United States District Court,
N.D. Illinois, Eastern Division.

ABBOTT LABORATORIES,
Plaintiff.
v.
TORPHARM, INC.; Apotex, Inc.; Apotex Corp,
Defendants.

March 30, 2001.

Manufacturer of anti-seizure drug sued competitor for infringement of patents covering active ingredient. On manufacturer's motion for summary judgment, the District Court, Norgle, J., held that: (1) patents were infringed; (2) patents were not obtained through inequitable conduct; and (3) patents were not invalid as anticipated or for lack of enablement.

Motion granted.

4,988,731, 5,212,326. Construed, Valid, Infringed.

Thomas David Brooks, Sperling, Slater & Spitz, P.C., Chicago, IL, Daniel E. Reidy, James R. Daly, Robert C. Micheletto, Jones, Day, Reavis & Pogue, Chicago, IL, for plaintiff. Hugh L. Moore, Richard Philip Beem, Scott B. Feder, Keith D. Parr, Paul J. Molino, William Andrew Rakoczy, Deanne M. Mazzochi, Lord, Bissell & Brook, Chicago, IL, for defendants.

OPINION AND ORDER

NORGLE**, District Judge.**

Before the court is Plaintiff's motion for summary judgment. For the following reasons, the motion is granted.

I. BACKGROUND

This patent infringement case arises from Defendants' (hereinafter "Torpharm") attempt to gain approval from the Food and Drug Administration ("FDA") to market the generic equivalent of DEPAKOTE(R) FN1, an anti-seizure medication produced by Abbott.

FN1. For the court's ease, it will omit the (R) symbol from any other references to DEPAKOTE.

A very brief discussion of the intersection between patent and drug laws places this dispute in context. With

what is commonly known as the Hatch-Waxman Act, Congress set up an expedited process for FDA approval of generic equivalents of previously approved drugs. *See* Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1244-45 (Fed.Cir.2000); Glaxo v. Novopharm, Ltd., 110 F.3d 1562, 1567-70 (Fed.Cir.1997); Jeffrey I.D. Lewis, *Declaratory Judgments of Patent Infringement: What They Forgot About Drug Applications,* 7 Fed. Cir. B.J. 35 (1997). The Hatch-Waxman Act allows generic drug manufacturers to gain FDA approval of generic drugs pursuant to an abbreviated new drug application ("ANDA"), which is substantially less expensive and time consuming than getting FDA approval for a brand new, or pioneer, drug. 21 U.S.C. s. 355(j); 21 C.F.R. s. 314.94; Bayer AG, 212 F.3d at 1244-45. As part of the ANDA, the generic manufacturer must submit one of four certifications concerning patents that may pertain to the previously approved drug: (1) that such patent information has not been filed (a "Paragraph I" certification); (2) that such patent has expired (a "Paragraph II" certification); (3) the date on which such patent will expire (a "Paragraph III" certification); or (4) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (a "Paragraph IV" certification). 21 U.S.C. s.s. 355(j)(2)(A)(vii)(I)-(IV); Bayer AG, 212 F.3d at 1244-45.

A Paragraph IV certification is an invitation to a patent infringement suit. Bayer AG, 212 F.3d at 1244-45. Paragraph IV certification requires the ANDA applicant to give notice of the certification to the patentee. 21 U.S.C. s. 355(j)(2)(B)(i); Bayer AG, 212 F.3d at 1244-45. The patentee then has forty-five days to file a patent infringement action under 35 U.S.C. s. 271(e)(2)(A). Bayer AG, 212 F.3d at 1244-45. If the patentee fails to file the infringement suit, the ANDA is approved immediately after meeting the applicable scientific and regulatory requirements. *Id*. Such is the case here. Torpharm is seeking FDA approval to market the generic equivalent of DEPAKOTE, and submitted an ANDA with a Paragraph IV certification. Abbott responded with this suit.

DEPAKOTE's active ingredient is divalproex sodium. Abbott owns two patents for sodium hydrogen divalproate oligomers, # 4,988,731 (the '731 patent), and # 5,212,326 (the '326 patent). Abbott asserts that both the '731 patent and the '326 patent cover divalproex sodium, including DEPAKOTE and Torpharm's proposed generic equivalent. Abbott moves for summary judgment, arguing that there is no genuine dispute of material fact that Torpharm's proposed product infringes the '731 and '326 patents. Torpharm asserts that the patents do not cover its proposed product and are invalid.

