United States District Court,
D. New Jersey.

In re GABAPENTIN PATENT LITIGATION

Aug. 25, 2005.

Background: Holder of patent for drug gabapentin sued prospective manufacturers of generic version, claiming patent infringement. Prospective manufacturers brought motion for summary judgment invalidating claims of patent as indefinite.

Holdings: The District Court, Lifland, J., held that:
(1) difficulty in determining whether particular preparation of gabapentin contained less than 20 parts per million (ppm) of acidic chloride ions did not require finding of indefiniteness;
(2) dispute between experts as to whether measurements of acidic chloride ions were correctly performed did not require finding of indefiniteness; and
(3) claim language, "less than 20 ppm," covered defined range that fell outside of 22 ppm limitation in alleged prior art, and did not require finding of indefiniteness.

Motion denied.

6,054,482. Construed.

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MEMORANDUM AND ORDER

LIFLAND**, District Judge.**

Plaintiffs Pfizer, Inc., Warner-Lambert Co., and Godecke Aktiengesellschaft (collectively, "Warner-Lambert") brought suit against Defendants Purepac Pharmaceutical Co., Faulding Inc., Apotex Corp., Apotex, Inc., TorPharm, Inc., Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Eon Labs Manufacturing, Inc., Zenith Laboratories, Inc., Zenith Goldline Pharmaceuticals, Inc., and Ivax Corporation (collectively, "Defendants"), alleging infringement of U.S. Patent No. 6,054,482, entitled "Lactam-Free Amino Acids" (" '482 patent"). FN1 Before the Court is the Joint Motion of Defendants for Summary Judgment Invalidating the Claims of the '482 Patent as Indefinite under 35 U.S.C. s. 112, para. 2. For the reasons set forth herein, Defendants' motion will be denied.

FN1. Warner-Lambert filed separate patent infringement actions against multiple generic drug manufacturers. The Judicial Panel on Multidistrict Litigation directed that all such actions be consolidated before this Court for coordinated pretrial proceedings. This Motion pertains to the "first-wave" defendants. There are also "second-wave" and "third-wave" defendants, sued by Warner-Lambert after close of discovery for first-wave defendants.

BACKGROUND

Neurontin(R) is sold by Warner-Lambert as an aid in the treatment of epileptic seizures and other cerebral disorders. The active ingredient in Neurontin(R) is a chemical compound called gabapentin. The chemical makeup of gabapentin allows the molecule, under certain conditions, to undergo an internal chemical reaction that results in a new compound called "gabapentin lactam." Gabapentin lactam, which is more than twenty-five times as toxic as gabapentin, actually causes rather than prevents seizures. Given the serious risks posed by gabapentin lactam, Warner-Lambert scientists sought to minimize its formation. They did so by way of a process ultimately disclosed in the '482 patent.

A. *Development of* Neurontin

When making a drug to market commercially, pharmaceutical companies generally prefer to use a "salt" of a drug in order to promote good stability and solubility, and to ensure that it is not irritating at the site of administration. A "salt" is formed as a result of the reaction between an acid and a base wherein a hydrogen ion from the acid is transferred to the base. Drugs that are "basic," like gabapentin, form a salt with hydrochloric acid (HCl). Upon discovering that the hydrochloride salt of gabapentin turned to lactam more quickly than gabapentin itself, Warner-Lambert scientists turned their attention from using the hydrochloride salt to using "free" gabapentin.

Gabapentin hydrochloride salt can be converted back to the neutral form of gabapentin through a process called ion exchange. Ion exchange involves a solution of gabapentin hydrochloride in water being passed through a column of ion exchange resin prepared in the "basic" form. Bartlett Decl. para. 15. The hydrochloric acid (HCl) stays on the column while the neutral form of gabapentin comes out the bottom. Id. Removal of HCl from gabapentin hydrochloride salt via ion exchange is a very efficient process. In a

sample that has been prepared from gabapentin hydrochloride by ion exchange, there is a one-to-one correspondence between the number of chloride ions and the number of gabapentin molecules that remain in the acidic form. FN2

FN2. Defendants dispute and/or challenge the background information provided by Warner-Lambert as irrelevant to the issues presented. Nonetheless, this background information is set forth because the Court believes that it will help in understanding Warner-Lambert's position herein.

