United States District Court,
D. New Jersey.

WARNER-LAMBERT COMPANY Plaintif,
WARNER-LAMBERT COMPANY Plaintiff.
v.
TEVA PHARMACEUTICALS USA Defendan,
TEVA PHARMACEUTICALS USA Defendant.

No. Civ.A. 99-922(DRD)

June 13, 2002.

Michael R. Clarke, Drinker, Biddle & Shanley, Florham Park, New Jersey, Robert L. Baechtold, Nicholas M. Cannella, Joseph M. O'Malley, Jr., (Argued), David Greenbaum, Fitzpatrick, Cella, Harper & Scinto, New York, New York, for Plaintiff, Warner-Lambert Company.

Arnold B. Calmann, Robert B. Nussbaum, Saiber, Schlesinger, Satz & Goldstein, Newark, New Jersey, Albert E. Fey, W. Edward Bailey, (Argued), A. Joy Arnold, (Argued), Sasha G. Rao, John P. Hanish, (Argued), Fish & Neave, New York, New York, for Defendant, Teva Pharmaceutical USA.

OPINION

DEBEVOISE**, Senior District Judge**

On January 15, 1999, defendant Teva USA ("Teva"), using a Federal Drug Administration ("FDA") procedure known as an Abbreviated New Drug Application ("ANDA") sought approval from the FDA to engage in the commercial manufacture, use and sale of a generic drug formulation containing the active ingredient quinapril hydrochloride. By filing its ANDA Teva was able to rely on portions of an FDA submission already on file for a corresponding branded formulation sold by plaintiff, Warner-Lambert Company ("Warner Lambert"). The FDA had approved Warner-Lambert's drug which is sold in the United States under the name Accupril and which is the subject of Warner-Lambert's U.S. Patent No. 4,743,450 ("the '450 patent").

In connection with its ANDA submission Teva filed a so-called "Paragraph IV Certification" with respect to the '450 patent, asserting that the '450 patent is invalid under 35 U.S.C. s. 102 and 103. In response to notice of Teva's Paragraph IV Certification and acting pursuant to statutorily prescribed procedures Warner-Lambert commenced this patent infringement action.

The parties submitted to the magistrate judge handling certain pretrial proceedings lists of disputed terms. The magistrate judge established a briefing schedule at the conclusion of which the court would hold a *Markman* hearing. Briefs and supporting materials were submitted. Thereafter the parties executed a stipulation (incorporated in an order) in which they agreed upon the meaning of eleven claim terms and

further agreed that the *Markman* hearing would be limited to five claim construction issues. The hearing was held on June 3 and 4, 2002. This opinion constitutes the Court's ruling on the disputed language.

I. *The Patent and Disputed Terms*

The '450 patent, which is entitled "Stabilized Compositions", issued on May 10, 1988 from patent application number 17,962 ("the '962 application"), filed February 24, 1987. The '450 patent is directed to stabilized compositions of certain Angiotension Converting Enzyme ("ACE") inhibitors. The ACE inhibitors of the '450 patent are prescribed for the treatment of hypertension. The problem that the '450 patent addresses is summarized in the section entitled "BACKGROUND":

Certain ACE (Angiotension Converting Enzyme) inhibitors, which are useful as antihypertensives, are susceptible to certain types of degradation. Specifically quinapril and structurally-related drugs can degrade via (1) cyclization via internal nucleophilic attack to form substituted diketopiperazines, (2) hydrolysis of the sidechain ester group, and (3) oxidation to form products having often unwanted coloration.

Cyclization takes place when one part of the ACE inhibitor compound reacts with a different part of the same compound to form an altered, inactive "cyclized" compound. Hydrolysis is the reaction with water to form a hydrolysis degradation product. Oxidation forms products having unwanted coloration. The invention of the '450 patent resulted from Warner-Lambert's efforts to develop a stable dosage of its ACE inhibitor, quinapril hydrochloride ("quinapril") which was subject to degradation due to cyclization, hydrolysis and oxidation.

