United States District Court,
E.D. New York.

KING PHARMACEUTICALS, INC., et al,
Plaintiffs/Counterclaim Defendants.
v.
EON LABS, INC,
Defendant/Counterclaim Plaintiff.

No. 04-cv-5540 (DGT)

Jan. 20, 2009.

Background: Patent holder filed action against competitor alleging infringement of patents directed toward methods of informing patients about and administering muscle relaxant metaxalone. Competitor asserted affirmative defenses and counterclaims for invalidity, fraud, and unclean hands. Competitor filed motion for summary judgment of invalidity.

Holdings: The District Court, Trager, J., held that:
(1) patent claim that had been based on discovery of naturally occurring side effect of increased bioavailability to known practice of administering metaxalone with food to decrease nausea was invalid due to anticipation;
(2) discussion or suggestion in prior art of taking metaxalone with food was sufficient to qualify as disclosure of "invention" of taking metaxalone with food, regardless of whether anyone actually ingested metaxalone with food;
(3) patent claim directed toward methods of informing patients about and administering muscle relaxant metaxalone was obvious;
(4) commercial success of patented product and generic manufacturers' proposal to use product labels and package inserts disclosing information regarding food effect of metaxalone were not objective indications of nonobviousness;
(5) "wherein" clause that merely recited inherent property of prior art could not be material to patentability;
(6) informing patient of effect of taking metaxalone with food, as inherent property of prior art, was unpatentable;
(7) claim which added step of informing patient that administration of metaxalone with food resulted in increase in Cmax and AUC(last) of metaxalone compared to administration without food was invalid as unpatentable; and
(8) claim which added step of limitation that metaxalone was from container with printed labeling advising of food effect was invalid as unpatentable.

Motion granted.

6,407,128, 6,683,102. Construed and Ruled Invalid by.

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MEMORANDUM AND ORDER

TRAGER**, District Judge:**

Plaintiffs King Pharmaceuticals, Inc. and King Pharmaceuticals Research and Development, Inc. (collectively, "King") brought this action against defendant Eon Labs, Inc. ("Eon") for infringement of U.S. Patents Nos. 6,407,128 ("the '128 patent") and 6,683,102 ("the '102 patent"), which are directed to methods of informing patients about and administering the muscle relaxant metaxalone-marketed by King under the brand name "Skelaxin(R)"-with food.

Eon now moves for summary judgment of invalidity of the '128 and '102 patents, and King moves to dismiss Eon's counterclaims.

Background FN1

FN1. Some information for the Background was taken from documents filed in a related case, *Elan Pharmaceuticals v. Corepharma, LLC,* 03-cv-2996 ("the *Corepharma* case").

The Food and Drug Administration ("FDA") first approved use of metaxalone in the early 1960s. The patent on metaxalone was issued in 1962 and expired long ago. *See* U.S. Patent No. 3,062,827. King's predecessor, Elan Pharmaceuticals, Inc. ("Elan") had been marketing Skelaxin in a 400 mg strength tablet for some time when it sought approval to market Skelaxin in an 800 mg strength tablet. In response, the FDA required Elan to conduct a bioequivalence study. Elan protested the requirement, writing to the FDA to explain the reasons it did not believe a bioequivalence study was necessary. Despite its initial reluctance, Elan ultimately did conduct a bioequivalence study. In the course of the study, Elan discovered that the drug is found in greater concentrations in the blood of fed subjects than in the blood of fasting subjects. Armed with these test results, Elan filed a patent application with the United States Patent and Trademark Office, claiming a method of increasing the bioavailability of metaxalone by administering it with food. This application eventually issued as the '128 patent. After purchasing certain patent rights from Elan, King filed a continuation patent application which issued as the '102 patent.

Discussion

(1)

Validity

[1] Eon alleges that all of the claims of the '128 and '102 patents are invalid for anticipation by the prior art under 35 U.S.C. s. 102(b), and that a subset of the claims are alternatively invalid for obviousness under 35 U.S.C. s. 103(a). The patents are presumed valid, and Eon has the burden of proving invalidity by clear and convincing evidence. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1374 (Fed.Cir.2001).

