UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EISAI CO., LTD. and EISAI INC., Plaintiffs, -v.- TEVA PHARMACEUTICALS USA, INC., Defendant.	03 Civ. 9223 (GEL) **OPINION AND ORDER**

Robert L. Baechtold, Joseph M. O'Malley, Bruce M. Wexler, Fitzpatrick, Cella, Harper & Scinto, New York, NY; David B. Tulchin, James T. Williams, and Bradley A. Harsch, Sullivan & Cromwell LLP, New York, NY, for Plaintiffs.

David M. Hashmall, Frederick H. Rein, and Elaine Herrmann Blais, Goodwin Proctor LLP, New York, NY, for Defendant.

GERARD E. LYNCH, District Judge:

Plaintiffs in this patent-infringement action move for summary judgment of the validity of their patent against defendant's counterclaim of obviousness. Specifically, pharmaceutical companies, Eisai Co., Ltd. and Eisai Inc. (collectively, "Eisai"), ask that U.S. Patent No. 5,045,552 ("'552 patent"), claiming inter alia the gastric-acid-inhibiting compound, rabeprazole, be declared valid in the face of defendant Teva Pharmaceuticals USA, Inc.'s ("Teva") allegation that the claims are obvious in light of a certain combination of prior art. The motion will be granted.

The relevant facts, including a description of the proceedings, the patent-in-suit, and the technical background, may be found in the Court's Opinion and Order addressing plaintiffs'

concurrent Motion for Summary Judgment of No Inequitable Conduct, Eisai Co., Ltd. v. Dr. Reddy's Laboratories, Ltd., et al., ___ F. Supp. 2d ___ (S.D.N.Y. Oct. 5, 2006). Additional facts will be mentioned as necessary during discussion of defendant's claim.

For the reasons below, summary judgment is granted.

LEGAL STANDARDS

I. Summary Judgment

The well known general standards for assessing motions for summary judgment are set forth in detail in the accompanying opinion. Eisai, ___ F. Supp. 2d at ___. The Federal Circuit has gone to some lengths to explicate the application of the standard regarding issues resembling those of the instant dispute. In a case where the trial court had granted summary judgment of validity to a patent-holder against an infringer's challenge of obviousness, the infringer appealed, asserting that "the district court, unskilled in the art . . . , was legally unable to resolve key, factual disputes on patent validity without the testimony of a qualified expert" and that "the court is required to defer to its expert testimony." Avia Group Int'l, Inc. v. L.A. Gear California, Inc., 853 F.2d 1557, 1562, 1564 (Fed. Cir. 1988). The appeals court rejected the argument as "wholly meritless," pointing out that the district court had not "resolved" facts but rather found the lack of a dispute of a material fact, and reminding that "[v]alidity is a question of law." Id. at1562.

The Federal Circuit further admonished, "To create a genuine issue of fact, the nonmovant must do more than present *some* evidence on an issue it asserts is disputed. . . . If the [nonmovant's] evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Id. at 1560 (internal quotation marks and citations omitted; emphasis

in original). Moreover, the court stressed, "The moving party need not produce evidence showing the absence of a genuine issue of material fact; rather, the burden on the moving party may be discharged by . . . pointing out to the district court[ ] that there is an absence of evidence to support the nonmoving party's case." Id. at 1560 (citing Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986) (internal quotation marks omitted).

II. Defense of Obviousness

Pursuant to statute and the case law, a patent is presumed valid. Id. at 1561; 35 U.S.C. § 282. In an infringement action where the accused counters by charging invalidity of the patent, that challenger, to prevail, "must establish facts, by clear and convincing evidence, which persuasively lead to the conclusion of invalidity." Id. There is no prima facie or other variety of showing that shifts the burden of proof; the presumption of validity persists through final judgment and consistently requires persuasion by the challenger. Id. at 1562.

Where the basis for alleging invalidity is a patent's purported obviousness, courts must consider an array of factors in determining whether the totality of the evidence warrants overturning the presumption and finding invalidity. Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 229 F.2d 1120, 1124 (Fed. Cir. 2000). These factors include: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims in issue, (3) the level of ordinary skill in the art when the challenged invention was made, and (4) any "secondary considerations" probative of nonobviousness, such as commercial success evidencing consumers' welcome of an unprecedented item. Id. at 1564; Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966) (aligning judicial standard for obviousness with statutory standard of 35 U.S.C. § 103(a)). The challenged claim may be found obvious as a matter of law, if a

review of the evidence shows that the challenged claim would have been obvious at a time preceding invention to a person of ordinary skill in the relevant art ("ordinary skilled person"). Id. at 3; see also Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566-68 (Fed. Cir. 1987).

