United States District Court,
D. New Jersey.

BIO-TECHNOLOGY GENERAL CORP,
v.
DURAMED PHARMACEUTICALS, INC.

No. CIV.A. 00-4509(NHP)

Dec. 6, 2001.

Assignee is a patent for an oral contraceptive brought a patent infringement suit against the filer of an Abbreviated New Drug Application (ANDA), who was seeking to market a generic version of the contraceptive. On a defense motion for summary judgment, the District Court, Politan, J., held that: (1) expert testimony was not required to interpret terms of patent specification, and (2) patent was not infringed, literally or by the doctrine of equivalents.

Motion granted.

35,724. Not Infringed.

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OPINION AND ORDER

POLITAN**, District Judge.**

This matter comes before the Court on a motion for summary judgment by Defendant, Duramed Pharmaceuticals, Inc. ("Defendant" or "Duramed"). Oral argument was heard on October 30, 2001. For the reasons expressed below, Defendant's motion for summary judgment will be granted.

STATEMENT OF FACTS

This is a patent infringement case involving oral contraceptives, otherwise known as birth control pills. Defendant filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of an oral contraceptive called Mircette. FN1 Mircette is produced by Organon, a division of the large pharmaceutical company Azko

Nobel. Plaintiff, Bio-Technology General Corp. ("Plaintiff" or "BTG") issued Organon a license to produce and market Mircette under the assumption that Mircette would otherwise infringe U.S. Patent No. 35,724 ("the '724 patent"). Plaintiff in the case at bar is the assignee of the ' 724 patent. Organon pays royalties to Plaintiff based on its sales of Mircette.

FN1. Mircette is a registered trademark of Organon.

[1] On September 14, 2000, after Defendant filed its ANDA, Plaintiff instituted this patent infringement action against Defendant pursuant to 35 U.S.C. s. 271(e)(2)(A). FN2 Plaintiff alleges that Defendant's proposed generic product infringes its ' 724 patent. FN3

FN2. When a patent infringement action is brought against a party who filed an ANDA, the ANDA will not be approved until resolution of the lawsuit or thirty months from commencement of the lawsuit, whichever is shorter. *See* 21 U.S.C. s. 355(j)(5)(B)(iii). Thus, Defendant's ANDA is currently on hold.

FN3. Defendant filed a Patent Certification along with the ANDA asserting non-infringement of U.S. Patent No. 4,921,843. The '843 patent was surrendered to the Patent and Trademark Office ("PTO") during Plaintiff's prosecution of Patent No. 35,724. The '724 patent is a reissue of the '843 patent, and therefore is the patent in suit.

The '724 patent was reissued to Plaintiff on February 3, 1998 and protects a particular contraceptive system invented by Dr. Samuel Pasquale, a well-known inventor in the oral contraceptive field. The '724 patent consists of twenty-eight claims. Plaintiff alleges infringement of claims 1, 3, 4, 18-20, and 24. The claims will be discussed more fully herein. Plaintiff contends that Mircette is covered by the patent, and Defendant's generic version of Mircette is also covered by the patent and thus infringes it. Plaintiff therefore seeks to enjoin Defendant from commercially making, using, selling, or offering its proposed generic version of Mircette for sale to the public.

It is undisputed that Defendant's proposed generic version of Mircette "is virtually identical to Mircette in terms of conditions of use, dosage form, dosage strength, active ingredients and the route of administration." Def. Br. at 5. The only discernable difference between Mircette and Defendant's proposed generic version is that the various pills in the package have different colors.

The crux of the matter here relates to the order in which the particular pills of the respective contraceptive systems are ingested-more precisely, the focus is on whether the order within one package of pills is an element or limitation of the '724 patent. Defendant contends that the '724 patent protects a contraceptive system that requires a particular ordering of the drugs. Defendant further argues that Mircette and the generic version of it are not covered by the '724 patent because the "drug delivery system" of each is not arranged in the particular order identified in the language of the patent. Instead, Mircette is administered in the reverse order of that articulated in the patent.

