

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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Ex parte ALAN L. WEINER, and PIETER R. CULLIS

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Appeal No. 2001-2633  
Application No. 07/323,182

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ON BRIEF

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Before WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 81-86 and 88-97, which are all the claims pending in the application.

Claim 81 is illustrative of the subject matter on appeal and is reproduced below:

81. A composition comprising a liposome which comprises:
- (i) a lipid component consisting essentially of a glycolipid; and,
  - (ii) a non-steroidal anti-inflammatory drug

The references relied upon by the examiner are:

Lenk et al. (Lenk)	4,522,803	Jun. 11, 1985
Kikuchi et al. (Kikuchi)	4,687,661	Aug. 18, 1987

### GROUND OF REJECTION

Claims 81, 83-86 and 88-97 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kikuchi.

Claim 82 stands rejected under 35 U.S.C. § 103 as being unpatentable over Kikuchi in view of Lenk.

We reverse.

### DISCUSSION

#### Kikuchi:

According to the examiner (Answer, page 4), Kikuchi provides a generic description of encapsulating drugs into liposomes. While the examiner finds (id.) that Kikuchi does not limit the types of drugs that can be encapsulated into liposomes, Kikuchi specifically mentions acetaminophen and sodium salicylate, both of which are non-steroidal anti-inflammatory drugs (NSAIDs). Likewise, the examiner finds (id.), Kikuchi “teach that the membrane component of their liposomes may be made of a variety of lipids” including glycolipids. Based on this evidence the examiner concludes (id.), “a liposome containing glycolipids as the membrane component, and an NSAID as the encapsulated drug would have been prima facie obvious.”

In response, appellants argue (Brief, page 4, emphasis removed), “Kikuchi lists at least 10 distinct lipids that may be used in its liposomes... [and] at least 15 different drugs.... ” We note that Kikuchi disclose (column 2, lines 28-29) that the identified liposome membrane components may be used alone or in combination. In this regard, we further note appellants’ use of the transitional

phrase “consisting essentially of” in reference to the glycolipid component. See e.g., appellants’ claim 81. “By using the term ‘consisting essentially of,’ the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” PPG Indus. Inc. v. Guardian Indus. Corp., 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). According to appellants’ specification (page 6, emphasis added), liposomes within the scope of the claimed invention may be composed of lipid mixtures:

Suitable lipids that may be used in the present invention include glycolipids such as glycosphingolipids and galactolipids such as digalactosyl diglyceride (DGDG) or monogalactosyl diglyceride (MGDG) and GDGD and/or MGDG in combination with phospholipids such as phosphatidylcholine, phosphatidylserine, phosphatidylinositol, or phosphatidylethanolamine and their derivatives and sterol or tocopherol monoesters of diacids, such as cholesterol hemisuccinate and tocopherol hemisuccinate, respectively.

However, notwithstanding that appellants’ liposomes may contain membrane components other than glycolipids, appellants’ claims require that the liposome must, at a minimum, contain glycolipids. Therefore, the examiner must identify some suggestion in the prior art to select glycolipids from the genus of membrane components set forth in Kikuchi. Similarly, the examiner must identify some suggestion in the prior art to select acetaminophen or sodium salicylate from the genus of drugs that can be encapsulated into liposomes according to Kikuchi.

In this regard, we remind the examiner that the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to

establish a prima facie case of obviousness. In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (“The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.”); In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has “decline[d] to extract from Merck[ & Co. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that ... regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it.”). See also In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995).

To the contrary, in order to establish a prima facie case of obviousness in a genus-species situation, as in any other 35 U.S.C. § 103 case, it is essential that examiner find some motivation or suggestion to make the claimed invention in light of the prior art teachings. See, e.g., In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996) (the mere possibility that the prior art could be modified such that it would lead to the claimed invention does not make the claimed process obvious unless the prior art suggested the desirability of such a modification); In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) (“[A] proper analysis under § 103 requires, inter alia, consideration of ... whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process.”).

On this record the examiner fails to provide any evidence that the prior art would have directed a person of ordinary skill in the art at the time the invention

was made to select a glycolipid from the genus of membrane components disclosed by Kikuchi. To the contrary, the examiner simply asserts (Answer, bridging paragraph, pages 4-5), “[o]ne would have been motivated to select glycolipids as the membrane component because they are listed as being among the [genus of] exemplary lipids.” For the foregoing reasons, it is our opinion that the examiner’s assertion is incompatible with the relevant legal precedent. Similarly, we are not persuaded by the examiner’s assertion (Answer, page 4), “[o]ne would have been motivated to use acetaminophen or sodium salicylate because they are mentioned by name in the patent.” The examiner failed to explain why one of ordinary skill in the art would have selected acetaminophen or sodium salicylate from the genus of drugs disclosed by Kikuchi for inclusion in a liposome consisting essentially of a glycolipid. Once again, for the reasons set forth above, it is our opinion that the examiner’s assertion is incompatible with the relevant legal precedent.

On reflection, it is our opinion that the examiner failed to meet his burden of providing the evidence necessary to establish a prima facie case of obviousness. Accordingly, we reverse the rejection of claims 81, 83-86 and 88-97 under 35 U.S.C. § 103 as being unpatentable over Kikuchi.

Kikuchi in view of Lenk:

Relying on Kikuchi as set forth above, the examiner finds (Paper No. 48, page 4), that Kikuchi do not teach a stable plurilamellar liposome as set forth in appellants’ claim 82. To make up for this deficiency, the examiner relies on Lenk. According to the examiner (Answer, page 5), “[o]ne would have been

motivated to make [stable plurilamellar vesicles] SPLV's of the liposome in view of Lenk et al[.], who teach that any liposome may be improved by conversion to SPLV. We recognize the examiner's reference (Paper No. 48, page 4) to Lenk's disclosure (column 6, lines 17-20) that a variety of protein, glycoproteins, glycolipids, mucopolysaccharides and any other hydrophobic and/or amphiphathic substance may be complexed with lipid bilayers. Apparently, the examiner believes that by listing "glycolipids" in this genus of molecules which may be complexed to a liposome is sufficient to suggest that a glycolipid should be included in a liposome according to appellants' claimed invention. For the foregoing reasons we disagree.

In our opinion, Lenk fails to make up for the deficiencies in Kikuchi. Accordingly, we reverse the rejection of claim 82 under 35 U.S.C. § 103 as being unpatentable over Kikuchi in view of Lenk.

REVERSED

Sherman D. Winters )  
Administrative Patent Judge )  
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) BOARD OF PATENT  
Toni R. Scheiner )  
Administrative Patent Judge ) APPEALS AND  
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) INTERFERENCES  
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Donald E. Adams )  
Administrative Patent Judge )

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