B. *The* '482 Patent

The '482 patent includes eleven claims-three independent claims (1,3,7) and eight dependent claims. Every claim in the '482 patent includes the limitation that gabapentin have "less than 20 ppm" of an anion of a mineral acid or that an anion of a mineral acid does "not exceed 20 ppm." An anion is a negatively charged ion. Mineral acids include nitric, sulfuric, and hydrochloric acids. An anion of hydrochloric acid, for example, is chloride.

Claims 1 through 6 of the '482 patent are process claims. '482 patent, col. 6, l. 55 to col. 8, l. 28. Independent claim 1 concerns a process for making gabapentin. Claim 1 specifies that the gabapentin compound resulting from the process must contain "less than 20 ppm" of an anion of a mineral acid. '482 patent, col. 6, ll. 56-67; col. 7, ll. 1-20. Claim 2 depends from claim 1 and, accordingly, includes the "less than 20 ppm" limitation. Id. at col. 7, ll. 21-22. Claim 3, the next independent claim, concerns a process for making a pharmaceutical composition containing gabapentin. Claim 3 specifies that the anion of a mineral acid remaining in the gabapentin compound produced during the process must "not exceed 20 ppm." Id. at col. 7, ll. 23-57; col. 8, ll. 1-16. Claims 4, 5, and 6 depend from claim 3 and, therefore, include the "not exceed 20 ppm" limitation.

Claim 7 of the '482 patent, the only independent product claim, covers a pharmaceutical composition containing gabapentin:

7. A stable and pure pharmaceutical composition in unit dry medicinal dosage form consisting essentially of:

(i) an active ingredient which is gabapentin in the free amino acid, crystalline anhydrous form containing less than 0.5% by weight of its corresponding lactam and *less than 20 ppm of an anion of a mineral acid* and

(ii) one or more pharmaceutically acceptable adjuvants that do not promote conversion of more than 0.2% by weight of the gabapentin to its corresponding lactam form when stored at 25C and an atmospheric humidity of 50% for one year.

Id. at col. 8, ll. 29-40 (emphasis added). Claims 8-11 depend from claim 7 and, therefore, incorporate all the limitations of claim 7, including the "less than 20 ppm" limitation.

The written description of the '482 patent states, "The active material of formula (I) must be prepared as highly purified, nonderivatized hydrochloride by ion exchange. The proportion of remaining hydrochloride admixture should thereby not exceed 20 ppm. The same also applies to other mineral acids." Id. at col. 5, ll.

24-29.

STANDARD OF REVIEW

Summary judgment is a procedural tool that obviates the need for trial by identifying and disposing of groundless claims and defenses. Celotex Corp. v. Catrett, 477 U.S. 317, 323-24, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Relief is warranted where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). To resist, the adverse party must set forth specific facts that demonstrate the existence of a genuine issue for trial and may not rest on bare allegations or unsubstantiated defenses. Fed.R.Civ.P. 56(e); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. Once the proponent discharges its Rule 56(c) duty, the burden shifts to the adverse party to show that material facts are genuinely controverted. Matsushita Electric Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986).

Materiality and genuineness are the touchstones of summary judgment law. A dispute is genuine only if the evidence is such that a reasonable fact-finder could find in favor of the nonmoving party. Anderson, 477 U.S. at 248, 106 S.Ct. 2505; Matsushita, 475 U.S. at 587, 106 S.Ct. 1348. To determine whether the proofs create a jury question, the Court must take into account the apposite evidentiary burden. Anderson, 477 U.S. at 254-55, 106 S.Ct. 2505. If the proofs presented would permit a jury applying the governing evidentiary standard to find for the adverse party, then a genuine factual dispute exists. Id. at 255, 106 S.Ct. 2505. Whether those disputed facts are material depends on the applicable substantive law. *Id.*

Because summary judgment involves a pretrial adjudication on the merits, the adverse party enjoys the benefit of various procedural protections. For example, the Court must view the evidence in the light most favorable to the adverse party and accord that party the benefit of all legitimate inferences. Matsushita, 475 U.S. at 587, 106 S.Ct. 1348. Moreover, the Court may not take credibility issues from the fact-finder. Anderson, 477 U.S. at 255, 106 S.Ct. 2505.

