United States District Court,
N.D. Texas.

CIBA VISION CORPORATION,
Plaintiff.
v.
ALCON LABORATORIES, INC,
Defendant.

No. Civ.A.3:97-CV-0626-G

Oct. 21, 1997.

FISH**, J.**

MEMORANDUM ORDER

Before the court is the motion of the defendant Alcon Laboratories, Inc. ("Alcon") for summary judgment. For the reasons set forth below, the motion is granted.

I. BACKGROUND

Plaintiff CIBA Vision Corporation ("CIBA") manufactures ophthalmic products, including Voltaren(R) Ophthalmic Eye Drops. Press Release, included in Exhibits in Support of Alcon's Motion for Summary Judgment ("Exhibits in Support of Motion") as Exhibit 3. CIBA claims that the Voltaren(R) drops are protected by patents issued to Ingrid Nagy ("Nagy") FN1 and Johann Doulakas ("Doulakas").FN2 *Id.*; Nagy and Doulakas Patents. The drops are used to treat intra-ocular inflammation caused by certain surgical procedures. Brief in Support of Alcon's Motion for Summary Judgment ("Brief in Support of Motion") at 3.

FN1. The Patent and Trademark Office ("PTO") issued the Nagy Patent, number 4,960,799, on October 2, 1990. Nagy Patent, included in Exhibits in Support of Motion as Exhibit 7.

FN2. The PTO issued the Doulakas Patent, number 4,829,088, on May 9, 1989. Doulakas Patent, included in Exhibits in Support of Motion as Exhibit 8.

Defendant Alcon is a competitor of CIBA and intends to manufacture for sale, if approved by the Food and Drug Administration ("FDA"), a solution which competes with the Voltaren(R) drops. Brief in Support of Motion at 1, 2. The solution contains the following ingredients: (1) diclofenac sodium, the active ingredient,FN3 (2) tocophersolan ("Vitamin E TPGS"), the solubilizing agent,FN4 (3) polyquaternium-1 ("Polyquad(R)"), the preservative, FN5 (4) Mannitol, an isotonizer,FN6 (5) boric acid, a buffer, FN7 (6) purified water, and (7) sodium hydroxide and/or hydrochloric acid.FN8 Motion para. 26. The solution

contains no stabilizer FN9 that can be identified apart from the foregoing ingredients. *Id*. para. 23. Alcon obtained a patent protecting the solution, in which Suketu Desai ("Desai") and Diane Nelms were identified as the inventors.FN10 Desai Patent.

FN3. The active ingredient accomplishes the desired result. Alcon's Motion for Summary Judgment ("Motion") para. 9.

FN4. The solubilizing agent prevents certain ingredients from dropping out of the solution. *Id*. para. 14.

FN5. The preservative maintains the sterility of the solution. *Id*. para. 13. For example, if a patient touches an infected eye with the bottle tip or leaves the bottle open to the atmosphere, a product lacking a preservative would be contaminated. *Id*.

FN6. The isotonizer ensures that the product is neither taking water away from nor adding water to the cells in the eye tissue. *Id*. para. 12.

FN7. The buffer maintains an appropriate pH. *Id*. para. 10.

FN8. Sodium hydroxide and/or hydrochloric acid are used to adjust the pH of the solution during the manufacturing process. *Id*. para. 11.

FN9. A stabilizer prevents certain diclofenac-preservative interactions, such as diclofenac-preservative binding, degradation of components in solution, settling of components, and general solution instability. *Id*. para. 17.

FN10. The PTO issued the Desai Patent, number 5,603,929, on February 18, 1997. Desai Patent, included in Exhibits in Support of Motion as Exhibit 11.

On December 11, 1996, Alcon filed with the FDA a new drug application ("NDA") for its solution and certified, pursuant to 21 U.S.C. s. 355(b),FN11 that the Nagy Patent would not be infringed by the manufacture, use, or sale of its solution.FN12 Certification, included in Exhibits in Support of Motion as Exhibit 16. Pursuant to 21 U.S.C. s. 355(b)(3),FN13 by letter dated February 5, 1997, Alcon notified CIBA that it filed the NDA. Letter of February 5, 1997, included in Exhibits in Support of Motion as Exhibit 17; *see also* Complaint para. 7. Within the forty-five day period prescribed by 21 U.S.C. 355(c)(3)(C),FN14 CIBA brought this action claiming infringement, pursuant to 35 U.S.C. s. 271(e)(2)(A),FN15 based on Alcon's filing of the NDA. Alcon now moves for summary judgment.

