

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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*Ex parte* PERIANNAN ADAIKAN and SOON CHYE NG

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Appeal 2007-3890  
Application 10/347,312  
Technology Center 1600

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Decided: January 25, 2008

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Before ERIC GRIMES, NANCY J. LINCK, and FRANCISCO C. PRATS,  
*Administrative Patent Judges.*

PRATS, *Administrative Patent Judge.*

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 involving claims to pharmaceutical compositions comprising prostaglandins. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.<sup>1</sup>

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<sup>1</sup> In this decision we consider only those arguments actually made by Appellants. Arguments that Appellants could have made but chose not to

STATEMENT OF THE CASE

*THE INVENTION*

The Specification discloses that various prostaglandins, including prostaglandin A2, can be used to treat priapism, a penile function disorder, without raising the systemic blood pressure of the subject receiving the treatment (Spec. 2).

Claims 3-5 are pending and on appeal (App. Br. 2), and read as follows:

3. A pharmaceutical composition comprising an amount of prostaglandin A1, prostaglandin B1, prostaglandin B2, or prostaglandin A2 effective to induce, promote, or otherwise facilitate contraction of *corpora cavernosa* muscle in the *cavernosum* in penile tissue of a subject to whom the composition is administered, in combination with one or more pharmaceutically acceptable carriers and/or diluents, said composition being formulated in a form suitable for intracavernous administration, wherein said composition does not raise the systemic blood pressure of the subject to whom it is administered.

4. The pharmaceutical composition of claim 3, comprising 150 µg of prostaglandin A2.

5. A pharmaceutical composition comprising an amount of prostaglandin A1, prostaglandin B1, prostaglandin B2, or prostaglandin A2 effective to induce, promote, or otherwise facilitate contraction of *corpora cavernosa* muscle in the *cavernosum* in penile tissue of a subject to whom the composition is administered, in combination with one or more pharmaceutically acceptable carriers and/or diluents, wherein said composition does not raise the systemic blood pressure of

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make in the Briefs have not been considered and are deemed to be waived.  
*See* 37 C.F.R. § 41.37(c)(1)(vii).

the subject to whom it is administered, said composition being configured to provide a dosage in the range of from 0.5 to 2.5 micrograms per kilogram of subject body weight.

### *THE REJECTIONS*

The Examiner applies the following document in rejecting the claims:

T. S. Chiang, *Effects of Epinephrine and Progesterone on the Ocular Hypertensive Response to Intravenous Infusion of Prostaglandin A<sub>2</sub>*, 4 Prostaglandins 415-419 (September 1973).

The following rejections are before us for review:

Claim 3 stands rejected under 35 U.S.C. § 102(b) as anticipated by Chiang (Ans. 2-3).<sup>2</sup>

Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Chiang (Ans. 3-4).

### ANTICIPATION

#### *ISSUE*

The Examiner cites Chiang as describing “a solution of prostaglandin A<sub>2</sub> with ethanol and sodium carbonate solution as the diluents” (Ans. 3 (citing Chiang 416, second paragraph)). The Examiner contends that “the recitation of ‘intended use’, e.g., facilitate contraction of corpora cavernosa muscle in the cavernosum in penile tissue of a subject, does not lend patentable weight to composition claims (See MPEP 2111.02) because it does not require any distinguishing structural characteristics of said composition” (Ans. 3).

Appellants contend that Chiang does not meet all of the limitations in claim 3 because Chiang discloses a formulation in a form suitable for

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<sup>2</sup> Examiner’s Answer mailed January 13, 2006.

infusion, whereas claim 3 recites that the composition is “formulated in a form suitable for intracavernous administration” (App. Br. 5). Appellants contend that those skilled in the art would recognize that the dosage of an infused drug is an order of magnitude lower than the dosage of an injected drug, and that the Examiner “has the *burden* of establishing his case of inherent anticipation by demonstrating that the infusion dosage taught by Chiang is the same as the injection dosage required by claim 3” (*id.*).

Appellants conclude that the Examiner has not met the burden of establishing “that all of the features required by claim 3 are found, expressly or inherently, in the Chiang article” (*id.* at 6).

The Examiner responds that the dosage disclosed by Chiang meets the dosage range encompassed by claim 3, and that Chiang’s composition “is structurally undistinguishable from what is recited in the claims since the composition of Chiang can be used or employed through intracavernous route of administration” (Ans. 5).