DISCUSSION

[1] The second paragraph of 35 U.S.C. s. 112 states that a patent "specification shall conclude with one or more claims *particularly pointing out* and *distinctly claiming* the subject matter which the applicant regards as his invention." 35 U.S.C. s. 112, para. 2 (emphasis added). That statutory provision sets forth a "definiteness" requirement. *See* Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 874-75 (Fed.Cir.1993). The definiteness requirement "focuses on whether the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the [scope of the] patentee's right to exclude." Honeywell Int'l, Inc. v. International Trade Comm., 341 F.3d 1332, 1338 (Fed.Cir.2003) (quoting S3 Inc. v. nVIDIA Corp., 259 F.3d 1364, 1371-72 (Fed.Cir.2001)).

[2] [3] Defendants bear the burden to prove by clear and convincing evidence that claims are invalid as indefinite. W.R. Grace & Co.-Conn. v. Intercat, Inc., 7 F.Supp.2d 425, 466 (D.Del.1997), *aff'd,* 155 F.3d 572 (Fed.Cir.1998). A claim that is not "amenable to construction" is invalid as indefinite under 35 U.S.C. s. 112, para. 2. Honeywell Int'l, Inc., 341 F.3d at 1338 (quoting Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed.Cir.2001)). Invalidity for indefiniteness turns on "whether those skilled in the art

would understand the scope of the claim when the claim is read in light of the specification." Union Pacific Resources Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed.Cir.2001) (citations omitted). The Supreme Court has expanded on indefiniteness as follows:

The statutory requirement of particularity and distinctness in claims is met only when they clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise. A zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field.... Whether the vagueness of the claims has its source in the language employed or in the somewhat indeterminate character of the advance claimed to have been made in the art is not material. An invention must be capable of accurate definition, and it must be accurately defined, to be patentable.

United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236-37, 63 S.Ct. 165, 87 L.Ed. 232 (1942). Thus, the patentee must provide clear, unambiguous notice of the full scope of its claimed patent rights to "provide clear warning to others as to what constitutes infringement of the patent." 3 Donald S. Chisum, *Chisum on Patents,* s. 8.03 at 8-14 (2000).

[4] [5] A patent claim may fail to give proper notice to the public, and thus violate the definiteness requirement, by the use of vague or ambiguous language. But, given that a claim is presumptively valid, a claim is indefinite only if it is "insolubly ambiguous, and no narrowing construction can properly be adopted." Honeywell, 341 F.3d at 1338-39 (quoting Exxon Research, 265 F.3d at 1375). "The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1340-41 (Fed.Cir.2005).

[6] A finding of indefiniteness is a question of law, Exxon Research, 265 F.3d at 1376, but, here, Warner-Lambert asserts there is an underlying factual dispute between persons skilled in the art as to practicable measurability that precludes summary judgment. Defendants respond that Warner-Lambert's concessions about the limitations of various methods of measurement result in there being no genuine issue of material fact.

A. Measurability of the 20 ppm Claim Limitation

At issue here is the claim language "less than 20 ppm of an anion of a mineral acid." '482 patent, col. 8,l 34. For purposes of this Motion, Defendants accept Warner-Lambert's proposed claim construction-that the claim term refers to chloride anions derived from a mineral acid.

To date, there is no analytical technique capable of matching a chloride anion to its associated cation and thus directly identifying the source of that anion. Warner-Lambert describes three different methods available to one skilled in the art for determining whether a batch of gabapentin contains less than 20 ppm of acidic chloride ions and thereby infringes the '482 claims: (1) indirectly measuring the amount of acid ion by measuring the amount of chloride ion associated with the acid ion; (2) measuring directly the amount of acid ion (H^+) by titration with base; and (3) measuring directly the amount of acid ion (H^+) by the pH of a solution of gabapentin and then comparing the amount of acid ion in the sample with the amount of acid ion in a known or standardized sample.