Plaintiff urges that although the '724 patent sets forth a particular ordering of drugs and lists "preferred embodiments," all of which contain the same ordering of drugs, it does not require that the pills be administered in that particular order in any one package of pills. Plaintiff claims that because oral

contraceptives are generally taken by women for more than one cycle, the patent contemplates repetition. Therefore, Plaintiff insists that the order of pills within one package is not a claim limitation. In other words, Plaintiff claims that although one package of the accused product would not infringe the patented system, ingestion of more than one package does infringe because the cycle *becomes* the same as the cycle covered by the '724 patent.

Whether the '724 patent is infringed or will be infringed by Defendant's generic version of Mircette is the question before the Court. Defendant moves for summary judgment of noninfringement on the basis that its proposed new oral contraceptive does not infringe Plaintiff's patent, either literally or under the doctrine of equivalents. Defendant contends that this question may be answered as a matter of law. Plaintiff maintains that there are disputed issues of material fact for which expert testimony is needed, rendering summary judgment at this juncture improper.

DISCUSSION

A. Summary Judgment Standard

The standard governing a summary judgment motion is set forth in Federal Rule of Civil Procedure 56(c), which provides, in pertinent part, that:

[t]he judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.

Fed.R.Civ.P. 56(c). A fact is material if it might affect the outcome of the suit under the governing substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). To defeat "a properly supported summary judgment motion, the party opposing it must present sufficient evidence for a reasonable jury to find in its favor." Groman v. Township of Manalapan, 47 F.3d 628, 633 (3d Cir.1995). On a motion for summary judgment, the Court must view the evidence in a light most favorable to the party against whom the motion is directed, resolving "all inferences, doubts and issues of credibility against the moving party." Smith v. Pittsburgh Gage & Supply Co., 464 F.2d 870, 874 (3d Cir.1972).

B. Patent Infringement

As indicated previously, Plaintiff brings this action against Defendant under 35 U.S.C. s. 271(e)(2)(A). It states, in relevant part, that: "[i]t shall be an act of infringement to submit-(A) an application under 505(j) of the Federal Food, Drug Cosmetic Act ... for a drug claimed in a patent or the use of which is claimed in a patent ..." 35 U.S.C. s. 271(e)(2)(A). It is undisputed that Defendant's ANDA for the generic version of Mircette was submitted to the FDA under s. 505(j) of the Federal Food, Drug, and Cosmetic Act.

[2] Courts employ a two-step analysis in making a determination of patent infringement.First, the Court must construe the scope and meaning of the claims contained in the patent. *See* Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1576 (Fed.Cir.1993). It is well-settled that claim construction is a question of law for the Court to decide. Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Next, the construed claims must be compared to the accused product to determine if it literally infringes the patent or if it infringes under the doctrine of equivalents. *Id*. at 976; Carroll Touch, Inc., 15 F.3d at 1576.

[3] [4] [5] A claim in a patent "covers an accused device if the device embodies every limitation of the claim, either literally or by an equivalent." *Id*. Typically, literal infringement or infringement under the doctrine of equivalents is a question of fact. *See* Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed.Cir.1998). But "where the parties do not dispute any relevant facts regarding the accused product ... the question of literal infringement collapses into claim construction and is amenable to summary judgment." General Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 983 (Fed.Cir.1997). Put differently, "a literal infringement issue is properly decided upon summary judgment when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." Bai, 160 F.3d at 1353. The parties do not dispute the relevant facts regarding the accused product, but do dispute the meaning of certain terms within the claims.

C. Literal Infringement

[6] To prove literal infringement of a patent, a plaintiff must demonstrate that the accused product contains every element and limitation of the patent. *See* General Mills, Inc., 103 F.3d at 981; Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed.Cir.1995). Where the accused product lacks any feature of the patent, it does not literally infringe. *See* Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1579 (Fed.Cir.1993).