The invention as described in the '450 patent is: "it has been discovered that stable compositions containing ACE inhibitors of the type discussed above can be produced by using certain additives as stabilizers ..." For example: "The invention deals with: ... III. A method of making a pharmaceutical dosage form which comprises the step of including in the formulation suitable amounts of: (a) on ACE inhibitor, and (b) stabilizers which contain alkaline agents alone or alkaline agents in combination with saccharides (i.e., sugars) as one or more cyclization, hydrolysis, and discoloration inhibitor(s)."

The '450 patent sets forth seventeen claims, two of which are independent claims. The independent claims read:

Claim 1

1. A pharmaceutical composition which contains:
(a) a drug component which comprises a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration;

(b) a suitable amount of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration, and

(c) a suitable amount of a saccharide to inhibit hydrolysis.

Claim 16

16. A process for stabilizing an ACE inhibitor drug against cyclization which comprises the step of contacting the drug with:

(a) a suitable amount of an alkali or alkaline earth-metal carbonate and,

(b) one or more saccharides.

The five construction issues are the following:

A. The construction of the phrase "an alkali or alkaline earth metal carbonate" as used in Claims 1 and 16 of the '450 patent;

B. The construction of the phrase "to inhibit cyclization and discoloration" as used in Claim 1 of the '450 patent;

C. The construction of the phrase "to inhibit hydrolysis" as used in Claim 1 of the '450 patent;

D. The construction of the phrase "A process for stabilizing" as used in Claim 16 of the '450 patent; and

E. The construction of the phrase "one or more saccharides" as used in Claim 16 of the '450 patent.

II. ***Discussion***

The determination of the meaning and scope of a patent is a matter of law "exclusively within the province of the court", Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996), *aff'g* 52 F.3d 967, 979 (Fed.Cir.1995) (en banc). To determine the meaning of patent claims, the court in the first instance considers "intrinsic evidence"-the language of the asserted patent claims and other claims of the patent, the patent specification and the prosecution history of the patent application. Of these sources of meaning the language of the claims takes priority. Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335 (Fed.Cir.1998).

Where doubt remains after resort to the above sources it is appropriate to turn to extrinsic sources such as technical treatises and dictionaries, testimony of the inventor or patentee, statements made to foreign patent officers, *e.g.,* Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576 (Fed.Cir.1996).

With these principles in mind the assertedly doubtful claim terms will be considered.

1. "***An alkali or alkaline earth metal carbonate***"

The most serious dispute concerns the construction of the phrase "an alkali or alkaline earth metal carbonate" as used in Claims 1 and 16 of the '450 patent. Teva contends that "carbonate" encompasses "carbonate or bicarbonate." Warner-Lambert contends the word means only a "carbonate" and does not include a bicarbonate.

By way of background, there are two categories of carbonate compounds, those containing the carbonate compound and those containing the bicarbonate compound. A carbonate has one formula-CO_3^{-2}; a bicarbonate has a different formula-HCO_3^{-1}. Depending on the context, authorities may define "carbonate" and "bicarbonate" separately or they may treat each of the two as part of a general group of "carbonates". For an example of separate treatment see Gould Medical Dictionary:

"car-bon-ate --- The divalent radical CO_3; any salt or ester containing this radical, as salts or esters of

carbonic acid" (WL Exh. 78, p 224)

"bi-car-bon-ate --- A salt of carbonic acid characterized by the radical HCO_3" (WL Exh. 78, p 168)

On the other hand in other contexts "carbonate" might be construed to include both forms of carbonates. In Dorland's Illustrated Medical Dictionary (26^{th} ed.1981) "carbonate" is defined as "any salt of carbonic acid." Teva's expert, Alfonso R. Gennaro, Ph.D., explained that Carbonic acid (H_2CO_3) dissociates in water to form two salts; one containing the carbonate anion (CO_3^{-2}) and the other containing the bicarbonate anion (HCO_3^{-1}).

The question, therefore, is which of these meanings of "carbonate" is intended as the word is employed in Claims 1 and 16 of the patent.