II. DISCUSSION

A. Standards for Summary Judgment:

Summary judgment is permissible when "there is no genuine issue as to any material fact and ... the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). The nonmoving party cannot rest on the pleadings alone, but must identify specific facts, *see* Cornfield v. Consolidated High School District No. 230, 991 F.2d 1316, 1320 (7th Cir.1993), that raise more than a mere scintilla of evidence to show a genuine triable issue of material fact. *See* Murphy v. ITT Educational Services, Inc., 176 F.3d 934, 936 (7th Cir.1999); *see also* Shank v. William R. Hague, Inc., 192 F.3d 675, 682 (7th Cir.1999) (stating that a party opposing summary judgment must present "what evidence it has that would convince a trier of fact to accept its version of events"). In deciding a motion for summary judgment, the court can only consider evidence that would be admissible at trial under the Federal Rules of Evidence. *See* Bombard v. Fort Wayne Newspapers, Inc., 92 F.3d 560, 562 (7th Cir.1996). The court views the record and all reasonable inferences drawn therefrom in the light most favorable to the party opposing summary judgment. *See* Fed.R.Civ.P. 56(c); *see also,* Perdomo v. Browner, 67 F.3d 140, 144 (7th Cir.1995). "In the light most favorable" simply means that summary judgment is not appropriate if the court must make "a choice of inferences." *See* United

States v. Diebold, Inc., 369 U.S. 654, 655, 82 S.Ct. 993, 8 L.Ed.2d 176 (1962); *see also,* First Nat'l. Bank of Arizona v. Cities Service Co., 391 U.S. 253, 280, 88 S.Ct. 1575, 20 L.Ed.2d 569 (1968); Wolf v. Buss (America) Inc., 77 F.3d 914, 922 (7th Cir.1996). The choice between reasonable inferences from facts is a jury function. *See* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

B. Infringement Analysis:

"A patent is a government grant of rights to the patentee." Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed.Cir.1995) *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The patentee's right is one of exclusion-for a limited time, the patentee has the right to exclude others from making, using, or selling the claimed invention. *Id*.

[1] [2] Patent infringement analysis is a two step process. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-82 (Fed.Cir.1996). The court first must construe, or interpret, the meaning of the patent claims. *Id*. The second question is whether the defendant has infringed on the patentee's rights. *Id*. Claim construction is a question of law, while infringement is a question of fact. *Id*. It is the patentee's burden to prove infringement. Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1566-68 (Fed.Cir.1997).

1. Claim Construction:

A short word is necessary here on the legal effect of a decision by Judge Zagel of the Northern District of Illinois in a similar case. This case is not the first time that Abbott has litigated an infringement issue related to DEPAKOTE. In 1997, Judge Zagel granted summary judgment in favor of Abbott, finding that a proposed generic form of DEPAKOTE infringed the '731 and '326 patents. *See* Abbott Labs. v. Alra Labs., Inc., No. 92 C 5806, 1997 WL 667796 (N.D.Ill. Oct.24, 1997). Abbott argues that this court should give Judge Zagel's claim construction stare decisis effect, while Torpharm urges the court to conduct its own construction analysis.

Abbott's authority for the stare decisis argument is Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), where the Supreme Court noted the need for intrajurisdictional uniformity of patent claim construction. Whether *Markman* gives district court claim construction binding effect is a question the court need not answer. The court has reviewed Judge Zagel's claim construction and agrees with it. Thus, regardless of whether stare decisis applies, as explained below, the court adopts Judge Zagel's construction of the patents.

The '731 patent claims:

1. An oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, $(CH_3CH_2CH_2)_2\ CHCO_2Na/\ (CH_3CH_2CH_2)\ _2CHCO_2\ H$, and containing about 4 such units.

2. An oral pharmaceutical dosage form for treating the symptoms of epileptic seizures or convulsions, containing as the active principal an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, $(CH_3CH_2CH_2)_2\ CHCO_2Na/(CH_3CH_2CH_2)_2CHCO_2\ H$, and containing about 4 such units.

(Pl.'s Local Rule 56.1 Ex. 1.)