The '724 patent describes the patented process, in the "summary of the invention" section, as follows:

The present invention relates to a **two-stage** oral contraceptive system in which an unopposed estrogenic compound is administered during a terminal portion of the **first** 7-day segment of the menstrual cycle, counting as Day 1 the onset of menses. In the contemplated method aspect, an **initial** composition containing an estrogenic compound as the sole contraceptive active ingredient is administered during the terminal portion of the first 7-day segment of the menstrual cycle, preferably from about Day 2 to about Day 7, inclusive, of the menstrual cycle, at a daily dosage equivalent in estrogenic activity to about 0.01 to about 0.04 mg of 17-alpha-ethinyl estradiol, to a human female of child bearing age for contraception purposes. **Following** this **initial** administration of a relatively small dosage of an unopposed estrogenic compound, the **second stage** of the contemplated contraceptive system is commenced. In the **second stage,** a daily administration of a **follow-up** composition containing a progestin, alone or in combination with an estrogenic compound, is continued to about Day 28 of the menstrual cycle.

The method of contraception of the present invention contemplates that the **follow-up** composition, administered during Days 7 to 28 of the menstrual cycle preferably contains a combination of an estrogenic compound and a progestin. The composition administered during the second stage can be a uniphasic, biphasic or triphasic combination oral contraceptive system.

Sipio Decl., Ex. A at col. 2, lines 26-59. (emphasis added).

[7] Plaintiff specifically alleges that Defendant infringes claims 1,3,4, 18-20, and 24 of the '724 patent. "A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." Corning Glass Works v. Sumitomo Electric U .S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989). In other words, the claims point out limitations which must be interpreted by the Court. *See id*. at 1258. Claim 1 reads as follows:

1. A method of contraception *by suppressing recruitment of the dominant follicle* comprising:

(a) administering *orally* to a human female of childbearing age, daily **from [about Day 2 to about]** ***Day 3 or Day 4 through*** **Day 7** of her menstrual cycle, wherein Day 1 is the first day of menses, a **first** composition containing as sole contraceptively active ingredient an estrogenic compound at a daily dosage equivalent in estrogenic activity in the range of about 0.01 to about 0.04 milligrams of 17-alpha-ethinyl estradiol: and **thereafter**

(b) administering *orally* to said female, daily through Day 28 of her menstrual cycle, at least one **follow-up** composition containing a contraceptively effective daily dosage of progestin.

Sipio Decl., Ex. A, at col. 7, lines 37-50 (emphasis in bold added). FN4 As in the specification, claim 1 of the ' 724 patent uses sequential words.

FN4. The text in brackets appears in the original '843 patent but forms no part of the reissued patent, whereas the text in italics indicate additions made to the '724 patent.

The language used in the patent specification and in claim 1 suggest, at least at first glance, that the patented invention involves particular dosages being delivered to a female user in a particular order. Defendant argues that the bolded words such as "initial," "first," "follow-up," and "thereafter" indicate that a certain order of pill ingestion was contemplated by the inventor of the patented system.

[8] Plaintiff, however, maintains that these terms should be read as meaning two different groups of pills, a first group and a second group, and that these words "do not connote a particular sequential order in a pack, but instead simply provide a way of distinguishing two pill types." Pl. Reply Br. at 13. Moreover, Plaintiff asserts that because there is a dispute as to these terms, expert testimony is needed to determine how the claims would be read through the eyes of a person of ordinary skill in the art.

[9] [10] The Court need not entertain expert testimony for an analysis of what these words mean if the patent history contains no indication that they mean something other than their ordinary meaning. *See* Key Pharm. v. Hercon Labs. Corp., 161 F.3d 709, 718 (Fed.Cir.1998). It is, in fact, improper for a district court to rely on expert testimony if that testimony contradicts the file history of the patent. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed.Cir.1996).

[11] It is well-settled that the language in a patent is afforded ordinary meaning unless the patent or its history makes clear that a different meaning was intended. *See* Vitronics Corp., 90 F.3d at 1582; Carroll Touch, Inc., 15 F.3d at 1577 (*citing* Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387 (Fed.Cir.1992)) ("words of a claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor.")

[12] The *Key Pharm*. Court stressed that courts may rely on expert testimony in claim construction only if the patent record "does not answer the question." *Id*. at 716. "Thus, if the meaning of a disputed claim term is clear from the intrinsic evidence-the written record-that meaning, and no other, must prevail; it cannot be altered or superseded by witness testimony or other external sources simply because one of the parties wishes it were otherwise." *Id*.FN5

FN5. Notably, The *Key Pharm*. Court entertained expert testimony for an interpretation of the term "pharmaceutically effective amount," which is perhaps a bit more challenging than words like "first" and "thereafter." *See* Key Pharm., 161 F.3d at 718.

