United States District Court,
D. New Jersey.

In re GABAPENTIN PATENT LITIGATION

Pfizer Inc., Warner-Lambert Co., and G'f6decke Aktiengesellschaft,
Plaintiffs.
v.
Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd,
Defendants.

Nos. MDL NO. 13874(JCL), 00-2931(JCL), CIV.A.00-4168(JCL), CIV.A.00-4589(JCL)

Aug. 25, 2005.

Background: Holder of patent for drug gabapentin sued prospective manufacturers of generic version, claiming patent infringement. Prospective manufacturer brought motion for summary judgment of noninfringement of claims of patent based on use of certain adjuvants.

Holdings: The District Court, Lifland, J., held that:
(1) claim excluded at least eight particular lactam-promoting adjuvants;
(2) term "adjuvant" meant that subset of inactive ingredients that was intimately mixed with active ingredient to form drug mixture; and
(3) claim was directed at gabapentin and substances mixed intimately therewith.

Motion denied.

6,054,482. Construed.

John J. Francis, Jr., Drinker Biddle & Reath, Florham Park, NJ, David S. Copeland, Leora Ben-Ami, Stephen J. Elliott, Kaye Scholer, LLP, New York City, for Plaintiffs.

Allyn Zissel Lite, Lite, Depalma, Greenberg and Rivas, LCC, Arnold B. Calmann, Saiber, Schlesinger, Satz & Goldstein, LLC, Newark, NJ, Patrick J. Hughes, Connell Foley, LLP, Roseland, NJ, Neil S. Cartusciello, Mendham, NJ, for Defendants.

MEMORANDUM AND ORDER

LIFLAND**, District Judge.**

Plaintiffs Pfizer, Inc., Warner-Lambert Co., and Godecke Aktiengesellschaft (collectively, "Warner-Lambert") brought suit against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva"), alleging infringement of U.S. Patent No. 6,054,482, entitled "Lactam-Free Amino Acids" (" '482 patent"). FN1 Before the Court is the Motion of Teva for summary judgment of noninfringement of claims 7-11 of the '482 patent based on use of certain adjuvants. For the reasons set forth herein, Teva's 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 a "first-wave" defendant. 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, discovered by Warner-Lambert in the mid 1970s. Early research demonstrated that gabapentin had a propensity to undergo a chemical reaction resulting in an impurity known as gabapentin lactam, which was more than twenty-five times as toxic as gabapentin. Lactam caused rather than prevented seizures. FN2 Subsequent research revealed that both the purity of the starting gabapentin and the "catalytic effects" of certain ingredients, or adjuvants, mixed therewith contributed to the production of lactam. The development of a stable gabapentin formulation became the focus of first a German, and then a United States patent application that ultimately issued to Warner-Lambert on April 25, 2000 as the '482 patent. The '482 patent expires on April 25, 2017.

FN2. Given the severe risk posed by lactam, the Food and Drug Administration capped the allowable lactam impurity in gabapentin.

A. *The* '482 Patent

The '482 patent includes eleven claims. Claims 1 through 6 of the '482 patent are process claims. (Col. 6, l. 55 to Col. 8, l. 28). Claim 7 of the '482 patent, the only independent product claim, states:

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 25 (deg.)C and an atmospheric humidity of 50% for one year.

(Col. 8, ll. 29-40 (emphasis added)). Claims 8-11 depend from claim 7 and, therefore, incorporate all the limitations of claim 7. Claim 8 limits the selection of "pharmaceutically acceptable" adjuvants. (Col. 8, ll.41-49). Claims 9 and 10 limit the dry medicinal dosage forms to a tablet and capsule, respectively. (Col.

8, ll.50-53). Claim 11 limits the mineral acid in claim 7(i) to hydrochloric acid. (Col. 8, ll.54-55).

The written description of the '482 patent explains research efforts concerning the role of certain adjuvants in the gabapentin lactam conversion process. Lactam formation in gabapentin formulations was caused in part by "catalytic effects" of the ingredients-the adjuvants-that are combined with gabapentin to make a formulation. (Col. 4, ll.58-62). For example, where Poloxamer NF was the "sole" adjuvant, it did not impair the stability of the active material gabapentin. (Col. 4, ll.64-67). The specification also indicates that an adjuvant can be acceptable under one condition but not acceptable under a different condition. In one test using polyethylene glycol (PEG) as an adjuvant, "cyclization to the lactam took place to a considerable extent"; whereas when used with "very pure active substance," *i.e.,* very pure gabapentin, "PEG was found to be indeed usable as an excipient." (Col. 5, ll.1-14). The specification goes on to explain that

[i]n order to establish which adjuvant materials promote the lactam formation, laborious serial investigation had, therefore, to be carried out....