The '326 patent claims:

1. An oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, $(CH_3CH_2CH_2)_2$ $CHCO_2Na/(CH_3$ $CH_2CH_2)_2CHCO_2$ H, and containing about 4 to 6 such units.

2. An oral pharmaceutical dosage form for treating the symptoms of epileptic seizures or convulsions, containing as the active principal an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, $(CH_3CH_2CH_2)_2$ $CHCO_2Na/(CH_3CH_2CH_2)_2CHCO_2$ H, and containing about 4 to 6 such units.

3. An oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, $(CH_3CH_2CH_2)_2$ $CHCO_2Na/(CH_3$ $CH_2CH_2)_2CHCO_2$ H, and containing about 6 such units.

4. An oral pharmaceutical dosage form for treating the symptoms of epileptic seizures or convulsions, containing as the active principal an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, $(CH_3CH_2CH_2)_2$ $CHCO_2Na/(CH_3CH_2CH_2)_2CHCO_2$ H, and containing about 6 such units.

5. An oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, $(CH_3CH_2CH_2)_2$ $CHCO_2Na/(CH_3$ $CH_2CH_2)_2CHCO_2$ H, and having physical/chemical properties as follows:

a. stable, white crystalline powder:

b. melting point of 98 (deg.)-100 (deg.) C; and

c. an infrared spectrum having strong absorption bands at about 2957, 2872, 2932, 1685, 1555 and 1370 cm^{-1}.

(Pl.'s Local Rule 56.1 Ex. 2.)

The parties dispute two portions of these claims: (1) the meaning of "oligomer;" and (2) the required number of repeating units. Abbott argues that the ordinary definition of oligomer applies, and that the number of repeating units are "about 4," "about 4 to 6," and "about 6." Torpharm seeks to define oligomer negatively, in that the court should not allow the definition to encompass a "salt," "mixed salt," "derivative," "dimer," or "ionic complex." Those terms were used during the patent prosecution prior to the use of "oligomer" to describe the new compound's structure. Torpharm also argues that the number of repeating units must be limited to "about 4" because of the PTO's rejection of an earlier application. The repeating unit argument goes to the validity of the patents, not their construction, and is analyzed infra at pages 16-18.

[3] [4] [5] [6] In general, claim terms are to be given their ordinary and accustomed meaning. Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999). This general rule is subject to two exceptions; where the patentee acts as his own lexicographer by setting forth an explicit definition for a claim term, or where the patentee's chosen term is so unclear that the court cannot ascertain the scope of the claim. *Id*. (citing cases). In construing a claim, the court should first look to the intrinsic evidence of record,

such as the claims, specifications, and prosecution history. Vitronics Corp., 90 F.3d at 1582. Of this intrinsic evidence, the specifications are the single best guide to construing the claim. *Id*. It is important in this case to remember that "claim terms cannot be narrowed by reference to the written description or prosecution history unless the language of the claims invites reference to those sources." Johnson Worldwide, 175 F.3d at 989-90 (citing McCarty v. Lehigh Val R.R., 160 U.S. 110, 116, 16 S.Ct. 240, 40 L.Ed. 358 (1895) ("[I]f we once begin to include elements not mentioned in the claim in order to limit such claim ..., we should never know where to stop.")). "In other words, there must be a textual reference in the actual language of the claim with which to associate a proffered claim construction." Johnson Worldwide, 175 F.3d at 989-90; *see also* 5A Donald S. Chisum, *Chisum on Patents,* s.s. 18.03(2)(c)(i) (discussing the ban on "reading in" and "reading out" claim limitations) & (iv) (discussing claim construction where the specification discusses a problem solved by the invention).

[7] Thus, the court begins with the general definition of oligomer. In the *Alra* case, Judge Zagel described the generally accepted definition of oligomer as "a composition made up of a relatively small number of repeating units joined end to end." Alra, 1997 WL 667796 at * 3 (citing Maitland Jones, Jr. *Organic Chemistry,* 821 (1997)). This court's own research shows similar definitions. *See e.g*. McGraw-Hill Dictionary of Scientific and Technical Terms 1314 (4th Ed.1989) (defining oligomer as "A polymer made up of two, three, or four monomer units."); *Webster's II New Riverside University Dictionary,* 819 (1988) (same). The court accepts Judge Zagel's description of oligomer as a generally accepted definition.