The issue with respect to this rejection, therefore, is whether the Examiner erred in finding that Chiang meets all of the limitations recited in claim 3, including the disputed formulation and dosage limitations.

*FINDINGS OF FACT*

1. Claim 3 recites a pharmaceutical composition having the following ingredients:

(a) prostaglandin A1, prostaglandin B1, prostaglandin B2, or prostaglandin A2; and

(b) one or more pharmaceutically acceptable carriers and/or diluents.

2. Chiang describes a composition, administered to rabbits by intravenous infusion, which contains:

(a) 0.03 mg/ml prostaglandin A2 (“PGA<sub>2</sub>”); and  
(b) ethanol and sodium carbonate in a “balanced salt solution.”  
(Chiang 416.) Chiang therefore describes a pharmaceutical composition having the claimed ingredients.

3. Because Chiang’s prostaglandin-containing solution was administered by intravenous infusion (Chiang 416), Chiang’s composition is also suitable for injection. The Specification discloses that “[t]he most effective administration is *via* injection into the corpus cavernosa. This is referred to as intracavernous drug delivery” (Spec. 6). Chiang’s injectable composition therefore meets claim 3’s limitation requiring the composition to be “formulated in a form suitable for intracavernous administration.”

4. Because Chiang discloses that the prostaglandin A2 composition “decreased mean arterial blood pressure in rabbits” (Chiang 415), Chiang meets the limitation in claim 3 requiring the composition to “not raise the systemic blood pressure of the subject to whom it is administered.”

5. Claim 3 recites that the prostaglandin must be present in the composition in “an amount . . . effective to induce, promote, or otherwise facilitate contraction of *corpora cavernosa* muscle in the *cavernosum* in penile tissue of a subject to whom the composition is administered.”

6. Claim 3 does not limit the “subject” to any particular species, and the Specification discloses that the prostaglandin’s contractile effect occurs in other mammals besides humans, including “stud bulls, horses, sheep, and pigs” (Spec. 5), as well as baboons (*id.* at 8-10). The Specification also discloses experiments in which prostaglandin A2 reduced cavernous pressure in electrically stimulated rats (*id.* at 10-12). The term “subject” in claim 3 therefore encompasses the experimental rabbits used in Chiang.

7. The Specification discloses that preferred dosages of the prostaglandin range “from 1 to 10, more preferably 0.5 to 2.5, micrograms per kilogram of patient body weight” (Spec. 6; *see also* claim 5). The Examiner states that “for a rabbit that weighs 2kg, the dosage is about 0.4 to 5  $\mu\text{g}$ ” (Ans. 4). The Examiner’s calculation is actually incorrect, as the preferred lower dosage limit is 0.5 micrograms of prostaglandin per kilogram of subject body weight (*see* Spec. 6).<sup>3</sup> We therefore find that, for a rabbit that weighs 2 kilograms, 1 to 5 micrograms of prostaglandin A2 meets claim 3’s “effective amount” limitation.

8. Prostaglandin A2 was infused to rabbits for 10 minutes at a rate of 0.24 micrograms per minute (Chiang 418 (Figure 1)). A total of 2.4 micrograms of prostaglandin A2 was therefore administered to the rabbits. Because 2.4 micrograms is within the dosage range effective to induce, promote, or otherwise facilitate contraction of *corpora cavernosa* muscle in the *cavernosum* in the penile tissue of 2 kilogram rabbits, Chiang’s composition meets claim 3’s limitation requiring prostaglandins in “an amount . . . effective to induce, promote, or otherwise facilitate contraction of *corpora cavernosa* muscle in the *cavernosum* in penile tissue of a subject to whom the composition is administered.”

#### *PRINCIPLES OF LAW*

“To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). During examination, the PTO must interpret terms in a claim using “the broadest reasonable meaning

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<sup>3</sup> This calculation error is harmless, however, as it does not impact our determination of the issues before us.

of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

"It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 128 F.3d at 1477. Moreover, as stated in *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (quoting *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971)):

[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

#### *ANALYSIS*

We agree with the Examiner that Chiang discloses a composition that meets all of the limitations in claim 3. Specifically, Chiang's composition has the ingredients required in claim 3 (*see* Findings of Fact ("FF") 1 and 2, above). Also, Chiang's composition is in a liquid solution form suitable for intercavernous injection (*see* FF 3), does not raise the systemic blood pressure of its recipients (*see* FF 4), and contains prostaglandin A2 in "an amount . . . effective to induce, promote, or otherwise facilitate contraction of *corpora cavernosa* muscle in the *cavernosum* in penile tissue of a subject to whom the composition is administered" (*see* FF 7-9). We therefore also agree with the Examiner that Chiang anticipates claim 3.