[2] A patent is invalid if the invention claimed in it was "described in a printed publication in this or a foreign country ... more than one year prior to the date of the application for patent in the United States." 35 U.S.C. s. 102(b). For a prior art publication to "anticipate" a patent claim, it must "expressly or inherently disclose each claim limitation." Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1334 (Fed.Cir.2008). On the other hand, a claim is invalid for obviousness when "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. s. 103.

a. The prior art

Eon points to six prior art references that it argues invalidate the claims of the '128 and '102 patents under either 35 U.S.C. s. 102(b) or s. 103.

i. Fathie I

In November 1964, Kazem Fathie, M.D., published an article titled, "A Second Look at a Skeletal Muscle Relaxant: A Double-Blind Study of Metaxalone," in 6 Current Therapeutic Research 677 ("Fathie I"). Decl. of Mher Hartoonian in Supp. of Def. Eon Labs, Inc.'s Mot. for Summ. J. that the '128 and '102 Patents Are Invalid for Anticipation and/or Obviousness ("Hartoonian Decl."), Ex. 3. Fathie I describes two double-blind studies in which patients with "low-back pain and discomfort" were administered either metaxalone or placebo. Those who received metaxalone were prescribed a recommended dose of "two [400 mg] tablets *after each meal* and at bedtime." *Id*. at 678-79 (emphasis added).

ii. Fathie II

In April 1965, Dr. Fathie published an article titled, "Musculoskeletal Disorders and Their Management with a New Relaxant," Clinical Medicine 678 ("Fathie II"). Hartoonian Decl., Ex. 4. In it, Dr. Fathie describes a clinical study in which metaxalone was administered to patients with musculoskeletal disorders. The patients were prescribed 800 mg of metaxalone, to be taken three or four times daily. The article notes that "[metaxalone was well accepted and except for mild nausea in six cases, was apparently well tolerated. Nausea might have been less prominent if the medication had been taken *with food*." *Id*. at 682 (emphasis added).

iii. Morey

Lloyd W. Morey and Allan R. Crosby published an article entitled, "Metaxalone, a new skeletal muscle relaxant," in The Journal of the American Osteopathic Association 517/61 in February 1963. Hartoonian Decl., Ex. 5. In it, they describe a study in which 61 patients suffering from striated muscular spasm were "given two tablets four times daily, *after meals* and at bedtime; the amount of the metaxalone per capsule was 400 mg., for those who received it." *Id*. at 518/62 (emphasis added).

iv. Albanese

Joseph A. Albanese published an entry on metaxalone in the 1982 edition of Nurses' Drug Reference (2d ed.). Hartoonian Decl., Ex. 6. Albanese teaches that metaxalone is available in 400 mg tablets, that the dose range for metaxalone is "800 mg 3-4 times daily" and also that "[a]dministration *with meals* will help reduce gastric upset." *Id*. at 427 (emphasis added).

v. Abrams

In 1995, Anne C. Abrams published *Clinical Drug Therapy* (4th ed.), in which she teaches that metaxalone should be administered in a dosage of "800 mg 3 or 4 times daily" and that it should be given " *with milk or food* [to] decrease gasrointestinal distress." Hartoonian Decl., Ex. 7 at 146-47 (emphasis added).

vi. Dent

In September 1975, R.W. Dent, Jr. and Dorothy K. Ervin published an article entitled, "A Study of Metaxalone (Skelaxin) vs. Placebo in Acute Musculoskeletal Disorders: A Cooperative Study," in Current Therapeutic Research, vol. 18, no. 3. Hartoonian Decl., Ex. 13. They describe a study in which "[p]atients were given either metaxalone 400 mg or placebo in tablets of identical appearance. The starting and most common dosage was two tablets *four times daily* .... However, the only other acceptable schedule was one tablet q.i.d. [four times daily]." *Id*. at 434 (emphasis added).

Thus, Fathie II, Albanese and Abrams all describe or suggest taking metaxalone with food; Fathie I and Morey both disclosetaking metaxalone after meals; and Dent describes taking metaxalone four times daily. King admits that each of these publications list publication dates that predate the applications for the '128 and '102 patents by more than one year, yet it denies that they qualify as prior art under 35 U.S.C. s. 102(b). FN2 The basis for King's denials is unclear, given that "[p]rinted materials purporting to be newspapers or periodicals" are self-authenticating under Fed.R.Evid. 902(6).

FN2. Section 102(b) defines prior art as an invention "described in a printed publication in this or a foreign country ... more than one year prior to the date of the application for patent in the United States."

b. The patents in suit

i. The '128 patent

[3] The '128 patent contains twenty-two claims, three of which are independent. Each of the independent claims (claims 1, 9 and 17) requires the steps of administering metaxalone to a patient with food.

Claim 1

Specifically, claim 1 of the '128 patent requires:

1. A method of increasing the oral bioavailability of metaxalone to a patient receiving metaxalone therapy comprising

administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food.