Next, the court looks at the specifications to ascertain if oligomer means something other than its generally accepted definition. The specifications teach that the inventions relate to salts of valproic acid. Valproic acid and sodium valproate have each been used to treat epileptic seizures or convulsions, but both substances have significant drawbacks. Valproic acid is a liquid, which makes it less desirable for oral dosages. Sodium valproate is a solid that is unstable due to hygroscopicity, which is a change in physical characteristics due to atmospheric moisture.

The inventor was able to bond valproic acid and sodium valproate to form a new compound consisting of one molecule each of valproic acid or diethylacetic and a sodium valproate salt. The new compound is a solid material that does not have the moisture instability problems associated with sodium valproate. The new compound retains the beneficial therapeutic effects of valproic acid and sodium valproate, while eliminating the drawbacks associated with both of those materials.

As reflected in the specifications, there was some uncertainty over the structure of the new compound, which was first believed to be a dimer, but was then found to be an ionic oligomer. The specification goes on to elaborate that "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." (Pl.'s Local Rule 56.1 Ex. 1, col. 1, line 56-60 & Ex. 2, col. 1 line 58-62.)

Torpharm urges the court to delve into the prosecution history of the patents, which shows that the patentee had difficulty characterizing the structure of the new compound. At various times the compound was called a "salt," "mixed salt," "derivative," "dimer," and "ionic complex." Torpharm claims, without citation to authority, that court cannot legally construe "oligomer" to cover these structures. The argument is not persuasive.

It is undisputed that there has been uncertainty as to the exact structure of the new compound. This uncertainty should not be held against Abbott, so as to exclude from the claims any and all terms that may

have been used to describe the structure during its development. *See e.g.* Johnson Worldwide, 175 F.3d at 989-90 (citing cases and noting the prohibition on limiting claim language unless the claim specifically references the limitation); 5A Donald S. Chisum, *Chisum on Patents,* s. 18.03(2)(c)(i) (same). Moreover, the specifications teach that the structure of the new compound is not nearly as significant as its physical properties, which is a solid hygroscopically stable substance. The uniqueness of the invention lies in the new compound created by bonding valproic acid and sodium valproate, rather than the label attached to the bond. This is not a case where Abbott has acted as its own lexicographer for "oligomer," or assigned it an unclear meaning so that the court cannot define the scope of the claims. Johnson Worldwide, 175 F.3d at 989. (Fed.Cir.1999). Accordingly, the court construes oligomer according to its generally accepted definition, which is "a composition made up of a relatively small number of repeating units joined end to end." Alra, 1997 WL 667796 at * 3.

Torpharm's construction would impermissibly read in limitations that are not part of the specification. *See generally* 5A Donald S. Chisum, *Chisum on Patents,* s. 18.03(2)(c)(i). At the same time, the court's construction does not read out limitations that are not part of the claims. *Id.* The specifications clearly contemplate that the new compound has been described by various terms, such as salt, ionic oligomer, and complex, which are consistent with the general definition of oligomer.

2. Infringement:

[8] At this point, it is necessary to streamline the parties' contentions. The Federal Circuit has recently decided an ANDA infringement case, and held that the proper analysis is to compare the patent claims to the generic product to be sold upon FDA approval of the ANDA. Bayer, 212 F.3d at 1247-50. The ANDA applicant is bound by its ANDA submissions, and is subject to civil and criminal sanctions if it fails to comply with ANDA procedures and requirements. Id. at 1249-50. Thus, it is proper to examine the ANDA and its supporting materials to determine infringement. *Id.* If the ANDA directly addresses the issue of infringement, the court should look no further, and simply compare the ANDA to the patent claims. *Id.* However, if the ANDA does not resolve the infringement, the court may consider a comparison between the patent claims and a "biobatch" of the generic drug created to facilitate FDA approval. *Id.* (noting that biobatches themselves do not infringe, and the focus should be on the product to be sold after approval) (citing Glaxo, 110 F.3d at 1569-70).