The following adjuvant materials, for example, reduced the stability of the compounds (I) and should be avoided in the preparation of pharmaceutical compositions: modified maize starch, sodium croscarmelose, glycerol behenic acid ester, methacrylic acid co-polymers (types A and C), anion exchangers, titanium dioxide, and silica gels such as Aerosil 200.

(Col. 4, l. 62-Col. 5, l. 10 (emphasis added)). It also identifies thirteen adjuvants found to have "no noticeable influence" on the stability of gabapentin. (Col. 5, ll.11-17).

The patent then summarizes the conditions that should be maintained to achieve a pure and stable pharmaceutical composition:

[i]n order not to exceed the upper limit of 0.5% by weight of gabapentin lactam (referred to the gabapentin), which is regarded as being permissible, and in order to ensure the storage stability not only of the active material but also of the corresponding pharmaceutical forms of preparation, the following procedures are to be maintained:

1. The active materials of formula (I) must be prepared as highly purified, nonderivatized free amino acids, for example, from the corresponding hydrochloride by ion exchange. The proportion of remaining hydrochloride admixtures should thereby not exceed 20 ppm. The same also applies to other mineral acids.

2. In the case of pharmaceutical preparations or compositions, *by the precise choice of adjuvant materials, every catalysis of the lactam formation must be suppressed.*

3. By controls, it must be ensured that the above conditions are fulfilled. As a rule, this is the case when the lactam formation, under the storage conditions generally applicable for medicaments, does not increase within a period of time of 1 year after production of the pharmaceutical compositions or of the active material by more than 0.2% by weight and preferably 0.1% by weight, referred to the pure active material.

(Col. 5, ll. 18-41 (emphasis added)).

B. *The* '482 Patent ***Prosecution History***

The grant of the '482 Patent came after a series of continuation United States patent applications and multiple reviews by the patent examiner. Warner-Lambert filed its initial patent application on August 21, 1990. Claim 5 of the application stated: "A pharmaceutical composition which comprises a therapeutically effective amount of a compound according to claim 1 in combination with a pharmaceutically acceptable carrier [*i.e.,* adjuvant]." (Rakoczy Decl., Ex. B at 00033).FN3 An April 1991 Office Action rejected all the claims (1-6) as being anticipated under 35 U.S.C. s. 102(b) and, alternatively, as obvious under 35 U.S.C. s. 103 in light of U.S. Patent No. 4,024,175 ("the Satzinger patent"), the products of which "appear [ed] to be substantially free from the corresponding lactam." (Id. at 00058-59).

FN3. For ease of reference, the Court cites to the bates-numbered version of the '482 Patent Prosecution History (00001-00342) attached as Exhibit B to the Declaration of William A. Rakoczy, which was submitted in support of the Motion of Apotex Corp., Apotex, Inc., and TorPharm, Inc. for summary judgment of noninfringement based on use of certain adjuvants (Civ.A. No. 01-611(JCL)).

Warner-Lambert responded by adding a new claim 7 that identified particular adjuvants found to "have no noticeable influence on the stability" of gabapentin. (*Id*. at 00071). The examiner again rejected the claims, stating:

Applicants' assertions as to certain additives affecting the stability of [gabapentin] is [sic] of no moment. First, claims 1, 2, 5 and 6 have no requirement of to [sic] specific additives. Second, the reference suggest [sic] the use of some of the specific additives listed in claim 7. Third, the allegations as to unexpected results are unsubstantiated and as such cannot be given any weight. Forth [sic], none of the claims, including claim 7, excludes that present [sic] of additives alleged to adversely affect the stability of [gabapentin], note the use of the open language 'comprising' in parent claim 5.

(*Id*. at 00078).