The obviousness inquiry must be approached from the correct temporal and objective perspectives. "Determinations of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." Crown Operations Int'l, Ltd. v. Solutia, Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002). The decision maker must step back in time to before the moment of actual invention, and out of the actual inventor's shoes into those of a hypothetical, ordinary skilled person who has never seen the invention. W.L. Gore & Assocs., Inc. v Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983). The legal question is whether, in light of the differences between the invention and the prior art, and all relevant facts, the invention would have been obvious at *that* time to *such a* person. Panduit Corp., 810 F.2d at 1566-68.

Where the patented claim is alleged to be obvious in light of a combination of prior art, "a showing of a suggestion, teaching, or motivation to combine the prior art references is an essential evidentiary component of an obviousness holding." Brown & Williamson, 229 F.2d at 1124-25, citing C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352 (Fed. Cir. 1998). Such a suggestion may be found in the knowledge of the ordinary skilled person, teachings of the prior art, or the nature of the problem. SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1356 (Fed. Cir. 2000). The suggestion must be one of some specificity, that is, "to look to particular sources, to select particular elements and to combine them as combined by the inventor." Crown Operations Int'l, Ltd., 289 F.3d at 1376. Indeed, there must be clear and

particular, actual evidence of a motivation, teaching, or suggestion so to combine the prior art. See, e.g., Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1334 (Fed. Cir. 2002), citing In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999). The Federal Circuit has explicitly "reemphasized the importance of the motivation to combine," warning:

> [A]n . . . accused infringer may often find every element of a claimed invention in the prior art . . . . [T]he suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness. At the heart of [the] validity dispute is whether one of skill in [the] art would have found motivation to combine the pieces from one . . . prior art patent with a piece of another . . . through a series of manipulations.

Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1343 (Fed. Cir. 2000) (original brackets omitted), citing In re Rouffet, 249 F.3d 1350, 1357-58 (Fed. Cir. 1998).

In addition to requiring the showing of such a suggestion, a conclusion of obviousness on this ground requires proof that the ordinary skilled person would have had, at the appropriate time, "a reasonable expectation" that making the asserted combination would have resulted in the patented claim. In re Merck & Co., 800 F.2d 1091, 1097 (Fed. Cir. 1986). In other words, the obviousness inquiry concerns "whether there is something in the prior art as a whole to suggest [to the ordinary skilled person] the *desirability*, and thus the obviousness, of making the combination." In re Fulton, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (citation and internal quotation marks omitted; emphasis in original).

Summary judgment of validity is appropriate where the accuser fails to make a showing sufficient ultimately to prove, by clear and convincing evidence, that the challenged claim is obvious in light of the professed combination. Fromson v. Citiplate, Inc., 886 F.2d 1300, 1302

(Fed. Cir. 1989). Put differently, a successful showing would suffice to prove by clear and convincing evidence that the ordinary skilled person would have made that asserted combination. See Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1350 (Fed. Cir. 2002).

DISCUSSION

Teva alleges that the claims of the '552 patent would have been obvious to the ordinary skilled person at the relevant time in light of a combination of three prior art references: Takeda's European Patent 174,726, claiming, inter alia, the ulcer-treatment compound lansoprazole ("'726 patent"); Junggren's U.S. Patent No. 4,255,431 ("'431 patent"), claiming, inter alia, the compound omeprazole, also used for treating ulcers; and, a scientific article by one A. Brandstrom and others, entitled "Structure Activity Relationships of Substituted Benzimidazoles" ("Brandstrom article"), describing characteristics of a relevant class of compounds.[1] According to defendant, the ordinary skilled person would have been motivated to select lansoprazole as her lead compound and then alter its structure in ways suggested by the '431 patent and the Brandstrom article, to arrive at rabeprazole.[2] (See D. Mem. 8-13.)

Summary judgment is granted because, even accepting as undisputed for the purposes of this motion all of Teva's representations of material fact,[3] the evidence is insufficient to sustain a judgment that the claims of the '552 patent are invalid as obvious. Even accepting Teva's

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[1] Defendant offers the following citation to the article: 20 (Supp. 108) Scandinavian J. Of Gastroenterology (1985).

[2] Eisai does not dispute that the validity of the rabeprazole compound determines the validity of all the claims of the '552 patent.

