United States District Court,
S.D. Florida.

MARION MERRELL DOW INC., and Merrell Dow Pharmaceuticals, Inc,
Plaintiffs.
v.
BAKER NORTON PHARMACEUTICALS, INC,
Defendant.

No. 94-1245-CIV-LENARD

Nov. 12, 1996.

Patentee brought action against generic drug manufacturer, alleging generic version of drug covered by expired patent infringed drug claim in unexpired patent. On motions for summary judgment, the District Court, Lenard, J., held that generic version of drug that was subject of expired patent did not literally infringe another, unexpired patent, which covered form of drug that would be metabolized in human liver after drug covered by expired patent was ingested.

Judgment accordingly.

4,254,129. Not infringed.

Gerald Sobel, Thomas L. Creel, and Joel Katcoff, Kaye, Scholer, Fierman, Hays & Handler, L.L.P., New York City, and John T. Kolinski, and Robert C. Fracasso, Shutts & Bowen, Miami, Florida, for Marion Merrell Dow, Inc. and Merrell Dow Pharmaceuticals, Inc.

William L. Mentlik, Roy H. Wepner, and Arnold H. Krumholz, Lerner David Littenberg Krumholz & Mentlik, Westfield, New Jersey, and Alan H. Fein, Stearns Weaver Miller Weissler Alhadeff & Sitterson, PA, Miami, Florida, for Baker Norton Pharmaceuticals, Inc.

ORDER ON MOTIONS FOR SUMMARY JUDGMENT

LENARD**, District Judge.**

Plaintiffs Marion Merrell Dow Inc. and Merrell Dow Pharmaceuticals, Inc. (collectively "MMD") filed this action for patent infringement against defendant Baker Norton Pharmaceuticals, Inc. ("Baker Norton"). Baker Norton counterclaimed for patent invalidity. Presently before the Court are (1) Baker Norton's Motion for Summary Judgment Based on Noninfringement of Patent (DE56), (2) MMD's Motion for Partial Summary Judgment on Noninfringement and for Dismissal of Baker Norton's Anticipation and Best Mode Defenses (DE183), (3) Baker Norton's Motion for Summary Judgment Based on Patent Invalidity (DE287), and (4) MMD's Motion for Preliminary Injunction (DE326). Although not filed as such, the Court will

consider the motions filed on the issue of infringement as cross-motions, FN1 with the result to render consideration of the invalidity defense and MMD's request for injunctive relief unnecessary. FN2

FN1. The Court heard oral argument on the parties' cross motions for summary judgment on the issue of patent invalidity on September 19, 1996.

FN2. This case was referred to the Magistrate Judge for disposition of all substantive and non-substantive matters by United States District Judge Federico Moreno, the judge to whom this case was originally assigned. Under the order of referral, the Magistrate Judge issued several reports and recommendations, the most recent of which he issued after the case was reassigned to this Court on February 23, 1996. After thorough consideration of the history of the case and because objections to all of the Magistrate Judge's reports were outstanding at the time the case was transferred to this Court, the Court elects to consider the matters expressed in the above-listed motions *de novo* and without regard to the Magistrate Judge's recommendations as is consistent with 28 U.S.C. s. 636(b)(1) and S.D.Fla.Mag.J.L.R. 4(b).

Background

This litigation concerns the effort of Baker Norton, a manufacturer of generic pharmaceuticals, to manufacture and sell the generic form of the drug commonly known as Seldane (R), via practice of now-expired United States Patent No. 3,878,217. MMD owned and had the exclusive right to practice the '217 Patent until its expiration in 1994. The '217 Patent covered the chemical compound terfenadine and its administration to treat allergic reactions. Baker Norton filed its Abbreviated New Drug Application (ANDA) with the Food and Drug Administration in 1994, seeking to practice the '217 Patent subsequent to its expiration. In response, MMD filed the instant lawsuit, alleging that Baker Norton's proposed manufacture and sale of terfenadine infringes a non-expired patent held by MMD, United States Patent No. 4,254,129. FN3 While proper construction of the claims set forth in the '129 Patent is contested by the parties and addressed herein, the Court notes for the convenience of the reader that the '129 Patent covers the chemical compound known as TAM, or terfenadine acid metabolite, and its administration to treat allergic reactions. Generally speaking, TAM is created as a result of the metabolism of terfenadine in the liver. The '129 Patent expires in 1998.