[9] That said, the court analyzes whether there is a dispute of material fact as to whether Torpharm's proposed product infringes Abbott's patents. Abbott's '731 and '326 patents have a total of seven claims. The first six claims share similar features, while the seventh claim (# 5 of the '326 patent) adds some additional features. (*See* supra pp. 741-42 for the claim language.) The court addresses each feature in turn.

a. 1:1 Molar Ratio:

The first feature is a 1:1 molar ratio of valproic acid and sodium valproate. Torpharm cannot dispute that its proposed product has that ratio. One of the required ANDA submissions is a proposed package insert, which must be the same as the package insert approved for the existing drug. 21 C.F.R. s. 314.94(8). Torpharm submitted its proposed package insert, which described its product as follows: "Divalproex sodium is a stable co-ordination compound comprised of sodium valproate and valproic acid in a 1:1 molar relationship and formed during the partial neutralization of valproic acid with 0.5 equivalent of sodium hydroxide...." (Pl.'s Local Rule 56.1 Ex. 18.) Consistent with the regulations, this language is identical to the language in Abbott's package insert for DEPAKOTE. Thus, Torpharm has represented that its proposed product is a 1:1 molar ratio, as described in the patents. Torpharm is bound by this representation, and runs the risk of civil

and criminal penalties if its proposed package insert does not accurately reflect the composition of its proposed product. Bayer, 212 F.3d at 1247-50.

Relying on another part of its ANDA, Torpharm strives to argue that its manufacturing process ensures that its product will not have a 1:1 molar ratio of valproic acid and sodium valproate. This, however, does not raise a question of fact. As a matter of law, Torpharm is bound to accurately represent its proposed product to FDA. *See* Bayer, 212 F.3d at 1247-50 (and authorities cited therein). The patents claim a product, not a process, and the product claimed has a 1:1 molar ratio of valproic acid and sodium valproate. Torpharm's proposed package insert unambiguously represents that the proposed product has the claimed 1:1 molar ratio. To the extent the ANDA is ambiguous, in that Torpharm's disclosed manufacturing process may result in a product that does not have a 1:1 molar ratio, the court must construe that ambiguity against Torpharm.

Torpharm seems to argue that its proposed package insert contains the 1:1 molar ratio description only because FDA required it do so, and also suggests that Abbott's description of DEPAKOTE is chemically incorrect. Neither of these points is persuasive. Torpharm's proposed package clearly states that its product is a 1:1 molar ratio of valproic acid and sodium valproate, which is what is claimed in Abbott's patents. These facts are indisputable.

b. Oligomer:

Torpharm's ANDA, and therefore its proposed product, describes an oligomer. Earlier, the court construed oligomer to mean a composition made up of a relatively small number of repeating units joined end to end. Torpharm's proposed package insert product description fits within this definition. The proposed package insert states that the product is a 1:1 molar ratio of valproic acid and sodium valproate. The proposed package insert also provides a chemical diagram of the proposed product, which shows a small number of repeating units joined end to end. Thus, Torpharm's proposed product is an oligomer.

The parties spend considerable portions of their briefs arguing over expert testimony concerning the oligomer issue. Abbott argues that its experts conducted various tests on its product and Torpharm's biobatch, which confirm that divalproex sodium is an oligomer. Torpharm counters that Abbott's reliance on the biobatch is misplaced, and that Torpharm's experts refute Abbott's analysis. Torpharm also relies on its own definition of "oligomer," which is overly narrow. The court does not enter this fray. Oligomer, as used in the patents, describes compositions made up of a relatively small number of repeating units joined end to end. Torpharm's proposed package insert describes such a composition, in words and in diagram. Thus, Torpharm's proposed product is an oligomer.

c. Unit Formula:

The claimed unit formula of the patents is $(CH_3CH_2CH_2)_2\ CHCO_2Na/\ (CH_3CH_2CH_2)_2CHCO_2\ H$. The parties' dispute here mirrors the dispute over whether Torpharm's proposed product has a 1:1 molar ratio. Abbott argues that the ANDA discloses the unit formula. Torpharm asserts that its proposed product cannot have the claimed unit formula because it requires a 1:1 molar ratio, which cannot occur under Torpharm's manufacturing process. As discussed above, Torpharm's argument is without merit. Torpharm's proposed package insert unambiguously states that the proposed product has a 1:1 molar ratio of valproic acid and sodium valproate. That is precisely the unit formula claimed in Abbott's patents.

d. Number of Repeating Units:

Abbott's patents call for "about 4," or "about 4 to 6," or "about 6" repeating units. Abbott argues that Torpharm's ANDA and Abbott's testing of Torpharm's biobatch demonstrate that Torpharm's proposed product has the requisite repeating units. Torpharm counters that Abbott's testing is flawed, and presents opinion evidence to the effect that Torpharm's proposed product does not have any repeating units, much less the number of repeating units called for in the patents. Torpharm's position is without merit.