[3] The Court disregards the various factual assertions of both parties regarding actions, methods, or goals of the *actual* inventor. As is clear from the case law, described supra, Eisai's subjective circumstances are irrelevant to the time-frozen, objective obviousness inquiry.

offered teachings as undisputed, the submissions are insufficient to sustain a judgment by clear and convincing evidence that the ordinary skilled person would have made the particular combination alleged of lansoprazole, the '431 patent, and the Brandstrom article, reasonably expecting rabeprazole to result. Specifically, defendant's submissions fall far short of sufficiency to prove the usage Teva claims would have been made of the '726 patent.[4]

The critical material facts are not in dispute. Eisai agrees that the prior art would include references extant as of November 13, 1986. (P. Mem. 7; D. Mem. 4.) For the purposes of its motion, Eisai concedes that the person of ordinary skill in the relevant art should be defined as Teva contends;[5] that the scope of the prior art covers the three items cited by Teva, the '726 patent, the '431 patent, and the Brandstrom article; and that lansoprazole's structure differs from rabeprazole's only by its trifluoroethyoxy (OCH_2CF_3) substituent at the 4-position of the pyridine ring, where rabeprazole bears a methoxypropoxy ($OCH_2CH_2CH_2OCH_3$) substituent. (P. Reply Mem. 4, n.3; see D. Mem. 8 for more detailed description of substituents.) Eisai has

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[4] Defendant mistakenly asserts that the ultimate conclusion, of whether the invention is indeed obvious because the professed combination of prior art would have been made, is a question of fact: "At minimum, there are genuine issues of material fact as to whether a [person of ordinary skill in the art] would have selected lansoprazole as a lead compound." (D. Mem. 15.) The scope and content of, and teachings involving, lansoprazole may present issues of fact – which issues the Court assumes, for purposes of this decision, would be resolved favorably to Teva. But whether the ordinary skilled person would have concocted the combination alleged, using lansoprazole to achieve rabeprazole, is most certainly a question of law: That is the very analysis of obviousness.

[5] As of November 1986, that ordinary skilled person "would have a graduate degree in one of the fields of medicinal chemistry, pharmacology, organic chemistry, biochemistry, or pharmaceutical chemistry, and would have practical experience in an academic or industrial laboratory." (D. R. 56.1 Stmt. ¶ 74, citing opinions of Teva experts, Fuller and Cooperman.) That person would have collaborated extensively with those in the referenced fields other than her own, thus becoming knowledgeable in those fields. (Id. ¶ 76.) She would also "have learned about patent protection of pharmaceuticals." (Id. ¶ 75.)

expressly declined to submit any evidence regarding the secondary-considerations prong of the obviousness analysis. (P. Reply Mem. 4.) Thus, the Court finds no dispute of material fact as to the Graham factors.

The Court further accepts as undisputed for the sake of resolving this motion all the teachings Teva asserts would have led to the making of the combination. These, and all the evidence as a whole, however, are inadequate to sustain a judgment by clear and convincing evidence that the ordinary skilled person would have made the combination alleged. It simply is not possible on this record for Teva to meet its considerable burden of proof that this particular combination of prior art renders rabeprazole obvious.

While obviousness analysis is a totality-of-evidence inquiry, it is unnecessary to this decision to discuss each step of the combination Teva has proposed. The inadequacy of proof as to one key step alone suffices to negate the possibility of ultimately persuading a reasonable factfinder on the stated standard. That step is the incorporation of lansoprazole as the conceptual foundation of the asserted combination.

Generously viewed, defendant offers three reasons an ordinary skilled person would have selected lansoprazole as her "lead compound." (D. Mem. 16.) First, Teva points to data disclosed in the '726 patent application showing lansoprazole to be "twenty times superior" to the then most widely known gastric-acid-inhibitor, omeprazole. (Id. at 2.) The superiority is asserted with respect to "[a]nti-ulcer action," as measured in an "indomethacin-induced gastric lesion assay in rats," described in the '726 patent as "a model mimicking human gastric ulcer." (D. Mem. 5, citing '726 Patent at 9-10.) Teva insists that the data – despite its rather broad label of "anti-ulcer" activity – would have been understood by the ordinary skilled person to be at

least indicative of the tested compounds' potency in inhibiting gastric-acid secretion, a property of rabeprazole. (D. Mem. 18, citing Fuller Decl. 1 ¶¶ 40-41, 61; D. Ex. 78, Fuller Tr. 270:23-273:2, 312:22-313:28; D. Ex. 77, Cooperman Tr. 125:9-18, 127:2-128:2.) Teva submits that the '726 patent application overall claims compounds "having excellent properties for gastric acid secretion" and useful for treating ulcers. (D. R. 56.1 Stmt. ¶ 64, citing P. Ex. 9, '726 Patent Application at 1, 10-11.) For present purposes, the Court accepts Teva's experts' interpretations of the data. As will be further discussed, this submission is the *only* evidence that would go to supporting defendant's proposition that the ordinary skilled person would have employed lansoprazole at all.[6]