As the starting point, one looks to the language of the claims themselves. They use the word "carbonate." "Carbonate" has its own chemical formula (CO_3^{2-}) which differs from the bicarbonate formula (HCO_3^{1-}). There is nothing in the patent specification that suggests in so many words that the word "carbonate" should include "bicarbonate", and the word "bicarbonate" does not appear in the specification. The examples set forth in the specification embodying the invention use a carbonate (CO_3^{2-}). Durel Corp. v. Osram Sylvania, Inc., 256 F.3d 1298, 1304 Fed. Civ.2001) (construing claim phrase narrowly based on specific chemical formulas set forth in patent examples).

Warner-Lambert incorporated into the '450 patent specification U.S. Patent Nos. 4, 425, 355 (the "355 patent") and 4, 344, 949 (the "949 patent"). In the '355 patent there was differentiation between "alkali metal carbonate" and "alkali metal bicarbonate." Also in the "9 patent there was differentiation between "alkali carbonates" and "bicarbonates." Although the inventors were not the same and the patents involved different subject matters, they were Warner-Lambert patents and its attorney on the application for the '355 patent was Ronald A. Daugnault, who was also the attorney who pursued the '450 patent. Telemac Cellular Corp. v. Topp Telecom. Inc., 247 F.3d 1316, 1328 (Fed.Cir.2001).

During the prosecution of the '450 patent the Examiner rejected the claims over Veber prior art. To overcome this objection Warner-Lambert noted the patent Examples and stated that its amendment was intended to "focus [ ] clearly on the use of an alkali or alkaline earth metal carbonate in combination with a saccharide." The amendment introduced into Claim 1 the language "contains ... (b) a suitable amount of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration." In an earlier submission the phrase "contains an alkali or alkaline earth metal carbonate" had appeared in dependent Claim 3, and the comparable limitation of independent Claim 1 read "contains ... a suitable amount of a metal containing stabilizer to inhibit cyclization and discoloration."

To counter this intrinsic evidence Teva points to the language appearing at Col. 3, lines 30-39 of the '450 patent specification which, Teva maintains, is dispositive:

The cyclization and hydrolytic instability which are exhibited by certain of the drugs discussed above can be overcome via the use of a suitable quantity, i.e., an effective amount of an alkaline stabilizer, together with saccharides.

The alkaline stabilizers of the invention include the inorganic salts of metals of Groups I and II of the Periodic Table. Thus, salts of alkali and alkaline earth metals are operable. Magnesium, calcium, and sodium are preferred. Magnesium is most preferred.

The anionic portion of the salt employed may be any which does not deleteriously affect the stability of the overall formulation. Thus, borates, silicates, and carbonates are contemplated. Carbonates are preferred. Mixtures are operable.

It is Teva's contention that the use of the plural, "carbonates", means more than one carbonate. That necessarily would bring bicarbonates within the language of Claims 1 and 16. Warner Lambert would have the court read the second and third paragraphs quoted above together and conclude that the plural of "carbonate" refers to sodium carbonate, magnesium carbonate or calcium carbonate.

Teva's construction is more likely correct. An alkali or alkaline earth metal carbonate is a salt, which like all salts is comprised of a positive ion (cation) and a negative ion (anion). The cation of the salt can either be an alkali metal or an alkaline earth metal. The alkali metals are the elements of Group I of the periodic table, including such metals as sodium, referred to in the second paragraph quoted above. Alkaline earth metals are elements of Group II a of the periodic table, including such elements as magnesium and calcium, also referred to in the second paragraph. These are the cations which the second paragraph enumerates. The third paragraph, on the other hand, refers to the anionic portion of the salt which can be borates, silicates and carbonates. (Warner-Lambert Exh. 25, p. 33 Amidon Declaration, para. 6) Thus it would seem that the "borates", "silicates" and "carbonates" referred to in paragraph 3 stand on their own and are not the plural of the salts referred to in the second paragraph.

It is true that where the patentee gives a term a certain meaning in the specification, that meaning will apply when interpreting the term as used in the claim. *See* ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1579-80 (Fed.Cir.1988).