FN3. By statute, a thirty (30) month stay of Baker Norton's proposed conduct went into effect upon the filing of MMD's complaint. 21 U.S.C. s. 355(j)(4)(B)(iii). The stay is scheduled to expire on November 12, 1996.

Legal Standard

On a motion for summary judgment, the court is to construe the evidence and factual inferences arising therefrom in the light most favorable to the nonmoving party. Adickes v. S.H. Kress & Co., 398 U.S. 144, 157, 90 S.Ct. 1598, 1608, 26 L.Ed.2d 142 (1970). Summary judgment can be entered on a claim only if it is shown "that there is no genuine issue 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). The Supreme Court explained the summary judgment standard as follows:

[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for

discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be no genuine issue as to any material fact, since a complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial.

Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 2552, 91 L.Ed.2d 265 (1986). The trial court's function at this juncture is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249-50, 106 S.Ct. 2505, 2511, 91 L.Ed.2d 202 (1986). A dispute about a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Anderson, 477 U.S. at 248, 106 S.Ct. at 2510; *see also* Barfield v. Brierton, 883 F.2d 923, 933 (11th Cir.1989). The party asking for summary judgment "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the 'pleadings, depositions, answers to interrogatories, and admissions of file, together with affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." Celotex, 477 U.S. at 323, 106 S.Ct. at 2553. Once this initial demonstration under Rule 56(c) is made, the burden of production, not persuasion, shifts to the non-moving party. The nonmoving party must "go beyond the pleadings and by [his] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.' " Celotex, 477 U.S. at 324, 106 S.Ct. at 2553. *See also* Fed.R.Civ.P. 56(e). In meeting this burden the nonmoving party "must do more than simply show that there is a metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S.Ct. 1348, 1355, 89 L.Ed.2d 538 (1986). That party must demonstrate that there is a "genuine issue for trial." Matsushita, 475 U.S. at 587, 106 S.Ct. at 1356. An action is void of a material issue for trial "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party." Matsushita, 475 U.S. at 587, 106 S.Ct. at 1356; *see also* Anderson, 477 U.S. at 249, 106 S.Ct. at 2510.

Discussion

MMD asks the Court to find that Baker Norton will infringe the '129 Patent as a matter of law by its planned manufacture and sale of terfenadine to treat allergic reactions. In response, Baker Norton asks the Court to find that it will not infringe the '129 Patent as a matter of law by its planned practice of the expired '217 Patent. Article I, Section 8, Clause 8 of the United States Constitution provides that "[the Congress shall have Power to] promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." In Graham v. John Deere Co., 383 U.S. 1, 6, 86 S.Ct. 684, 688, 15 L.Ed.2d 545 (1966), the U.S. Supreme Court noted that "Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict access to materials already available." Similarly, in Scott Paper Co. v. Marcalus Mfg. Co., 326 U.S. 249, 255, 66 S.Ct. 101, 104, 90 L.Ed. 47 (1945), the Court stated that the "aim of the patent laws is not only that members of the public shall be free to manufacture the product or employ the process disclosed by the expired patent, but also that the consuming public at large shall receive the benefits of the unrestricted exploitation, by others, of its disclosures."

A. Literal Infringement

[1] MMD argues that Baker Norton's proposed practice of the expired '217 Patent covering terfenadine and its administration will literally infringe the '129 Patent because when a patient takes the Baker Norton product, his or her liver will necessarily produce TAM. Therefore, Baker Norton will induce infringement in

patients taking its product in violation of 35 U.S.C. s. 271(b). The first of the two steps necessary to the literal infringement analysis is construction of the alleged infringed claims to establish their meaning and scope. *See Markman v. Westview Instruments, Inc.,* 517U.S. 370, ----, 116 S.Ct. 1384, 1393, 134 L.Ed.2d 577 (1996). *See also* Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1563 (Fed.Cir.1996); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-82 (Fed.Cir.1996). Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), contains a recent discussion by the Federal Circuit of the procedures which courts must employ to determine the scope of the claims of the alleged infringed patent. The *Markman* court stated:

[T]he court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim. As such, "[a] patent covers the invention or inventions which the court, in construing its provisions, decides that it describes and claims." ... "To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history." ... "Expert testimony, including evidence of how those skilled in the art would interpret the claims, may also be used."