Second, Teva contends that the ordinary skilled person would have been attracted to lansoprazole for its lipophilicity,[7] a trait that would have been identifiable from the presence of fluorine atoms (at the 4-position of lansoprazole's pyridine ring).[8] (D. Mem. 10; Cooperman

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[6] It is undisputed that there were no published clinical data for lansoprazole as of 1986 and that, indeed, the only publicly available information regarding lansoprazole at the time existed in the '726 application itself. (D.. R. 56.1 Stmt. ¶¶ 11-12.) Teva's expert, Fuller, opines that the ordinary skilled person "would have understood that ['726's inventors] . . . would have obtained in vitro and in vivo assays of the compounds disclosed in [] '726 to characterize their anti-secretory properties before obtaining the results reported[,] . . . because that was the standard practice in the art." (Fuller Decl. 1, ¶ 66.) Even taking this opinion as undisputed, it does not serve to widen the scope of the data that an ordinary skilled person would have been able to consider; Fuller does not venture to surmise what the ordinary skilled person would have presumed about the '726 inventors' private assays.

[7] Teva's definition of the term is undisputed: "Lipophilicity is a measure of the ability of a drug compound to cross lipid membranes." (D. Mem. 10 at n.16.)

[8] Teva does not attribute lansoprazole's purported efficacy solely to its fluorinated substituent, but rather asserts that the compound's activity also derives from the 3-, 4-position substitution pattern of its pyridine ring. (See, e.g., D. R. 56.1 Stmt. ¶ 31.) However, this assertion, taken as undisputed for present purposes, goes toward justifying Teva's vision of the *modification* of the compound once lansoprazole had already been selected, not toward the original *selection* of the lead compound.

Decl. 1 ¶¶ 84, 119.) For purposes of this decision, it is assumed as undisputed that Teva would prove lansoprazole's "desirable lipophilicity."[9] (D. Mem. 19.)

Yet the opinions of Teva's own experts suggest that lipophilicity was a pharmacological property already considered to be important, based on background knowledge in the art, by the ordinary skilled person. (D. R. 56.1 Stmt. ¶ 33, citing portions of reports and testimony of Cooperman and Fuller.) Teva nowhere asserts that lansoprazole or the '726 patent more broadly were the sources that taught ordinary skilled persons this property; indeed, existing background knowledge is what Teva argues would have caused the ordinary skilled person to recognize this attribute of lansoprazole in the first place. Construing Teva's presentation most favorably, defendant could be taken to argue that lansoprazole – while not the teacher of lipophilicity itself – taught a *special path* to achieving lipophilicity, via its fluorinated substituent. But Teva's expert, Cooperman, in fact identifies a different reference that teaches that fluorine-substituted groups increase lipophilicity. (Cooperman Decl. 1 ¶ 85, citing secondary-source textbook.) Moreover, if that *is* lansoprazole's particular lipophilicity teaching, then the fact would do nothing to make sense of Teva's proffered narrative of combination, wherein the fluorinated substituent is deliberately dropped to form rabeprazole.[10] (D. Mem. 10-11.)

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[9] It is also assumed, arguendo, that lipophilicity is a claimed trait of rabeprazole, making that property a viable factor of obviousness.

[10] If anything, the representations of Teva expert, Cooperman, dissuade the Court from considering whether the ordinary skilled person would have viewed lipophilicity as a grounds for selecting lansoprazole in the first place. He cautions that his opinions should not be taken to suggest that "maximiz[ing] lipophilicity" would necessarily have been a priority for the ordinary skilled person looking to make a new proton-pump inhibitor such as rabeprazole; rather, the known benefits of lipophilicity would merely have "motivated [the ordinary skilled person] to maintain the level of lipophilicity of a lead compound so as not to have to re-optimize it." (Cooperman Decl. 3 ¶ 45.) In other words, he shies from advancing lipophilicity as a rationale

The lipophilicity-related rationale for selecting lansoprazole does not merely fail to help support Teva's allegation by clear and convincing evidence; rather, Teva's own submissions tend to make clear a contrary conclusion: that the ordinary skilled person, already schooled to seek lipophilicity in designing a compound, would *not* have selected lansoprazole for this reason – certainly not just in order to, then, proceed to drop the feature that defendants assert endowed lansoprazole with impressive lipophilicity.