The first way of determining whether a sample of gabapentin contains less than 20 ppm acid ion is to measure the chloride ion content of the sample. Chloride ion content may be determined through the so-called silver nitrate method and the ion chromatography method. Bartlett 12/20/02 Decl. para. 25. Based upon the results of the initial chloride test, there are a variety of ways to then verify that the sample of gabapentin meets the '482 patent's acid limitation. If the sample of gabapentin has less than 20 ppm of chloride ion then the analysis is complete. Id. para. 26. That is, the sample must contain less than 20 ppm of "acidic chloride" and thus falls within the claim's 20 ppm limitation. The presence of other sources of chloride, such as sodium chloride, can only demonstrate that the acid sources of chloride are even lower. Id. In that case, it does not matter what cations are associated with the chloride ions because the sample of gabapentin cannot have any more "acidic chloride" ions than it does total chloride ion. Id. If the sample of gabapentin contains more than 20 ppm of chloride ion, the sample may still contain less than 20 ppm of acid ion. Id. para. 27. That depends on what other cation (or positive ions) are present in the sample. Id. One must therefore further investigate whether the sample of gabapentin falls within the 20 ppm limitation of the claims.

Defendants maintain-and Warner-Lambert concedes-that direct measurement of acid by titration with base is difficult to perform in the low range required by the '482 patent (amounts as small as 20 ppm) and therefore may be impractical. Bartlett 12/20/02 Decl. para. 15; Pl.'s Br. at 4. This method measures total chlorides regardless of their source, Ex. 5, Bartlett Dep. at 98:1-18, but cannot determine whether gabapentin having greater than 20 ppm total chloride anion falls within the scope of the asserted claims.

The next method, known as the pH test, is used as a comparative means for determining whether the sample of gabapentin falls within the 20 ppm limitation. A pH test measures the acidity of a solution and thus gives a direct indication of the acid content of the sample. Bartlett 12/20/02 Decl. para. 15. The comparative method begins with a standard or a sample of gabapentin with a known amount of "acidic chloride." Bartlett 12/20/02 Decl. para. 29. The standard is prepared using a sample of gabapentin that is virtually free of any residual hydrochloric acid (HCl). Id. Once such a sample is prepared, aliquots of known amounts of hydrochloric acid may be added to the standard to prepare samples that contain known amounts of acid (and thus chloride ion). Id. The measured pH of the "unknown" gabapentin sample is compared to that of the standard with its known value of acid ion and chloride ion. Id. If the pH of the unknown sample measures higher than the standard, then that sample must contain less acid than the standard. Id. On that basis it may be determined whether the unknown sample falls within the acid limitation of the '482 patent. Id.

The pH method has limited precision of measurement. Bartlett 12/20/02 Decl. para. 15. As estimated by Warner-Lambert's expert, Dr. Paul Bartlett, ten parts per million of acid as measured by chloride is within the range that one could differentiate, using pH, but five parts per million of acid as measured by chloride is "certainly at the edge" of what level could be determined by pH measurements. Bartlett Dep. at 266:19-267:3; 268:3; 269:1; Ex. Rpt. of Professor Purnendu K. Dasgupta, 3/8/02 para. 70.

An alternative, indirect method involves subtracting the "non-acidic" cations from the total chloride content of the sample. Bartlett 12/20/02 Decl. para. 30. That leaves a number reflecting the amount of "acidic chloride" in the sample of gabapentin. Id. By example, if the total chloride ion content of a sample measured 30 ppm and if sodium chloride-the only "non-acidic" chloride-containing component of the hypothetical sample of gabapentin-was responsible for 15 ppm of the total chloride ion content, then the sample would contain 15 ppm of "acidic chloride" and would fall within the '482 patent's 20 ppm limitation. The drawback to this method is that it rests on the assumption that all the possible sources of chloride ion have been identified and that all the possible cations have been tested for. Bartlett 12/20/02 Decl. para. 31.

Taking pH measurements by the comparative method has the advantage over this "subtraction" method in that the comparative pH method measures the acid content of the gabapentin sample more directly. Id.