[4] Claim 1 can be broken into a preamble, which ends with the word "comprising," and the steps of the claimed method. King argues that the preamble of claim 1 is a limitation, while Eon contends that the preamble merely expresses the intended purpose of the claimed invention and is, therefore, not limiting. The limiting effect of the preamble is critical for claim 1's survival, because the remainder of the claim-administering metaxalone with food-is disclosed in Fathie II, Albanese and Abrams.

[5] [6] It is noted that King argues that none of the prior art publications describe anyone actually taking metaxalone with food. That may be true,FN3 but it is also irrelevant, as "anticipation does not require actual performance of suggestions in a disclosure." Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1379 (Fed.Cir.2001). "Rather, anticipation only requires that those suggestions be enabling to one of skill in the art." Id. Thus, the fact that Fathie II, Albanese and Abrams each discuss or suggest taking metaxalone with food is sufficient to qualify as a disclosure of the "invention" of taking metaxalone with food, regardless of whether anyone actually ingested metaxalone with food.

FN3. Of the publications suggesting taking metaxalone with food, only Fathie II involved a clinical trial in which patients actually ingested the drug and its suggestion to take metaxalone with food is mentioned as a hindsight analysis of something that might have helped patients tolerate the drug better.

King further argues that none of the prior art publications would enable one of skill in the art to practice the claimed methods without undue experimentation. Specifically, King asserts that one of skill in the art would need to see pharmacokinetic studies about the metaxalone food effect in order to practice the claimed inventions. Perhaps this argument would be persuasive if the claims required modulating the amount or type of food in order to achieve a specific increase in bioavailability, but as they stand, all but claims 12-15 of the '102 patent require simply administeringmetaxalone with food or informing a patient that taking metaxalone with food will increase bioavailability.

[7] Generally, a preamble limits a claim only "if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Symantec Corp. v. Computer Assocs. Intern., Inc., 522 F.3d 1279, 1288 (Fed.Cir.2008) (quoting Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed.Cir.2002)). Thus, a preamble is not limiting where it is used "only to state a purpose or intended use for the invention." Id.

[8] Although the preamble of claim 1 clearly states a purpose or intended use for the invention, King offers three arguments for why the preamble should, nonetheless, be construed as a limitation.FN4 First, King argues that the preamble provides an antecedent basis for the term "the patient" referred to in the body of the claim. However, defining "the patient" as one who is "receiving metaxalone therapy" merely duplicates the step of administering metaxalone to the patient and is thus unnecessary as an antecedent basis. Second, King argues that the examiner understood "increasing oral bioavailability" to be an essential element of the claimed method, because he suggested that applicants amend the claim to add that language to the preamble. Third, King argues that its construction is supported by the doctrine of claim differentiation, because without their preambles, claims 1 and 9 of the ' 128 patent would be identical. However, not only is claim differentiation "a guide, not a rigid rule," but "two claims with different terminology can define the exact same subject matter." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380

(Fed.Cir.2006).

FN4. In the *Corepharma* case, which involved the same patents, King argued to the contrary that the preambles of claims 1-4 and 6 of the ' 102 patent were not limitations, noting that the preambles merely "state a purpose or the intended use of the invention." King Pharmaceuticals, Inc. and Jones Pharma Inc's Opp'n to Corepharma LLC's Mot. for Summ. J. on the Issues of Infringement and Inducement of Infringement (docket entry no. 175), at 12.

Even if the examiner understood the preamble to distinguish the claim from the prior art, Eon argues persuasively that the preamble should, nonetheless, be non-limiting. Significantly, the preamble "does not result in a *manipulable difference* in the steps of the claim." Ben Venue, 246 F.3d at 1376. In other words, the physical steps claimed in claim 1-administering metaxalone with food-are identical to those set forth in Fathie II, Albanese and Abrams. The only difference between claim 1 and the prior art is the thought process of the practitioner (i.e., is the direction to take metaxalone with food given to increase bioavailability or to decrease nausea?).

[9] For over forty years it has been known to give metaxalone with food. The fact that King discovered a naturally occurring side effect to the known practice of administering metaxalone with food does not entitle it to a valid patent. "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." Ben Venue, 246 F.3d at 1376. The Federal Circuit has warned not to parse too finely the requirement that the prior art and patented processes be "directed to the same purpose":

Both the '211 and the '176 patents disclose methods which held to ensure that sevoflurane will be of a high purity at the time it is administered to patients. The [prior art] '211 patent discloses a method of achieving that end by adding water and then distilling the solution, which results in removing impurities from the sevoflurane, while the '176 patent [in suit] accomplishes the same objective by merely adding water, which results in safeguarding the sevoflurane against impurities generated by the presence of Lewis acids. All of the steps of the '176 patent are thus disclosed in the ' 211 patent in furtherance of the same purpose: the delivery of safe, effective sevoflurane anesthetic. All that is contributed by the method claims of the '176 patent is the recognition of a new property of the prior art process.