First, Torpharm's proposed package insert discloses a diagram demonstrating that Torpharm's proposed product has repeating units. The ANDA does not disclose the number of repeating units, but it unambiguously shows that the product has repeating units. Torpharm cannot dispute this fact. Bayer, 212 F.3d at 1247-50.

Second, Abbott has tested Torpharm's biobatch to determine the number of repeating units, and found that the biobatch has the same number of repeating units called for in the patents. Biobatch testing is appropriate when the ANDA does not directly address the infringement issue. Bayer, 212 F.3d at 1250. In this instance, biobatch testing to discover the number of repeating units is appropriate because Torpharm's proposed package insert diagram does not specify that fact. *Id*. Abbott conducted a number of tests demonstrating that Torpharm's biobatch has the same number of repeating units called for in the patents.

Torpharm submits no tests of its own, but presents opinion evidence to attempt to refute Abbott's testing. Specifically, Torpharm argues that the tests performed by Abbott do not show chemical structure, and that the only test that would show such a structure is x-ray diffraction testing. This is unpersuasive. As Judge Zagel found in the *Alra* case, the tests Abbott performed are sufficient to show the chemical structure of divalproex sodium. *See* Alra, 1997 WL 667796 at *5-8. Torpharm criticizes Abbott for not performing x-ray diffraction analysis, but then neither did Torpharm. Torpharm asks the court to speculate as to the results of tests not performed. The court is mindful that it is Abbott's burden to prove infringement, and is satisfied that Abbott has done so. Abbott conducted multiple tests on Torpharm's biobatch, which show that Torpharm's proposed product has the same repeating units claimed in the patents. Torpharm offers no evidence to rebut this finding.

e. '326 Claim Five:

In addition to the features discussed above, '326 claim five has the following physical/chemical features: (1) a stable, white crystalline powder; (2) a melting point of 98 (deg.)-100 (deg.) C; and (3) an infrared spectrum having strong absorption bands at about 2957, 2872, 2932, 1685, 1555 and 1370 cm^{-1}. These features are not addressed in the ANDA, but Abbott has conducted tests on Torpharm's biobatch, and found that the proposed product has these features. Torpharm's briefs are silent on this issue. Thus, the court accepts Abbott's uncontradicted evidence that Torpharm's proposed product has these features.

C. Invalidity Analysis:

[10] Patents are presumed valid. 35 U.S.C. s. 282. On summary judgment, a party seeking to invalidate a patent must present clear and convincing evidence of invalidity. Eli Lilly and Co. v. Barr Labs., Inc., 222 F.3d 973, 980 (Fed.Cir.2000). Thus, it is Torpharm's burden to present clear and convincing evidence that Abbott's patents are invalid. Torpharm presents three invalidity arguments: (1) Abbott engaged in inequitable conduct before the PTO; (2) the claims are anticipated; and (3) the patents fail to comply with the enablement requirements. None of these arguments are persuasive.

1. Inequitable Conduct:

[11] Torpharm fails to present clear and convincing evidence that Abbott engaged in inequitable conduct before the PTO. "Applicants for patents have a duty to prosecute patent applications in the PTO with candor, good faith, and honesty." Li Second Family Ltd. Partnership v. Toshiba Corp., 231 F.3d 1373, 1378 (Fed.Cir.2000). A breach of this duty can include, inter alia, failure to disclose material information when such failure is coupled with an intent to deceive. *Id.; see also* Baxter Int'l. Inc. v. McGaw, Inc., 149 F.3d 1321, 1329-30 (Fed.Cir.1998) ("mere gross negligence is insufficient to justify an inference of an intent to deceive the PTO... and intent is generally inferred from the sum total of the applicant's conduct."). Here, Torpharm asserts that Abbott intentionally withheld material evidence from the PTO during its prosecution of both patents. Specifically, Torpharm asserts that Abbott performed single crystal x-ray analysis on a crystal of the purported divalproex sodium, which showed that the compound was not an oligomer, and was not a 1:1 molar ratio. Torpharm claims that Abbott had a duty to inform the PTO of this test and failed to do so.