In response to subsequent claim rejections on the basis of the Satzinger patent, Warner-Lambert amended claim 5 by (1) replacing the term "comprises" with "consists of" and (2) requiring a pharmaceutically acceptable carrier "wherein the carrier does not promote the formulation of a lactam." (*Id*. at 00122). Warner-Lambert explained the amendments as "exclud[ing] the presence of additives which would adversely affect the stability of a compound of [gabapentin]." (*Id*. at 00129).

A May 1994 Office Action allowed claim 5. Warner-Lambert subsequently petitioned to withdraw its application and requested entry of, *inter alia,* an amendment canceling the allowed claim 5 and replacing it with a new claim 21 in independent form. (*Id*. at 00175-77).

On January 25, 1995, Warner-Lambert filed the '618 application,FN4 which ultimately issued as the '482 patent in suit. Claim 21 was directed to a

FN4. The '618 application was a continuation of application No. 08/020,270, February 18, 1993, abandoned, which was a continuation of application No. 07/865,723, April 8, 1992, abandoned, which is a continuation of application No. 07/570,500, Aug. 21, 1990, abandoned.

pharmaceutical composition which consists of a compounds of Formula VII wherein n is an integer of 5

containing less than 0.5% by weight of a compound of Formula VIII wherein n is as defined above and less than 20 ppm of an anion of a mineral acid in combination with a pharmaceutically acceptable carrier wherein the carrier does not promote the formation of a lactam of formula VIII.
(Id. at 00176). In the same filing, Warner-Lambert distinguished U.S. Patent No. 4,894,476 ("the Butler patent") as not recognizing "the need for a stable lactam-free gabapentin product" and, instead, teaching the use of additives that would result in an "unstable product." (Id. at 00179-80).
In a November 1995 Office Action, the patent examiner rejected claim 21 as anticipated and, alternatively, unpatentably obvious in light of prior art. (Id. at 00185-87). Warner-Lambert responded that it had "provided support in the specification ... that only certain adjuvants can be used in preparing a stable pharmaceutical preparation" because some "common adjuvants actually promote lactam formation." (Id. at 00200).

In further response to the November 1995 Office Action and a July 1996 examiner interview, Warner-Lambert submitted declarations of named inventors. The declaration of Uwe Gebhardt stated that "without knowledge of the teaching of the present invention, the list of excipients suggested by Satzinger would result in an unstable product containing at least one excipient *promoting instability* concerning the lactam content." (Id. at 00211) (emphasis in original). In November 1996, the examiner issued a "final" rejection of Warner-Lambert's claims 1, 6, 7, and 21-23 under 35 U.S.C. s. 103 as unpatentable over prior art. (Id. at 000249-55). Warner-Lambert responded by filing an amendment that replaced claim 21 with new claim 24. New claim 24, which ultimately became claim 7 of the '482 patent, described a gabapentin composition "consisting essentially of" the "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 for one year under specified atmospheric conditions. (Id. at 00258). Still more rejections based on prior art followed.

A January 1998 Office Action again prompted Warner-Lambert to distinguish its gabapentin formulation from prior art on the basis of certain adjuvants. In a December 9, 1999 Second Submission After Final Rejection, Warner-Lambert focused on the specific elements of Claim 24, and noted that it required three things:

1. The GABAPENTIN in the solid dosage form must have a low level of lactam, *i.e.,* less than 0.5%;

2. The GABAPENTIN used to prepare the solid dosage form must have a low level of mineral acid as measured by mineral acid anion, *i.e.,* less than 20 parts per million; and

3. The composition must be formulated with an excipient that does not catalyze the formation of GABAPENTIN lactam, *i.e.,* no more than 0.2% over one year at 25 (deg.)C.

(Pros. Hist. at 00308). Warner-Lambert further emphasized that "all three claim limitations must be considered as a whole." (Id.). As to prior art, Warner-Lambert noted that "[o]ut of the universe of available adjuvants, one must select particular ones, and avoid others. Applicants submit that there is nothing in the prior art that suggests that better stability will result from selecting those particular adjuvants." (Id. at 00291). It further pointed out that while it might have been obvious to try an adjuvant from Butler that works, "it would not have been obvious how to obtain a stable pharmaceutical formulation each and every time since Butler provides no guidance as to which excipients to use." (Pros. Hist. at 00313). A December 1999 declaration of Friedrich Trondlin, submitted in support of Warner-Lambert's filing, similarly explained that

excipients that catalyze lactam formation in GABAPENTIN, and that *must be avoided* to obtain good long-term stability, are among the common excipients that are frequently used. There is no suggestion in the prior art that it is necessary to both (1) reduce the mineral acid level below a critical level; and (2) *use only excipients that do not catalyze lactam formation*.