Abbott Labs. v. Baxter Pharma. Prods., Inc., 471 F.3d 1363, 1369 (Fed.Cir.2006). Here, the overarching purpose of both the prior art and claim 1 is to treat effectively musculoskeletal disorders with metaxalone. The fact that taking it with food happened to increase bioavailability in addition to decreasing nausea is no different from the result in the Abbott Labs case, in which the addition of water neutralized Lewis acids in both the prior art and the claimed invention, even though the prior art did not recognize that particular effect of adding water. Likewise here, the prior art's failure to recognize that taking metaxalone with food also increased bioavailability does not make it a new method.

[10] Eon argues that even if the preamble were limiting, claim 1 would still be anticipated by the prior art, because an increase in the bioavailability of metaxalone is inherent when the drug is taken with food. Indeed, the '128 patent does not identify any additional conditions that must be present for the food effect to occur. Rather, it occurs naturally in most people when they take metaxalone with food. "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed.Cir.1999). It

is irrelevant that Fathie II, Albanese and Abrams did not recognize that administering metaxalone with food would increase its bioavailability. Id. ("Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art."); *see also* Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 1378 (Fed.Cir.2003) ("[T]his court's precedent does not require a skilled artisan to recognize the inherent characteristic in the prior art that anticipates the claimed invention.").

Indeed, the patent claim at issue in the MEHL/Biophile case included the preamble, "A method of hair depilation," whereas the inherently anticipating reference involved a study of the epilated backs of guinea pigs and did not mention hair depilation as a goal. MEHL/Biophile, 192 F.3d at 1364, 1366. The only factors that mattered to the inherent anticipation analysis were that the steps of the claimed method were disclosed in the prior art reference and that the result claimed in the patent was "a necessary consequence of what was deliberately intended" in the prior art reference. Id. at 1366. Here, the steps of administering metaxalone with food are disclosed in the prior art, and an increase in bioavailability was a necessary consequence of the deliberate administration of metaxalone with food.

King argues that increased bioavailability does not "necessarily" result from ingesting metaxalone with food, pointing to the clinical studies disclosed in the '128 patent. King's Mem. of Law in Opp'n to Eon Labs, Inc.'s Mot. for Summ. J. of Invalidity at 8, n. 7; Elia Decl. para.para. 26-29; Barber Decl. para. 93. Indeed, Table I of the '128 patent shows that of 42 patients to complete the bioavailability study, 9 (subjects 2, 3, 19, 26, 29, 34, 36, 39 and 44) FN5 experienced decreased concentrations of metaxalone when taken with food. Thus, the ' 128 patent itself does not show that an increase in bioavailability is present each and every time metaxalone is administered with food. Assuming that the clinical studies described in the ' 128 patent were representative of the food effect of metaxalone on the general population, the result of increased bioavailability must have occurred to the same extent in the prior art-when food was given with metaxalone to decrease nausea-as it does in the ' 128 patent. King's demand that, in order to anticipate, a reference must show increased bioavailability each and every time metaxalone is administered with food thus holds the prior art to a higher standard than the patent. Not only is this argument unsupported by the case law; it would also present substantial obstacles for King to ultimately prove infringement. Given the bedrock principle of "that which infringes if later, anticipates if earlier," SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1321 (Fed.Cir.2006), King's argument would appear to require actual tests of blood serum levels to prove any single act of infringement.

FN5. Both parties (and King's experts) note that four subjects showed a decreased amount of metaxalone absorbed when taken with food, but they neglect to mention the five subjects listed in the continuation of Table I on the next page of the patent that also showed a decrease.

[11] The case King relies on for requiring that a prior art reference lead to the claimed result "each and every time" the prior art process is practiced involved a prior art practice which could lead to two different types of crystal-one claimed by the patent and one not. Glaxo, Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047-48 (Fed.Cir.1995). Rather than set forth an "each and every time" requirement, the Federal Circuit merely affirmed the district court opinion, stating that it was "not persuaded that [the district court's] findings are clearly erroneous." Id. More recently, the Federal Circuit has found that a prior art patent inherently disclosed light emitting diodes ("LEDs") that are "effective to impinge sufficient UV light on the ink to substantially cure the ink" where the LEDs could perform such substantial curing under certain controlled circumstances, but not necessarily under normal operating conditions. Leggett & Platt, Inc. v. VUTEk, Inc.,

537 F.3d 1349, 1354-55 (Fed.Cir.2008). Thus, to inherently anticipate, the prior art need only give the same results as the patent, not better.