However, there remains the fact that a reading of Claims 1 and 16 and the other intrinsic evidence points to a construction that "carbonate" is limited to carbonate having the specific chemical formula CO_3^{-2} and does not include bicarbonate having the specific chemical formula HCO_3^{-1}. Thus the intrinsic evidence supports Warner-Lambert's construction.

This could well end the inquiry concerning this disputed term. However, Teva refers to certain matters of extrinsic evidence. Even were they to be considered they would not lead to a different conclusion.

First, the definition of "carbonate" which appears in Dorland's Illustrated Medical Dictionary 219 (26^{th} ed.1981), namely, "any salt of carbonic acid" has already been referred to. This definition finds its parallel in non-medical dictionaries, e.g., The Random House Dictionary of the English Language, 2d ed.1987. (" 'Carbonate' a salt or ester of carbonic acid"; " 'Bicarbonate' a salt of carbonic acid, containing the (HCO_3^{1-}) group; an acid carbonate, as sodium bicarbonate, $NaHCO_3$").

Teva's expert, Alfonso R. Gennaro, Ph.D., as stated previously, noted that "Carbonic acid (H_2CO_3) dissociates in water to form two salts: one containing the carbonate anion (CO_3^{-2}) and the other containing the bicarbonate anion (HCO_3^{-1})." Although generally alkaline earth metals can only combine with the

carbonate anion, it is possible for alkali metals to combine with both bicarbonate and carbonate anions. Thus, Teva argues, the plain meaning of the language of the patent claims necessarily encompasses both carbonates and bicarbonates. Depending on the context or the dictionary selected, definitions of "carbonate" vary. The marshaling of dictionaries is not an appropriate way to determine the meaning of a claim when the meaning can be derived from the patent itself and the prosecution history.

Second, Teva notes that the specification states that "sodium" and "carbonates" are preferred components of the claimed alkali or alkaline earth metal carbonate stabilizers. The patent discloses and claims pharmaceutical or drug formulations (and processes for making the same) which necessarily are intended to be administered for treatment purposes. It is Teva's contention that "[a]s of the filing date of the '450 patent, however, it was well known by those of skill in the an that sodium carbonate has a toxicity profile that precludes its use in pharmaceutical preparations. Sodium bicarbonate (also known as 'baking soda' or 'monosodium carbonate'), on the other hand, was commonly used in products intended for ingestion." (Initial Teva Brief at p. 29). From these propositions Teva concludes that "... a person of skill in the art would have understood that the 'alkali or alkaline earth metal carbonate' limitation to include sodium bicarbonate (monosodium carbonate), the only nontoxic carbonate that could be combined with sodium for use in an orally administered pharmaceutical or drug preparation." (Id. at pp. 29, 30).

The testimony and other evidence confirm that sodium bicarbonate is used much more frequently than sodium carbonate in products that are ingested by human beings. This is of minimal relevance for present purposes. It is outweighed by the testimony of one of the inventors of the '450 patent, Dr. Michael R. Harris, that when seeking to formulate a stable compound using sodium bicarbonate they obtained poor results. Tanabe Seivaku Co., Ltd. v. United States Int'l Trade Comm'n, 109 F.3d 726, 733 (Fed.Cir.1997) (inventor's unsuccessful experiments with butanone indicated that patentee did not consider butanone was within the scope of the invention). FN1

FN1. Early in its development program Warner-Lambert was aware that sodium bicarbonate held out promise as a stabilizer. For a time it worked with ICI to develop a product using sodium bicarbonate and it knew that Merck's enalapril product contained sodium bicarbonate as a stabilizer. Subsequently in its own work, however, Warner-Lambert "ruled sodium bicarbonate out, because it didn't seem to help .... we did not find it to be very helpful from the standpoint of stability." Inventor Kuchi Murthy, Warner-Lambert Exh. 28, p. 46.

Thirdly, Teva argues that its position that alkali or alkaline earth metal carbonate must encompass sodium bicarbonate is supported by an admission Warner-Lambert made in connection with the prosecution of the corresponding European Patent Application No. 88 102 643.9 (the "EPO application").

