NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TYCO HEALTHCARE GROUP LP and MALLINCKRODT INC., Plaintiffs, v. MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC., Defendants.	Civil Action No. 07-1299 (SRC) **OPINION**

CHESLER, U.S.D.J.

This matter comes before the Court on five motions: 1) the motion for summary judgment of invalidity for improper inventorship and derivation by Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. (collectively, "Mutual"); 2) Mutual's motion for summary judgment of noninfringement; 3) Mutual's motion for summary judgment of obviousness; 4) the cross-motion for partial summary judgment of invalidity for improper inventorship and derivation by Plaintiffs Tyco Healthcare Group LP and Mallinckrodt Inc. (collectively, "Tyco"); and 5) Tyco's cross-motion for partial summary judgment of obviousness. For the reasons stated below, Mutual's motion for summary judgment of obviousness will be granted, and the remaining motions will be denied.

BACKGROUND

This case arises out of an action for patent infringement. Briefly, Mallinkrodt Inc. owns

U.S. Patent No. 5,211,954 (the "'954 patent"), which is directed to a low-dose temazepam composition. The '954 patent was issued on May 18, 1993, and it will expire on May 18, 2010. Tyco Healthcare Group LP holds an FDA-approved supplement to new drug application No. 18-163 for Restoril® temazepam capsules. On November 1, 2006, Mutual filed ANDA No. 78-581, seeking approval from the FDA to engage in the manufacture and sale of certain temazepam products. On March 20, 2007, Plaintiffs responded with this infringement action. Plaintiffs originally asserted infringement of four patents, but three of those patents have since expired, leaving only the '954 patent at issue.

The '954 patent was originally issued to Sandoz Ltd. ("Sandoz"); Tyco acquired ownership of the patent in 2001.

APPLICABLE LEGAL STANDARDS

I. Motion for summary judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to "set forth specific facts showing that there is a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "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, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

II. Patent invalidity due to obviousness

"A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

In deciding an obviousness challenge to the validity of a patent, the Court relies on these principles:

> [B]y statute a patent is valid upon issuance, 35 U.S.C. § 282, and included within the presumption of validity is a presumption of non-obviousness. Since we must presume a patent valid, the patent challenger bears the burden of proving the factual elements of invalidity by clear and convincing evidence. . . The trial court has the responsibility to determine whether the challenger has met its burden by clear and convincing evidence by considering the totality of the evidence, including any rebuttal evidence presented by the patentee.

Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1359-60 (Fed. Cir. 2007) (citation omitted).

In Graham, the Supreme Court outlined the obviousness inquiry as follows:

> While the ultimate question of patent validity is one of law, the § 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but

> unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 17-18 (1966) (citation omitted).

ANALYSIS

I. The '954 patent is invalid for obviousness

The '954 patent contains two claims:

> 1. A hard gelatin capsule containing a temazepam formulation consisting essentially of 6 to 8 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m.sup.2 /g and 95% of the temazepam having a particle size of less than 65 microns in admixture with a pharmaceutically acceptable carrier therefor.
>
> 2. A hard gelatin capsule containing a temazepam formulation consisting essentially of 7.5 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m.sup.2 /g and 95% of the temazepam having a particle size of less than 65 microns in admixture with a pharmaceutically acceptable carrier therefor.

The only aspect of the claims at issue here is the dosage amount of temazepam in the capsules, 6mg to 8mg in claim 1, and 7.5mg in claim 2. The parties do not dispute that the prior art contained 15mg temazepam capsules, manufactured by Sandoz, and that the only difference between these prior art temazepam products and the claimed invention is the dosage. (See Orr Dec. ¶ 38.)

Mutual argues that the '954 patent is invalid for obviousness because, at the time of the invention (September of 1986), a skilled artisan would have been motivated to lower the dosage of the existing temazepam product to 7.5mg, and would have had a reasonable expectation of success in treating insomnia. In particular, Mutual contends that use of a 7.5mg dose was obvious in view of the 1983 British National Formulary ("BNF.")

Mutual argues that the use of a 7.5mg dose was obvious for these reasons: 1) one of skill in the art would have been motivated to use a lower dosage;[1] 2) the reduction of dosage from 15mg to 7.5mg was a trivial modification requiring no special skill; and 3) one of skill in the art would have expected the lower dose to be effective in treating insomnia. Tyco disputes only the last of these propositions.