(Id. at 00319) (emphasis added). Table 1 of the Trondlin declaration sets forth stability data obtained by testing various adjuvants with gabapentin stored under conditions that roughly corresponded to atmospheric conditions set forth in claim 7(ii). Nearly all adjuvants tested promoted lactam formation to some degree, but only some adjuvants promoted lactam formation resulting in unstable formulations, *i.e.,* more than 0.2% by weight gabapentin lactam formed. (Id. at 000321-22).

A Notice of Allowance issued on January 4, 2000, approximately one month after submission of the Trondlin declaration. The Examiner stated that "as pointed out by applicants, it is considered that the prior art did not recognize the causes of lactam formation in gabapentin formulations. It is considered that applicants' particular combination of limitations is not suggested by the prior art of record." (Id. at 00342).

C. *Teva's Gabapentin Formulations*

Teva has submitted two Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration ("FDA") seeking approval to market generic gabapentin tablets and capsules. Teva's capsule product contains gabapentin as its active pharmaceutical ingredient ("API"), as well as modified maize starch and titanium dioxide as adjuvants, or inactive ingredients.

Teva's capsule formulations are dose proportionate and have the following composition: 74.07% gabapentin API in the granulation; 20% talc USP extra fine in the granulation, which serves as both a glidant and a lubricant; and 5.93% Starch 1500 LM, or pregelatinized starch, in the granulation, which serves as a disintegrant and capsule filler. Starch 1500 LM is a modified maize starch in which the polymer bonds within the starch are physically ruptured. The process of splitting the bonds results in a modified maize starch with better flow and compressibility than unmodified maize starch.

Teva's capsule shell contains titanium dioxide, gelatin, iron oxides, and FD & C dyes. The capsule shell is imprinted with ink 1012. The titanium dioxide that is in Teva's gabapentin capsules is a coloring component of the gelatin capsule shell. In fact, Teva purchases pre-manufactured capsule shells from Warner-Lambert's subsidiary, Capsugel. Capsugel's capsule shells are made up of gelatin and comprise two parts: a body and a cap. Teva uses a grey capsule body and a grey cap for 100-mg capsules, an orange body and an orange cap for 300-mg capsules, and a brown body and a brown cap for 400-mg capsules. The percentage of titanium dioxide in the capsule bodies is 2.0000%, 1.7000%, and 1.3333%, respectively. The percentage of titanium dioxide in the capsule caps is the same as in the capsule bodies.

Teva's gabapentin tablet formulations are dose proportionate and have the following composition: 70.9% gabapentin API; 4.4% povidone USP as a binder; 15.9% microcrystalline cellulose NF as a filler; 1.4% crospovidone NF as a disintegrant; 2% talc USP extra fine as a glidant; 2.9% hydrogenated vegetable oil NF type 1 as a lubricant; 2.5% Opadry(R) Y-1 7000H white as a coating solution; alcohol as a granulation solvent, and purified water as a coating solvent. The Opadry(R) coating solution consists of 1.56% HPMC 2910 5cP USP; 0.78% titanium dioxide; and 0.16% polyethylene glycol 400 NF.

The titanium dioxide in Teva's tablets is a coloring component of the tablet film coating. A film coating is applied to the core of tablet products for a variety of reasons, including protecting the drug from its surrounding environment, masking unpleasant tastes or odors, and easing the swallowing of drugs. The titanium dioxide percentage in Teva's tablets is less than 0.8%.

Teva's capsules form less than 0.2% additional lactam when stored for 24 months at room temperature. Those conditions are harsher than those set out in the '482 patent. Teva's tablets formed less than 0.2% additional lactam when stored for 12 months at room temperature. Those conditions are equivalent to the conditions set out in the '482 patent.

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.

