

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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*Ex parte* TORSTEN SELZER

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Appeal 2006-0760  
Application 10/312,417  
Technology Center 1600

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ON BRIEF

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Before MILLS, GREEN, and LEOVITZ, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims to a dermal therapeutic system for delivery of a COX-2 inhibitor. The Examiner has rejected the claims as anticipated and obvious over prior art. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part and reverse-in-part.

DISCUSSION

Claims 13-27, which are all the pending claims, are on appeal (Br. 3). The claims are subject to two prior art rejections (*Id.* at 4). In the first rejection, claims 13-19 are rejected under 35 U.S.C. § 102. In the second rejection, claims 20-27 are rejected under 35 U.S.C. § 103. We focus on

claim 13 as representative of the first grouping. For the second grouping, the claims stand or fall together because Appellant has not provided separate arguments for patentability of any of the claims. We select claim 20 as representative claim of the second grouping. 37 C.F.R. § 41.37(c)(1)(vii).

13. A dermal therapeutic system comprising as an active pharmaceutical ingredient for the treatment of symptoms associated with irritation from degenerative joint disorders and for the treatment of postoperative and menstrual pain at least one COX-2 inhibitor, characterized in that the COX-2 inhibitor is a 3-aryl-4-(4-methylsulfonylphenyl)-2(H5) furanone or a 4-[5-aryl-3-(trifluoromethylpyrazol-1-yl)]benzenesulfonamide.

20. A dermal therapeutic system for the delivery of a medical substance to the skin, which consists of:

a) a support layer, which is impermeable to the medical substance;  
b) a reservoir or matrix layer that contains the medical substance wherein said medical substances consists of:

1. at least one COX-2 inhibitor wherein said COX-2 inhibitor is selected from the group consisting of 3-aryl-4-(4-methylsulfonylphenyl)-2(H5) furanones and 4-[5-aryl-3-(trifluoromethylpyrazol-1-yl)]benzenesulfonamides; and
2. optionally, at least one compounds selected from the group consisting of a plasticizers, tackifiers, stabilizers, fillers, carrier and permeation enhancer(s);

wherein, said permeation enhancer(s), when present, is (are) a compound selected from the group consisting of fatty alcohols, fatty acids, polyoxyethylene fatty alcohols ethers, sorbitan monolaurate, long-chain fatty acids with methyl, ethyl or isopropyl alcohols, esters of fatty alcohols with acetic or lactic acid, and oleic acid diethanolamine, and

wherein, when a reservoir layer is present, said reservoir layer optionally contains a high viscosity liquid, a semisolid matrix, a thixotropic matrix, and/or a gel former;

c) optionally, a control membrane;

- d) a contact adhesive layer for attachment of the dermal therapeutic system to the skin and which is optionally identical to the layer containing the medical substance; and
- e) a protective layer.

*Anticipation under 35 U.S.C. § 102(e)*

Claims 13-19 stand rejected under 35 U.S.C. § 102(e) as anticipated by Levin.

Levin<sup>1</sup> describes “cetyl myristoleate (CMO) and CMO compounds in combination with other compounds useful for treating inflammatory disease.” (Levin at 2, ll. 8-10.) Cox-2 inhibitors are listed by Levin in a group of others compounds which can be combined with CMO (*id.* at 3, ll. 27-33). Levin states that “[c]ompositions of the invention can be administered by a variety methods which are well known in the art. Routes of administration include, but are not limited to oral, topical, sublingual, rectal, intranasal, intraocular, intravenous, intramuscular, transdermal, and by inhalation.” (*Id.* at 11, ll. 14-17.)

The Examiner asserts that Levin teaches the limitations recited in claim 13.