FN11. Section 355(b)(1) requires any person filing a NDA to include in the application the patent number and the expiration date of any patent which claims the drug for which the applicant

submitted the application ... and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Section 355(b)(2)(A) requires a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted ... and for which information is required to be filed under paragraph (1) of this section-

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) *that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted....*

(emphasis added).
FN12. Alcon did not make a certification with respect to the Doulakas patent because CIBA did not list it in the FDA's "Orange Book." Motion para. 32.

FN13. Section 355(b)(3)(A) provides:
An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to-

(i) each owner of the patent which is the subject of the certification....

Section 355(b)(3)(B) provides:

The notice referred to in subparagraph (A) shall state that an application has been submitted under this

subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

FN14. Section 355(c)(3)(C) provides:
If the applicant made a certification described in clause (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received.

FN15. Section 271(e)(2)(A) provides that it shall be an act of infringement to submit
an application ... described in section 505(b)(2) [of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2))] for a drug claimed in a patent....

II. ANALYSIS

A. *Evidentiary Burdens*

Summary judgment is proper when the pleadings and evidence on file show that no genuine issue exists as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c).FN16 "[T]he substantive law will identify which facts are material." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The movant makes such a showing by informing the court of the basis of its motion and by identifying the portions of the record which reveal there are no genuine material fact issues. See Celotex Corporation v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Once the movant makes this showing, the nonmovant must then direct the court's attention to evidence in the record sufficient establish that there is a genuine issue of material fact for trial. Id. at 323-24. To carry this burden, the opponent must do more than simply show some metaphysical doubt as to the material facts. Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corporation, 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). Instead, it must show that the evidence is sufficient to support a resolution of the factual issue in its favor. Anderson, 477 U.S. at 249. All of the evidence must be viewed, however, in a light most favorable to the motion's opponent. Id. at 255 (citing Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970)). Summary judgment is properly entered against the opponent if after adequate time for discovery, it fails to establish the existence of an element essential to its case and as to which it will bear the burden of proof at trial. Celotex, 477 U.S. at 322-23.

FN16. The disposition of a case through summary judgment "reinforces the purpose of the Rules, to achieve the just, speedy, and inexpensive determination of actions, and, when appropriate, affords a merciful end to litigation that would otherwise be lengthy and expensive." Fontenot v. Upjohn Company, 780 F.2d 1190, 1197 (5th Cir.1986). See also Celotex Corporation v. Catrett, 477 U.S. 317, 327, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 45 F.3d 1550, 1560 (Fed.Cir.1995) ("The purpose of summary judgment is to avoid an unnecessary trial").

B. *Infringement Under the Doctrine of Equivalents*

CIBA concedes that Alcon's solution does not literally infringe either the Nagy or Doulakas Patents, arguing instead that Alcon's solution infringes the patents in suit under the doctrine of equivalents. Brief in Opposition to Motion at 2. The determination of infringement requires a two-step analysis. The first step is claim construction, a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 983-84 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The proper construction of the claims is based upon the claim language, the specification, the prosecution history, and extrinsic evidence. Id. at 979-80. Terms used in the claims are given their ordinary and customary meaning in the field of the invention, unless a special definition is clearly stated in the specification. See *id*.

The second step in the infringement analysis, a question of fact,FN17 is a determination whether the accused device infringes the claims, properly construed, of the patent in suit. Infringement is found under the doctrine of equivalents when, in the absence of estoppel, every limitation of the asserted claim, or its equivalent, is found in the accused subject matter, the latter differs from what is literally claimed only insubstantially, and it performs substantially the same function in substantially the same way to achieve substantially the same result. *Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc.,* 62 F.3d at 1512, 1517-18 (Fed.Cir.1995), *rev'd on other grounds,* 520 U.S. 17, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997); Pennwalt Corporation v. Durand-Wayland, Inc., 833 F.2d 931, 934-35 (Fed.Cir.1987), *cert. denied,* 485 U.S. 961, 108 S.Ct. 1226, 99 L.Ed.2d 426 (1988). As a result, the doctrine of equivalents prevents an accused infringer from avoiding infringement by changing only minor or insubstantial details of a claimed invention while retaining their essential functionality. See *Hilton Davis,* 62 F.3d at 1517.

FN17. Although the determination of equivalents is a question of fact, the court should grant summary judgment in those cases where no reasonable fact finder could find two elements to be equivalent. Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co., ---U.S. ----, 117 S.Ct. 1040, 1053 n. 8, 137 L.Ed.2d 146 (1997).