"Summary judgment is as appropriate in a patent case as it is in any other case." C.R. Bard, Inc. v. Advanced Cardiovascular, Inc., 911 F.2d 670, 672 (Fed.Cir.1990). Where the material facts regarding the contents of the accused product are not in dispute, "the question of whether [the accused product] literally infringes the asserted claim of the ... patent turns on the interpretation of those claims," which is purely a legal question for the court amenable to summary judgment. K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1362 (Fed.Cir.1999) (citing Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1578 (Fed.Cir.1996)).

ANALYSIS

[1] Warner-Lambert asserts that Teva's capsule and tablet products infringe the '482 patent. Teva moves for summary judgment of noninfringement on the ground that its capsule and tablet products contain adjuvants excluded from claim 7 of the '482 patent.

A. ***Literal Infringement***

[2] [3] [4] Literal infringement is determined in a two-step process. First, a court must determine a claim's acquired meaning and scope. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (in banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Second, the claim as construed must be compared to the accused product to ascertain whether it "reads" on the accused product. Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed.Cir.1995). "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Id*. Where there is no dispute as to any relevant facts regarding the accused product, literal infringement is solely a matter of claim construction. Athletic Alternatives, Inc., 73 F.3d at 1578.

1. Claim Construction FN5

FN5. Warner-Lambert argued in its brief that the Court should hold a Markman hearing. At oral argument on the pending summary judgment motions, all parties, including Warner-Lambert, agreed that a separate Markman hearing was not necessary.

The operative claim language of claim 7 is "consisting essentially of ... 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 25 (deg.)C and an atmospheric humidity of 50% for one year." At issue is whether that language should be construed to exclude at least the eight exemplary lactam-promoting adjuvants referred to in the patent as adjuvants that "reduce the stability" of gabapentin compounds and which "should be avoided." ('482 Patent, Col. 5, ll. 5-10). Teva urges a construction of claim 7 excluding the eight adjuvants, relying on the specification and prosecution history. Warner-Lambert argues that claim 7 broadly covers any "pharmaceutically acceptable adjuvants," FN6 provided that their use meets the 0.2% limitation on lactam formation. Warner-Lambert further argues that even if the term "avoid" in the specification were construed to mean "do not use," that limitation cannot be imported into claim 7 for purposes of limiting the scope of the claimed invention.

FN6. Warner-Lambert invokes the following standard dictionary definitions: "Adjuvants" is defined as a "substance which is added to a drug formulation to improve the manufacturing process, product quality or pharmacological action; example, methyl cellulose to aid in suspending drug particles in a liquid." (Lorenz Decl., Ex. 8, *Dictionary of Pharmacy* 10 (1986)). "Pharmaceutics" refers to "that branch of pharmacy involving the study of the chemical, physical and biological factors which influence formulation, manufacture, stability and efficacy of dosage forms." (Id. at 229). The term "acceptable" has been defined as "capable or worthy of being accepted"; "barely satisfactory or adequate' " and "meeting only minimum requirements; barely adequate." (*Merriam-Webster's Collegiate Dictionary* 6 (10th ed.1993)).

[5] For reasons discussed more fully in this Court's Memorandum and Order granting Apotex Corp.,

Apotex, Inc., and TorPharm, Inc. summary judgment of noninfringement based on use of adjuvants, the Court construes clause (ii) of claim 7 to exclude the eight lactam-promoting adjuvants listed in the specification as those that should be avoided.FN7 In summary,the Court reasoned that while the plain language of the claim does not refer to useable and non-useable adjuvants, the written description and prosecution history require the interpretation of that claim to exclude particular adjuvants listed in the written description as those that should be avoided due to their negative effect on stability of the compounds.

FN7. The Court acknowledges language to the contrary in its October 13, 2004 bench opinion denying Warner-Lambert's application for preliminary injunctive relief directed to Purepac's entry into the market for AB-rated gabapentin capsules. The Court stated that it was inclined, at that time, to agree with Warner-Lambert's claim construction arguments. Now, having had an opportunity to consider the record in more depth, the Court concludes otherwise. Findings of fact and conclusions of law made in the context of a preliminary injunction, let alone observations, do not foreclose conclusions to the contrary at later stages of the litigation. *See* New Jersey Hosp. Assn. v. Waldman, 73 F.3d, 509, 519 (3d Cir.1995).