Levin teaches compositions comprising COX-2 inhibitors (NSAIDS) including celecoxib [its chemical name “4-[5-aryl-3-(trifluoromethylpyrazol-1-yl)benzenesulfonamides” is recited in claim 13] and rofecoxib [its chemical name “3-aryl-4-(4-methylsulfonylphenyl)-2(H5) furanones” is recited in claim 13] formulated in transdermal bandages or patches for topical administration. (abstract, page 7, lines 7-9, page 11, lines 14-17, page 12, lines 9-1, page 21, claim 42).

(Answer 4.)

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<sup>1</sup> Levin, WO 01/41783 A1, published Jun. 14, 2001.

Appellant argues that “Levin contains no examples which clearly, unequivocally and *simultaneously* contain all of the requisite elements of the Appellant’s claimed invention, i.e. (1) being a dermal system and (2) containing” celecoxib and rofecoxib (Br. 5). He acknowledges that “specific examples may not be necessary to establish anticipation,” but (citing *In re Petering*, 301 F.2d 676, 133 USPQ 275, 278 (CCPA 1962) argues that “this is generally limited to situations where the scope of the embodiments of the inventions are so few in number such that one of ordinary skill in the art could envisage every embodiment of the invention.” (Br. 5.) Because of the generality of Levin’s disclosure, he urges that selection of two specific COX-2 inhibitors for transdermal delivery as recited in claim 13 would have required “one of ordinary skill in the art . . . to resort to the type of picking and choosing which is precluded” in a rejection based on anticipation (Br. 7).

An anticipating “reference must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention.” *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed. Cir. 2002); *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) (“the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it”).

Transdermal and topical delivery are listed by Levin among ten different routes of administration for its compositions (at 11, pp. 15-17).

However, topical administration is specifically disclosed by Levin for tetracycline components, proteases, steroids, and topical antibiotics, but not for Cox-2 inhibitors (Levin at 10, ll. 28-30; 20 (cl. 33); 21 (cl. 43); 23 (cl. 55)). In anticipation cases based on the disclosure of a genus, a “pattern of preferences” had been found that narrowed the generic formula to limited class of compounds which included anticipatory species. *See In re Petering*, 301 F.2d 676, 681, 133 USPQ 275, 279 (CCPA 1962); *In re Schaumann*, 572 F.2d 312, 315, 197 USPQ 5, 8 (CCPA 1978); *Sanofi-Synthelabo v. Apotex Inc.*, 470 F.3d 1368, 1377, 81 USPQ2d 1097, 1102-03 (Fed. Cir. 2006). In this case, there is no clear “pattern of preferences” that would serve to narrow Levin’s generic disclosure to the specific embodiment in which a Cox-2 inhibitor is administered by topical administration.<sup>2</sup> The Examiner has not provided sufficient evidence to establish that the skilled worker would have recognized in Levin a “dermal therapeutic system” for delivery of a Cox-2 inhibitor. Because the Examiner’s burden to establish a case of prima facie anticipation has not been met, we reverse the rejection of claims 13-19.

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<sup>2</sup> The Examiner presumed that Levin’s “topical” administration is a disclosure of a dermal therapeutic system as required by claim 13. Appellant do not challenge this presumption, and we adopt it here for the purpose of this discussion.

*Obviousness under 35 U.S.C. § 103*

Claims 20-27 stand rejected under 35 U.S.C. § 103(c) as obvious over Levin in view of Lee.<sup>3</sup>

Claim 20 is drawn to a dermal therapeutic system that consists of a) a support layer which is impermeable to the Cox-2 inhibitor, celecoxib or rofecoxib; b) a reservoir or matrix layer that contains the Cox-2 inhibitor; c) optionally a control membrane; d) a contact adhesive layer to attach the dermal therapeutic system to the skin; and e) a protective layer. According to the Examiner, the only difference between the claimed subject matter and Levin is that Levin does not describe the specific elements a) through e) of the dermal therapeutic system recited in claim 20 (Answer 6). However, the Examiner states that Lee teaches a drug delivery device for administering NSAIDS that comprises the elements required by claim 20 (*id.*). The Examiner concludes:

It would have been obvious to one of ordinary skill in the art to formulate the COX-2 inhibitors including celecoxib and rofecoxib (NSAIDS) in a transdermal delivery device taught by Lee et al. because [the] transdermal device . . . delivers any NSAIDS in general to treat pain and . . . [increase] compliance for the user. One would have been motivated to formulate COX-2 inhibitor in [a] transdermal delivery system taught by Lee et al. in order to successfully treat patients suffering from pain and to increase the compliance.