[13] Where there is a dispute as to a term in the patent, courts should look to the patent specification for guidance, as the Federal Circuit has referred to the specification as "the single best guide to the meaning of a disputed term." Vitronics Corp., 90 F.3d at 1582. Here, the patent specification contains no indication that the inventor intended different meanings for the words "initial," "first," "following," "follow-up," and "secondstage." Indeed, the patent specification indicates that the particular sequence of pills is an important aspect of the invention, stating that the "drug delivery system embodying the present invention contains a pharmaceutical package having at least 24 active dosage units arranged *sequentially* therein. Preferably, the pharmaceutical package contains 28 dosage units, including placebo units." Sipio Decl., Ex. A, at col. 5, lines 33-37 (emphasis added).

Because no other definition was assigned these words in the patent specification, the Court will interpret them in accordance with their ordinary meaning. Accordingly, the Court will not consider the testimony of Dr. Gutmann proposed by Plaintiff for an analysis of these disputed terms. The Court is capable, without expert assistance, of figuring out what these words mean. But to be certain, the Court looked some of them up in the dictionary. The dictionary defines "initial" as "happening or being at the very beginning: first." Webster's New Riverside Univ. Dictionary. "Follow" means "[t]o come or go after." *Id*.

[14] Claim 1 indicates that certain pills, specifically an estrogenic compound, are to be taken in the first stage. After all of these pills are taken, the user shall take "follow-up" doses of progestin. In this Court's view, claim 1 therefore requires that an estrogenic FN6 compound be administered first, i.e., from about Day 2 or 3 to Day 7 of the cycle, with the first one or two pills being placebos, and thereafter, the pills to be taken contain progestin FN7, which the woman takes for the remaining twenty-one days of her cycle.

FN6. "Estrogenic compounds, as the term is used herein, includes hormones as well as other compounds that exhibit estrogenic activity ." Sipio Decl., Ex. A, col. 3, lines 28-30. Such compounds include "17-alpha-ethinyl estradiol 3-methylether mestranol, 17-beta-estradiol, 17-alpha-ethinyl estradiol, and the like." *Id.,* at lines 34-37.

FN7. "Progestins utilizable in the present invention include progestrone and its derivatives such as, for example, 17-hydroxy progestrone esters, 17-alhpa ethinyl-testosterone, 17-alphaethinyl-19-nortestosterone and derivatives thereof." *Id.,* at lines 38-42.

The specification contains rationale for administering the estrogen early in the cycle. Because Defendant's product does not administer an estrogenic compound in the first-stage and progestin in the second-stage, it does not contain all elements and limitations of the claim and, therefore, does not literally infringe claim 1.

Claim 18 reads as follows FN8:

FN8. Claims 3 and 4 are dependent on Claim 1 and simply detail the substance of the compounds. Similarly,

Claims 19, 20, and 24 are dependent upon Claim 18, i.e., they simply identify the particular compounds referred to in Claim 18. Thus, these claims are not reproduced in this opinion.

18. A drug delivery system constituted by at least 24 separate daily dosage units, adapted for oral administration and comprising:
at least four *but not more than five* **initial** dosage units each containing as the sole contraceptively active ingredient the same contraceptively effective daily dosage of an estrogenic compound;

followed by twenty-one **follow up** dosage units each containing a contraceptively effective daily dosage of a progestin.

Sipio Decl, Ex. A, at col. 8, lines 38-48. Claim 18 also contains the by-now-familiar sequential words, indicating that a particular order of dosing is an essential aspect of the patented invention. Claim 18 refers to the "drug delivery system," which simply means the packaging or arrangement of the various pills. *See* Sipio Decl., Ex. A, col. 5, lines 33-41.
Again, Plaintiff maintains that these sequential words are used loosely, and that the particular ordering of the pills within one pack is not important to the effectiveness of the patented system. Specifically, Plaintiff maintains in its brief in opposition to this motion that the '724 patent does not "recite or require a specific order of pills" in a blister pack.