2. Comparing Teva's Gabapentin **Compositions to Construed Claim-Does Teva Use "Excluded" Adjuvants? Does Teva Use Excluded Substances, But Not as Adjuvants?**

Having construed claim 7 to exclude the eight lactam-promoting adjuvants listed as those to be avoided, the Court now turns to comparing Teva's formulation with the construed claim. Teva's position is that its formulations do not infringe the '482 patent because they contain modified maize starch and titanium dioxide, irrespective of the function those substances perform.

In support of its position Teva reasons that the '482 patent is silent on how the lactam-promoting adjuvants function as part of the claimed gabapentin formulation; it instructs only that those adjuvants are to be "avoided." Warner-Lambert responds that the modified maize starch and titanium dioxide are not necessarily relevant to infringement of the '482 patent and, at best, there are disputed issues of material fact with regard to whether the "modified starch" used by Teva in its capsules is the type of "modified maize starch" referred to in the patent as an example of an adjuvant that "should be avoided"; whether the titanium dioxide in Teva's capsule shells and tablet film coatings is being used as an "adjuvant" as that term is used in the '482 patent; and whether the amounts of titanium dioxide used by Teva in its capsule shells and tablet film coatings are sufficient to produce a "material effect on the basic and novel properties" of Warner-Lambert's invention of stable and pure gabapentin compositions.

a. Modified Maize Starch

According to Warner-Lambert, the "pregelatinized" starch used by Teva is not the same as the "modified maize starch" referenced in the '482 patent because the prosecution history indicates that the "modified maize starch" referred to in the patent as reducing gabapentin's stability is in fact "maize starch modified by acid treatment." (Pros.Hist.00320). Warner-Lambert also maintains that a skilled formulator would understand that the "modification" referred to in the patent specification is not pregelatinization because the specification states that sodium starch glycolate-an example of pregelatinized starch-has "no noticeable influence" on the stability of gabapentin.

Teva uses pregelatinized starch, which Dr. Klibanov (Warner-Lambert's expert) acknowledges is physically modified maize starch. (Klibanov 12/6/02 Decl. para. 66). The gelatinization process involves only a

physical modification of the starch converting it into gelatinous form (no chemical additives or surfactants are used). (Id.). Pregelatinization results in partial solubility, increased particle size, improved flow properties and compactability. (Id.). Teva contends that the reference in the '482 patent to "modified maize starch," with no further discussion, is not limited to maize starch modified by acid treatment and includes even starch modified only physically, not chemically. The Court disagrees. There is support in the prosecution history for construing the language "modified maize starch" to mean maize starch modified by acid treatment, as Warner-Lambert suggests. (Pros. Hist. at 00322). The Court also cannot ignore Warner-Lambert's argument that the modification referred to in the specification cannot be pregelatinization because the specification makes clear that another pregelatinized starch (sodium starch glycolate) has "no noticeable influence" on the stability of gabapentin. ('482 patent, Col. 5, ll. 11-16).

While Teva's gabapentin capsules contain a maize starch that has been physically modified and claims 7-11 have been construed to exclude "modified maize starch," Teva has not met its burden of convincing the Court that its pregelatinized maize starch is one of the excluded substances.

Accordingly, summary judgment of noninfringement on this basis is not proper.

b. Titanium Dioxide

[6] [7] For purposes of completeness, and because it relates to other pending motions for summary judgment, the Court will also address Teva's use of titanium dioxide as a colorant in capsule shells and tablet coatings. The issue is whether claim 7, describing "[a] stable and pure pharmaceutical composition in unit dry medicinal dosage form consisting essentially of ... one or more pharmaceutically acceptable adjuvants [that meet certain stability requirements]" is directed at ingredients in capsule shells and tablet coatings.

Teva argues that claim 7 covers all inactive ingredients, regardless of whether they are intimately mixed with the gabapentin or serve as an ingredient to the capsule shell. Teva equates "adjuvant" with any inactive ingredient, invoking the expansive FDA definition of inactive ingredient as any component in the pharmaceutical dosage form other than the "active ingredient," 21 C.F.R. s. 210.3(b)(8). An FDA definition for something other than "adjuvant," specifically, while important for FDA purposes, does not advance the claim construction inquiry here.