(*Id.*)

Appellant does not challenge the Examiner's finding that Lee teaches a dermal therapeutic system that contains the same elements which are recited in claim 20. However, he argues that the phrase "consists of" recited

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<sup>3</sup> Lee et al. (Lee), U.S. Pat. No. 5,284,660, issued Feb. 8, 1994.

in claim 20 excludes the presence of CMO (Br. 8-9). “Given that CMO is a critical element of Levin's invention, there is no motivation or suggestion to remove this critical element from Levin's composition nor is there any reasonable expectation of success that Levin’s invention would be practicable without the presence of CMO.” (*Id.* at 9.)

Appellant also argues that Example 3 of Levin is a “teaching away” from using a Cox-2 inhibitor in the absence of CMO. He asserts that, without CMO, it was necessary to increase the doses “to two to three times the initial dose in order to maintain adequate symptomatic relief.” (Br. 10.) At these dosages, side effects, including “dizziness, nausea and abdominal pain” were observed. (*Id.*) The addition of CMO permitted the doses to be decreased to their initial levels. (*Id.*)

Finally, Appellant asserts that Lee does not teach or suggest the use of Cox-2 inhibitors alone for transdermal administration. Br. 10. “Lee offers no additional insight into Levin’s problems with the use of COX-2 inhibitors alone and are directed toward transdermal delivery of nicotine and melatonin, two drugs which differ greatly both structurally and functionally from the compounds used by Levin.” (Br. 10-11.)

After considering the record before, it is our opinion that there is sufficient evidence to establish that the subject matter recited in claim 20 is obvious. As indicated by the Examiner, Lee generally teaches that any NSAID can be administered transdermally (Answer 5). Lee at col. 8, ll. 3. Because celecoxib and rofecoxib are known NSAIDS, their administration via a transdermal delivery device is merely following Lee’s suggestion. While Lee does not explicitly disclose celecoxib and rofecoxib, a reference

must be “considered in its entirety for what it fairly suggests to one skilled in the art.” *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 687 (Fed. Cir. 1986). We find that Lee’s teaching that an NSAID can be administered by its drug delivery device “fairly suggests” that any NSAID can be used, including celecoxib and rofecoxib, which are known NSAIDS.

In reaching an obviousness determination, it is necessary to identify the differences between the claimed invention and the prior art, and then to determine whether these differences are obvious in view of the scope and content of the prior art and the level of skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 13-14, 148 USPQ 459, 465 (1966). Lee’s broad disclosure of agents which can be administered by its transdermal delivery device, including seven broad classes of agents (painkillers, steroidal anti-inflammatory drugs, NSAIDS, cardiovascular drugs, beta blockers, vasodilators and ACE inhibitors) and many additional examples of specific agents (*e.g.*, nicotine, caffeine, and melatonin) establish that choosing a particular agent to administer by Lee’s device is within the level of ordinary skill in the art. Because the only difference between the subject matter of claims 20-27 and the prior art is the choice of a known NSAID, celecoxib and rofecoxib, for Lee’s delivery device, its selection would have been obvious to the person of ordinary skill in the art in view of Lee’s explicit disclosure that its device is useful for administering NSAIDS.<sup>4</sup> (Col. 7, l. 55 to col. 8, l. 3.) In the absence of secondary considerations,

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<sup>4</sup> This same reasoning appears applicable to the subject matter of claims 13-19. Upon return of this application to the technology center, the Examiner should consider whether it is appropriate to reject claims 13-19 under this same grounds of rejection.

patents are not granted for merely following the suggestion of the prior art in a manner commensurate with the level of ordinary skill in the art.

