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for publication and is not binding precedent of the Board.

Paper No. 19

# UNITED STATES PATENT AND TRADEMARK OFFICE

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte ROBERT A. HOLTON, SUHAN TANG,
FENG LIANG and CARMEN SOMOZA

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Appeal No. 2000-1294
Application No. 08/850,924

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH 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 2-9, 11-15, 17, 18, 20-37 and 40[1]. The only remaining claims, claims 19 and 39, were indicated by the examiner as allowed.

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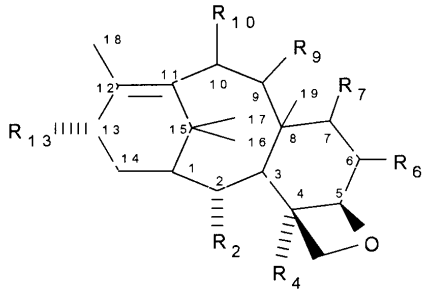
[1] We note that two consecutive Final Office Actions (Paper No. 11, mailed March 24, 1999 and Paper No. 12, mailed June 3, 1999) are present in the administrative file. While they were mailed less than three months apart, there is no statement on the record as to why a second Final Office Action was mailed in the absence of a response from appellants. Upon review of the two Office Actions, we note that they introduce a significant amount of confusion, into the record, with regard to which claims are indicated as allowed. The first (Paper No. 11) indicates that claims 39 and 40 are allowed. See pages 1 and 3. The second Final Office Action (Paper No. 12) indicates that claim 39 is allowed. See page 1. However, this same Action also indicates that both claims 39 and 40 are allowed. See page 4. In addition, while claim 40 is included in the listing of claims under rejection (see Paper No. 12, page 1), claim 40 is not included in the statement of the rejection at page 2. Notwithstanding the examiner's confusion, it appears that appellants correctly interpreted the examiner's intention (see Brief, page 1) finding "[t]his is an appeal from the final rejection of pending claims 2-9, 11-15, 17-37 and 40. Claim 39 was allowed." Nevertheless, while appellant did not separately argue any claim, the examiner finds (Answer, page 2) appellants' statement of the status of the claims incorrect finding instead (Answer, page 2) that "this appeal involves claims 2-9, 11-15, 17-18, 20-37 and 40. Claim 19 is now allowed and 39 was allowed." We believe the status of the claims is correctly reproduced above. Given our disposition, any error in correctly reciting the claims under rejection is harmless.

Claim 2 is illustrative of the subject matter on appeal and is reproduced below:

2. A compound having the formula:



wherein

M comprises ammonium or is a metal;

$R_2$ is $-OT_2$, $-OCOZ_2$, or $-OCOOZ_2$;

$R_4$ is $-OT_4$, $-OCOZ_4$, or $-OCOOZ_4$;

$R_6$ is hydrogen, keto, $-OT_6$, $-OCOZ_6$ or $-OCOOZ_6$;

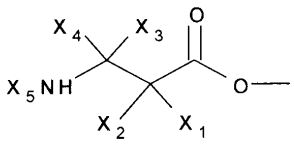
$R_7$ is hydrogen, halogen, $-OT_7$, $-OCOZ_7$ or $-OCOOZ_7$;

$R_9$ is hydrogen, keto, $-OT_9$, $-OCOZ_9$ or $-OCOOZ_9$, wherein $-OT_9$, $-OCOZ_9$ or $-OCOOZ_9$ have the beta stereochemical configuration;

$R_{10}$ is hydrogen, keto, $-OT_{10}$, $-OCOZ_{10}$ or $-OCOOZ_{10}$, wherein $-OT_{10}$, $-OCOZ_{10}$ or $-OCOOZ_{10}$ have the beta stereochemical configuration;

$R_6$ and $R_7$ independently have the alpha or beta stereochemical configuration;

$R_{13}$ is keto, MO-, hydroxy, protected hydroxy, or



;

$T_2$, $T_4$, $T_6$, $T_7$, $T_9$ and $T_{10}$ are independently hydrogen or hydroxy protecting group;

$X_1$ is $-OX_6$;

$X_2$ is hydrogen, hydrocarbon, heterosubstituted hydrocarbon, or heteroaryl;

$X_3$ and $X_4$ are independently hydrogen, hydrocarbon, heterosubstituted hydrocarbon, or heteroaryl;

$X_5$ is $-COX_{10}$, $-COOX_{10}$, $-COSX_{10}$, or $-CONX_8X_{10}$;

$X_6$ is hydrogen, hydrocarbon, heterosubstituted hydrocarbon, heteroaryl, or hydroxy protecting group or a functional group which increases the water solubility of the taxane compound;

$X_8$ is hydrogen, hydrocarbon, heterosubstituted hydrocarbon;

$X_{10}$ is hydrocarbon, heterosubstituted hydrocarbon, or heteroaryl; and

$Z_2$, $Z_4$, $Z_6$, $Z_7$, $Z_9$ and $Z_{10}$ are independently hydrocarbon, heterosubstituted hydrocarbon, or heteroaryl.