Warner-Lambert responds that even if the Court construes claim 7 to exclude the eight lactam-promoting adjuvants listed in the '482 patent specification, which it has, Teva's use of titanium dioxide for coloration is irrelevant. The reasoning goes that an "adjuvant" is an ingredient intimately mixed with gabapentin and that while all "adjuvants" are "inactive ingredients," it does not logically follow that all inactive ingredients are adjuvants. Rather, adjuvants are that subset of inactive ingredients intimately mixed with gabapentin to form the drug mixture.

The Court agrees with Warner-Lambert that Teva's use of titanium dioxide as a colorant is irrelevant for purposes of the '482 patent.FN8 Intrinsic evidence and extrinsic evidence considered in context support this conclusion.

FN8. Warner Lambert alternatively argues that Teva's use of titanium dioxide as a colorant is insufficient to take it outside claim 7's preamble language "consisting essentially of." The Court need not reach that argument in light of its conclusion that use of titanium dioxide as a colorant is irrelevant for purposes of the

'482 patent.

The Court observes that there is nothing in the patent or prosecution history that suggests that ingredients only present in capsule shells or tablet coatings affect the stability of the pharmaceutical formulation, so as to be considered an adjuvant within the meaning of claim 7. Therefore, the fact that Warner-Lambert did test capsule shells for lactam promotion (see 11/18/04 transcript at 108-09; Trondlin Decl.) is not helpful to claim construction.

Ingredients of dosage capsules or coatings could conceivably have an effect on the stability of a gabapentin formulation. Indeed, Warner-Lambert selected talc as a colorant for the film coating of Neurontin(R) tablets because it discovered that talc had 20 times less of an effect on lactam formation than titanium dioxide. (Warner-Lambert Opp. at 41 n. 7; Trondlin Decl., Table 1). It is argued that Warner-Lambert thus recognized that a colorant in a tablet's film coating was relevant to lactam formation, even though not intimately mixed with the active ingredient. However, Warner-Lambert also chose to use titanium dioxide in the capsule shells for its gabapentin product. (*See* Warner Lambert's Opp. at 41 n. 7) ("Warner-Lambert selected titanium dioxide as a colorant for the gelatin capsule shells of Neurontin(R) capsules."); Teva's Mem. of Law in Support of Summary Judgment on Non-Infringement at 11 ("The Physician's Desk Reference ("PDR") for Neurontin(R) lists titanium dioxide as an inactive ingredient in Warner-Lambert's Neurontin(R) capsule formulation." (citing Ex. 5, PDR at 2655 (2002))). This suggests that Warner-Lambert did not consider titanium dioxide, when used as a colorant in a capsule shell, to be a significant threat to stability of a gabapentin formulation.FN9 Thus, when viewed as Warner-Lambert admissions against interest, the foregoing considerations advanced by Teva are somewhat equivocal. In any event, Warner-Lambert's apparent concession that ingredients used in tablet coatings may affect lactam formation does not determine whether the language of the '482 patent is directed at ingredients of capsule shells.

FN9. Notably, Warner-Lambert's use of titanium dioxide as a colorant in a capsule shell is consistent with its position (rejected by the Court) that it is permissible to use any adjuvant, even those that are "excluded," if such use is judicious, and is not necessarily inconsistent with a conclusion that an ingredient in a capsule or a tablet coating is not covered by the patent. Warner-Lambert's use of titanium dioxide as a colorant in its capsule shells is certainly consistent with its position (and the Court's claim construction) that titanium dioxide, as so used, is not an "adjuvant."

The Court rejects the argument briefed and jointly advanced by the generic defendants at oral argument on November 18, 2004 (Tr. at 106) that the titanium dioxide present in capsule shells or tablet coatings is used as an adjuvant for purposes of claim 7. While dependent claim 9 refers to the dry medicinal dosage form as a tablet, and dependent claim 10 refers to the dry medicinal dosage form as a capsule, titanium dioxide as a colorant/coating of those capsules/tablets is not referenced in the patent or prosecution history. There is nothing in the patent that references capsule shells or tablet coatings. The fact that capsule shells (with no defined ingredients) appear in the Trondlin declaration as being tested for their effect on lactam promotion does not answer whether the language of the '482 patent covers those ingredients. This leads the Court to conclude that claim 7 is directed at gabapentin and substances mixed intimately therewith, not the colorants used in capsule shells or tablet coatings.

