NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CONNETICS CORPORATION and CONNETICS AUSTRALIA PTY. LTD., Plaintiffs, v. AGIS INDUSTRIES (1983) LTD., Defendant.	Civ. No. 05-5038 (GEB) **MEMORANDUM OPINION**

BROWN, Chief Judge

This matter comes before the Court upon the motion of defendant Agis Industries (1983) Ltd. ("Agis") for summary judgment of non-infringement in this patent infringement suit. In a hearing on March 19, 2008 ("March 19th Hearing"), the Court ruled on certain aspects of Agis' summary judgment motion and reserved judgment on other aspects. The Court will now address the issues on which it reserved judgment.

I. BACKGROUND

This patent infringement suit stems from an Abbreviated New Drug Application ("ANDA") filed by Agis in anticipation of marketing a generic version of Connetics' OLUX® brand drug product. (L.R. 56.1 Statement of Facts ("SOF") ¶ 5; Counter-Statement of Facts ("CSOF") ¶ 5.) On October 19, 2005, Connetics filed a Complaint against Agis asserting that Agis' use of the product disclosed in its ANDA will infringe claims 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, and 12 of Connetics' U.S. Patent No. 6,126,920 ("the '920 patent"). On September 21, 2007,

Agis filed its motion for summary judgment of non-infringement. On March 7, 2008, this case was transferred to the undersigned.

The '920 patent was issued on October 3, 2000. (SOF ¶ 6; CSOF ¶ 6.) The '920 patent is entitled "Method of Treating A Skin Disease With A Corticosteroid-Containing Pharmaceutical Composition" and discloses "[m]ethods of treating various skin diseases, and in particular, scalp psoriasis, utilizing a foamable pharmaceutical composition comprising a corticosteroid active substance, a quick break foaming agent, a propellant and a buffering agent." (SOF ¶¶ 6, 38; CSOF ¶¶ 6, 38). The '920 patent contains 15 claims. Claims 1 and 4 are independent claims and the remaining claims are dependent on claim 1. (SOF ¶ 39; CSOF ¶ 39.) Claim 1 and 4 of the '920 patent read as follows:

> 1. A method of treating a skin disease susceptible to treatment with corticosteroid active substances, said method comprising administering topically to a patient in need thereof, an effective amount of a foamable pharmaceutical composition comprising a corticosteroid active substance, a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent; a propellant; and a buffering agent present in an amount sufficient to provide a pH within the range of 3.0 to 6.0.
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> 4. A method of treating a skin disease susceptible to treatment with corticosteroid active substances, said method comprising administering topically to a patient in need thereof an effective amount of a foamable pharmaceutical composition comprised of a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent a propellant; an active isomer of an isomeric corticosteroid active substance; and an amount of a buffering agent effective to stabilize the active isomer against isomerization to a less active isomer.

(SOF ¶ 40; CSOF ¶ 40.)

Agis argues that it is entitled to summary judgment of non-infringement because its future use of its ANDA product would not literally infringe the '920 patent and would not infringe

under the doctrine of equivalents. At the March 19th Hearing, the Court found that there were genuine issues of fact regarding whether the ANDA compositions contains a "buffering agent" and a "propellant." (March 19th Hr'g Tr. at 71-72.) The Court reserved judgment on the issue of whether summary judgment of no literal infringement is appropriate due to a failure of a buffering agent "to provide a pH within the range of 3.0 and 6.0." (Id.) The Court also reserved judgment on whether summary judgment of non-infringement under the doctrine of equivalents is appropriate. (Id.)

B. Summary Judgment

1. Standard

In deciding a motion for summary judgment, a court should grant the motion if "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Schwarz Pharma, Inc. v. Paddock Laboratories, Inc., 504 F.3d 1371, 1375 (Fed. Cir. 2007). The threshold inquiry is whether "there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). In deciding whether triable issues of fact exist, the court must view the underlying facts in the light most favorable to the non-moving party and draw all reasonable inferences in favor of the non-moving party. Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1307 (Fed. Cir. 1998). In arguing against a motion for summary judgment, "an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response . . . must set forth specific facts showing that there is a genuine issue for trial." FED. R. CIV. P.

56(e).