1. *How Should the Claims of the Patents in Suit Be Construed?*

To determine this motion, it is only necessary to consider the arguments and proof concerning the stabilizer element FN18 of claim 1 in each of the patents in suit.FN19 *See* Brief in Opposition to Motion at 5; Brief in Support of Motion at II, 24. By focusing on just this one element, claim construction is straightforward. In relevant portion, claim 1 of the Nagy Patent should be construed as claiming an opthalmic solution containing EDTA as a stabilizer, and claim 1 of the Doulakas Patent should be construed as claiming an opthalmic solution containing trometamol as a stabilizer.

FN18. The stabilizer element in the Nagy Patent is ethylenediamine tetraacetic acid ("EDTA"), and in the Doulakas Patent it is formula I ("trometamol"). Brief in Opposition to Motion at 4.

FN19. Claim 1 of the Nagy patent reads:
A storage stable aqueous substantially isotonic solution of a pharmaceutically acceptable salt of ortho-(2,6-d icholorophenyl)aminophenylacetic acid for the treatment of ocular inflammation, said solution having a pH between about 7.0 and 7.8 and comprising, per ml solution:

(a) about 0.1 to about 5.0 mg of a pharmaceutically acceptable salt of ortho-(2,6-dicholorophenyl)amino)phenylacetic [sic] acid;

(b) about 0.1 to about 10 mg of a pharmaceutically acceptable salt of *ethylenediamine tetraacetic acid;*

(c) about 0.01 to about 5 mg of a pharmaceutically acceptable bacteriostat;

(d) about 0.5 to about 200 mg of a pharmaceutically acceptable solubilizer, or mixtures thereof; and

(e) the remainder water.

Nagy Patent (emphasis added).
Claim I in the Doulakas patent reads:

In a medicament for the treatment of inflammations of the eye, containing an aqueous solution of diclofenac-sodium in an amount of from 0.01 to 0.15%, a buffer, an isotinising agent, a solution aid and a preservative, the improvement wheein [sic] the medicament contains a compound of the general *formula I*

in which m, n and o, independently of one another, each represents an integer of at least 1 and the sum of m, n and o is in the range of from 3 to 9, in an amount of from 0.05 to 5% as stabilizer for the active ingredient and the preservative and also as additional buffer.

Doulakas Patent (emphasis added).

2. *Does Alcon's Solution Infringe?*

Alcon presents evidence that its solution does not contain EDTA, trometamol, or their equivalents. Alcon's expert, David Marsh, asserts that Alcon's diclofenac-Polyquad(R)-Vitamin E TPGS solution requires no "separate stabilizer," such as EDTA or trometamol, which are claimed in the Nagy and Doulakas Patents. Declaration of David A. Marsh ("Marsh Declaration") para. 28, included in Exhibits in Support of Motion as Exhibit 1. Marsh explains that Alcon's solution is a stable alternative opthalmic solution, which

eliminates the need for such "separate stabilizers." *Id*. In other words, Marsh presents evidence that the Alcon solution contains more than simply minor or insubstantial differences as compared to the solutions claimed in the Nagy and Doulakas Patents. Moreover, Marsh's declaration tends to prove that Alcon's solution does not perform substantially the same function in substantially the same way to obtain substantially the same result.

In response, CIBA has not come forward with evidence to support a resolution in its favor of this factual issue, *i.e.*, that Alcon's solution infringes the stabilizer element of claim I of either patent in suit. First, CIBA fails to coherently identify which component(s) of Alcon's solution is (are) equivalent to either EDTA or trometamol. In response to Alcon's first FN20 and third FN21 interrogatories, CIBA stated, in pertinent part:

FN20. Interrogatory No. 1 inquires:
For each claim of the Nagy patent that CIBA Vision contends to be infringed by Alcon's formulation, describe in full detail the basis for the contention, including providing an element-by-element comparison of each ingredient(s) of Alcon's formulation that corresponds to each such element.

CIBA Vision's Responses to Alcon's First Set of Interrogatories ("Responses") No. 1, included in Exhibits in Support of Motion as Exhibit 21.
FN21. Interrogatory No. 3 inquires:
For each claim of the Doulakas patent that CIBA Vision contends to be infringed by Alcon's formulation, describe in full detail the basis for the contention, including providing an element-by-element comparison of each ingredient(s) of Alcon's formulation that corresponds to each element of the claim.