During the mid-1980's Merck, Inc., commercialized a tableted ACE inhibitor-containing formulation for the treatment of hypertension. The product was sold in the United States under the name "Vasotec" and abroad under various names, including "Renitec." Renitec was described in a publicly available monograph. It contains an ACE inhibitor drug (enalapril maleate), lactose, sodium bicarbonate, maize starch and magnesium stearate.

Warner-Lambert's EPO application claimed the benefit of the filing date of the '962 application. As initially filed Claim 1 of the EPO application was identical to Claim 1 as initially filed in the '962 application. It read:

A pharmaceutical composition which contains:

(a) a drug component which comprise[s] an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration.

(b) a suitable amount of a metal containing stabilizer to inhibit cyclization and discoloration, and

(c) a suitable amount of saccharide to inhibit hydrolysis.

Warner-Lambert revised the language somewhat in response to two rejections. After a third rejection and an interview with the Primary Examiner of the EPO application, Warner-Lambert agreed "to make a disclaimer regarding the Enalopril-composition as disclosed "in the Renitec monograph". A new Claim 1 that expressly excluded the Renitec "composition containing for [Claim 1 subparts] (a), (b) and (c) enalapril maleate, lactose and monosodium carbonate [sodium bicarbonate]" was submitted following the interview. Thereafter the EPO application issued as a patent.

Teva contends that Warner-Lambert's willingness to amend Claim 1 of the EPO application to exclude the Renitec formulation demonstrates that Warner-Lambert recognized that the language of Claim I was broad enough to include sodium bicarbonate and that this same recognition of the breadth of the Claim I language was further evidenced by Warner-Lambert's failure to argue its narrow claim interpretation for the term "carbonate" during the prosecution of the EPO application. Although Warner-Lambert argues that it amended the EPO application because its Claim 1 did not include bicarbonate, it is unnecessary to divine its intentions. The circumstances of the EPO application cannot change the meaning of Claims 1 and 16 derived from the patent and the patent history.

In addition Teva points to several instances of statements by inventors of the '450 patent that demonstrate that they understood that sodium bicarbonate is, like magnesium carbonate, a carbonate salt. Dr. Kuchi Murthy is identified as an inventor of the subject matter disclosed in patent application WO92/15285 entitled "Starch-based Controlled Release Composition." Page 26 of that application states:

One preferred class of excipients is carbonate salts. These salts include, but are not limited to, sodium carbonate, sodium bicarbonate, calcium carbonate and magnesium carbonate.

(Arnold Ex. 32)

Initially in his deposition testimony Dr. Harris distinguished carbonates and bicarbonates:

Q. Do you have any information concerning whether the sodium bicarbonate which is identified as part of the Vasotec product in Exhibit 1033 is an alkaline or alkaline earth metal carbonate?

A. It's a bicarbonate.

Q. Is it also an alkali or alkaline earth metal carbonate or not?

A. It's a bicarbonate, and carbonates have different properties.

Q. So the answer is no, it's not an alkali or alkaline earth metal carbonate?

A. It's a bicarbonate.

Q. Can it be a bicarbonate and an alkali or alkaline earth metal carbonate?

A. No.

(Arnold Ex. 29, pp. 263, 264)

At a later point in his disposition Dr. Harris's testimony might be interpreted to evidence an understanding that "carbonate" includes a bicarbonate:

Q. In subpart B of claim 1, can you tell me what is your understanding of the phrase "a suitable amount of an alkali or an alkaline earth metal carbonate" as used in the context of claim 1 [of the '450 patent]?

A. As stated there, suitable amount of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration. As exemplified in examples here, magnesium carbonate, and I think we mention sodium bicarbonate and calcium carbonate also.

(Arnold Ex. 29, p. 336).

The examples to which Dr. Harris referred did not mention sodium bicarbonate, and in light of his deposition testimony quoted above he obviously mispoke.

Even if it were appropriate to consider extrinsic evidence to provide the meaning of "an alkali or alkaline earth metal carbonate", the evidence before the court would not establish that the term "carbonate" included "bicarbonate."