Appellant argues that there was no motivation to have excluded CMO from Levin's delivery device (Br. 9). We are not persuaded. Appellant's own evidence establishes that both celecoxib and rofecoxib are administered in the prior art alone, without CMO. (*See* Exhibits 1 and 2.) As pointed out by the Examiner (Answer 9), Example 3, which Appellant relies on for his "teaching away" theory, includes doxycycline in addition to a Cox-2 agent (Levin at 14, ll. 20). Consequently, it is not clear whether the side effects are due to the Cox-2 agent, its combination with doxycycline, or the doxycycline alone.

Appellant also urges that Lee does not teach or suggest administering Cox-2 inhibitors because its disclosure is directed to the delivery of nicotine and melatonin, which differ "structurally and functionally" from Levin's compounds (Br. 10-11.) We disagree with Appellant's characterization of Lee's disclosure. Lee's specific working examples show delivery of nicotine and melatonin (cols. 9 to 11), but its disclosure suggests numerous other therapeutic agents (col. 7, l. 60 to col. 8, l. 22) that may be administered in his transdermal delivery device. In evaluating the scope and content of the prior art, "[a]ll the disclosures in a reference must be evaluated . . . a reference is not limited to the disclosure of specific working examples." *In re Mills*, 470 F.2d 649, 651, 176 USPQ 196, 198 (CCPA 1972). The structural diversity of agents<sup>5</sup> described by Lee as useful for

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<sup>5</sup> For example: nicotine, melatonin, steroids, and non-steroids. Col. 7, l. 62 to col. 8, l. 14.

transdermal administration suggests, contrary to Appellant's argument, that the person of ordinary skill in the art would have reasonably believed that transdermal delivery was not limited by a compound's structure.

For the foregoing reasons, we affirm the rejection of claim 20 as obvious over Levin in view of Lee. Because claims 21-27 were not separately argued, they fall with claim 20.

#### OTHER ISSUES

PCT International Publication WO 00/00120 was cited in an Information Disclosure Statement filed December 23, 2002. It is in the same patent family as the Murdock<sup>6</sup> patent, having a filing date of at least Jun. 29, 1999, which is earlier than the filing date of the instant application. Murdock discloses a transdermal composition which comprises a non-steroidal anti-inflammatory compound. Celecoxib and Vioxx® are specifically mentioned (Col. 2, ll. 48-54; col. 8, ll. 44-47). In Example 73, celecoxib is formulated with solvents and carriers as a gel for transdermal use (Col. 31, ll. 40-45). The Examiner should consider whether this example (and/or other disclosure in Murdock) anticipates and/or makes obvious the subject matter of claim 13 (and other pending claims), alone, or in combination with other prior art.

We also draw the Examiner's to U.S. Pat. 5,466,823<sup>7</sup> which discloses celecoxib, a compound of Formula I (Col. 4, ll. 64-65). The patent discloses that Formula I compounds can be administered topically (Col 47, l. 24). The Examiner should consider whether this disclosure anticipates and/or makes

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<sup>6</sup> Murdock et al., U.S. Patent 6,479,074 B2, issued Nov. 12, 2002.

<sup>7</sup> Talley et al. U.S. Patent 5,466,823, issued Nov. 14, 1995.

Appeal No. 2006-0760  
Application No. 10/312,417

obvious the subject matter of claim 13 (and other pending claims), alone, or in combination with other prior art.

TIME PERIOD

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-IN-PART/REVERSED-IN-PART*

DEMETRA J. MILLS )  
Administrative Patent Judge )  
)  
)  
) BOARD OF PATENT  
LORA M. GREEN )  
Administrative Patent Judge ) APPEALS AND  
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Appeal No. 2006-0760  
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