Mutual points to two principal pieces of evidence in support. First, Mutual points to the undisputed fact that a 5mg dosage form had been sold commercially outside of the United States since the 1970's. Second, Mutual cites the entry for temazepam in the 1983 BNF. The parties do not dispute that the BNF is a joint publication of the British Medical Association and The Pharmaceutical Society of Great Britain. The entries in the BNF generally begin with four sections: indications, cautions, side effects, and dose. (Ex. 10 within Winkelman Dec. Ex. 1.) The entry for temazepam states:

> ***Indications:*** Insomnia (useful in the elderly)
> ***Cautions: Side-effects:*** see under Nitrazepam, but except at high dosage hangover is uncommon and doses less cumulative. Less appropriate in patients with early wakening.
> ***Dose:*** 10-30 mg (elderly patients 5-15 mg), increasing in severe insomnia to 60 mg, 30 minutes before bedtime.

(Id.) This entry plainly tells one of skill in the art to treat insomnia in the elderly by administering a dose in the range of 5 to 15 mg.[2] The entry includes a list of the forms of the

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[1] The motivation would have come from the desire to reduce the incidence of adverse effects, often more frequent at higher dosages. Tyco does not dispute that, as a general rule, in order to minimize side effects, "physicians always seek to prescribe the lowest effective dose of any medication." (Tyco's 56.1 Opp. Stmt. ¶ 5.)

[2] Also, the side-effects information suggests to the reader to reduce the dosage to minimize hangover.

medication commercially available.

Tyco attempts to counter the BNF evidence with a number of arguments. First, Tyco observes that the list of forms of the medication includes nothing at a 5mg dose. This is incorrect. The list includes an elixir and provides the information necessary for one of skill in the art to know that a 5mg dosage would be 2.5ml of elixir.[3] Second, Tyco states that no data is presented about the effect of any dose on sleep. This is true but irrelevant, since the question here is whether the use of a 7.5mg dose would have been obvious to the skilled reader, not whether a convincing scientific case was made. Lastly, and most importantly, Tyco contends that the BNF entry would not inform one of skill in the art that a 5mg dose would be effective in the treatment of insomnia, and offers the affidavit of its expert, Dr. Orr, in support. Indeed, Dr. Orr does state this. (Orr Dec. ¶¶ 20, 41, 42, 52.)

Dr. Orr does not offer a factual basis for his opinion, nor explain the rationale underlying it. This Court therefore cannot credit his expert opinion. Moreover, this Court finds it somewhat incomprehensible that an expert can opine that a recognized publication, which has the purpose of directing practitioners to the appropriate use of medications, and which clearly states that doses in the range of 5mg to 15mg may be used to treat insomnia in the elderly, does not teach the use of doses in that range for the treatment of insomnia.[4] Rather, the BNF appears to be

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[3] Moreover, Tyco does not dispute that a 5mg temazepam capsule for the treatment of insomnia has been sold internationally under the name Levanxol® since the 1970's.

[4] Moreover, in support of this view, Mutual offers the "Memo for the Record" of the November 29, 1984 Sandoz-FDA teleconference. (Dec. 7, 2009 Lowe Dec. Ex. 12.) The memo states that Dr. Hillary Lee of the FDA "also felt that the doses proposed in our studies were too high, citing that in Great Britain, temazepam doses from 5-15 mg are recommended for geriatrics." (Id. at 2.) While this does not state that Dr. Lee based her statement on the BNF, the coincidence is suggestive.

compelling prior art. Dr. Orr's opinions on this point do not help the finder of fact, and such expert opinion would be excluded under Rule 702. United States v. Gibbs, 190 F.3d 188, 212 (3d Cir. 1999) ("We have upheld the exclusion of expert testimony when that testimony ventures into areas in which the jury needs no aid or illumination.") This Court would exclude Dr. Orr's expert testimony on what the BNF entry says. Tyco has failed to raise any factual dispute in connection with the BNF evidence.

To support its legal argument, Mutual cites Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311 (Fed. Cir. 2006) (citation omitted), which states:

> Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness. The presumption can be rebutted if it can be shown that the prior art teaches away from the claimed range, or the claimed range produces new and unexpected results.

This is on point. The '954 patent claims a range of 6mg to 8mg, which overlaps with the range disclosed in the BNF.[5] This raises a presumption of obviousness.