2. Literal Infringement

A determination of patent infringement involves a two-part analysis. "First, the court determines the scope and meaning of the patent claims asserted.... [Second,] the properly construed claims are compared to the allegedly infringing device." Cybor Corp. v. FAS Techs. Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc) (citations omitted). Claim construction, the first part of the analysis, is an issue of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir.1995) (en banc), aff'd, 517 U.S. 370 (1996). The second part of the analysis requires a determination that every limitation or its equivalent be found in the accused product; this involves questions of fact. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998).

In order to succeed on a claim of literal infringement, the patentee must prove by a preponderance of evidence that an accused device contains "each and every limitation set forth in a claim." Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc., 389 F.3d 1370, 1378 (Fed. Cir. 2004). "Even if an accused product differs enough from an asserted claim to preclude literal infringement, that product may infringe under the doctrine of equivalents if there is equivalence between those elements of the accused product and the claimed limitations of the patented invention that are not literally infringed." Zelinski v. Brunswick Corp., 185 F.3d 1311, 1316 (Fed. Cir. 1999). The doctrine of equivalents "does not require complete identity for every purpose and in every respect, . . . but does require substantial identity of function, means, and result." Lear Siegler, Inc. v. Sealy Mattress Co. of Mich., Inc., 873 F.2d 1422, 1425 (Fed. Cir. 1989) (internal quotations omitted).

After the March 19th Hearing, the only remaining literal infringement issue for the Court to address is whether, as Agis argues, the ANDA composition does not literally infringe claim 1 because a buffering agent is not present in an amount sufficient "to provide a pH within the range of 3.0 to 6.0." At the March 19th Hearing, the parties agreed that the Court did not need to construe the term "to provide a pH within the range of 3.0 and 6.0." (March 19th Hr'g Tr. at 30-31.)

The Court concludes that summary judgment for Agis on this issue is not warranted because Connetics has set forth facts sufficient to show that there is a genuine issue of fact as to whether the ANDA composition would provide a pH within the range of 3.0 to 6.0. First, the parties agree that the pH of batches of the ANDA composition were measured with pH levels of 6.0, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8 and 7.0. (SOF ¶¶ 85, 87, 88; CSOF ¶¶ 84, 87, 88.) The parties apparently agree that these batches are the same as the product that would be produced pursuant to the ANDA. (SOF ¶ 84; CSOF ¶ 84.) In light of the 6.0 pH measurement, the Court concludes there is, at the least, an issue of fact as to whether a buffering agent in the ANDA composition will provide a pH within the 3.0 to 6.0 range. Bell Comm'n Res., Inc. v. Vitalink Comm. Corp., 55 F.3d 615, 622-23 (Fed. Cir. 1995) ("[a]n accused product [that] sometimes, but not always embodies a claimed method" still infringes). Second, Connetics tests taken of "development batches" of the ANDA composition measured pH values of 5.8, 5.9 and 6.0. (CSOF ¶ 87.) This evidence supports a finding that there is an issue of fact regarding literal infringement. Although Agis argues that the pH of the "development batches" should not be considered because it is irrelevant, (Reply Br. at 13), the cases cited by Agis do not support this. Indeed, development batches may be considered where the ANDA specification does not define

the compound in a manner that directly addresses the issue of infringement. See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1250 (Fed. Cir. 2000); Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569-70 (Fed. Cir. 1997).[1] The Glaxo court "properly considered" data from a "biobatch" where the ANDA allowed the product to contain "either Form 1 or Form 2 ranitidine hydrochloride ("RHCI"), and the asserted patent covered mixtures that contained Form 2 RHCI." Bayer AG, 212 F.3d at 1250. Similarly, here the ANDA does not directly address the issue because it provides that the pH may be within the range of 5.0 to 7.0. That is, the ANDA provides that the Agis' composition may or may not provide a pH within the range of 3.0 to 6.0 claimed in the '920 patent. Under the analysis in Bayer AG, Agis' ANDA does not address the question of infringement. See Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc., 482 F. Supp. 2d 478, 503 (D.N.J. 2007) (ruling that an ANDA that permits a product either within or without the claimed range does not directly resolve the precise infringement issue, and therefore the Court will examine more than just the ANDA text). Therefore, the Court will consider the data from the "development batches" as providing evidence in support of infringement.