B. Parties' Arguments

Defendants argue that, under Warner-Lambert's construction, claim 7 of the '482 patent is invalid under 35 U.S.C. s. 112, para. 2 because the scope of the claim (1) cannot be measured and (2) cannot be distinguished from prior art. Defendants' argument is that the claim must fail for indefiniteness in that there is no dispute that the claims all include the limitation that the claimed gabapentin contain "less than 20 ppm" of an "anion of a mineral acid."; there is no dispute that, while it is possible to measure the level of total chloride anion in gabapentin, no analytical technique will match a chloride anion to its associated cation and thus directly identify the "source" of that anion; and that there is no dispute that measuring the pH level of the gabapentin does not directly quantify either the amount of chloride anion or "acidic chlorides" therein. Moreover, Warner-Lambert's expert, Dr. Bartlett, admitted that pH readings cannot distinguish gabapentin near the high end of the range claimed in the '482 patent from gabapentin with chloride levels known in the prior art. This is relevant inasmuch as prior art, namely, U.S. Patent No. 4,894,476 ("Butler"), discloses gabapentin containing 22 ppm of chloride anion and Warner-Lambert referenced Butler to the Examiner as being "outside the claim limitation" of the '482 patent.

Warner-Lambert counters that the purpose of the "less than 20 ppm of an anion of a mineral acid" claim limitation is to ensure that gabapentin does not convert to its toxic "lactam" form and that there are various methods available to one skilled in the art for determining whether a batch of gabapentin contains less than 20 ppm of acidic chloride ion and thereby infringes the '482 claims. Warner-Lambert challenges Defendants' suggestion that the applicable law regarding "practicable measurability" of numerical claim limitations under s. 112, para. 2 demands a finding of indefiniteness here because only the "direct" techniques available fail to measure the key claim parameter. Rather, according to Warner-Lambert, a patent claim will fail for "indefiniteness" only if there is no practicable means whatsoever for detecting infringement and this is not the case here.

C. Analysis

[7] The record shows that inventors of gabapentin chose to rely upon total chloride measurements because of the particular process employed to make gabapentin: "Fortunately, the scientists knew ... that the only source of chloride ion in their process was hydrochloric acid." Pl.'s Opp. at 9; Bartlett 12/20/02 Decl. para. 15. The indirect measurement of total chlorides suited inventors because there were no other sources of chloride ions. Bartlett 12/20/02 Decl. para. 15. The inventors also knew that they could measure the amount of chloride ion left over in the gabapentin easily and with precision. Id.

Here, Defendants focus the indefiniteness inquiry on whether there are practicable methods for ascertaining infringement of the '482 patent on the basis of the 20 ppm limitation. As noted, Warner-Lambert urges that it is the "acidic chloride"-chloride ion associated with the acid ion (H^+)-that determines how much acid ion is present in the product, and it is this acid ion (H^+) that contributes to the undesirable formation of gabapentin lactam. Measuring total chlorides may not identify the relevant acidic chlorides and, in turn, the associated acid ions. Yet it is not possible to directly measure the level of protons in gabapentin at the minute levels of acidity relevant to the '482 patent. Defendants' expert and Warner-Lambert's inventors have so testified. See Ex. 7, Dasgupta Rpt. para.para. 69-77; Ex. 11-Excerpts from the Deposition Transcript of Dr. W. Herrmann ("Hermann Dep."), dated Jan. 10, 2002, 79:22-80:13.

The relevant question, according to Defendants, is whether practicable methods exist for ascertaining the level of residual mineral acids in the generic product. Therein lies the dispute between the parties: Warner-Lambert maintains that there are practicable methods for doing so and Defendants say there are no such methods. Defendants point out that Warner-Lambert's expert has acknowledged that measuring total chlorides will not suffice if the total exceeds 20 ppm; that direct measurement of the ion is impractical; and that the pH comparison method has precision limitations, Bartlett Dep. at 266:19-267:3; 268:3;269:1 ("I think ten parts per million of acid as measured by chloride is within the range that you could differentiate, using pH, if the experiments are conducted carefully.").

Defendants invoke Morton International, Inc. v. Cardinal Chemical Co., 5 F.3d 1464, 1470 (Fed.Cir.1993), wherein the Federal Circuit upheld a district court's finding of invalidity for indefiniteness based on measurability:

The [district] court found that the claimed compounds cannot be identified by testing and that one skilled in the art could not determine whether a given compound was within the scope of the claims. The record supports this conclusion. Since the evidence shows that the claims at issue here are not sufficiently precise to permit a potential competitor to determine whether or not he is infringing we ... agree with the district court's determination that the claims are invalid for failure to satisfy the 'definiteness' requirement of section 112, second paragraph.