In rebuttal, Tyco contends that the motion for summary judgment of obviousness must be denied because Mutual "has failed to show that no reasonable jury could find for Tyco on any of the essential elements" of the obviousness defense. (Tyco's Opp. Br. 12.) This fails to state accurately Mutual's summary judgment burden. Mutual bears the initial burden of presenting evidence sufficient to persuade a reasonable jury of every element of its case. It has met this burden. The burden then shifts to Tyco to point to evidence which raises a genuine dispute as to

[5] The parties do not raise "obvious to try" issues, but this Court notes that this does not appear to be the kind of situation in which an impermissible "obvious to try" problem arises, within the meaning of In re Kubin, 561 F.3d 1351, 1359 (Fed. Cir. 2009). Rather, the range of 5mg to 15mg appears to present a "a finite number of identified, predictable solutions." KSR, 550 U.S. at 421.

some material fact, or which demonstrates that Mutual is not entitled to judgment as a matter of law. This is where Tyco has failed to defeat the motion for summary judgment.

Tyco's principal argument in rebuttal is that the 7.5mg dosage was nonobvious because the prior art taught away from the invention, and because the use of the 7.5mg dose produced unexpected results.[6] These are very similar ideas. As evidence in support of its rebuttal case, Tyco offers two research studies by Nicholson and Stone, a 1984 internal Sandoz memo, and the Matejcek reference.

Tyco offers two studies on the effect of temazapam on sleep by Nicholson and Stone, one in 1976 and the other in 1979. (Orr Decl. Ex. D, E.) Tyco points to the fact that these studies found that the 10mg temazapam dose did not produce increased total sleep time. This is true, but misleading. Both studies also found that the 10mg dose lowered sleep onset latency. Table 1 in the 1976 study, in fact, shows that the average sleep onset latency for subjects taking the 10mg temazepam dose (16.7 minutes) was slightly lower than the average sleep onset latency for subjects taking the 20mg temazepam dose (16.8 minutes), whereas average sleep onset latency for subjects taking the placebo was 21.9 minutes. In the 1979 study, Table 2 shows that the average sleep onset latency for subjects taking the 10mg temazepam dose (17.75 minutes) was 15 seconds greater than the average sleep onset latency for subjects taking the 20mg temazepam dose (17.5 minutes), whereas average sleep onset latency for subjects taking the placebo was

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[6] Tyco discusses teaching away in its section on the content of the prior art, and treats unexpected results as a secondary consideration. While there is some ambiguity in Federal Circuit cases about whether unexpected results are classified as a secondary consideration, it is clear that both teaching away and unexpected results are recognized parts of a rebuttal case. See, e.g., In re Peterson, 315 F.3d 1325, 1330-31 (Fed. Cir. 2003).

22.33 minutes. Tyco states correctly that the difference was not sufficient to reach the .05 level of statistical significance. The absence of statistical significance is misleading here, however. Tyco offers these studies to support its position that the studies taught away from the view that a 10mg dose could be effective to treat insomnia. Even if the effects on sleep onset latency were not statistically significant, these results most definitely did not teach away from using a 10mg dose to treat insomnia. Rather, they taught toward this idea, as both studies showed that the 10mg dose lowered sleep onset latency – which is what a sleeping pill is supposed to do. No reasonable jury could hear the evidence of these two studies and conclude that the studies taught away from the use of the 10mg dose to treat insomnia.

The Nicholson and Stone studies fail to raise any genuine factual issue. Both studies show that use of a 10mg dose gets people to fall asleep faster. The fact that the studies showed no effect on total sleep time is irrelevant, and this Court would exclude the total sleep time evidence both under Rule 401 and under Rule 403, since it would only serve to confuse the finder of fact.

Tyco points to two other pieces of evidence, the 1984 internal Sandoz memo, and the Matejcek reference. As to the internal Sandoz memo, Tyco presents it as evidence of what outside consultants understood and told Sandoz in 1984. Yet this Court cannot find in that memo evidence that an outside consultant expressed the view that the 7.5mg dose would not be effective. (Divinigracia Dec. Ex. 2.) Rather, what the memo says is that the Sandoz personnel and the outside consultants discussed a potential study of the use of different doses of temazepam to treat insomnia, and considered as possible both that the 7.5mg dose might prove to be effective and that it might not. (Id.) It is not clear from the memo who argued which position. The memo

provides no relevant evidence as to teaching away.