Drawing all reasonable inferences in favor of Connetics as the nonmovant, the Court concludes that there is sufficient evidence to create a genuine issue of material fact regarding whether the ANDA composition meets the pH limitation. Therefore, the Court concludes that Agis' motion for summary judgment regarding literal infringement must be denied.

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[1]Agis also cites Merck KGAA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005). In Merck, the Supreme Court ruled that the statutory exemption from infringement under 35 U.S.C. § 271(e)(1) "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." The Merck case is not controlling in the present case. Here, the Court must determine whether the product likely to be marketed in the event that the ANDA is approved would infringe the '920 patent, not whether Agis' use of the "development batches" constitutes infringing use of the '920 patent.

3. The Doctrine of Equivalents

"[T]he determination of infringement under the doctrine of equivalents is limited by two primary legal doctrines: (1) prosecution history estoppel; and (2) the 'all elements' rule." Lockheed Martin Corp. v. Space Sys., 324 F.3d 1308, 1318 (Fed. Cir. 2003).

Agis argues that prosecution history estoppel prevents Connetics from asserting infringement under the doctrine of equivalents. Agis also argues that the doctrine of equivalents theory asserted by Connetics violates the "all limitations rule." At the March 19th Hearing, the Court reserved judgment on whether summary judgment of non-infringement under the doctrine of equivalents is appropriate. (March 19th Hr'g Tr. at 72.)

a. Prosecution History Estoppel

Prosecution history estoppel "limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution." Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1363 (Fed. Cir. 2006). The Federal Circuit has "recognized that prosecution history estoppel can occur during prosecution in one of two ways, either: (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')." Id.

Here, Agis claims that argument-based estoppel applies. (S.J. Br. at 31-33.) "To invoke argument-based estoppel, the prosecution history must evince a 'clear and unmistakable surrender of subject matter.'" Eagle Comtronics, Inc. v. Arrow Communication Laboratories, Inc., 305 F.3d 1303, 1316 (Fed. Cir. 2002) (citation omitted). Furthermore, if statements made during prosecution have "multiple reasonable interpretations," those statements cannot be

considered a "clear and unmistakable surrender of subject matter." Cordis Corp. v. Medtronic AVE, 339 F.3d 1352, 1359 (Fed. Cir. 2003).

Agis contends that the patentees argued to the patent examiner that the '920 patent does not encompass compositions that are devoid of a "buffering agent." (SJ Br. at 33.) Specifically, the patentees distinguished prior patents by arguing that the "present inventors have discovered that the stability of such preparations may be improved by controlling the acidity of the composition and the claims thus require the presence of a buffering agent to maintain the pH within the range of 3 to 6." (SOF ¶ 54; CSOF ¶ 54.) The patentees stated that "by contrast" the prior art "shows no recognition of the problems associated with stability . . . and as such, the reference can not be said to lead one of skill to a solution for the problem." (Id.) The patentees further argued that prior art did not "provide[] any disclosure with respect to controlling the pH of the composition between 3 and 6" and that the requirement of a "buffering agent to maintain the pH within the range of 3 to 6" was not "taught nor even recognized by" the prior patents. (SOF ¶55; CSOF ¶ 55.)

Connetics failed to address this issue in their opposition brief. However, at the March 19th Hearing, Connetics asserted that the inventors never argued that impurities were improper buffering agents, only that the prior art did not recognize the need for a buffering agent. (March 19th Hr'g Tr. at 62-63.)

The Court cannot conclude at this time that the prosecution history of the '920 patent estops Connetics' argument under doctrine of equivalents. The Court has not been presented with evidence of a "clear and unmistakable surrender" of equivalent formulations, much less a formulation wherein impurities perform the same function in the same way and achieve the same

result as the claimed buffering agent. The prosecution history cited by Agis merely indicates that Connetics argued that the prior art did not recognize the need to control the pH, which was accomplished in the '920 patent by the presence of a buffering agent. The Court concludes that in their argument before the patent examiner, the patentees "simply made explicit the meaning of the term "buffering agent" and did not clearly and unmistakably surrender equivalents of the "buffering agent." See Cordis Corp. v. Medtronic Ave, Inc., 511 F.3d 1157, 1178 (Fed. Cir. 2008) (finding no prosecution history estoppel where argument merely informed the meaning of claim term). Therefore, the Court concludes that summary judgment of non-infringement on these grounds would be improper.