Plaintiff's contention is belied by the language of the '724 patent. The patent specification states that the invention includes a package containing twenty-eight dosage units (pills). Sipio Decl., Ex. A, col. 5, at lines 33-36. Indeed, the file history of the '724 patent suggests that ordering of the pills was a way of distinguishing it from the prior art. A Patent Examiner indicated that the cited prior art "does not teach or suggest a contraceptive method whereby an estrogen is administered alone for 4 or 5 days starting not later than the fourth day after the beginning of menstruation and then followed by 21 days where progestin is administered." *Id.,* Ex. H, at 4. The patent claims contemplate the ingestion of twenty-eight pills over a period of twenty-eight days "in a sequential order." *Id*. Thus, it appears that the patent was issued in part because of its unique drug delivery system.

Both Mircette and Defendant's proposed generic product are administered through a "blister pack." The blister pack is rectangular in shape, contains four rows (representing four weeks) and seven columns (representing each day of the week). The female user takes one pill per day, beginning with day one, which is represented by the pill in the upper, left-hand corner of the package. The woman pushes down on the pill, and the pill pops out of the back of the packaging.

Defendant asserts that its product does not infringe the patent because the arrangement of pills in its package are reversed from that in the patented system. Plaintiff avers that the accused product infringes claim 18 of the patent, stating:

a woman taking Mircette (or Duramend's copy) will repeat the cycle every 28 days, by opening a new package and beginning with the white combination pills. Thus, immediately after taking 5 unopposed estrogen pills, a woman taking Mircette (or Duramed's copy) will take 21 follow-up pills containing EE and a progestin, just as surely as day follows night.

Pl. Reply Br. at 7. The '724 patent is silent, however, with respect to a second 28-day cycle; the patent

speaks only of one package of pills. The so called "follow-up" pills referred to in the above-quoted paragraph, using Plaintiff's logic, would actually be the first pills in a new package of Mircette or the generic version.

[15] Tracing the language of the '724 patent, one would need to have at least two packages of the accused product to complete the cycle which was invented. *See* Pl. Opp. Br. at 25. However, none of the three tables depicted in the examples to the '724 patent display more than one twenty-eight day cycle. Nor is there a reference elsewhere in the patent indicating that the patent covers contraceptive systems which require more than one package to complete the patented cycle. Put simply, the patent contemplates that its cycle be embodied within one package of pills.FN9

FN9. Plaintiff also asserts that this Court should not declare Mircette and the accused product as outside the scope of the '724 patent because the prosecution history reveals that the Patent Office accepted Mircette's regimen as being representative of the patented invention. This Court is not, however, bound by determinations made by the Patent Office and disagrees with it (after thorough analysis) on this point. *See* Visual Security Concepts, Inc. v. KTV, Inc., 111 F.Supp.2d 649, 651 (E.D.Pa.2000).

Plaintiff argues that Defendant's product inevitably involves repetition, and therefore, with repetition comes infringement. *See* Pl. Br. at 15. "When the two stages of pills are taken month after month, it is meaningless to say that one group of pills comes before, and not after, another." *Id*. Similarly, at oral argument, Plaintiff asserted that Mircette and Defendant's product essentially have a three-week "launching pad" before the infringement of the process begins. *See* 10/30/01 Tr. of Proceedings, at 38, lines 19-24. This argument goes back to the notion that the '724 patent contemplated the user of the contraceptive using the product for longer than twenty-eight days. But, the patent indicates that its system takes place within one, and only one, twenty-eight day time period. Therefore, a system which requires more than one cycle to achieve the results contemplated by the invention does not literally infringe.

Comparing the instructions included with the accused product to the claims listed in the '724 patent, it is clear that the dosing regimen of the accused product contemplates administration of pills in a different order than the patented invention. Specifically, the two-stages are reversed within the package.

Nowhere in the patent is there an indication that the two stages could be interchanged or altered in any way. The claims do not read this way, nor is a reverse order contemplated in any of the examples or preferred embodiments cited in the patent. Yet, in a reverse order is how the accused product is administered to the female user.