The Matejcek reference is a research article in which, as a parenthetical comment, the author states that the 5mg dose was not tested in one part of the study "since this dose is known to be of no clinical importance as a hypnotic." (Orr Dec. Ex. H at 61.) As Mutual notes, the Matejcek study was not a sleep study and made no conclusions about the effectiveness of any treatment for insomnia. The only evidence of teaching away in this reference is this one parenthetical comment. This is extremely weak evidence of teaching away.

Viewing the prior art evidence as a whole, no reasonable jury could hear this evidence and find that the prior art taught away from use of a 7.5mg dose for the treatment of insomnia. The Third Circuit has established the "mere scintilla" threshold for the quantum of evidence required to create a genuine factual dispute. Big Apple BMW, Inc. v. BMW of North America, Inc., 974 F.2d 1358 (3d Cir. 1992). This isolated reference in one study, made without any support, is not sufficient under this standard. As to the issue of teaching away in the prior art, the evidence "is so one-sided that one party must prevail as a matter of law." Anderson, 477 U.S. at 252. This court finds no factual dispute about the issue of whether the prior art taught away from the claimed invention that might preclude a grant of summary judgment.

In view of the applicable law, this Court finds Tyco's rebuttal case, which relies principally on the alleged evidence of teaching away, unpersuasive. In KSR, the Supreme Court discussed the role of teaching away in the obviousness inquiry, and the discussion implies a two-phase process in the examination of the content of the prior art. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007). First, the Court applies the teaching-suggestion-motivation test to the relevant pieces of prior art. If this inquiry produces the inference that the combination was

obvious, the inquiry moves to the second phase, in which the prior art is examined as a whole to ascertain whether it taught away from combining the elements. The conclusions from the inquiry into teaching away must then be weighed against the inference of obviousness.

As an example of the role of teaching away in the inquiry, the Supreme Court discussed United States v. Adams, 383 U.S. 39 (1966). KSR, 127 S. Ct. at 1739-40. Adams concerned a patent on a battery. The Supreme Court commented on Adams as follows:

> The Court relied upon the [] principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art.

KSR, 127 S. Ct. at 1740. Thus, in Adams, the fact that the prior art taught away from the combination that produced the invention was weighed against the finding that the invention resulted from the combination of well-known elements, and yielded a conclusion of nonobviousness.

Adams, however, may be distinguished from the instant case. The Adams Court found that the prior art taught away from making the combination that resulted in the patented invention and stated:

> These long-accepted factors, when taken together, would, we believe, deter any investigation into such a combination as is used by Adams. . . . We do say, however, that known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness.

Adams, 383 U.S. at 52.

This Court now looks to the prior art evidence in light of the teachings of KSR and

Adams. This Court finds that the evidence does not support the conclusion that the prior art would have deterred an investigation into a 7.5mg dose. The evidence of teaching away is far too weak to counterbalance the evidence that the combination was obvious.[7]

Furthermore, the Federal Circuit has stated: "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." Pfizer, 480 F.3d at 1364. At best, Tyco's evidence does no more than show a small amount of unpredictability in the art, insufficient to counter Mutual's showing of a reasonable probability of success.

Tyco's rebuttal position is also weakened by its puzzling formulation of its position. Rather than argue that the skilled artisan would not have been motivated to use a 7.5mg dose, Tyco contends that "the skilled person would not have been motivated to try a temazepam dose lower than 15 mg to treat insomnia." (Tyco Opp. Br. 14.) This assertion is untenable in view of the fact that the '954 patent itself states: "At doses of 10 and 20 milligrams, the soft gelatin capsules have also been found to be effective." '954 patent col.1 ll.29-31. This absolutely refutes Tyco's contention. The evidence of record clearly shows that the prior art would have motivated the skilled artisan to use a dose lower than 15mg to treat insomnia.

Tyco also argues, in rebuttal, that the secondary consideration of commercial success indicates nonobviousness. It is clear that Tyco's sales of the 7.5mg temazepam product have been substantial and are evidence of commercial success. Yet the Federal Circuit cautions: "if

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[7] Moreover, even if the Court were to give greater weight to the prior art statement that a 5mg dose is of no clinical importance as a hypnotic, the patent does not claim a 5mg dose. Teaching away from a 5mg dose would not necessarily teach away from a 7.5mg dose. This leaves a gap in Tyco's argument.

the feature that creates the commercial success was known in the prior art, the success is not pertinent." Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1312 (Fed. Cir. 2006). Overseas, 5mg and 10mg temazepam products had been sold since the 1970's. Low-dosage temazepam products were known in the prior art, and, accordingly, the success here is not pertinent.