Accordingly, because the '128 patent teaches nothing more than administering metaxalone with food to increase its bioavailability and because Fathie II, Albanese and Abrams all teach administering metaxalone with food-which inherently increases metaxalone's bioavailability-claim 1 is anticipated by Fathie II, Albanese and Abrams.

[12] Anticipation by Fathie I, Morey and Dent is not so clear. The doctrine of claim differentiation teaches that an independent claim is generally broader than the claims which depend from it. *See* Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed.Cir.2005); Dow Chem. Co. v. United States, 226 F.3d 1334, 1341-42 (Fed.Cir.2000). Here, claim 1 requires administration of metaxalone "with food," whereas claim 4 narrows the time frame for which metaxalone administration may be considered to be "with food" to between 30 minutes prior to 2 hours after consuming food. Thus, claim 1 must allow for administration "with food" to be outside the parameters set by claim 4. King's experts opine that "with food" means from about 1 hour before to about 2 hours after eating. Barber Decl. para. 60; Elia Decl. para. 30. Fathie I and Morey both teach administration of metaxalone after each meal and at bedtime, and Dent teaches administration four times daily. Assuming normal eating patterns, the schedules prescribed by Fathie I, Morey and Dent would likely, although not necessarily, lead to ingestion of metaxalone within at least three hours of consumption of food. It is, of course, theoretically possible that patients given instructions to take metaxalone after meals and at bedtime would space out their medication so as to take it many hours after their last meal and before their next. Indeed, King's experts opine that "after meals" can mean anytime at all after a meal. Barber para. 60; Elia para. 30. This is highly improbable, given normal eating habits and an explicit instruction to take the medication after meals, but viewing the evidence in the light most favorable to King, claim 1 is anticipated by Fathie II, Albanese and Abrams, but not by Fathie I, Morey or Dent.

Claims 2 and 3

Claim 2, which depends from claim 1, requires that the therapeutically effective amount of metaxalone be 200 mg to 900 mg. This claim is anticipated by each of Fathie II, Albanese and Abrams, which teach administering 800 mg of metaxalone with food three to four times daily. Claim 3, which also depends from claim 1 and requires that the therapeutically effective amount of metaxalone be 400 mg to 800 mg, is likewise anticipated by Fathie II, Albanese and Abrams.

Claims 4-7

Claim 4 depends from claim 1 and requires that administration of metaxalone to the patient occur between 30 minutes prior to 2 hours after consuming food. As with claim 1, this claim is anticipated by Fathie II, Albanese and Abrams. Claim 5 also depends from claim 1, and requires that administration of metaxalone to the patient is substantially at the same time as consumption of the food. This claim is anticipated by Fathie II, Albanese and Abrams, but for the same reasons stated above with respect to claim 1, it is not anticipated by Fathie I, Morey or Dent. Claim 6 depends from claim 1 and requires that administration to the patient is immediately after consumption of the food up to 1 hour after consumption. Like claims 4 and 5, claim 6 is anticipated by Fathie II, Albanese and Abrams. Claim 7 depends from claim 1 and further requires that the pharmaceutical composition comprise a tablet. This claim is anticipated by Albanese, which discloses that metaxalone is available in 400 mg tablets.

Claim 8

[13] [14] Claim 8, which depends from claim 7, requires that the tablet be in unit dosage form. The parties disagree as to the meaning of "unit dosage form." Neither party points to any intrinsic evidence (i.e., the claim language, specification or file history) that defines "unit dosage form." King argues, relying on its experts, that "unit dosage form" means that the entire dosage be contained in a single tablet, whereas Eon argues that two tablets could constitute a unit dosage form, pointing to testimony by one of the inventors that: "It's the dose that you-For example, you can give a dose, let us say, 800 milligram. The unit dose would be two-would be a 400 milligram tablet, that you would give two of them." Hartoonian Decl. Ex. 15 (Dep. of Michael Scaife) at 152.

The specification of the '128 patent does not define the term "unit dosage form," but the clinical study it describes involved the administration of one 400 mg tablet of metaxalone with food and water. The Dictionary of Pharmacy (Pharmaceutical Heritage), ed. Dennis B. Worthen, The Haworth Press (2004) defines "dosage form" as "pharmaceutical preparation intended for use by or administration to a patient with a minimum of further processing; examples: tablet, capsule, elixir, suspension." Meanwhile, it defines "dose" as "volume or quantity of a medicinal agent to be taken at one time (unit dose) or in a given time period; example: daily dose." Thus, the specification and dictionary definitions support King's construction.