Id. No. 3.
Vitamin E TPGS, Mannitol, Polyquaternium-1 *and/or* Boric Acid of the Alcon formulation, *individually or in combination,* corresponds to a pharmaceutically acceptable salt of ethylenediamine tetraacetic acid ("EDTA") of the Nagy Patent.
Vitamin E TPGS, Mannitol, Polyquaternium-1 *and/or* Boric Acid of the Alcon formulation, *individually or in combination,* correspond to a compound of the general formula I in which m, n, and o, independently of one another each represents an integer of at least 1 and the sum of m, n and is in the range of from 3 to 9 of the Doulakas patent claims.

Responses Nos. 1, 3 (emphasis added). A review of these interrogatory responses thus reveals that CIBA identified all but three components FN22 of Alcon's solution as "possible" equivalents.
FN22. CIBA did not identify diclofenac sodium, water, or sodium hydroxide and/or hydrochloric acid as equivalents.

In addition, CIBA presents evidence to satisfy only the "function" prong of the function, way, and result test. CIBA argues:

Vitamin E TPGS in Alcon's formulation can exhibit and perform the same *functions* in Alcon's formulation as EDTA and compounds of formula I perform in the Nagy and Doulakas patent formulations. (Anderson Decl. para.para. 23, 36). Mannitol, another ingredient in Alcon's accused formulation, is also a known

antioxidant, free radical scavenger and metal chelator, particularly in large concentrations. Accordingly, it can perform the same *functions* in Alcon's formulation as EDTA and compounds of formula I in the patents-in-suit. (*Id.,* para. para. 24-25, 37). Polyquaternium-1 and boric acid, according to Alcon's own patent describing its diclofenac formulation, provide a storage-stable composition. Since Vitamin E TPGS, Mannitol, polyquaternium-1 and/or boric acid perform an equivalent *function* to EDTA, they can be considered to be in the same *functional* class. (*Id.,* para.para. 43-44).

Brief in Opposition at 23 (emphasis added) (citing Declaration of Dr. Bradley D. Anderson, included in Declarations in Support of CIBA Vision's Brief in Opposition to Alcon's Motion for Summary Judgment).

Finally, CIBA fails to explain how the use of "Vitamin E TPGS, Mannitol, polyquaternium-1 and/or boric acid" as stabilizers is only a minor or insubstantial change from using EDTA or trometamol. CIBA would have this court give the doctrine of equivalents such broad play so as to effectively eliminate the EDTA and trometamol elements in their entirety. See Warner-Jenkinson, --- U.S. at ----, 117 S.Ct. at 1049 ("It is important to ensure that the application of the doctrine [of equivalents], even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety."); Conopco, Inc. v. May Department Stores Company, 46 F.3d 1556, 1562 (Fed.Cir.1994), *cert. denied,* 514 U.S. 1078, 115 S.Ct. 1724, 131 L.Ed.2d 582 (1995) ("The doctrine of equivalents cannot be used to erase 'meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement.' ") (citations omitted).

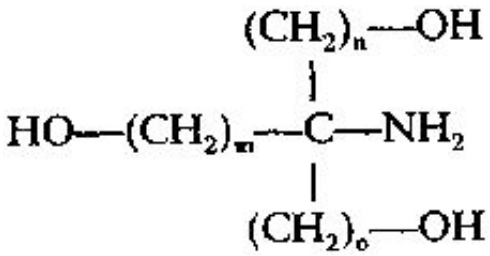
For these reasons, the court concludes that Alcon's solution does not infringe either of the patents in suit.FN23

FN23. Because CIBA fails to make a sufficient showing of equivalency, it is unnecessary for the court to address Alcon's arguments of waiver of infringement with respect to the Doulakas Patent based on CIBA's failure to file the patent in the FDA's "Orange Book" and prosecution history estoppel with respect to the Nagy and Doulakas Patents.

III. CONCLUSION

Alcon may prevail on this motion by pointing out the "absence of evidence to support the nonmoving party's [CIBA's] case" with respect to an issue-such as infringement-on which CIBA will bear the burden of proof at trial. Celotex, 477 U.S. at 325. Here, CIBA has conceded the absence of literal infringement, and it has failed to produce evidence on which a reasonable factfinder could base a finding that the stabilizer element of claim 1 of the patent in suit is met equivalently by Alcon's solution. Because CIBA has failed to demonstrate a triable issue on the stabilizer element of claim 1, Alcon is entitled to summary judgment. Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1389 (Fed.Cir.1992).

SO ORDERED.



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