Considering the evidence as a whole, however, this Court concludes that this commercial success is not sufficiently probative to rebut Mutual's strong showing of obviousness. "Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion." Pfizer, 480 F.3d at 1372.

This Court finds that a grant of summary judgment is appropriate. Tyco has failed to raise any genuine disputes over material facts. "The underlying factual determinations [to be made] include (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness." Pfizer, 480 F.3d at 1360 (citation omitted). This Court finds no genuine factual disputes in these four areas. The parties do not contend that the level of ordinary skill in the art is disputed or material to the matter at hand. As to the objective indicia of nonobviousness, the parties do not dispute the facts as to the commercial success of the 7.5mg product. It is undisputed that the only difference between the patented invention and the prior art temazepam products was the dosage. The only real and material area of dispute is the content of the BNF reference. Because this Court has excluded the evidence of the opinion on this subject of Tyco's expert, Dr. Orr, Tyco has failed to raise a factual dispute over the content of the BNF reference. No material factual disputes preclude a grant of summary judgment.

The BNF reference discloses the use of a dose in the range of 5mg to 15mg for the

treatment of insomnia in the elderly.

> [W]here, as here, all claim limitations are found in a number of prior art references, the burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.

Id. at 1361. Mutual has made its case by clear and convincing evidence on both counts. Mutual has shown that a skilled artisan would have been motivated to try to use the lowest effective dose to minimize side effects such as hangover. Both of the Nicholson and Stone studies would have given the artisan a reasonable expectation of success in lowering the dose to 10 mg, and the BNF entry would have given the artisan a reasonable expectation of success in using a 7.5mg dose. There has been no showing that the experimentation that would have been required to arrive at the 7.5 mg dose was anything other than routine. See Merck & Co. v. Biocraft Laboratories, Inc., 874 F.2d 804, 809 (Fed. Cir. 1989). It would have been obvious to the skilled artisan to combine the existing 15mg temazepam capsule with the dosage range taught by the BNF. Moreover, in view of the fact that 5mg and 10mg temazepam products were being sold and used overseas, mere common sense would suggest to the skilled artisan to try doses in the range of 5mg to 10mg to treat insomnia.

Another path of reasoning leads to the same conclusion. The Supreme Court stated in KSR:

> If the claim extends to what is obvious, it is invalid under § 103. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

KSR, 550 U.S. at 420. The parties do not dispute that the problem of finding a treatment for

insomnia with minimal adverse effects was a known problem at the time of invention. The solution – use of a 7.5mg dose of temazepam – was not merely an obvious solution at the time of invention; as the BNF reference shows, it was a known solution.

Moreover, based on Tyco's explanation of how this patent was obtained, it is possible to ascertain the flaws in the arguments that the applicant made:

> Sandoz argued that there was nothing in the cited prior art that would have suggested or led one of ordinary skill in the art to hard gelatin capsules having the claimed amounts of temazepam, and that the prior art taught away from temazepam doses less than 10 mg. Sandoz also argued that its discovery that 7.5 mg was effective to treat insomnia was unexpected. Based on those arguments, and the limitation of the claims to the "6 to 8" and "7.5" mg amounts of temazepam, the USPTO allowed the claims, and the '954 patent issued.

(Tyco's Opp. Br. 7.) When the BNF reference is also considered, and the other prior art references carefully examined, it is clear that these arguments are incorrect. Claims 1 and 2 are obvious and should not have been allowed.

"Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate." KSR, 127 S. Ct. at 1745-1746. Having considered the evidence as a whole, this Court finds that Mutual has shown by clear and convincing evidence that the '954 patent is invalid due to obviousness. Mutual has met its burden of showing that it is entitled to judgment as a matter of law.

The decision that the '954 patent is invalid due to obviousness moots the four remaining motion and cross-motions for summary judgment.

CONCLUSIONS

For the reasons stated above, as to Mutual's motion for summary judgment of obviousness, Mutual has shown that it is entitled to judgment as a matter of law. Mutual's motion for summary judgment of obviousness is granted. Pursuant to 35 U.S.C. § 103(a), U.S. Patent No. 5,211,954 is invalid due to obviousness. This renders moot the remaining four motions and cross-motions for summary judgment, which are denied on that ground.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: May 4, 2010