52 F.3d at 979 (citations omitted). *See also* Vitronics, 90 F.3d at 1582 (claims, specification and prosecution history constitute intrinsic evidence, the "most significant source of the legally operative meaning of disputed claim language").

1. The Claims

"The claims of the patent provide the concise formal definition of the invention.... Although courts are confined by the language of the claims, they are not, however, confined to the language of the claims in interpreting their meaning." Autogiro Co. v. United States, 181 Ct.Cl. 55, 384 F.2d 391, 395-96 (C.C.P.A.1967). MMD alleges in its complaint that claims 1, 6, 8 and 11 of the '129 Patent will be infringed by Baker Norton's proposed course of conduct. The asserted claims are as follows:

We claim:

1. A compound of the formula wherein R_1 represents hydrogen or hydroxy; R_{2+} represents hydrogen; or R_1 and R_2 taken together form a second bond between the carbon atoms bearing R_1 and R_2; n is an integer of from 1 to 5; R_3 is-COOH or-COOalkyl wherein the alkyl moiety has from 1 to 6 carbon atoms and is straight or branched; each of A and B is hydrogen or hydroxy; with the proviso that at least one of A or B is hydrogen; and pharmaceutically acceptable salts and individual optical isomers thereof.

6. A compound of claim 1 of the formula wherein R_4 is hydroxy and R_5 is hydrogen, or R_4 and R_5 taken together form a second bond between the carbon atoms bearing R_4 and R_5; n is the integer 3; and R_3 is-COOH or a pharmaceutically acceptable salt thereof.

8. A compound of claim 1 which is 4-[4-[-4-(hydroxydiphenylmethyl)-1-piperidinyl]-1-hydroxybutyl]-(alpha),(alpha)-dimethylbenzeneacetic acid or a pharmaceutically acceptable salt thereof.

11. A method of treating allergic reactions in a patient in need thereof which comprises administering to said patient an effective amount of a compound of claim 1.

U.S. Patent No. 4,254,129, issued Mar. 3, 1981.

First, the Court need only focus on claim 1, because if it is infringed, all of the others are infringed as well. Claim 1 appears to claim the novel chemical compound commonly known as "terfenadine acid metabolite" or TAM. The crux of the dispute between the parties is focussed upon the meaning of the word "compound" as used in claim 1. MMD insists that the term refers to the compound TAM regardless of whether it is created by the liver's metabolism of terfenadine (inter vivo conversion) or by synthetic means. FN4 Baker Norton argues that the inventors of the '129 Patent meant only synthetically produced TAM when they used the term "compound." Although there is no language within the claim which would explicitly limit the meaning of the term "compound" to exclusively TAM synthetically produced, there is no language within the claim which refers in any way to the inter vivo manufacture of TAM either. The process of construing the claim does not end with consideration of the explicit language of the claims, however. As the *Autogiro* court noted,

FN4. In its briefs, MMD relies heavily on the Federal Circuit's opinion in Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed.Cir.), *cert. denied,* 513 U.S. 995, 115 S.Ct. 500, 130 L.Ed.2d 409 (1994), for the proposition that "when a patent claims a compound by its chemical formula (as the '129 Patent does), the patent covers that compound regardless of whether it is made synthetically or is produced in the body after ingestion of a different compound." Plaintiff's Supplemental Brief, Sept. 13, 1996, at 4. In *Zenith,* the alleged infringer argued that a patent containing only one claim should be construed as limited to chemical compound it described in its pre-ingested form. The court construed the claim and determined based upon its language and prosecution history that it should not be so limited. The Court declines to find a per se rule in *Zenith* which requires that all claims which describe a compound be construed as covering both the metabolically produced and synthetic produced forms of the compound, without regard to the language of the claims, the specification of the patent or the prosecution history. Instead, the Court will conduct the construction pursuant to *Markman,* and as will be demonstrated *infra,* the reference points for construction in this case are much more replete with evidence that a different interpretation of the term "compound" is appropriate here than was the case in *Zenith*.

the fact that claims are free from ambiguity is no reason for limiting the material which may be inspected for the purpose of better understanding the meaning of claims.... Claims cannot be clear and unambiguous on their face.

