fast atom bombardment (FAB), vapor phase osmometry (VPO), and freezing point depression (FPD). FAB, VPO, and FPD are commonly accepted methods of evaluating the molecular weight of a compound. Molecular weight measurements reflect the mass of individual chemical entities relative to the atoms from which they are made. Thus, the molecular weight of a compound reveals how many atoms are contained within a molecular grouping, and therefore, the number of repeating units that characterize an oligomer.

Alra argues that FAB, VPO and FPD are not valid methods to determine the molecular weight of a compound held together by ionic or hydrogen bonds. However, Abbott conducted all three tests in the prosecution history, all three of which returned consistent results. Alra gives no reason to dispute in this contest the conclusion that when three tests support the proposition, it is very strong evidence that the proposition is correct. FAB, VPO and FPD are commonly used tests to determine molecular weight and are considered to be highly valid and accurate. Thus, I find these three tests appropriate to determine infringement.

While Alra has not conducted any of these three tests on either Depakote or DepaTab, Alra's expert has admitted that if these tests were done on DepaTab, the results would indicate four to six repeating units. Based on this admission, it is clear that Alra has infringed this second claim.

Obviousness Alra next seeks summary judgment that the '731 and '326 patents are obvious under 35 U.S.C. § 103. Section 103 states: "[a] patent may not be obtained . . . 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." Obviousness may not be established using hindsight or in view of the teaching or suggestions of the inventor. *Para-Ordnance Mfg., Inc. v. SGS Importers Intern., Inc.*, 73 F.3d 1085, 1087 (Fed. Cir. 1995). Secondary considerations include commercial success, long felt but unsolved needs, failures of others, and copying. *Id.* at 1088. In addition, obviousness must be established by clear and convincing evidence. *Id.*

Alra claims the patented product is obvious because it is well known to administer acidic drugs in buffered form. A buffer is a mixture of an acid and its salt in solution in a proportion to maintain its pH. Alra claims that someone of ordinary skill in the art at the time of the alleged invention would have known the principles of buffering an acidic preparation to avoid gastrointestinal

irritation as well as the fact that acid salts of organic acids like valproic acid can be prepared and can be expected to be less hygroscopic. In addition, Alra claims the preparation of an acid salt of valproic acid in a one to one molar ratio was obvious in view of the fact that most, if not all, organic acids form acid salts, and the one to one molar ratio provides a convenient buffered dose of a drug in a single compound.

The patented claims are entitled to a presumption of validity. Thus, Alra faces the burden of showing, by clear and convincing evidence, the invalidity of the claims. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990). This burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application. *Id.* In a case such as this, where the invention is a combination of prior art elements that perform the same function, we must look to the claimed invention as a whole. *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 724 (Fed. Cir. 1990). It is the claimed combination that must be found obvious. *Id.*

It is undisputed that the '731 and '326 patents explain that valproic acid and sodium valproate were the most relevant prior art. In fact, valproic acid was synthesized in the 1890's and both the acid and its salts were known to have pharmacological properties since at least the early 1960's. However, both valproic acid and its salt had drawbacks when administered as drugs. It was not until the late 1970's that the two were combined to form the new invention which is a more successful drug form. The commercial success of the new invention in addition to the fact that it met the need of creating a more easily administered drug goes against a finding of obviousness. Alra has thus failed to submit clear and convincing evidence that the new invention was obvious.

### Best Mode

Alra also argues that the '731 and '326 patents are invalid because Abbott failed to disclose the best mode for making sodium hydrogen valproate in either of its patents. 35 U.S.C. § 112 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A patent specification must "set forth the best mode contemplated by the inventor for carrying out his invention." 35 U.S.C. § 112. *Minco, Inc. v.*

Combustion Engineering, Inc., 95 F.3d 1109, 1115 (Fed. Cir. 1996). Compliance with the best mode requirement focuses on the state of mind of the inventor at the time the inventor files the patent application. *Minco*, 95 F.3d at 1115. The inventor's intent controls. *Id.* The trier of fact determines compliance with the best mode requirement. *Id.* "To invalidate a patent under the best mode requirement, an accused infringer must show by clear and convincing evidence that the inventor both knew of and concealed a better mode of carrying out the claimed invention than was set forth in the specification." *Id.* (internal quotation omitted). The record must show that the inventor considered a different mode that was better than the disclosed mode. *Id.* at 1115-16. The '731 and '326 patents disclose two methods to prepare sodium hydrogen divalproate, both involve the use of acetone in their preparation. Alra claims the best mode to prepare sodium hydrogen divalproate is the aqueous method. Alra also claims that Abbott knew the aqueous method was the best mode, but did not disclose it in the patent specifications, thus invalidating the patent.

Alra supports its claim that Abbott knew the aqueous method was the best mode since before the time it filed its application which resulted in the '731 patent with the testimony of Charles Lex, the Section Manager of Chemical Development for Abbott. Mr. Lex testified that Abbott utilized the aqueous method only to produce the Divalproate Sodium bulk drug and Depakote tablets since 1981. Alra claims Mr. Lex's statements are supported by Abbott's action in filing a Patent Cooperation Treaty ("PCT") application on July 28, 1980 in which Dr. Meade, the inventor, and Abbott specifically disclosed the aqueous method of making the '731 patent invention. In the PCT application, Meade expressly stated the aqueous method was another method for manufacturing the '731 invention. Alra claims the action of filing a PCT application illustrates that the applicant knew of a mode of practicing his claimed invention that he considered to be better than any other.

The requirements for the application of the best mode doctrine are stringent. It is what the inventor knew of and concealed that is relevant to this doctrine. Dr. Meade is the inventor. Thus, it is his knowledge that is relevant. Alra has produced no evidence of Dr. Meade's knowledge regarding the aqueous method other than the filing of the PCT application. The knowledge of Mr. Lex cannot be imputed to Dr. Meade as there is no violation of the best mode requirement by reason of knowledge of the purported best mode on the part of employees of the inventor, other than the inventor, when the inventor did not know of or conceal this best mode. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1050 (Fed. Cir. 1995) (knowledge of employees of the assignee of patent cannot be imputed to the inventor). Abbott claims the information in the application can also not be imputed to Dr. Meade because the application was filed in the name of the owner of the invention, Abbott, and not by the individual inventor, Dr. Meade,

and thus there is no evidence of Dr. Meade's knowledge. At best, the PCT application discloses that Dr. Meade knew that the aqueous method was another method to manufacture the invention, but there is no indication from this application that Dr. Meade believed it was the best mode. Alra claims correspondence between Dr. Meade and Abbott's patent lawyers exist that might shed light on Dr. Meade's knowledge, but without that information this Court is unable to determine what Dr. Meade did in fact know. Alra has failed to produce clear and convincing evidence that Dr. Meade both knew that the aqueous method was a better mode of carrying out the claimed invention than was set forth in the specifications or that he concealed this knowledge. Alra's motion for summary judgment on the best mode is denied.

#### Fraud

Alra sets forth a claim for common law fraud and fraud under the Illinois Consumer Fraud and Deceptive Business Practices Act on the basis that Abbott made misrepresentations when it claimed to the FDA that the '731 covered Depakote. Because I have found that the '731 patent covers both DepaTab and Depakote, the fraud counts are dismissed.

#### Conclusion

Alra's motion for summary judgment is denied. Abbott's motion for summary judgment is granted.

Enter:

James B. Zagel  
United States District Judge  
Date: 10/20/97