Abbott counters that the single crystal tested was not subject to controlled growing conditions, and the test results showed that the crystal was not divalproex sodium. Thus, according to Abbott, the test results were not material to the patent applications. The record does not reveal how the crystal in question was formed, the material used to form the crystal, or the controls used in its formation. There is nothing from which a jury could infer that the crystal was made in the same manner as the subject of the patent prosecution. Indeed, the crystal, once tested, was found not to be divalproex sodium. This record does not demonstrate clear and convincing evidence of materiality, non-disclosure, or intent to deceive. *See* Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261-64 (Fed.Cir.2001).

2. Anticipation of the '326 Patent**:**

[12] Torpharm argues that the '326 patent, issued on May 18, 1993, is anticipated by the '731 patent, which was issued on January 29, 1991. This argument has no merit.

Patents can only be issued for new inventions. In re Schreiber, 128 F.3d 1473, 1477 (Fed.Cir.1997) (citing cases). 35 U.S.C. s. 102(b) states that a person is entitled to a patent unless "the invention was patented or described in a printed publication ... more than one year prior to the date of the application for a patent in the United States." 35 U.S.C. s. 102(b). When all elements of a patent can be found in a single previously issued patent, or prior art reference, the later patent is said to be anticipated, and is invalid. In re Schreiber, 128 F.3d at 1477.

35 U.S.C. s. 120 provides a statutory "safe harbor" for inventors to avoid anticipation invalidity. Section 120 states in relevant part:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States ... which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting [of] ...the first application ...if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. s. 120. The key issues, then, are whether the '326 patent complies with s. 112 para. 1, was filed prior to the issuance of the '731 patent, and makes a specific reference to the '731 patent. The '731 patent was issued on January 29, 1991. Abbott applied for the '326 patent approximately three weeks earlier, on

January 7, 1991, and specifically referenced the '731 patent. Thus, the only issue is whether the '326 patent complies with s. 112 para. 1. It is Torpharm's burden to present clear and convincing evidence that the '326 patent does not satisfy para. 1 of s. 112. Eli Lilly, 222 F.3d at 980. Torpharm fails to do so.

The basis for Torpharm's argument is the PTO's rejection of one of Abbott's earlier applications, which was affirmed by the PTO Board of Patent Appeals. The rejected application disclosed the repeating unit claims of '326. According to Torpharm, the rejection is binding upon Abbott under the doctrine of collateral estoppel. Abbott counters that the Board of Patent Appeals did not prohibit Abbott from presenting additional proof of the rejected claims. And, Abbott did just that. Abbott submitted additional proof of its repeating unit claims, and received the '326 patent. Torpharm presents no evidence, much less clear and convincing evidence, that the PTO improperly allowed the '326 claims. Accordingly, the anticipation argument is meritless.

3. Non-enablement:

[13] Torpharm's last argument is that the patents are invalid because they do not teach one of ordinary skill in the art how to make the new compound with the required physical/chemical properties. 35 U.S.C. s. 112 para. 1 requires that the patent specifications describe the invention in such terms that it enables any person skilled in the art to which it pertains to make and use the invention. *See* National Recovery Tech., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195 (Fed.Cir.1999) (discussing invalidity due to non-enablement). If there is clear and convincing evidence that the specifications fail to do so, the patent may be declared invalid. *Id*. Torpharm presents two non-enablement arguments: (1) the patents are non-enabled because they require an oligomer that does not exist; and (2) as to '326 claim 5, Abbott's internal documents require a curing process to reach the melting points disclosed in the claim. Neither of these points has merit.

First, the non-existent oligomer argument is based on Torpharm's overly narrow definition of oligomer. The court has already rejected this argument, and there is no need to repeat that analysis here.

Second, it is undisputed that Abbott has prepared divalproex sodium in accordance with Example 1 method set forth in the patents. The Example 1 compound had the melting points described in '326 claim 5, proving that the patents are enabled. The additional curing steps are steps that Abbott takes for its commercial product. That Abbott take an additional curing step in its commercial embodiment is irrelevant to enablement. *Cf.* Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed.Cir.1990).

III. CONCLUSION

For the foregoing reasons, the court grants summary judgment in favor of Plaintiff. Case terminated.

IT IS SO ORDERED.

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