384 F.2d at 396 (citations omitted).

Next, the Court notes that claim 10, though not asserted in this action, claims the pharmaceutical composition of TAM in unit dosage form. As a result, clearly claim 10 can be limited to synthetically produced TAM reduced to tablet form. In addition, claim 10 claims the combination of an effective amount of TAM with a "significant amount of a pharmaceutically acceptable carrier" in order to produce the "unit dosage form" to be administered. Baker Norton persuasively points out that if as MMD suggests the term "compound" refers to impure TAM created in the body by metabolism, claim 10 could be construed as the removal of impure TAM from human bodies to then be combined pharmaceutically with a synthetic, or pure, carrier, which as a practical matter the Court finds to be a tenuous assertion leading to an absurd result. FN5 Further, each of the unasserted claims 6 through 9 specify the inclusion of "pharmaceutically acceptable salts" in the variations of the TAM compound described in those claims. The Court finds this inclusion further evidence that the inventors' sought a patent on chemical formulations of TAM only.

FN5. Indeed, at oral argument counsel for MMD suggested somewhat disingenuously that "if it was

economic you could extract [TAM] from people who had metabolized terfenadine." Transcript, at 67. Counsel further stated that "[t]here was a comment about oh, I don't know how I'd get it out of the liver. I guess there isn't a practical way. Patents don't have to be practical." Transcript, at 67.

Finally, the claims are organized such that claims 1 through 9 claim the compound TAM and various chemical variations thereof, with claim 10 claiming TAM in "unit dosage form" and Claim 11 claiming administration of TAM in effective amounts. The Court finds that the structure of the claims provides some evidence in favor of a construction of the term "compound" as used in claim 1 as covering only TAM which is synthetically produced.

2. The Specification

"Claims must be read in view of the specification of which they are a part." Markman, 52 F.3d at 979 (citing Autogiro, 384 F.2d at 397). *See also* Vitronics, 90 F.3d at 1582 ("specification acts as a dictionary ... when it defines terms by implication.... [I]t is the single best guide to the meaning of a disputed term" (citations omitted)). "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it." Vitronics, 90 F.3d at 1582.

The specification accompanying the claims of the '129 Patent exhaustively discusses and gives examples of the chemical formulations of TAM, the usefulness of TAM as an antihistamine, and the modes for administering TAM in effective amounts. *See generally* U.S. Patent No. 4,254,129. By contrast, the specification contains no reference whatsoever to TAM created inter vivo by metabolism. The Court finds that the lack of such a reference in what is otherwise a comprehensive description of TAM and its administration gives further support for Baker Norton's position that the term "compound" as used in claim 1 refers only to synthetically produced TAM.

3. The Prosecution History

Far more compelling than the language of the claims themselves and of the specification, however, is the history of the prosecution of the '129 Patent before the U.S. Patent Office. *Markman* teaches that the prosecution history of the alleged infringed patent is of "primary significance" in the Court's infringement inquiry. 52 F.3d at 980 (citing Autogiro, 384 F.2d at 397).

The Court has broad power to look as a matter of law to the prosecution history of the patent in order to ascertain the true meaning of language used in the patent claims: "Th[e] construction of the patent is confirmed by the avowed understanding of the patentee, expressed by him, or on his half [sic], when his application for the original patent was pending."

Markman, 52 F.3d at 980 (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L.Ed. 149 (1880)) (alterations in the original). *See also* Vitronics, 90 F.3d at 1582 ("[The prosecution] history contains the complete record of all the proceedings before the [Patent Office], including any express representations made by the applicant regarding the scope of his claims"); Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution"), *cert. denied,* 516 U.S. 987, 116 S.Ct. 515, 133 L.Ed.2d 424 (1995); Senmed, Inc. v. Richard-Allan Medical Indus., Inc., 888 F.2d 815, 818-20 (Fed.Cir.1989) (same); ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1580 (same).