Id. Defendants argue here that the claims of the '482 patent are not sufficiently precise to enable a potential competitor to determine infringement. The Court disagrees.

SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331 (Fed.Cir.2005), is instructive on indefiniteness. In that case, the Court of Appeals disagreed that *Morton* stood for the proposition that a claim fails for indefiniteness if potential infringers would not be able to determine infringement. Id. at 1340. The court emphasized that the record in *Morton* contained (1) evidence showing that skilled artisans could not make the claimed compounds using the procedures set forth in the specification and (2) no evidence suggesting that the claimed compound even existed. *Id*. (quoting Morton, 5 F.3d at 1469-70). The panel concluded that *Morton* stood for the "unremarkable proposition" that a claim must apprise one skilled in the art of the scope of the claim in order to be definite. *Id*. As noted above, the court also made clear that "[t]he test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *Id*. at 1340-41.

In *SmithKline,* the Court of Appeals addressed whether the district court had erred when construing a claim to preserve validity in the face of a challenge to indefiniteness under s. 112. The district court considered the claim indefinite if construed to cover undetectable trace amounts of a particular substance: "[T]he trial court feared that potential infringers would not be able to determine (and avoid) infringement if they cannot detect the claimed compound." SmithKline, 403 F.3d at 1340 (citing Morton Int'l Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1469-70 (Fed.Cir.1993)). The Court of Appeals disagreed, holding that the claim covered a definite chemical structure and did not fail for indefiniteness even though the accused infringer could not accurately ascertain the nature of its own product. Id. at 1341.

Likewise, this Court concludes that whatever practicable measurability problems may ultimately be established, they do not support a finding of indefiniteness. Defendants have not met their burden to

demonstrate clearly and convincingly that the '482 patent is indefinite as a matter of law simply because it is difficult to ascertain the level of acidic chlorides for purposes of infringement. The Court is persuaded that claim 7 clearly delineates to a skilled artisan the bounds of the invention, which is the essence of the s. 112 definiteness requirement.

[8] In supplemental submissions and at oral argument, Defendants invoked Honeywell International, Inc., 341 F.3d 1332 (involving melting point elevation of polyester yarn) and Marley Mouldings Ltd. v. Mikron Indus., 2004 WL 416359 (N.D.Ill. Feb. 20, 2004) (involving percent volume of wood flour) to urge an alternative basis for a finding of indefiniteness. In both cases, a finding of indefiniteness resulted (1) where there were several methods for measuring a claimed parameter, (2) the different methods produced different results (e.g., within and outside the scope of the claims), and (3) the patent and its prosecution history failed to indicate which method must be used. Likewise, Defendants argue that the '482 patent is invalid as indefinite because (1) there is more than one way to measure acidic chloride content, (2) the different methods, particularly subtraction method and pH testing, produce different results, and (3) neither the patent nor prosecution history specify which method should be used to measure the claimed parameter.

Warner-Lambert distinguishes *Honeywell* and *Marley Mouldings* on the basis that measurements in those cases varied depending on how the samples were physically prepared for testing, whereas, here, the amount of mineral acid in the '482 patent is a precise parameter for which there can only be one correct value. Warner-Lambert maintains that the value should be the same regardless of which testing method is used.

The Federal Circuit Court of Appeals recently reversed the district court's finding of invalidity in *Marley Mouldings*. *See Marley Mouldings Limited v. Mikron Industries, Inc.,* 417 F.3d 1356, 1357 (Fed.Cir.2005). In so doing, the Court of Appeals distinguished the facts of *Marley Mouldings* and *Honeywell* :

In Honeywell, 341 F.3d 1332, this court held indefinite a claim that

included a specified melting parameter of a polymeric yarn but did not state which of four known methods of preparing and testing the yarn was used. In *Honeywell* there was evidence that the method of preparation and testing was critical to the measurement, and that only one of the four methods produced a measurement within the claimed range; whereby the court concluded that the claims were "insolubly ambiguous, and hence indefinite." *Id*. at 1340. In *Honeywell* it was shown that persons in the field of polymer chemistry understood that polymer melting point determinations vary significantly with the method used, rendering the claims "insolubly ambiguous." In contrast, it was not disputed that persons of experience in the field of the '927 invention would understand how to measure parts by volume, and how to convert weight into volume from bulk density data. AcceptingMikron's argument that shaking the wood flour may change its compactness, and thus produce different weight values for a given volume of wood flour, this argument relates to whether there is infringement of the claims. Although the district court was concerned that the claims encompass a range of volumes and thereby also of weights, s. 112 para. 2 is satisfied when the relevant values can be calculated or measured.