We do not agree with Appellants that the Examiner has failed to meet the burden of establishing inherency. Because Chiang's composition was in the form of a solution suitable for intravenous infusion, we find that the Examiner reasonably concluded that the composition was in a form suitable for intracavernous administration. Because Chiang's composition contained prostaglandin A2 in an amount that would be effective to induce, promote, or otherwise facilitate contraction of the *corpora cavernosa* muscle in the *cavernosum* in penile tissue of "a subject," *i.e.* rabbits like those that actually received the composition, we also find that the Examiner reasonably concluded that Chiang met that limitation. Given the reasonableness of the Examiner's conclusions regarding Chiang's inherent disclosures, Appellants actually bear the burden of establishing that the Examiner's conclusions were erroneous. *See In re Best*, 562 F.2d at 1255.

Appellants' arguments do not demonstrate any defect in the Examiner's reasoning. As noted above, the PTO must give claims their broadest reasonable interpretation consistent with the specification. *See In re Morris*, 127 F.3d at 1054. Thus, even assuming for argument's sake that one of ordinary skill would have recognized that infused compositions generally contain less active ingredient than injected compositions, claim 3 requires only that the prostaglandin is present in an amount capable of exerting the contractile effect in "a subject." Claim 3 therefore does not limit the claimed effect to any particular patient, and encompasses rabbits as the subjects. Moreover, claim 3 does not exclude infusion as the mode of intracavernous administration. For these reasons, we agree with the Examiner that claim 3 is sufficiently broad to encompass Chiang's compositions.

As noted above, “[i]t is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 128 F.3d at 1477. Thus, while MPEP § 2111.02 may only address the effect of intended use recitations in the preamble (*see* Reply Br. 1-2),<sup>4</sup> functional limitations directed to intended uses in the body of a product claim do not serve to distinguish a claimed product from prior art products inherently capable of performing the claimed function. *See Schreiber*, 128 F.3d at 1478-79 (holding that a prior art apparatus meeting all claimed structural limitations was anticipatory because it was inherently capable of performing the claimed function).

For the reasons discussed above, we agree with the Examiner that Chiang’s composition is amenable to intracavernous administration, and also meets the limitation requiring a contractile effect in a subject. Because Chiang’s composition meets the other limitations in claim 3, we agree with the Examiner that Chiang anticipates claim 3. We therefore affirm the Examiner’s anticipation rejection.

#### OBVIOUSNESS

##### *ISSUE*

Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Chiang (Ans. 3-4).

The Examiner concedes that “Chiang does not expressly teach the herein claimed dosage of prostaglandin A2 as 150µg or 0.5 to 2.5 micrograms per kilogram” (Ans. 4). The Examiner nonetheless contends that one of ordinary skill studying the effect of prostaglandin A2 on

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<sup>4</sup> Reply Brief filed February 10, 2006.

intraocular pressure according to Chiang “would have found it obvious to adjust the dosage of prostaglandin A2 to the herein claimed amount as the optimizing the effect parameters of the experiments” (*id.*). The Examiner also reasons that, given the rate and duration of prostaglandin A2 administration in Chiang, the dosage administered to Chiang’s rabbits would have rendered the claimed dosage rate obvious (*id.*).

Appellants contend that Chiang does not render claim 4 obvious when that claim is considered as a whole, because Chiang’s disclosure is concerned with analyzing the effect of prostaglandin A2 on intraocular pressure, whereas the claimed composition is a treatment for priapism (App. Br. 7). Appellants contend that the “Examiner does not explain how Chiang suggests a dose of 150 µg of prostaglandin A2 formulated for intracavernous administration” (*id.* at 8).

Appellants make similar arguments with respect to claim 5, contending that, when considered as a whole, the Chiang reference is concerned with analyzing the effect of prostaglandin A2 on intraocular pressure, whereas the claimed composition is a treatment for priapism, and that one of ordinary skill would only have arrived at the claimed dosage from Chiang through impermissible hindsight (App. Br. 9-10).