Furthermore, claim 7 plainly covers a composition "in unit dry medicinal dosage form," of which tablets and capsules are examples. ('482 patent, col. 8, ll. 28-30). It does not follow that an ingredient of the capsule

shell or tablet coating should be treated the same way as an ingredient of the composition. However, such would be the result of Teva's argument. While the inventors could have made that connection, nothing in the patent or prosecution history suggests that they did.

It is clear that the inventors were concerned about a catalytic reaction in the presence of certain adjuvants. ('482 patent, col. 5, ll. 30-33). Obviously, that concern is most relevant where the catalyst is intimately mixed with the reactive material, suggesting to the Court that peripheral or partial contact, as in a capsule shell or tablet film coating, between a catalyst and the reactive material was of lesser concern. This, in conjunction with the lack of reference in the patent to ingredients of capsule shells or tablet film coatings, further suggests to the Court that claim 7 of the '482 patent is directed to gabapentin and substances intimately mixed therewith, not the actual ingredients used in capsule shells or tablet film coatings.

[8] When considered in light of the patent claims and specification, extrinsic evidence also supports this conclusion. Phillips v. AWH Corp., 415 F.3d 1303, 1322-23 (Fed.Cir.2005) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584, 1585 n. 6 (Fed.Cir.1996) (courts are free to consult and rely on dictionary definition when construing claims so long as definition is not at odds with definition found in patent documents)). There is a strong presumption that a claim term carries its ordinary meaning. W.E. Hall Co., Inc. v. Atlanta Corrugating, LLC, 370 F.3d 1343, 1350 (Fed.Cir.2004). Warner-Lambert's position-that ingredients of capsule shells or tablet coatings are not "adjuvants" because they are not mixed with the drug formulation-comports with the commonly understood definition of adjuvant: "A pharmacological agent added to a drug, predictably affecting the action of the drug's active ingredient." *The American Heritage Stedman's Medical Dictionary* (2002); A "substance added to a prescription to aid the effect of the main ingredient." *The Random House Dictionary of the English Language* (2d ed.1987); "A pharmacological agent added to a drug to enhance its effect." *Webster's II New Riverside University Dictionary* (1984). While these dictionary definitions do not necessarily defeat Teva's construction of adjuvant as being any "ingredient" that aids the effect of the main ingredient, including those of capsule shells or tablet coatings, the Court finds the general emphasis on ingredients being "added to" a drug to be more consistent with Warner-Lambert's construction.

For these reasons the Court concludes that a skilled formulator would understand the term "adjuvant" in claim 7 to mean that subset of inactive ingredients that is intimately mixed with gabapentin to form the drug mixture, and thus construes claim 7 so as not to refer to the ingredients of capsule shells or tablet coatings. Accordingly, Teva's use of titanium dioxide does not itself compel a finding of noninfringement.

B. *Doctrine of Equivalents*

[9] [10] An accused product that does not literally infringe may nonetheless still infringe under the "doctrine of equivalents," which allows a patentee to claim insubstantial alterations not expressly captured in drafting of the original patent claim. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki, 535 U.S. 722, 733, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). The underlying rationale of the doctrine is that language may not capture the true essence of an invention. Id. at 734, 122 S.Ct. 1831. There are two major limitations on the doctrine of equivalents. First, a patentee cannot claim that which could not have been patented based on prior art. Marquip, Inc. v. Fosber Am. Inc., 198 F.3d 1363, 1367 (Fed.Cir.1999). Second, a patentee cannot recapture subject matter surrendered during prosecution to obtain patentability. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 30, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

Teva argues that prosecution history estoppel bars Warner-Lambert from asserting that Teva's gabapentin

product infringes the '482 patent under the doctrine of equivalents. Under the point heading, "Defendants' Doctrine of Equivalents Arguments Have No Foundation," (Warner-Lambert Opp. at 61), Warner-Lambert represents that it "does not, and need not, invoke the doctrine of equivalents to prove infringement." There being no dispute over it, the Court need not reach Teva's doctrine-of-equivalents argument.

CONCLUSION

For the foregoing reasons, the Court concludes that Teva is not entitled to summary judgment of noninfringement based on use of an adjuvant excluded from claims 7-11 of the '482 patent.

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

ORDERED that the Motion of Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. for summary judgment of noninfringement of U.S. Patent No. 6,054,482 based on use of certain adjuvants is denied.

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