Eon argues that, even if King's construction is accepted, claim 8 is obvious from Albanese in view of Dent. Dent discloses a unit dosage form as King construes the term (i.e., one 400 mg tablet four times daily), while Albanese teaches administration of metaxalone with meals. King reiterates its view that none of the prior art teaches administration of metaxalone with food-a view that is flatly contradicted by a plain reading of the prior art articles.

[15] King also argues that the commercial success of its Skelaxin product between 1998 and 2003 and the fact that generic manufacturers such as Eon propose to use product labels and package inserts disclosing information regarding the food effect of metaxalone are objective indications of nonobviousness. However, Eon points out that the commercial success King relies on existed prior to the study leading to the '128 and '102 patents. Furthermore, Eon's and other generic manufacturers' copying of King's package insert was required by the FDA. Accordingly, these factors do not weigh in favor of nonobviousness.

The Supreme Court has held that the proper question to ask in an obviousness analysis is whether a person of ordinary skill in the art, "facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to" combining the claimed prior art steps. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, ----, 127 S.Ct. 1727, 1744, 167 L.Ed.2d 705 (2007). King's experts have both defined a person of ordinary skill in the art as "a person familiar with the treatment of musculoskeletal conditions, general principles relating to pharmacokinetics, including a basic understanding of the parameters that reflect a drug's bioavailability, and general practices for administering drugs." Elia Decl. para. 9; Barber Decl. para. 9. Eon does not dispute this definition. Thus, the question is whether a person of such skill, confronted with Dent's teaching to take one 400 mg tablet of metaxalone four times daily and Albanese's suggestion to take metaxalone with food, would have seen a benefit to administering a 400 mg tablet of metaxalone at mealtimes. It seems quite clear that the answer is yes. As discussed above, although it is theoretically possible that a patient would take metaxalone four times daily but not at mealtimes, it is more likely that the patient would take the medication with meals, particularly in light of Albanese's suggestion that taking it with food can reduce stomach upset. Accordingly, claim 8 is obvious in light of Dent and Albanese.

Claims 9-16

Claim 9 requires:

9. A method of increasing the rate and extent of absorption of an oral dosage form of metaxalone as measured by the drug concentration attained in the blood stream over time in a patient in need of a therapeutic effect thereof comprising, administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food.

Claim 9 effectively reiterates the limitations of claim 1. For the same reasons stated above in connection with claim 1, claim 9 is anticipated by Fathie II, Albanese and Abrams. Claims 10-15, which depend from claim 9, mirror the added limitations of claims 2-7, and claim 16, which depends from claim 15, mirrors the limitation of claim 8. Thus, claims 10-15 are also anticipated by Fathie II, Albanese and Abrams, while claim 16 is obvious in light of Albanese in view of Dent.

Claim 17

Claim 17 requires:

17. A method of increasing the oral bioavailability of metaxalone to a patient receiving metaxalone therapy comprising administering to the patient a pharmaceutical tablet comprising 400 mg to 800 mg of metaxalone, with food, wherein the administration results in an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food.

[16] [17] The only difference between claim 17 and Albanese, which teaches administration of two 400 mg tablets of metaxalone with food, is the claimed result of increasing plasma concentration and absorption of metaxalone as compared to administration without food. Eon argues that the clause beginning with the word "wherein" should not be construed as a limitation, because it merely states an intended result of the claimed steps of administration of metaxalone with food. Indeed, the Federal Circuit has held that "[a] whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." Minton v. Nat'l Assoc. of Securities Dealers, 336 F.3d 1373, 1381 (Fed.Cir.2003). On the other hand, "when the 'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." Hoffer v. Microsoft Corp., 405 F.3d 1326, 1329 (Fed.Cir.2005).

Here, however, the "wherein" clause cannot be material to patentability, because it merely recites an inherent property of the prior art. Accordingly, claim 17 is anticipated by Albanese.

Claims 18-20

Claims 18-20, which depend from claim 17, mirror the timing limitations of claims 4-6. They are, therefore, anticipated for the same reasons claims 4-6 are anticipated.

Claims 21 and 22

[18] Claims 21 and 22 depend from claim 1. Claim 21 adds the step of informing the patient that administration of metaxalone with food results in an increase in Cmax and AUC(last) of metaxalone

compared to administration without food. Because the food effect is an inherent property of the prior art and, therefore, unpatentable, then informing a patient of that inherent property is likewise unpatentable. *See* Parker v. Flook, 437 U.S. 584, 594, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978) ("[T]he discovery of ... a phenomenon [of nature] cannot support a patent unless there is some other inventive concept in its application."). The Court of Appeals for the Federal Circuit recently clarified what processes or methods are eligible for patent protection. In re Bilski, 545 F.3d 943 (Fed.Cir.2008). In particular, the Federal Circuit held that a claimed method is patent-eligible under 35 U.S.C. s. 101 if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." Id. at 954. Claim 21 fails this test, because the act of informing anotherperson of the food effect of metaxalone does not transform the metaxalone into a different state or thing. Furthermore, "even if a claim recites a specific machine or a particular transformation of a specific article, the recited machine or transformation must not constitute mere 'insignificant postsolution activity.' " Id. at 957 (quoting Flook, 437 U.S. at 590, 98 S.Ct. 2522).