a. The All-Elements Rule

"[T]he all limitations rule requires that equivalence be assessed on a limitation-by-limitation basis as opposed to from the perspective of the invention as a whole." Freedman Seating Co. v. Am. Seating Co., 420 F.3d 1350, 1358 (Fed. Cir. 2005). Moreover, "an element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation." Id. The Federal Circuit has recognized that "[t]here is no set formula for determining whether a finding of equivalence would vitiate a claim limitation, and thereby violate the all limitations rule. Rather, courts must consider the totality of the circumstances of each case and determine whether the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless." Freedman Seating, 420 F.3d at 1359. Of course, the doctrine of equivalents should not "be rendered superfluous" by a "reduc[tion] of the application of the doctrine to nothing more than a repeated analysis of literal infringement."

Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1317 (Fed. Cir. 1997). According to the Federal Circuit, a "good example of the multi-factored analysis required by the doctrine of equivalents" is found in the Ethicon case. Freedman Seating, 420 F.3d at 1358.

The Ethicon case concerned a patent for a surgical stapler. 149 F.3d at 1311. The court affirmed summary judgment of non-infringement as to one claim, but reversed as to a second claim. Id. at 1321. The first claim contained limitations requiring a particular part of the stapler referred to as the "lockout" to be "connected to said longitudinal slots" and to be "in a staple cartridge." The court found that these limitations tied the "lockout to a specific place." Id. at 1318-19. Because the allegedly infringing lockout was located "nowhere near" the specific place, the Federal circuit ruled that no reasonable jury could have found "that the difference between the location of the [allegedly infringing product's] lockout and the location of the lockout as claimed was insubstantial." Id. at 1319. The second claim in the Ethicon case required a "restraining structure" which contacted a barrier "during staple firing." In the allegedly infringing product, the "restraining structure" lost contact with the barrier for "a period that is perhaps as short as a few thousandths of a second." Id. at 1319-21. The Ethicon court ruled that it could not determine as a matter of law that this difference was substantial. In so ruling, the Federal Circuit distinguished "a clear, substantial difference or difference in kind," from "a subtle difference in degree." Id. at 1321. The former requires a ruling of non-infringement under the doctrine of equivalents, while the latter does not.

Similarly, in Freedman Seating, the Federal Circuit found that the difference between the allegedly infringing "rotably mounted" seat support member and the claimed "slidably mounted" seat support member constituted a "clear, substantial difference or difference in kind" as opposed

to a "subtle difference in degree." 420 F.3d at 1359-61. Therefore, the Freedman Seating court ruled that summary judgment of non-infringement was appropriate.

1. Buffering Agent - All Claims

The Court construed the term "buffering agent," which is present in all of the contested claims, to mean "a separate component in the pharmaceutical composition that serves to achieve and maintain the desired pH for that pharmaceutical composition." (March 19th Hr'g Tr. at 39.) The Court also ruled that there is a genuine issue of fact as to whether the ANDA composition contains a "buffering agent," such that the ANDA composition would literally infringe the '920 patent. (Id. at 71.)

Agis asserts that Connetics's doctrine of equivalents argument impermissibly read the term "buffering agent" out of the claims, because Connetics does not argue that it adds "some additional ingredient(s) in place of the required 'buffering agent.'" (S.J. Brief at 34-36.) Agis argues that "Connetics has no evidence that the inactive ingredients (or their impurities)" are functioning as a "buffering agent." (Reply Br. at 17.) Agis contends that Connetics has merely presented "[a]ttorney conjecture and speculative expert opinions about what *possibly* could happen." (Id. (emphasis in original).)

Connetics counters that "[t]he 'all elements' rule does not preclude one element of an accused product from satisfying more than one claim limitation." (Opp. Br. at 34.) Connetics argues that the impurities "perform the same function as the claimed buffering agent in the same way to achieve the same result." (Id. at 33-34.)