The blister pack for the accused product is arranged in a manner similar to the tables in the examples listed in the '724 patent in that they have four rows and seven columns. According to the instructions included with the accused product, the user of the contraceptive is to begin with the pill in the top left-hand corner on day one. However, with the accused product,instead of an unopposed estrogenic compound being taken in the first seven days, a combination containing progestin is ingested. The instructions included with the proposed generic version require that the woman take the pills "exactly as directed" to achieve "maximum contraceptive effectiveness." Presumably, the user would follow the instructions and would therefore ingest progestin in the first stage of her cycle.

This Court believes that if Plaintiff's patent were to cover a drug delivery system which administered the

progestin first and the estrogen last, the patent would say that. Although the '724 patent gives a number of "preferred embodiments," not one of the examples listed conforms with the way Mircette or Defendant's product is administered. The patent contains no suggestion that the stages could be reversed within one package to achieve the same result.

Additionally, claim 18 requires that an initial dosage of "at least four *but not more than five* initial dosage units." The alleged infringing product's initial dosage unit contains twenty-one pills. For this additional reason, the accused product does not literally infringe claim 18 the '724 patent.

For the reasons detailed above, the Court finds, as a matter of law, that Defendant's product does not literally infringe claim 1 or claim 18 of the Plaintiff's '724 patent. Because claims 1 and 18 are not literally infringed, claims 3, 4, 19, 20, and 24 cannot be literally infringed as they are dependent upon claims 1 and 18 respectively. *See* Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed.Cir.1989)("It is axiomatic that dependent Claims cannot be found infringed unless the claims from which they depend have been found to be infringed.").

D. Doctrine of Equivalents

[16] Though Plaintiff's product does not literally infringe Defendant's patent, the question of whether it infringes under the doctrine of equivalents still remains. The doctrine of equivalents provides that a product may infringe a patent if it contains each limitation of the claim or the equivalent of each limitation of a claim. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997); Cybor Corp. v. FAS Tech., 138 F.3d 1448, 1459-60 (Fed.Cir.1998).

Having construed the relevant claims here, it is apparent to the Court that the patent contemplates a particular order of pill ingestion within one package. Specifically, the first stage requires a dosage of estrogen pills for seven days, while the second-stage requires ingestion of a progestin compound for twenty-one days.

[17] [18] The question to be asked by this Court in deciding infringement under the doctrine of equivalents is whether the accused infringing product "perform[s] substantially the same function in substantially the same way to obtain the same result." Graver Tank & Mfg. v. Linde Air Prod., 339 U.S. 605, 607, 70 S.Ct. 854, 94 L.Ed. 1097 (1950); Goodwall Constr. v. Beers Constr., 991 F.2d 751 (Fed.Cir.1993). Notably, there can be no infringement where the defendant "achieves the same result ... but does so by a *different arrangement of elements*." Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1425 (Fed.Cir.1997). To be considered equivalent, the changes made to the accused product must be merely insubstantial. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39-40, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997); Overhead Door Corp. v. The Chamberlain Group, 194 F.3d 1261, 1269 (Fed.Cir.1999).

Here, the alleged infringing product is, like the patented system, a twenty-eight day system. Unlike the '724 patent, however, the Duramed product is sequenced differently.

Plaintiff relies on Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 50 S.Ct. 9, 74 L.Ed. 147 (1929), and Corning Glass Works, 868 F.2d 1251, for the proposition that Defendant's changes to the contraceptive system are insubstantial. The Supreme Court in *Sanitary Refrigerator Co*. held that the accused product, a latch for a door, infringed the patented door latch because it operated under the same mechanical principle, the only differences between the two latches being the length of the arm of a lever and the placement of a

lug. Sanitary Refrigerator Co., 280 U.S. at 40-41, 50 S.Ct. 9. Otherwise the accused device was an "exact reproduction" of the patented device. *See id*. at 41, 50 S.Ct. 9. The Court found that because the accused device performed substantially the same function, in substantially the same manner, to achieve substantially the same result, it infringed the patent in suit under the doctrine of equivalents. *See id*.