Finally, construing Teva's submissions most favorably, defendant could be taken to assert that lansoprazole would have been selected, in part, for its molecular weight, lower molecular weight being a feature that for present purposes is assumed to have been valued by the ordinary skilled person at the time. (Cooperman Decl. 3 ¶ 59.) But Teva nowhere offers evidence of the particular desirability of lansoprazole's weight. Indeed, like the lipophilicity argument, this one attempts to explain the alleged path of *modification*, not the initial choice of lansoprazole. (See Cooperman Decl. 3 ¶ 59, "Keeping the molecular weight of candidate compounds at or below a particular range was the practice of the [ordinary skilled person] . . . in 1986.")

Nor is the alleged usage of lansoprazole necessitated or explained by teachings, taken for now as undisputed, that Teva asserts may be found in the other art suggesting rabeprazole. Briefly, these teachings include the following from the Brandstrom article: That a benzimidazole-sulfinylmethyl-pyridine chemical structure is necessary for anti-ulcer activity (D. Mem. 9, citing Brandstrom article at p. 21); that the benzimidazole ring should be unsubstituted

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for *choosing* lansoprazole from among the universe of possible compounds, instead explaining it as a factor to consider in *modifying* a compound once it is chosen.

(Cooperman Decl. 1 ¶¶ 66, 79); that improving a compound's anti-ulcer activity relates to drawing higher electron density to its pyridine ring (D. Mem. 10, citing Cooperman Decl. 1 ¶¶ 76, 85-86; D. Ex. 77, Cooperman Tr. 259-60); that it is best not to place substituents at each of the 3-, 4-, and 5-positions of the pyridine ring, because of the risk of "steric crowding" (Cooperman Decl. 3 ¶ 43); that substituting the 3- and 4-positions – and not the 5-position – of the pyridine ring of a benzimidazole-based compound is preferred, since the compound in Brandstrom displaying the highest in vitro activity exhibited such a substitution pattern (D. Mem. 9, citing Cooperman Decl. 3 ¶ 44); that the 3-position of the pyridine ring of a benzimidazole-based compound may be a methyl group (D. Mem. 9, citing Cooperman Decl. 1 ¶ 82); and that the 4-position substituent of the pyridine ring may be varied (D. Mem. 9, citing Cooperman Decl. 1 ¶ 82.)

Other teachings alleged by Teva and taken arguendo as undisputed include: that, according to the '431 patent, methoxy, ethoxy, methoxyethoxy, or ethoxyethoxy were candidates for substituting the 4-position of a benzimidazole-based compound's pyridine ring (D. Mem. 10-11, citing Cooperman Decl. 1 ¶¶ 90-92; Cooperman Decl. 2 ¶ 21); that ethoxyethoxy would have struck the ordinary skilled person, based on general knowledge, as preferable for its lipophilicity (D. Mem. 11, citing Cooperman Decl. 1 ¶ 85); that the ordinary skilled person, based on her familiarity with patenting concerns, would have sought a 4-position substituent that would not have infringed the claims of the '431 patent (D. Mem. 11, n.11); and, that by exploring possible variations on the ethoxyethoxy suggested by the '431 patent, the ordinary skilled person would eventually have come up with methoxypropoxy as a reasonable option (D. Mem. 11-12, 22, citing Cooperman Decl. 1 ¶¶ 25, 85, 95, 97).

Nothing about these teachings requires or even suggests the use of of lansoprazole as a lead compound. Rather, Teva offers these teachings solely to explain modifications that would have been performed once lansoprazole was selected. Thus, the key showing upon which the very selection of lansoprazole must rest – and upon which the possibility of Teva's purported combination must, necessarily, also rest – is that lansoprazole bested a competitor compound, omeprazole, in an "indomethacin-induced" test on rats ("indomethacin test") to show "[a]nti-ulcer action" (D. Mem. 5), and that the ordinary skilled person would have taken these *anti-ulcer* data as indicating superior ability to *inhibit acid secretion*, the uncontested chief property of rabeprazole.[11]