In the present case, the Court cannot conclude that, with respect to the "buffering agent" limitation, Connetics' theory of equivalence is legally insufficient. If there is no literal

infringement, the difference between the "buffering agent" disclosed by the '920 patent and the impurities present in the inactive ingredients in the ANDA composition may constitute a "subtle difference in degree," not a "clear, substantial difference or difference in kind." The Court concludes that whether this difference is substantial is a question of fact. See Depuy Spine, Inc. v. Medtronic Sofaor Danek, Inc., 469 F.3d 1005, 1020 (Fed. Cir. 2006) (holding that whether a substantial difference exists between the claim limitation and the alleged equivalent is a question of fact). Connetics has presented evidence supporting its argument that the acid and base impurities perform the same function, in the same way to achieve the same result as the claimed buffering agent. Specifically, Connetics relies upon the expert report of Dr. Steven Schwendeman, wherein Dr. Schwendeman concludes that the acids and bases in the ANDA composition perform the same function, in the same way, to achieve the same result as the buffering agent, because they stabilize the active ingredient by achieving and maintaining a desired pH. (Schwendeman Report ¶¶ 166-176.)

Agis criticizes Dr. Schwendeman's opinion as "speculative," and asserts that it only concerns "what possibly could happen" and therefore is an improper basis on which to deny summary judgment. (Reply Br. at 17.) The Court disagrees. First, the report of Dr. Schwendeman plainly states that "the acids and bases . . . in Agis' product stabilize the clobetasol proportionate . . . by achieving and maintaining the pH," not that it is a mere possibility. (Schwendeman Report ¶ 170.) Second, although Agis properly notes that speculative conclusions that are "'devoid of facts upon which the affiant[s'] conclusions, as experts, were reached'" are insufficient to overcome a motion for summary judgment, Phillips Petroleum Co. v. Huntsman Polymers Corp., 157 F.3d 866, 876 (Fed. Cir. 1998), here, Connetics has presented

facts that support Dr. Schwendeman's opinion. More specifically, Connetics refers the Court to portions of Agis' patent application, Agis' own testing and Dr. Schwendeman's calculations. Given that this evidence must be viewed in the light most favorable to Connetics and that all reasonable inferences be drawn in Connetics' favor, the Court concludes that a reasonable jury could find that the difference between the impurities in the ADNA composition and the claimed buffering agent is insubstantial. Therefore, the Court will not grant summary judgment of non-infringement on these grounds.

2. "Against Isomerization To A Less Active Isomer" - Claim 4

Agis argues that Connetics' theory also "completely reads out the claim limitation 'against isomerization to a less active isomer.'"[2] (S.J. Br. at 36.) Agis claims that Connetics has "no scientific support" for the proposition that "'isomerization' (a very specific kind of degradation) is the same as 'degradation' in general." (S.J. Br. at 36; Reply Br. at 17-18.) Therefore, Agis concludes that Connetics' argument "improperly vitiate[s]" this claim limitation. (S.J. Br. at 36.)

Connetics asserts that "'isomerization' is just a type of degradation." (Opp. Br. at 41.) According to Connetics, the limitation in claim four that the buffering agent inhibit isomerization is "insubstantially different from the buffering agent in Agis' formulation, which is used to inhibit degradation." (Opp. Br. at 41.) As support for this proposition Connetics again references the expert reports of Dr. Schwendeman, which in turn relies upon Agis' test results,

[2]Claim 4 of the '920 patent requires, in part: "an amount of a buffering agent effective to stabilize the active isomer against isomerization to a less active isomer." No other claim at issue contains this language.

the ANDA application and the OLUX® New Drug Application. (CSOF ¶ 92; Schwendeman Report ¶¶ 206 - 214.)

The Court will not grant summary judgment for Agis on this ground. The Court must view the facts in the light most favorable to Connetics and make all reasonable inferences in Connetics' favor. The Court concludes that the parties' experts simply disagree over whether, in the context of the ANDA composition, the difference between isomerization and degradation is "a clear, substantial difference or difference in kind," or "a subtle difference in degree." The Court concludes that this a fact issue properly resolved at trial.

III. CONCLUSION

For the foregoing reasons and for the reasons discussed at the March 19th Hearing, the Court denies Agis' summary judgment motion.

Dated: April 14, 2008

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.