The reference relied upon by the examiner is:

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| Holton | 5,254,703 | Oct. 19, 1993 |

## GROUND OF REJECTION

Claims 2-9, 11-15, 17, 18, 20-37 and 40 stand rejected under 35 U.S.C. § 103 as being unpatentable over Holton.

We reverse.

## DISCUSSION

To establish a prima facie case of obviousness, there must be more than the demonstrated existence of all of the components of the claimed subject matter. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge cannot come from the applicants' disclosure of the invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger,

815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).

On this record, the examiner finds (Answer, page 4) that "Holton generically discloses compounds of the instant claims and their use as anti-tumor agents." According to the examiner (id.) "[t]he difference between the instant invention and that of Holton is in the generic descriptions of the claimed compounds." Stated differently, Holton does not specifically teach the claimed compounds, instead, Holton discloses a genus of compounds that encompass appellants' claimed compounds. While appellants do not dispute that their claimed invention may be included within the Holton genus, they point out (Brief, page 5) that "[t]he issue is NOT whether persons of ordinary skill would be led to prepare additional compounds. Rather, the issue is whether a person of ordinary skill would be led to prepare the tetracyclic, 1-deoxy compounds specifically defined by claim 2."

To make up for the deficiency in Holton, the examiner simply concludes (Answer, page 4) "the instantly claimed invention is prima facie obvious from the teaching of Holton because the indiscriminate selection of 'some' among 'many' is prima facie obvious. In re Lemin, [332 F.2d 839,] 141 USPQ 814 [CCPA 1964)]." In response, appellants argue (Reply Brief, page 2) "to arrive at the compounds claimed herein is not as simple as merely selecting C1-deoxy from among the C1 substituents. The claims herein also require a specific set of C2, C4, C6, C7, C9, C10 and C13 substituents. While many of these substituents also fall within the generic structure disclosed by Holton, nowhere in Holton is it

suggested that these substituents should be selected among the vast number of possibilities when C1 is deoxy." In addition, appellants point out (Brief, page 5), "in the most preferred embodiment of the Holton process, the process is used to prepare 1-hydroxy and NOT 1-deoxy compounds [footnote omitted]."

We must emphasize, there are no per se rules of obviousness or nonobviousness. In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995) ("reliance on per se rules of obviousness is legally incorrect."). Accord, In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996); In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Therefore, 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. See, Baird, 16 F.3d at 382, 29 USPQ2d at 1552 ("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."). As the court recognized in Deuel, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214-1215 (Fed. Cir. 1995) in those cases where a prima facie case of obviousness is based upon structural similarity "the prior art teaches a specific, structurally-definable compound and the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention." Stated differently, there must be some reason or

motivation to carve appellants' claimed compounds from the genus disclosed by Holton.

On this record, the examiner fails to identify any factual evidence suggesting that a person of ordinary skill in the art would modify Holton, to obtain appellants' claimed invention. Instead, as appellants point out (Reply Brief, page 2) C1-hydroxy compounds are the "most preferred alternative," not the C1-deoxy compounds claimed by appellants. We remind the examiner as set forth in In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (citations omitted):

> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so." Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."

On the record before us, we find no suggestion to modify Holton as relied upon by the examiner in a manner that would have reasonably led one of ordinary skill in this art to arrive at the claimed invention. The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In our opinion the examiner failed to provide the evidence necessary to support a prima facie case of obviousness. Where the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Accordingly, we reverse the rejection of claims 2-9, 11-15, 17, 18, 20-37 and 40 under 35 U.S.C. § 103 as being unpatentable over Holton.

REVERSED

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| SHERMAN D. WINTERS<br>Administrative Patent Judge | )<br>)<br>)<br>) BOARD OF PATENT |
| WILLIAM F. SMITH<br>Administrative Patent Judge | )<br>) APPEALS AND<br>)<br>) INTERFERENCES |
| DONALD E. ADAMS<br>Administrative Patent Judge | )<br>) |

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