But Teva has made no persuasive showing that a compound's performance in this anti-ulcer test would have been taken by an ordinary skilled person at the time as a telling measure of its power to inhibit acid secretion. Its own pharmaceuticals expert testified that "[t]he level of acid secretion . . . from these data . . . cannot be determined," and that it was impossible to discern from the test data the relative acid-secretion levels among rats treated with lansoprazole as opposed to omeprazole. (Teva Ex. 78, Fuller Tr. 271:13-273:2.) Moreover, that expert acknowledged that the indomethacin test could have been used by those skilled in the art to measure properties other than acid-inhibition. (Id. at 285:2-25, 289:13-19.) The expert also testified that, while the indomethacin test on rats would have been "one of the battery of tests that would be used to validate activity," the "standard test for quantitating *antisecretory* activity

[11] For further information about rabeprazole's claimed properties and about omeprazole and lansoprazole, see Eisai, ___ F. Supp. 2d. at ___.

in intact animals in 1986 would have been the fistula [dog test]."[12] (Id. at 312:22-313:18.)

Against these deficiencies in its own presentation, Teva's supporting submissions fail to convince. To overcome the presumption of validity and prevail at trial, Teva would have to show by "clear and particular . . . actual evidence," Teleflex, 299 F.3d at 1334, the existence of a specific suggestion to the ordinary skilled person in 1986 of "the desirability, and thus the obviousness, of making the combination" based on lansoprazole. In re Fulton, 391 F.3d at 1200. While Teva would not need to show the "absolute predictability" of its lansoprazole-based combination (D. Mem. 4), it would nevertheless have to prove with particularity the obviousness of choosing that path across an uncontestedly wide terrain of numerous similar compounds – including the "gold standard," omeprazole, for which relatively plentiful data proving efficacy was publicly available. (D. R. 56.1 Stmt. ¶ 63.) Teva's fact and expert evidence cannot justify with the required particularity the foundational step of selecting lansoprazole to achieve its proposed combination.

That the indomethacin test was said, in a scientific article then available, to be "a disease model used to measure the anti-ulcer efficacy of gastric acid anti-secretory agents" (Fuller Decl. 1 ¶ 40), cannot prove that *this* test, disclosed in the '726 application, was used in such a way or that the data would have led the ordinary skilled person to deduce lansoprazole's anti-secretory superiority. The contrary opinion of expert Fuller merely assumes that the test data signify what

[12] Teva makes much of Eisai's typographical error appearing to concede the major point that the "rat test in [] '726 was a standard test for measuring anti-secretory activity." P. R. 56.1 Stmt. ¶ 25. Teva, pointing to that statement, declares that "it is undisputed in this litigation that the data from the indomethacin test . . . measure the effects of gastric acid secretion." D. R. 56.1 Stmt. ¶ 26. However it is clear from the citation attached to Eisai's statement – to the very Fuller testimony quoted in the accompanying text to this note – that plaintiffs meant to write that the rat test, unlike the dog test, was *not* a standard test for measuring anti-secretory activity.

Teva has not shown it can prove: "Because of its high oral *in vivo* anti-secretory anti-ulcer potency lansoprazole would be recognized as a good starting point compound." (Id. ¶ 48.) Another Teva expert testifies that the indomethacin test data would have been viewed by the ordinary skilled person as "consistent with [the] anti-secretory properties" that the compounds of the '726 would have been "reasonably expect[ed]" to exhibit, thus providing a "reasonable basis on which to select one of the compounds of [] '726 as a starting point." (Forte Decl. 1 ¶¶ 79,80.) But this attenuated conclusion hardly approaches the heightened standard of proof required to explain the choice of lansoprazole to produce rabeprazole.[13] Expert testimony of a "good" or "reasonable" starting point is not sufficient to permit a finding by clear and convincing evidence that this combination is not just attractive in hindsight, but rather would have been made at the relevant time.

Without persuasive evidence of lansoprazole's place in the pattern, Teva's asserted combination falls apart. A reasonable factfinder could not, on the existing record, conclude that a person of ordinary skill in the art would have made the asserted combination, thus rendering the challenged invention obvious, at the time it was made.

CONCLUSION

For the reasons stated above, summary judgment of patent validity is granted.

[13] Eisai correctly notes that Teva expert Cooperman "admitted that he is not qualified to opine on the interpretation of the anti-ulcer tests in the [] '726 patent" and instead testified that he would rely on Fuller's opinion. (P. Mem. 6; see Teva Ex. 77, Cooperman Tr. 108:2-14, 127:7-19, 128:3-23.)

SO ORDERED.

Dated: New York, New York
October 5, 2006

GERARD E. LYNCH
United States District Judge