The issue with respect to the obviousness rejection, therefore, is whether the Examiner erred in concluding that one of ordinary skill would have considered claims 4 and 5, including the claimed dosage limitations, obvious in view of Chiang.

#### *FINDINGS OF FACT*

9. Claim 4 recites “[t]he pharmaceutical composition of claim 3, comprising 150 µg of prostaglandin A2.”

10. Chiang does not explicitly disclose a pharmaceutical composition comprising 150 micrograms of prostaglandin A2.

11. Claim 5 recites a composition having the same limitations as recited in claim 3, with the additional limitation that the composition is “configured to provide a dosage in the range of from 0.5 to 2.5 micrograms per kilogram of subject body weight.” Claim 5 does not limit the “subject” to any particular patient. Claim 5 therefore encompasses compositions that meet the limitations of claim 3, and which are also capable of being administered to a subject at a dosage of 0.5 to 2.5 micrograms per kilogram of subject body weight.

#### *PRINCIPLES OF LAW*

Recently addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 U.S.C. § 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is . . . a person of ordinary creativity, not an automaton.” *Id.* at 1742.

The Supreme Court also emphasized that a claim must be considered *prima facie* obvious when the prior art suggests its practice, even if the prior art’s reason for practicing the claimed subject matter is different than the applicant’s. *Id.* at 1741-1742 (“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.”); *see also In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992) (“[T]he law

does not require that the references be combined for the reasons contemplated by the inventor.”); *In re Lintner*, 458 F.2d 1013, 1016 (CCPA 1972) (“The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be prima facie obvious from the purpose disclosed in the references.”).

#### *ANALYSIS*

We agree with the Examiner that one of ordinary skill would have considered a pharmaceutical composition comprising 150 micrograms of prostaglandin A2 obvious in view of Chiang’s disclosure of administering that compound to rabbits to test the compound’s effect on intraocular pressure. Specifically, Chiang’s experiments include administering prostaglandin A2 to rabbits by intravenous infusion for 10 minutes at a rate of 0.24 micrograms per minute (Chiang 418 (Figure 1)). Chiang’s solution contained 0.03 mg/ml, or 30 micrograms per milliliter, of prostaglandin A2 (Chiang 416). Therefore, 5 milliliters of Chiang’s solution contained 150 micrograms of prostaglandin A2.

Given the prostaglandin concentration and the administration rate used in Chiang’s experiments, one of ordinary skill, being a person of ordinary creativity and common sense, *see KSR*, 127 S. Ct. at 1742-43, would have reasonably inferred that an injectable solution comprising 150 micrograms of prostaglandin A2 would be useful in those experiments. We therefore agree with the Examiner that claim 4 would have been obvious to a person of ordinary skill.

Appellants argue that Chiang’s disclosure taken as a whole is unrelated to the subject matter of claim 4 taken as a whole, and that therefore “[n]othing in the Chiang reference would induce one of ordinary skill in the

art to believe that he or she could successfully treat priapism with a composition for intracavernous administration containing 150 µg of prostaglandin A2” (App. Br. 7; *see also* Reply Br. 3-4).

We are not persuaded by this argument.

Claim 4 is not directed to a method of treating priapism. Rather, claim 4 is directed to a pharmaceutical composition that contains 150 micrograms of prostaglandin A2. Thus, the issue with respect to claim 4 is not whether Chiang would have rendered treating priapism with prostaglandin A2 obvious. Rather, the issue with respect to claim 4 is whether one of ordinary skill would have considered a composition comprising 150 micrograms of prostaglandin A2 obvious in view of Chiang.

As discussed above, because one of ordinary skill would have considered a composition comprising 150 micrograms of prostaglandin A2 to be useful for performing Chiang’s experiments, we agree with the Examiner that claim 4 would have been obvious to one of ordinary skill. The fact that prior art’s reason for preparing the claimed composition is different than Appellants’ reason does not render the claim any less obvious. *See KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741-42 (2007) (“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.”); *see also In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992) (“[T]he law does not require that the references be combined for the reasons contemplated by the inventor.”); *see also In re Lintner*, 458 F.2d 1013, 1016 (CCPA 1972) (“The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a

prior art composition would be prima facie obvious from the purpose disclosed in the references.”).

Appellants also argue that the Examiner’s calculations of record do not demonstrate the obviousness of claim 4 because none of the numbers lead directly to 150 micrograms of prostaglandin A2 (App. Br. 7-8). We are not persuaded by this argument.

As noted above, the Supreme Court recently advised that the analysis under 35 U.S.C. § 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Claim 4 is therefore not rendered unobvious by the absence of a precise teaching in Chiang of a composition comprising 150 micrograms of prostaglandin.

Thus, we agree with the Examiner that one of ordinary skill, being a person of ordinary creativity and common sense, *see KSR*, 127 S. Ct. at 1742-43, would have reasonably inferred that a pharmaceutical composition comprising 150 micrograms of prostaglandin A2 would be useful in Chiang’s experiments, given the prostaglandin concentration (30 micrograms per milliliter) and the administration rate (0.24 micrograms per minute) used by Chiang. We therefore also agree with the Examiner that claim 4 would have been obvious to a person of ordinary skill.

We affirm the Examiner’s obviousness rejection of claim 4.

With respect to claim 5, as discussed above, we agree with the Examiner that Chiang anticipates claim 3. Chiang therefore meets all of the limitations that claim 5 has in common with claim 3.

Claim 5 is directed to a product, not a process. Thus, claim 5's limitation that the composition be "configured to provide a dosage in the range of from 0.5 to 2.5 micrograms per kilogram of subject body weight" does not require the composition to actually be administered. Rather, claim 5 only requires the composition to be capable of the claimed administration rate. Moreover, claim 5 does not limit the subject to any particular patient.

As noted above (*see* FF 7), for a rabbit that weighs 2 kilograms, claim 5's range of 0.5 to 2.5 micrograms per kilogram of subject body weight equates to 1 to 5 micrograms of prostaglandin. As also noted above (*see* FF 8), Chiang's administration of prostaglandin A<sub>2</sub> to rabbits for 10 minutes at a rate of 0.24 means that a total of 2.4 micrograms of prostaglandin A<sub>2</sub> was administered. Because the 2.4 micrograms of prostaglandin A<sub>2</sub> in Chiang's composition is an amount within the dosage range of claim 5, we agree with the Examiner that the dosage range recited in claim 5 would have been obvious to a person of ordinary skill. Moreover, given Chiang's dosage rate, we also agree with the Examiner that one of ordinary skill would have considered compositions meeting claim 5's range of dosages to be useful in performing Chiang's experiments.

Appellants argue that, assuming an 80 kilogram human, the dosage rate recited in claim 5 equates to 40 to 200 micrograms of prostaglandin (App. Br. 9). Appellants urge that Chiang as a whole is directed to different subject matter than claim 5 as a whole, and that "[b]ecause Chiang relates to infusion of PGA<sub>2</sub> rather than to injection of PGA<sub>2</sub>, none of the

pharmaceutical compositions disclosed by Chiang involves 40-200  $\mu\text{g}$  of prostaglandin” (App. Br. 10).

We are not persuaded by this argument. Claim 5 does not recite a composition comprising 40 to 200 micrograms of prostaglandin. Nor does claim 5 limit the subject to any particular patient. As discussed above, because Chiang’s composition can be administered to a subject at the claimed dosage rate, we agree with the Examiner that one of ordinary skill would have considered it obvious to configure Chiang’s composition “to provide a dosage in the range of from 0.5 to 2.5 micrograms per kilogram of subject body weight” as required by claim 5.

While we again note that the Chiang’s rationale for making such a composition is different than Appellants’, that fact does not render claim 5 any less obvious. *See KSR*, 127 S. Ct. at 1741-42 (“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.”); *see also In re Beattie*, 974 F.2d at 1312 (“[T]he law does not require that the references be combined for the reasons contemplated by the inventor.”); *In re Lintner*, 458 F.2d at 1016 (“The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be prima facie obvious from the purpose disclosed in the references.”).

In sum, we agree with the Examiner that one of ordinary skill would have considered it obvious to configure Chiang’s composition “to provide a dosage in the range of from 0.5 to 2.5 micrograms per kilogram of subject body weight” as required by claim 5. Because Chiang meets all of the other

Appeal 2007-3890  
Application 10/347,312

limitations in claim 5 we affirm the Examiner's obviousness rejection of claim 5.

#### SUMMARY

We affirm the Examiner's rejection of claim 3 under 35 U.S.C. § 102(b) as anticipated by Chiang.

We affirm the Examiner's rejection of claims 4 and 5 under 35 U.S.C. § 103(a) as obvious in view of Chiang.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

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