The Federal Circuit has precluded a finding of patent infringement based solely on dissemination of information. McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576, 1583 (Fed.Cir.1993). McElmurry was not a case dealing with pharmaceuticals and their labels, but rather a device used in coal-powered power plants. The plaintiff in that case argued that the defendant exceeded the scope of any right it may have had to practice the patented invention when it disseminated the design and specifications of the patented device to private contractors. The court rejected this argument, noting that "[t]he owner of a patent right may exclude others from making, using or selling the subject matter of a claimed invention. [The defendant's] dissemination of information obviously does not fall into any of these categories." Id.

[19] Claim 21 would be infringed by practicing the teachings of Fathie II, Albanese or Abrams and providing the patient with a copy of the '128 patent. Such a claim, which effectively allows a patentee to exclude others from informing people of (unpatentable) scientific discoveries is anathema to the aims of the patent statute, which favors disclosure. Claim 21 is, therefore, invalid.

[20] Claim 22 adds the limitation that the metaxalone is from a container with printed labeling advising of the food effect. Thus, the only difference between claim 22 and Fathie II, Albanese and Abrams is the addition of a printed label. The Federal Circuit has held that "simply attaching a set of instructions to [a known] product" does not entitle one to a patent. In re Ngai, 367 F.3d 1336, 1339 (Fed.Cir.2004). In Ngai, the prior art taught a kit comprising instructions and a buffer, whereas the patent claim at issue claimed a kit with the same buffer and a new set of instructions. Id. at 1338. Because the printed instruction sheet was the only difference between the claim and the prior art, and because the instruction sheet was not "functionally related" FN6 to the kit, the Federal Circuit held that the claim was not patentable. Id. at 1339. Otherwise, "anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product." Id. Accordingly, claim 22 is anticipated by Fathie II, Albanese and Abrams.

FN6. An example of printed matter that is "functionally related" to an invention is a band with printed digits developed by an algorithm that can be used for "educational and recreational mathematical" purposes. In re Gulack, 703 F.2d 1381, 1387 (Fed.Cir.1983).

ii. The '102 patent

The '102 patent is a continuation of the '128 patent and contains fifteen claims, four of which are independent. Three of the four independent claims (claims 1, 6 and 8) require informing a patient that taking

metaxalone with food increases the drug's bioavailability. The fourth independent claim (claim 7) requires obtaining the metaxalone from a container providing information regarding the food effect.

Claims 1-5

Specifically, claim 1 of the '102 patent reads:

1. A method of using metaxalone in the treatment of musculoskeletal conditions comprising:

providing the patient with a therapeutically effective amount of metaxalone; and

informing the patient that the administration of metaxalone with food results in an increase in at least one of C(max) and AUC (last) of metaxalone compared to administration without food.

Thus, claim 1 requires giving a patient metaxalone and informing the patient about an inherent property of the drug. All six of the prior art references cited by Eon describe administering metaxalone. For the same reasons discussed above in connection with claim 21 of the '128 patent, claim 1 of the '102 patent is invalid under 35 U.S.C. s. 101.

Claim 2 depends from claim 1 and requires that the amount of metaxalone be between 200 mg to 900 mg. Claim 3 depends from claim 2 and further requires that the amount of metaxalone be between 400 mg to 800 mg. As with claims 2 and 3 of the '128 patent, these claims are anticipated by Fathie II, Albanese and Abrams, which teach administering 800 mg of metaxalone with food three to four times daily. Claim 4 depends from claim 1 and requires that the metaxalone be in tablet form. As with claim 7 of the '128 patent, this claim is anticipated by Albanese, which discloses that metaxalone is available in 400 mg tablets. Claim 5 depends from claim 4 and requires that the tablet be in unit dosage form. Claim 5 is obvious for the same reasons claim 8 of the '128 patent is obvious.

Claim 6

Claim 6 of the '102 patent provides:

6. A method of using metaxalone in the treatment of musculoskeletal conditions comprising:

informing a patient with musculoskeletal conditions that the administration of a therapeutically effective amount of metaxalone with food results in an increase in at least one of C(max) and AUC(last) of metaxalone compared to administration without food.