2. "***To inhibit cyclization and discoloration***"

Warner-Lambert contends that cyclization is "inhibited" when the result is a stabilized composition that will meet regulatory (most notably FDA) requirements in effect when the application was filed.

Teva, on the other hand "proposes that the word 'inhibit' as used in Claim 1 be construed to mean either a reduction or an elimination of the identified forms of degradation" (Teva's brief at p. 33). As a consequence, "[a] drug which does not meet the FDA's requirements, however, could have an inhibition of cyclization, discoloration or hydrolysis that is within the scope of the claims."

When one views the patent and its purposes, Teva's interpretation of "inhibit" makes little sense. The purpose and functional effect of the '450 patent is product stability, i.e., stable compositions containing ACE inhibitors. This was to be achieved through the use of additives as stabilizers. Cyclization was not inhibited until the product was stable. From the title of the patent ("Stabilized Compositions") through the specification the theme is stabilization.

In the formulation field in 1987 it was recognized that a stable product was one that would be approved by the FDA. As a general rule in the pharmaceutical industry such a product after a minimum of two years

shelf life would still retain at least 90% (or at most 110%) of the amount of its active ingredients. To ensure such potency there was an established rule of thumb among pharmaceutical formulators that total measured degradation at the end of the two-year shelf life should not exceed 5%. Since often it was not practical to take measurements over a two year period, when necessary stability was determined on the basis of "accelerated stability" or "stress testing", under which the drug product was stored for a lesser period of time under high temperatures and, when appropriate, higher than normal humidity conditions.

Teva's Vice President of Generic Research and Development, Christopher Pelloni, testified on Teva's behalf as a Fed.R.Civ.P. 30(b)(6) corporate representative. His understanding of "inhibit" closely parallels that of Warner-Lambert:

"Q. So, if I understand your answer correctly, your conclusion or Teva's knowledge that cyclization has been inhibited is based on the fact that it was stable enough to garner approval from the FDA.

Is that a fair summary?

A. What I am saying is any regulatory authority.

Q. OK.

A. Any regulatory authority would expect the product that is to be marketed to be stable. And I think that the pharmaceutical industry, in general, part of what they do is they develop products for the market and they certainly do their best to put products on the market that are stable and meet whatever regulatory authorities' requirements there are at the time."

(Exh. 60, 9/13/00 Rule 30(b)(6) Tr. p. 54).

In Teva's closing argument it stated that "[w]e equate inhibition and stability" (June 4 Transcript at p. 114). Referring to the 90% to 110% rule Teva did not "dispute that that rule was known by people in the art in 1987" (Id.) Teva objects to importing into Claims 1 and 16 the 90% to 110% rule and the 5% rule. But that is not what these claims do. Evidence of those guidelines is simply to show that in 1987 there was a common understanding in the pharmaceutical industry about what would constitute inhibition, i.e., stabilization of cyclization or discoloration.

"Inhibit", as used in Claim 1 means, as Warner-Lambert contends, that degree of stability as would secure regulatory approval of distribution of the drug product. It does not mean, as Teva argues, any lesser amount of stability. This meaning is derived from the claims and specifications and from the patent prosecution.

By the same token inhibition of discoloration as used in Claim 1 means similar minimization or elimination of an unwanted color change in the drug product ('450 patent, Col. 1, lines 11-12, 29-33).

3. *To inhibit hydrolysis*"

Warner-Lambert and Teva present the same arguments with respect to the term "inhibit" as it is used in the phrase "to inhibit hydrolysis" as used in Claim 1 of the '450 patent. "Inhibit" has the same meaning in each context. Teva argues that there are a variety of saccharides (or alkaline earth metal carbonates) which could be used for other purposes than inhibiting hydrolysis (or cyclization). They could be used for PH buffering

or as a filler. Thus if "you put your ingredient into the formulation, and they happen to be things you selected for buffering purposes or purposes of being a filler, and it turns out that you have a stable product, you could very well infringe this patent and yet you wouldn't be using the disclosure of the patent to accomplish a stability of the patent." (June 4 Transcript at pp 117-118)

This scenario ignores the functionality element of the word "inhibit." If a saccharide were used for some purpose other than inhibiting hydrolisis and did not inhibit hydrolysis or if an alkaline earth metal carbonate were used for some purpose other than inhibiting cyclization and discoloration and did not in fact inhibit cyclization and discoloration their use would not be within the scope of the claims.