Further, "[c]laims may not be construed one way in order to obtain allowance and in a different way against accused infringers." Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed.Cir.1991).

At the time that MMD prosecuted the '129 Patent before the Patent Office, it submitted claim 1 as it appears in the '129 Patent and a "claim 2," which was identical to claim 1 except in that it specified the compound as "an essentially pure compound of the formula [that is TAM]." By notice of January 14, 1980, the examiner rejected both claims 1 and 2, stating that "[i]n view of the nature of the instant disclosure,FN6 no proper distinction is seen in scope between claims 1 and 2 ... based upon the additional recitation in claim [ ] 2 of "essentially pure." By submission dated May 1, 1980, MMD canceled claim 2 stating, "with the cancellation of claim[ ] 2 ..., the rejection of claim[ ] 1 ... on the basis that there is no proper distinction from claim [ ] 2 ..., is no longer applicable." By letter of July 9, 1980, claim 1 was allowed absent the "essentially pure" language and prosecution of the patent closed, the '129 Patent being formally issued on March 3, 1981.

FN6. The disclosure of which the patent examiner spoke was the patent specification, which as the Court noted above, contains no reference to TAM produced by metabolism.

When it canceled claim 2 in response to the examiner's rejection of it as identical to claim 1, MMD necessarily adopted the examiner's interpretation of "compound" as limited to that formed by synthetic means. In Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1564 (Fed.Cir.1994), the Federal Circuit approved such a result when it stated that "[a]n appropriate method for resolving the [problem of diverse definitions of a claim term] is to avoid those definitions upon which the PTO could not reasonably have relied when it issued the patent." Therefore, the Court finds that the prosecution history provides further support for limitation of the meaning of the language of claim 1 to synthetically produced TAM.

That metabolically produced TAM is excluded under the "essentially pure" construction is confirmed by the ordinary meaning of those words to one skilled in the art. The former head of clinical pharmacology at MMD testified at deposition to this effect, stating that

[i]n my wildest dreams I wouldn't think of [contemplating that the claims of the '129 Patent application could cover the swallowing of terfenadine and the subsequent conversion to TAM] because I was aware that terfenadine has been swallowed for many, many years and that its action was known ... There was nothing I could see invented of utility.... And for that reason *I didn't conceive that the well-known product* terfenadine *could come under a patent for something into which it is converted in the body*.

Deposition of Murray Weiner, M.D., July 7, 1995, at 317-18. The after the fact assertions to the contrary by the inventors of the '129 Patent FN7 submitted by MMD, are "of little weight compared to the clear import of the patent disclosure itself." North Am. Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571 (Fed.Cir.1993) (citing Senmed, 888 F.2d at 819 n. 8), *cert. denied,* 511 U.S. 1069, 114 S.Ct. 1645, 128 L.Ed.2d 365 (1994). Further, by repeatedly asserting that MMD's patent attorney did not agree with the examiner's finding that claim 1 and claim 2 were equivalent in scope and so instead canceled claim 2 in favor of the "broader claim," MMD itself argues by implication that the claim as finally allowed is limited to synthetically produced TAM.FN8 To construct a claim as encompassing a different scope than that contemplated by the examiner when she allowed the claim effectively allows an end run by MMD around the authority of the Patent Office in its role as executor of Congress' mandate as expressed in the laws governing the issuance of patents. The Court cannot sanction such activity by construing claim 1 in any other fashion. As stated by the *Genentech* court, such a result is appropriate,

FN7. *See, e.g.,* Deposition of Albert A. Carr, Feb. 8, 1995, at 142-47; Deposition of Joseph Dolfini, January 25, 1995, at 87; Deposition of George J. Wright, Ph.D., May 18, 1995, at 50-52.