Claim 6 does away with all physical steps and attempts to claim a monopoly on information. This claim is unpatentable under 35 U.S.C. s. 101 for the same reasons set forth with respect to claim 21 of the '128 patent.

Claim 7

Claim 7 of the '102 patent provides:

7. A method of using metaxalone in the treatment of musculoskeletal conditions comprising altering the oral bioavailability of metaxalone by:

obtaining metaxalone from a container providing information that administration of metaxalone with food increases at least one of C(max) and AUC(last) of metaxalone compared to administration without food, and

ingesting the metaxalone with food.

Claim 7 is invalid for the same reasons set forth with respect to claim 22 of the '128 patent.

Claim 8

Claim 8 of the '102 patent provides:

8. A method of using metaxalone in the treatment of musculoskeletal conditions comprising:

administering to a patient in need of treatment a therapeutically effective amount of metaxalone, with food, wherein the administration of the metaxalone with food results in an increase in at least one of C(max) and AUC(last) of metaxalone as compared to administration of metaxalone in a fasted state; and

informing the patient that the administration of a therapeutically effective amount of metaxalone in a pharmaceutical composition with food results in an increase in at least one of C(max) and AUC(last) of metaxalone compared to administration in a fasted state.

Claim 8 is invalid for the same reasons set forth with respect to claim 21 of the '128 patent.

Claim 9 depends from claim 8 and further requires that the metaxalone be from a container with printed labeling advising of the food effect. For the reasons set forth with respect to claim 22 of the '128 patent, claim 9 is invalid. Claim 10 depends from claim 9 and further requires that the metaxalone be in tablet form. As with claim 7 of the '128 patent, this claim is anticipated by Albanese, which discloses that metaxalone is available in 400 mg tablets. Claim 11 depends from claim 10 and further requires that the tablet contain 400 mg of metaxalone. This claim is also anticipated by Albanese.

[21] Claim 12 depends from claim 9 and further requires that the printed labeling advise that administering metaxalone with food results in an increase in C(max) of 177.5%. Claim 13 depends from claim 9 and further requires that the printed labeling advise that administering metaxalone with food results in an increase in AUC(last) of 123.5%. Claim 14 depends from claim 9 and further requires that the printed labeling advise that administering metaxalone with food results in an increase in AUC(inf) of 115.4%. Claim 15 depends from claim 8 and further requires that the metaxalone be in a 400 mg tablet and that the printed labeling advise that administration of metaxalone with food results in an increase in C(max), AUC(last) and AUC(inf) of 177.5%, 125.5% and 115.4%, respectively, compared to administration in a fasted state. All four of claims 12-15 thus differ from the prior art only in the content of the written material that accompanies the metaxalone. Because, as discussed above, a variation in written material that is not functionally related to the invention does not render a known product patentable, none of claims 12-15 is patentable. *See* In re Ngai, 367 F.3d at 1339.

Conclusion

Accordingly, all of the claims of the '128 and '102 patents are invalid.

(2)

Counterclaims

[22] King moves to dismiss Eon's affirmative defenses and counterclaims for invalidity under 35 U.S.C. s. 101, fraud, and unclean hands, arguing that Eon failed to provide fair notice of its s. 101 allegations, that it failed to plead fraud with particularity and that it failed to plead an "unconscionable act" in support of its unclean hands counterclaim. Eon counters that it has provided fair notice and properly pled its counterclaims and that they should not be dismissed with prejudice.

The counterclaims at issue, if resolved in Eon's favor on the merits, would result in nothing more than the '128 and '102 patents being held invalid or unenforceable. Because, as set forth above, all claims of the '128 and '102 patents have already been held invalid, it is not necessary to litigate the counterclaims at issue.

However, Eon has made a claim under 35 U.S.C. s. 285 that this is an exceptional case and that it should be awarded reasonable attorney's fees, both for this case and for a related case dealing with an 800 mg dose of metaxalone, docket no. 03-cv-0006. A finding of exceptional case is usually predicated on a holding of inequitable conduct, which is an issue for the court.

Accordingly, because the '128 and '102 patents are invalid, King's complaint is dismissed. King's motion to dismiss Eon's counterclaims is granted, as the counterclaims at issue are moot in light of the patents' invalidity. Eon may submit briefing concerning exceptional case and any underlying issues within sixty days of this order. King may respond within thirty days thereafter, and Eon may reply within twenty days of King's response.

SO ORDERED.

E.D.N.Y.,2009.
King Pharmaceuticals, Inc. v. Eon Labs, Inc.

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