Marley Mouldings, 417 F.3d 1356, 1360-61 (citation omitted).

Against that backdrop, the Court is not persuaded that the '482 patent is indefinite because it is not clear that the pH method and the subtraction method yield different results. Defendants' subtraction method rests on an assumption called into question by Warner-Lambert's testing, *i.e.,* that all "non-acidic" cations have been identified. This is not an inherent measurability problem, but a dispute between experts as to whether the

measurements were correctly performed.

[9] Alternatively, Defendants contend that the full scope of the '482 patent claims cannot be distinguished from the prior art and are thus invalid as indefinite. Defendants rely on Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed.Cir.1991), wherein the Federal Circuit Court of Appeals upheld a lower court decision invalidating certain claims as indefinite. In *Amgen,* the patent claims at issue included a limitation on the specific activity of the claimed protein-"at least about 160,000 IU per absorbance unit at 280 nanometers." *Id.* at 1203. The court held that this limitation rendered the claim indefinite based on imprecise language, the existence of close prior art, and the margin of error available in the best available measurement technique that together rendered it impossible to differentiate the claimed invention from the prior art. *See id.* at 1217-18. Citing the lower court decision, the Federal Circuit noted that

"bioassays provide an imprecise form of measurement with a range of error" and that use of the term "about" 160,000 IU/AU, coupled with the range of error already inherent in the specific activity limitation, served neither to distinguish the invention over the close prior art (which described preparations of 120,000 IU/AU), nor to permit one to know what specific activity values below 160,000, if any, might constitute infringement.

Id. at 1217. According to Defendants, the key factor in that ruling was that one of ordinary skill in the art could not prospectively distinguish infringing from non-infringing. From there Defendants argue (1) that Warner-Lambert's "acidic chloride" claim construction renders the claim language "less than 20 ppm" of "an anion of a mineral acid" imprecise and (2) there exists close prior art, the Butler '476 patent, showing gabapentin containing 22 ppm of chloride anion, which Warner-Lambert referenced as outside the scope of the patent; and (3) the only analytical test method proffered by Warner-Lambert to identify and measure the "acidic chlorides" (pH measurements) admittedly lacks the sensitivity to differentiate the gabapentin near the top end of the range claimed in the '482 patent from that prior art.

The Court is not persuaded that *Amgen* supports a finding of indefiniteness in this case. In *Amgen,* the claim language in dispute was a limitation on the specific activity of "at least about 160,000." 927 F.2d at 1217-18. The inventors distinguished the claimed composition from prior art based on a numerical limitation. Because there was no indication in the specification or prosecution history as to what values of specific activity between prior art values in the 120,000 range and 160,000 range are covered by "about," the district court found the claim to be invalid as indefinite. Here, unlike *Amgen,* the claim language "less than 20 ppm" covers a defined range that falls outside the 22 ppm limitation in the alleged prior art.

In *Amgen,* the problem with imprecise claim language was compounded by the fact that bioassays that were the subject of the limitation at issue already provided "an imprecise form of measurement with a range of error." *Id.* at 1218. Measurability concerns in this case, as already discussed, do not direct a finding of indefiniteness.

CONCLUSION

For the foregoing reasons, the Motion of Defendants for summary judgment invalidating claims of the '482 patent as indefinite under 35 U.S.C. s. 112, para. 2 is denied.

Accordingly, **IT IS** on this 22nd day of August 2005,

ORDERED that the Motion of Defendants Purepac Pharmaceutical Co., Faulding Inc., Apotex Corp., Apotex, Inc., TorPharm, Inc., Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Eon Labs Manufacturing, Inc., Zenith Laboratories, Inc., Zenith Goldline Pharmaceuticals, Inc., and Ivax Corporation for summary judgment invalidating the claims of U.S. Patent No. 6,054,482 as indefinite under 35 U.S.C. s. 112, para. 2 is denied.

D.N.J.,2005.
In re Gabapentin Patent Litigation

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