Hydrolysis is inhibited when there is achieved that degree of stability as would secure regulatory approval of the drug product.

4. "***A process for stabilizing***"

Claim 16 of the 450 patent is "[a] process for stabilizing an ACE inhibitor drug against cyclization ..." The process "comprises the step of contacting the drug with: (a) a suitable amount of an alkali or alkaline earth metal carbonate and, (b) one or more saccharides."

Teva derives two alternative constructions for "[a] process for stabilizing an ACE inhibitor drug against cyclization." The first is that the recited "suitable amount of an alkali or alkaline earth metal carbonate" and the recited "one or more saccharides" must each play a role in achieving stabilization against cyclization. Teva's second interpretation of Claim 16 "acknowledges the functionality described in the specification and in Claim 1(b) for 'alkali or alkaline earth metal carbonate' and the functionality recited in the specification and in Claim 1(c) for 'a saccharide to inhibit hydrolysis' and incorporates both functionalities into the Claim 16" (Teva's Brief at p. 37).

Warner-Lambert rejects both of these constructions and asserts that Claim 16 claims but one function, stabilization of an ACE inhibitor against cyclization. This is accomplished through use of an alkali or alkaline earth metal carbonate. This function is performed with the presence of one or more saccharides which for the purposes of Claim 16 need perform no particular function. It may be, as Dr. Paul Wray testified, if the one or more saccharides did not inhibit hydrolysis "[y]ou would only be halfway home" (June 3 Transcript at p 99), but such a function is not an element of Claim 16.

The plain language of Claim 16 supports Warner-Lambert's interpretation of that Claim. It claims a process for stabilizing an ACE inhibitor *against cyclization*. Claim 16(b) does not include the phrase "a suitable amount" in conjunction with "one or more saccharides", thus omitting the link between the pharmaceutical component it is modifying and the referenced functional effect-preventing cyclization. It would be inappropriate to import from Claim 1 into Claim 16 a functionality that is not contained in Claim 16, namely, preventing hydrolysis. Only Claim 16(a), which recites "a suitable amount of an alkali or alkaline earth metal carbonate," plays a role in stabilizing against cyclization.

5. "***One or more saccharides***"

Related to the previous interpretation issue is the dispute over the meaning of the term "one or more saccharides" as used in Claim 16 of the '450 patent. The saccharides do not play a functional role in stabilizing against cyclization. As set forth in Claim 1, they are included in the drug product in a suitable amount to inhibit hydrolysis, but their inclusion does not play a functional role in Claim 16.

III. *Conclusion*

The disputed terms have the following meanings:

1. "an alkali or alkaline earth metal carbonate" as used in Claims 1 and 16 of the '450 Patent means the salt of an alkali metal or alkaline earth metal cation, and a carbonate (CO_3^{-2}) anion; it does not include a bicarbonate (HCO_3^{-1}) anion.

2. "to inhibit cyclization and discoloration" as used in Claim 1 of the '450 Patent means reducing cyclization and discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval.

3. "to inhibit hydrolysis" as used in Claim 1 of the '450 Patent means reducing hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval.

4. "a process for stabilizing" as used in Claim 16 of the '450 Patent means a method of making a pharmaceutical dosage form of an ACE inhibitor in which cyclization has been inhibited.

5. "one or more saccharides" as used in Claim 16 of the '450 Patent means a saccharide or saccharides which are a component of a dosage form of an ACE inhibitor in which cyclization has been inhibited but which have no function with respect to Claim 16.

D.N.J.,2002.
Warner-Lambert Co. v. Teva Pharmaceuticals USA

Produced by Sans Paper, LLC.