FN8. The MMD attorney who prosecuted the '129 Patent before the patent examiner stated at deposition that he disagreed with the examiner's statement because he felt that there was a difference between the claim including the "essentially pure" language and the claim without such language. Deposition of John Kolano, Feb. 23, 1995, at 55. When asked "why did you cancel claim 2 if you disagreed with what the examiner stated in her office action," Kolano stated: "Because I was satisfied that we would be obtaining protection on claim 1 and the question of how readily it would have been possible to overcome the examiner's rejection." Kolano Deposition, at 56.

because it avoids the possibility of an applicant *obtaining in court a scope of protection which encompasses subject matter that, through the conscious efforts of the applicant, the PTO did not examine*. An applicant should not be able to deliberately narrow the scope of examination to avoid during prosecution scrutiny by the PTO of subject matter with the objective of more quickly obtaining a patent (or avoiding the risk of an estoppel), and then obtaining in court, either literally or under the doctrine of equivalents, a scope of protection which encompasses the subject matter.

Genentech, 29 F.3d at 1564 (omitting footnote) (emphasis added). *See also* North Am. Vaccine, Inc., 7 F.3d at 1577 (stating that "[a] patent applicant cannot disclose and claim an invention narrowly and then, in the course of an infringement suit, argue effectively that the claims should be construed to cover that which is neither described nor enabled in the patent").

4. Comparison

The second step in the literal infringement analysis requires comparison of the claims properly construed with the alleged infringing activity. *See* Vitronics, 90 F.3d at 1582; Markman, 52 F.3d at 976. "To literally infringe,the accused device or process must contain every limitation of the asserted claim." Texas Instruments, 90 F.3d at 1558. Baker Norton plans to practice the expired '217 Patent, which teaches the composition and administration of terfenadine to treat allergic reactions. The administration of Baker Norton's terfenadine product will cause the formation of TAM by metabolism in the ingesting patient's liver. Given the Court's construction of claim 1 as covering only synthetically produced TAM, the production of TAM induced by the administration of the Baker Norton product will not infringe the '129 Patent.FN9 Simply stated, Baker Norton's proposed activity is outside the scope of the '129 Patent.

FN9. Because the other alleged infringed claims, 6, 8 and 11, are dependent on claim 1, non-infringement is established as to all of the claims asserted in this case.

B. Infringement by the Doctrine of Equivalents

[2] MMD asserts that even if the proposed Baker Norton product does not literally infringe the '129 Patent, the Court may find that the Baker Norton product infringes the asserted claims by the doctrine of equivalents. A product may infringe under the doctrine of equivalents if "it performs substantially the same function in substantially the same way to obtain the same result." Southwall Technologies, 54 F.3d at 1579

(quoting Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, 70 S.Ct. 854, 856, 94 L.Ed. 1097 (1950)). The *Southwall Technologies* court further instructed that

[O]nly if an accused product contains specific structure which meets all limitations of an asserted claim directed to structure, at least equivalently, can that product infringe under the doctrine of equivalents.... The doctrine of equivalents, however, is not a tool for expanding the protection of a patent after examination has been completed.

54 F.3d at 1579 (citations omitted). The Court declines to accept MMD's invitation to expand the scope of the asserted claims in order to find that Baker Norton's proposed practice of the expired '217 Patent, the manufacture and sale of terfenadine, infringes the '129 Patent, which the Court found above covers only synthetically produced TAM. In so doing, the Court heeds the language of Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558 (Fed.Cir.1990), which states that

[i]nfringement under the doctrine of equivalents *is an equitable doctrine intended,* "*in situations where there is no literal infringement but liability is nevertheless appropriate,* to prevent what is in essence a pirating of the patentee's invention."

904 F.2d at 1564 (quoting Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 870 (Fed.Cir.1985)) (emphasis added). The Court determines that this is neither a situation in which equitable remedies are called for nor where liability is appropriate, and therefore declines to apply the doctrine of equivalents to this case.

Conclusion

Based upon the foregoing,

1. Baker Norton's Motion for Summary Judgment Based on Noninfringement of Patent (DE56) is **GRANTED;**

2. Marion Merrell Dow's Motion for Partial Summary Judgment on Noninfringement (DE183) is **DENIED;**

3. The Clerk shall close this case, with all other pending motions to be **DENIED** as moot.

IT IS SO ORDERED.

S.D.Fla.,1996.
Marion Merrell Dow Inc. v. Baker Norton Pharmaceuticals, Inc.