In *Corning Glass Works,* the question before the Court was whether the accused device performed in substantially the same way as the patented device. The parties agreed that both devices performed the same function and achieved the same result. According to the Federal Circuit, an accused device performs in substantially the same way "if an equivalent of a recited limitation has been substituted in the accused device." Corning Glass Works, 868 F.2d at 1259. *Corning Glass Works* involved optical waveguide fibers, and specifically, the difference between the two devices related to the dopant that was utilized in each. The accused device used a dopant in the cladding which negatively altered the index of refraction, whereas the patented device used a dopant in the core which positively altered the index of refraction. *See id*. at 1259-60. The different dopants were deemed equivalent because one could be substituted for the other to achieve the same result. *See id*. at 1260.

Both of these cases involve the substitution of an equivalent of a limitation of the patent. A limitation of the '724 patent is the ordering of drugs within the package. The accused product does not contain an equivalent of this limitation. Instead, the elements of the accused product are placed in a reverse order to achieve a different result than that obtained in the patented system. In this Court's view, this change is not insubstantial. Indeed, the change in sequence of ingestion of the pills affects the female user's body in an entirely different manner than with the patented system.

With the patented system, due to arrangement of the pills in the pack, menses begins on or about day one of the cycle. With the accused product, menses begins on or about day twenty-one of the twenty-eight day cycle. It may be the case that over the course of a few months, female users taking the respective contraceptives will experience the same menstrual cycle, but, in any one given period, the cycles are reversed. As discussed above *ad nauseum,* the patent covers only one order in a package-the first stage containing estrogen, and the second stage containing progestin. The accused product works in the reverse order.

For these reasons, the Court finds that Defendant's proposed generic version of Mircette does not perform in substantially the same way to achieve substantially the same result as the patented system. Consequently, Defendant's product does not infringe the '724 patent under the doctrine of equivalents. Again, because there is no infringement of claims 1 and 18 under the doctrine of equivalents, there can be no infringement of the dependent claims under the doctrine of equivalents.

E. Indirect Infringement/Inducement to Infringe/Negligent Infringement FN10

FN10. Plaintiff's Complaint does not allege a claim for indirect infringement, however, the Court briefly addresses the potential for this claim since the parties argue about this point in their briefs.

To demonstrate indirect infringement under 35 U.S.C. s. 271(b) and (c), Plaintiff would have to show that Defendant is knowingly inducing others to infringe Plaintiff's patent, or that by offering the accused product for sale, Plaintiff intends for it to be used in a manner described in the patent. *See* Johns Hopkins Univ. v. Cellpro, 894 F.Supp. 819, 835-36 (D.Del.1995). Of course, there must be an act of direct infringement of the

patent in order for Plaintiff to succeed on an indirect infringement claim. *See* Moleculon Research Corp. v. CBS, Inc., 872 F.2d 407, 410 (Fed.Cir.1989). Because there has been no showing of direct infringement here, the sale of the product could not constitute indirect infringement.

Moreover, Plaintiff cannot show that a user of the proposed product would use it in an infringing way, i.e., that the user would take the proposed product in an order which is the reverse of that indicated in the instructions. In fact, the instructions to the accused product specifically instruct the user to take the pills in sequential order.FN11 There is no other evidence that Defendant would urge users to take its product in the reverse order. Thus, no reasonable jury could conclude that Defendant is inducing potential users to take its product in an infringing manner.

FN11. The instructions to Mircette were submitted to the Court as Joint Exhibit 3. The parties agree that the accused product contains instructions which are identical to Mircette's instructions in all material respects.

CONCLUSION

Based on the foregoing analysis, the Court finds that summary judgment in favor of Defendant is proper as the accused product does not infringe claims 1, 3, 4, 18, 19-20, or 24 of the '724 patent either literally or under the doctrine of equivalents. An appropriate order accompanies this Letter Opinion.

ORDER

THIS MATTER having come before the Court on Defendant's motion for summary judgment; and oral argument having been heard on October 30, 2001; and for the reasons articulated in the above opinion,

IT IS on this __ day of December, 2001

ORDERED that Defendant's motion for summary judgment is

GRANTED; and it is

FURTHER ORDERED that Plaintiff's Complaint is **DISMISSED WITH**

PREJUDICE; and it is

FURTHER ORDERED that this case is now **CLOSED.**

D.N.J.,2001.
Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc.