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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HUAI-HUNG KAO, ANAND R. BAICHWAL,
TROY MCCALL, and DAVID LEE

Appeal 2009-013711
Application 12/167,859
Technology Center 1600

Decided: January 12, 2010

Before DONALD E. ADAMS, ERIC GRIMES, and RICHARD M.
LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods and compositions for treating pain using controlled release formulations of oxymorphone, which is an “opioid agonist, widely used in the treatment of acute and chronic pain” (Spec. 1, ¶ 3). The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 8-27 are pending and on appeal. Claims 8 and 21 are representative and read as follows:

8. A method for treating pain in a human subject in need of acute or chronic pain relief, comprising the steps of:

(a) Providing a solid oral dosage form comprising about 5 mg to about 80 mg oxymorphone or a pharmaceutically acceptable salt thereof in a controlled release delivery system with a release rate profile designed to provide an adequate blood plasma level over at least 12 hours to provide sustained pain relief over this same period, the system comprising a filler and a hydrophilic material, wherein oxymorphone is the sole active ingredient; and

(b) administering the dosage form to the subject, wherein the oxymorphone C_{\max} is at least about 50% higher when the dosage form is administered to the subject under fed versus fasted conditions.

21. A method for treating pain in a human subject in need of acute or chronic pain relief, comprising the steps of:

(a) Providing a solid oral dosage form comprising about 5 mg to about 80 mg oxymorphone or a pharmaceutically acceptable salt thereof in a controlled release delivery system with a release rate profile designed to provide an adequate blood plasma level over at least 12 hours to provide sustained pain relief over this same period, the system comprising:

- (i) a hydrophilic material
- (ii) a hydrophobic material
- (iii) a cationic cross-linking agent, and
- (iv) a filler,

wherein oxymorphone is the sole active ingredient; and

(b) administering the dosage form to the subject, wherein the oxymorphone C_{\max} is at least about 50% higher when the dosage form is administered to the subject under fed versus fasted conditions.

The claims stand rejected under 35 U.S.C. § 103(a) as follows:

- Claims 8-15 and 18-20 based on Maloney,¹ by itself or combined with Calanchi² (Ans. 3);
- Claims 16 and 17 based on Maloney, by itself or combined with Calanchi, and further in view of Baichwal³ (Office action mailed Jan. 12, 2009, p. 8);⁴ and
- Claims 21-27 based on Maloney, Calanchi, Baichwal, and Oshlack⁵ (Ans. 6).

OBVIOUSNESS

Issue

Appellants state that “because the application on appeal was filed under the Accelerated Examination program, Appellant is precluded from arguing separate patentability of dependent claims on appeal” (Appeal Br. 9, n.3). And, because Appellants have not presented separate arguments with respect to claims 8 and 19, all of the claims stand or fall with claims 8 and 21. 37 C.F.R. § 41.37(c)(1)(vii). The only issues presented on appeal, therefore, relate to whether the methods of claims 8 and 21 would have been obvious in view of the cited references.

¹ Maloney, WO 01/08661 A2, Feb. 8, 2001

² Calanchi et al., US 5,047,248, Sept. 10, 1991

³ Baichwal et al., US 5,128,143, July 7, 1992

⁴ This rejection was set out in the Final Rejection (mailed Jan. 12, 2009). Although it was not repeated in the Answer, Appellants understood claims 16 and 17 to be rejected (Appeal Br. 5) and the Examiner confirmed that that understanding was correct (Ans. 2). We therefore understand the omission of the rejection of claims 16 and 17 from the Answer to be inadvertent and not an indication that the rejection was withdrawn.

⁵ Oshlack et al., US 5,266,331, Nov. 30, 1993

The Examiner finds that Maloney “teaches oral sustained release preparations of opioid analgesics” and “in particular prefers oxycodone, oxymorphone etc” (Ans. 3-4). The Examiner also finds that the “example compositions of [Maloney] include methocel K100M, which is a hydrophilic polymer” (*id.* at 4). The Examiner concludes that:

[w]hile [Maloney] does not mention the claimed amounts of oxymorphone or the pharmacological parameters such as C_{max}, . . . the sustained release delivery system described by [Maloney] reads on the claimed as well as the described systems of the instant application. Therefore, the burden is on applicants to show that the matrix system of [Maloney] does not provide the claimed parameters with opioid analgesic oxymorphone.

(*Id.* at 4-5.)

The Examiner concludes that Appellants’ evidence of unexpected results and commercial success does not rebut the prima facie case of obviousness because, among other things, the evidence is based on the Opana ER[®] composition, which is not commensurate in scope with the claims (*id.* at 17, 19).

Appellants contend that the food effect and release rate profile recited in claims 8 and 21 are not inherently disclosed in Maloney or Calanchi, and that skilled workers would not have known what dissolution rate would provide an effective oxymorphone composition with a 12-hour dosing cycle. Appellants also contend that the evidence of secondary considerations (unexpected results and commercial success) rebuts any prima facie case of obviousness.

The specific issues presented are:

(a) Have Appellants shown that the Examiner erred in concluding that Maloney’s disclosure, alone or combined with Calanchi, would have made

obvious a method of treating pain with a controlled-release oxymorphone composition that provides 12 hours of pain relief and a C_{\max} that is at least 50% higher when administered under fed versus fasted conditions, as recited in claims 8 and 21?

and

(b) Have Appellants presented evidence of secondary considerations that outweighs the evidence in favor of obviousness?

Findings of Fact – Prima Facie Obviousness

1. Maloney discloses a “solid, oral controlled release dosage form comprising a therapeutically effective amount of opioid compound, . . . between about 30 and 65% of a matrix-forming polymer, . . . and between 5 and 15% of a[n] ionic exchange resin” (Maloney 8).

2. Maloney discloses that “[p]referred opioid compounds useful in the present invention” include oxycodone hydrochloride and oxymorphone (*id.* at 13).

3. Maloney discloses “formulations having from about 5 to about 100 mg oxycodone” (*id.* at 7).

4. Maloney discloses that matrix-forming polymers include hydroxypropylmethylcellulose, hydroxypropyl cellulose, and hydroxyethyl cellulose, and that a “preferred matrix-forming material is alkylcellulose-based, more particularly hydroxyalkylcellulose-based” (*id.* at 9).

5. The Specification states that hydroxypropylmethylcellulose, hydroxyethyl cellulose, and hydroxypropyl cellulose are hydrophilic materials suitable for use in controlled release formulations (Spec. 12, ¶ 42).

6. Maloney discloses that its formulations “may include diluents, lubricants, glidants, and additives, as known to those of ordinary skill in the

art to improve compaction, augment swallowability, [and] decrease gastrointestinal irritation” (Maloney 10).

7. Maloney discloses that suitable diluents include calcium sulfate (*id.* at 11).

8. The Specification discloses that “suitable cationic cross-linking agents include calcium sulfate” (Spec. 15, ¶ 52).

9. Maloney discloses that suitable diluents also include lactose, microcrystalline cellulose, sucrose, dextrose, fructose, and sorbitol (Maloney 11).

10. The Specification discloses that “suitable inert pharmaceutical fillers include sucrose, dextrose, lactose, microcrystalline cellulose, fructose, xylitol, [and] sorbitol” (Spec. 14, ¶ 51).

11. Maloney discloses that suitable lubricants include “hydrogenated vegetable oil (type 1)” (Maloney 11).

12. The Specification discloses that hydrophobic materials include hydrogenated vegetable oils (Spec. 16, ¶ 54).

13. Maloney discloses that its dosage form provides a “dissolution rate *in vitro*, when measured by the USP Basket Method . . . [of] between 5 and 25% (by weight) oxycodone released over the first hour . . . and between about 60 and 80% (by weight) oxycodone released after twelve hours” (Maloney 12).

14. The Specification defines C_{\max} as “[m]aximum observed drug concentration” (Spec. 21, ¶ 66).

15. The Specification provides an example showing that for oxymorphone controlled-release tablets “[l]east squares (LS) mean C_{\max} was

58% higher . . . for the fed condition (Treatment B) compared to the fasted condition (Treatment A)” (*id.* at 31, ¶ 97).

16. The Specification’s example also shows that for oxymorphone immediate-release solution “LS mean C_{\max} was 50% higher . . . for the fed condition (Treatment D) compared to the fasted condition (Treatment C)” (*id.* at 31, ¶ 98).

Principles of Law – Prima Facie Obviousness

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (quoted with approval in *KSR*, 550 U.S. at 418).

“The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art.” *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991).

Analysis – Prima Facie Obviousness

Maloney discloses a controlled release formulation comprising an opioid compound (FF 1) in amounts of 5-100 mg (FF 3), and discloses that oxymorphone is a preferred opioid compound (FF 2). Maloney’s formulation also comprises a matrix-forming polymer (FF 4), including polymers described by the Specification as hydrophilic materials (FF 5).

Maloney also discloses that its formulation can include other conventional pharmaceutical excipients such as calcium sulfate, lactose, and

hydrogenated vegetable oil (FFs 6, 7, 9, 11), which the Specification describes as a cross-linking agent, filler, and hydrophobic material, respectively (FFs 8, 10, 12). Based on these disclosures, it would have been obvious to a person of ordinary skill in the art to formulate a controlled-release formulation comprising 5-80 mg of oxymorphone, a filler, and a hydrophilic material (as recited in claim 8), or a controlled-release formulation comprising 5-80 mg of oxymorphone, a hydrophilic material, a hydrophobic material, a cationic cross-linking agent, and a filler (as recited in claim 21), because Maloney expressly suggests those ingredients for its compositions, and to administer the formulation to a human subject to treat pain.

Claims 8 and 21 also require that the dosage form “provide[s] an adequate blood plasma level over at least 12 hours to provide sustained pain relief over this same period.” Appellants argue that this limitation is not inherent in Maloney’s dosage form (Appeal Br. 12). However, Maloney discloses that its dosage form provides a dissolution rate of 60-80% active agent released after 12 hours (FF 13). It is reasonable to conclude that Maloney’s active agent would still be effective after 12 hours because it is still being released from Maloney’s dosage form at 12 hours. Appellants have not pointed to evidence of record showing that Maloney’s dosage form would not provide the plasma levels of oxymorphone required by claims 8 and 21.

Finally, claims 8 and 21 require that the dosage form provides a C_{\max} “at least about 50% higher when the dosage form is administered to [a] subject under fed versus fasted conditions.” Appellants argue that this limitation is not inherent in Maloney’s dosage form (Appeal Br. 12).

However, the Specification discloses that even an immediate release oxymorphone solution provides a C_{\max} that is 50% higher when it is administered to a subject under fed versus fasted conditions (FF 16). Since the food effect recited in claims 8 and 21 occurs with both immediate-release and controlled-release dosage forms of oxymorphone, it is reasonable to conclude that it is due to the oxymorphone itself, rather than the particular dosage form. Therefore, it is reasonable to expect that the controlled-release oxymorphone formulation made obvious by Maloney would show the same food effect.

In summary, Maloney would have made obvious to a person of ordinary skill in the art methods of treating pain with a controlled-release dosage form of oxymorphone that reasonably appear to meet all the limitations of claims 8 and 21.

Appellants argue that it would not have been obvious to modify Maloney's composition to have the properties recited in claims 8 and 21 because persons skilled in the art would not know "what the appropriate dissolution rates are in order to achieve the goal of developing a safe, effective controlled release oxymorphone formulation with a 12 hour dosing cycle" (Appeal Br. 12). Appellants argue that they have provided evidence that oxymorphone is subject to an extensive first-pass effect and has a lower bioavailability than oxycodone, and therefore Maloney's disclosure of the release rate of oxycodone-containing compositions would not have suggested an appropriate release rate for oxymorphone-containing compositions (*id.* at 13-14).

These arguments are not persuasive, because claims 8 and 21 do not recite any specific dissolution rate; the claims only require that the dosage

form has a release rate profile that provides plasma levels of oxymorphone adequate to provide at least 12 hours of pain relief. As discussed above, Maloney's disclosure of a controlled release dosage form with 60-80% dissolution after 12 hours reasonably appears to meet the limitations of claims 8 and 21, and Appellants have not provided adequate evidence to show that Maloney's dosage form would not provide plasma levels of oxymorphone adequate to provide 12-hour pain relief.

Appellants also argue that their position is supported by *Ex parte Affrime*, 2008 WL 460213 (BPAI 2008) because in *Affrime* the "Board reversed because the Examiner could not adequately show that administration of the compound according to the prior art reference would necessarily achieve the claimed PK profile" (Appeal Br. 17). Similarly, Appellants argue that the facts of this appeal are like those of *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008) (Appeal Br. 17-18).

These arguments are not persuasive because the claims on appeal differ materially from the claims in *Affrime* or *Abbott Labs.* The claims in *Affrime* required a particular pharmacokinetic profile, including specific values for C_{\max} and T_{\max} . 2008 WL 460213 at *1. Claim 1 in *Abbott Labs.* was directed to an extended release composition of an erythromycin derivative that "induces statistically significantly lower mean fluctuation index in the plasma than an immediate release composition of the erythromycin derivative while maintaining bioavailability substantially equivalent." 544 F.3d at 1344. The principal opinion⁶ in *Abbott Labs.*

⁶ Judge Newman's opinion was not joined in relevant part by either of the other judges on the panel and therefore does not represent the view of the court.

concluded that the accused infringer had not shown that the prior art disclosed compositions having the pharmacokinetic properties recited in the claims because different erythromycin derivatives (e.g., azithromycin and clarithromycin) had different chemical and biological properties and were metabolized differently. *Id.* at 1352.

The facts of this case differ from those of *Affrime* and *Abbott Labs.* in that instant claims 8 and 21 do not recite specific pharmacokinetic parameters. The functional limitations of claims 8 and 21 require only a dosage form that provides 12 hours of pain relief and 50% higher C_{\max} in fed versus fasted subjects, and Maloney provides a reasonable basis on which to conclude that the product suggested by the prior art meets these limitations.

Findings of Fact – Secondary Considerations

17. The Specification states that the “oxymorphone controlled release oral solid dosage form of this invention can be made using any of several different techniques for producing controlled release oral solid dosage forms of opioid analgesics” (Spec. 10, ¶ 33).

18. The Specification states that, “[i]n one embodiment, a core comprising oxymorphone or an oxymorphone salt is coated with a controlled release film” (*id.* at 10, ¶ 34).

19. The Specification states that, “[i]n a second embodiment, the oxymorphone or oxymorphone salt is dispersed in a controlled release delivery system that comprises a hydrophilic material which upon exposure to gastrointestinal fluid forms a gel matrix” (*id.*).

20. The Specification states that a “third embodiment is a combination of the first two: a controlled release matrix coated with a controlled release film” (*id.*).

21. The Specification states that “[i]n a fourth embodiment the oxymorphone is incorporated into an osmotic pump” (*id.*)

22. All of the compositions exemplified in the Specification use a controlled release delivery system (“Formulation 1”) made from locust bean gum, xanthan gum, dextrose, calcium sulfate dihydrate, ethylcellulose, and alcohol (*id.* at 17, ¶ 57; see also 18, ¶¶ 58, 59 (describing tablets prepared using Formulation 1)).

23. Appellants have provided evidence that the “commercial Opana ER® 20 mg product . . . is very similar to the formulation of Example 4 of the [instant] Application” (Declaration under 37 C.F.R. § 1.132 of Sou-Chan Chang dated May 21, 2008, ¶ 12). Example 4 is of tablet prepared with the Formulation 1 controlled release delivery system (Spec. 18, ¶ 59).

24. The Specification discloses a study in which fasted subjects were given either an immediate release oxymorphone solution or a controlled release oxymorphone composition (including the Formulation 1 controlled release delivery system) (Spec. 22, ¶ 71).

25. The Specification discloses that the “immediate release liquid . . . shows a classical curve, with a high and relatively narrow peak, followed by an exponential drop in plasma concentration. However, the controlled release oxymorphone tablets exhibit triple peaks in blood plasma concentration.” (*Id.* at 23, ¶ 73.)

26. The Specification discloses a study in which fed subjects were given either an immediate release oxymorphone solution or a controlled release oxymorphone composition (including the Formulation 1 controlled release delivery system) (*id.* at 25, ¶ 79).

27. The Specification discloses that, “[a]s with Study 1, the immediate release liquid . . . shows a classical curve, with a high and relatively narrow peak, followed by an exponential drop in plasma concentration, while the controlled release oxymorphone tablets exhibit triple peaks in blood plasma concentration” (*id.* at 26, ¶ 81).

28. Appellants have provided a declaration under 37 C.F.R. § 1.132 of David C. Yeomans (dated May 6, 2008).

29. Dr. Yeomans declares that he examined “a number of clinical studies performed by Endo, in which its Opana[®] ER is orally administered to healthy volunteers and the resultant pK [pharmacokinetics] of oxymorphone is tracked” (Yeomans Declaration, ¶ 16).

30. Dr. Yeomans declares that “[i]n almost every case, the curves for the extended release formulations showed a second peak and, frequently, a third peak in concentration, resulting from the administration of a single dose of extend[ed] release oxymorphone” (*id.*).

31. Dr. Yeomans declares that “this feature illustrates that oxymorphone enters a patient’s bloodstream in a biphasic or triphasic manner” (*id.* at ¶ 17).

32. Dr. Yeomans states:

In my opinion, this will likely have an ameliorating effect on the problem of analgesic tolerance. As an expert in the field of pain management with narcotic analgesics particularly strong opioids, I expect that extended release formulations of oxymorphone will display more reliable analgesia while minimizing the need to increase the dose or decrease the dosing interval because of this multiphasic effect.

(*Id.*)

33. Dr. Yeomans declares that he “did not observe this second peak behavior to a pharmacologically significant degree, nor did [he] ever observe a third peak in the literature” he reviewed pertaining to pK behavior of extended release morphine, hydromorphone, or oxycodone (*id.* at ¶ 19).

34. Dr. Yeomans concludes that the two- or three-peak pK curve of extended release oxymorphone is “a surprising and unexpected feature . . . highly likely to have a beneficial impact on the pharmacological effect of the formulations” (*id.* at ¶ 20).

35. Appellants have provided a declaration under 37 C.F.R. § 1.132 of Nancy Wysenski (dated May 28, 2008).

36. Ms. Wysenski declares that “Opana[®] ER . . . has displayed unqualified commercial success” (Wysenski Declaration, ¶ 11), as shown by “dramatic growth in the number of prescriptions written” (*id.* at ¶ 13), the amount of revenues generated (*id.* at ¶ 16), and its acceptance in the market (*id.* at ¶¶ 18-25).

Principles of Law – Secondary Considerations

“If a *prima facie* case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.” *In re Hedges*, 783 F.2d 1038, 1039 (Fed. Cir. 1986).

“The evidence presented to rebut a *prima facie* case of obviousness must be commensurate in scope with the claims to which it pertains.” *In re Dill*, 604 F.2d 1356, 1361 (CCPA 1979).

Analysis – Secondary Considerations

The Specification provides evidence that administering compositions of oxymorphone that include the Formulation 1 controlled release delivery system results in triple peaks in plasma oxymorphone concentration, while immediate release oxymorphone solution “shows a classical curve, with a high and relatively narrow peak, followed by an exponential drop in plasma concentration” (FFs 24-27).

Dr. Yeomans provides evidence that the double- or triple-peak pharmacokinetics seen in clinical studies of Opana[®] ER was unexpected in view of the properties of other extended release opioids (FFs 29-33) and is “highly likely to have a beneficial impact on the pharmacological effect” of Opana[®] ER (FF 34). Ms. Wysenski provides evidence that Opana[®] ER has enjoyed commercial success and acceptance in the market since its introduction (FF 36).

We will assume that the evidence shown in the Specification and in the Yeomans and Wysenski Declarations establishes that the controlled release formulations addressed therein have unexpectedly superior properties and commercial success that would overcome a prima facie conclusion of obviousness *with respect to those formulations*. The issue, then, is whether the showing of secondary considerations is commensurate in scope with the claims on appeal.

We conclude that it is not. Claims 8 and 21 encompass treating pain using any oxymorphone dosage form that has the recited 12-hour effectiveness and food effect. The Specification makes clear that such compositions can comprise any of a variety of controlled-release delivery systems (FFs 17-21). All of the compositions relied upon by Appellants,

however, include the Specification's controlled-release delivery system of Formulation 1 (FF 22) or something "very similar" to it (FF 23).

The Specification provides evidence that the two- or three-peak pharmacokinetic behavior of extended-release oxymorphone compositions is not due to the oxymorphone itself, because an immediate-release oxymorphone solution showed a "classical curve" rather than multiple peaks (FFs 25, 27). Since both the immediate-release and controlled-release formulations contained oxymorphone, the only reasonable conclusion to be drawn is that the different pharmacokinetic behavior of the formulations is due to differences in the other components of the formulations. That is, the multiple peaks seen in the studies in the Specification and in the clinical studies examined by Dr. Yeomans must have been due to the components of the controlled-release delivery system in those formulations.

All of the Specification's exemplified formulations include the same controlled-release delivery system. Opana[®] ER uses a controlled-release delivery system that is very similar to the one used in the Specification's examples. But the claims are not limited to that controlled-release delivery system, or even controlled-release delivery systems that are similar to it. The claims encompass, among other things, formulations using a controlled-release film (FF 18), different controlled-release matrices (FF 19), controlled-release matrices coated with a controlled-release film (FF 20), or an osmotic pump (FF 21).

The evidence shows, at best, unexpectedly superior results for one specific controlled-release matrix. The evidence does not show that unexpectedly superior results result from using any of the other controlled-release delivery systems encompassed by the claims that produce the

12-hour effectiveness and food effect recited in claims 8 and 21. The evidence of unexpected results therefore is not commensurate with the scope of the claims on appeal.

In addition to their arguments based on the Yeomans and Wysenski Declarations, Appellants also argue that unexpected results are shown in the declaration under 37 C.F.R. § 1.132 of William Fiske (Appeal Br. 19). Specifically, Appellants argue that, as discussed in the Fiske Declaration, “one of skill in the art would have expected that decreasing the release rate of oxymorphone would have caused an increase in the first-pass effect of oxymorphone, thus preventing achievement of a sustainable systemic therapeutic concentration” but Appellants found that “a sustainable systemic therapeutic concentration was achieved” (*id.*).

This argument is also unpersuasive. Maloney expressly contemplates controlled-release formulations of oxymorphone (FFs 1-2). Prior art references are presumed to be enabled for what they disclose, and the burden is on Appellants to show that they are not. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). Appellants have not provided sufficient evidence to show that the prior art disclosures would not have led skilled workers to expect that they could make an effective controlled-release formulation of oxymorphone without undue experimentation.

With respect to claim 21, Appellants argue that “the Examiner did not indicate where in the prior art the limitation of the ‘cationic cross-linking agent’ appears This alone is sufficient to overturn the Examiner’s rejection of claim 21.” (Appeal Br. 24.) In response to this argument, the Examiner pointed to Baichwal’s disclosure of cross-linking agents (Ans. 20-

21), but Appellants argue that Baichwal's cross-linking agents "are not cationic crosslinking agents" (Reply Br. 5). Regardless of whether Baichwal discloses cationic cross-linking agents, however, Maloney discloses that calcium sulfate is a conventional pharmaceutical excipient (FF 7) and the instant Specification describes calcium sulfate as a cationic cross-linking agent (FF 8); therefore, a person of ordinary skill in the art would have considered it obvious to include calcium sulfate (a cationic cross-linking agent) in Maloney's controlled-release formulation.

Conclusions of Law

Appellants have not shown that the Examiner erred in concluding that Maloney's disclosure would have made obvious a controlled-release oxymorphone composition meeting the limitations of claims 8 and 21. And Appellants have not presented evidence of secondary considerations that outweighs the evidence in favor of obviousness.

SUMMARY

We affirm the rejections under 35 U.S.C. § 103(a) of claims 8-15 and 18-20 based on Maloney, by itself or combined with Calanchi, and of claims 21-27 based on Maloney, Calanchi, Baichwal, and Oshlack. Because Appellants did not argue it separately, we also affirm the rejection of claims 16 and 17 under 35 U.S.C. § 103(a) based on Maloney, by itself or combined with Calanchi, and further in view of Baichwal.

TIME PERIOD FOR RESPONSE

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

Appeal 2009-013711
Application 12/167,859

AFFIRMED

lp

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