

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* GUY T. CARTER,  
DAVID R. WILLIAMS  
and JOSEPH D. KORSHALLA

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Appeal No.95-0777  
Application 07/756,411<sup>1</sup>

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ON BRIEF

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Before WINTERS, METZ and WALTZ, *Administrative Patent Judges*.

WALTZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 4 and 5, which are the only claims remaining in this application.

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<sup>1</sup> Application for patent filed September 9, 1991.

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The subject matter on appeal is directed to the antibiotic LL-E19020 Gamma (hereafter "Gamma"), its composition and method of use for treating bacterial infections. The subject matter on appeal is adequately illustrated by appealed claim 1, which is reproduced and attached to this decision as an Appendix.

The references relied upon by the examiner are:

Naito et al. (Naito)                    3,872,079                    Mar. 18, 1975

Carter et al. (Carter)                4,705,688                    Nov. 10, 1987

Carter et al. (Carter II), "LL-E19020" and **S**, Novel Growth Promoting Agents: Isolation, Characterization and Structures", 41 *The Journal of Antibiotics*, no. 10, 1511-1514 (October 1988).

Claims 1, 4 and 5 stand rejected under 35 U.S.C. § 103 as unpatentable over Carter II in view of Naito. Claim 1 stands rejected under 35 U.S.C. § 102(b) as anticipated by Carter<sup>2</sup>. We reverse both stated rejections.

#### OPINION

##### A. *The Rejection under 35 U.S.C. § 103*

The claimed antibiotic compound Gamma is concededly produced by fermentation of the same strain of microorganism as Carter II uses to produce LL-E19020 alpha and beta (hereafter "alpha" and "beta", see the brief, page 3). The claimed compound Gamma

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<sup>2</sup> This rejection was a new ground of rejection made for the first time on page 5 of the examiner's answer.

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differs from alpha by having a hydroxyl group located at the 4-position of the phenylacetate ester group of position C-23 (see the brief, page 4, and the answer, page 4).

The examiner finds that the Gamma compound is structurally similar to the compounds alpha and beta of Carter II (answer, page 6). The examiner cites Naito as a secondary reference which "discloses various groups which can be substituted on antibiotic glycosidic compounds and includes phenyl moieties which can have substituents such as -OH" (answer, page 7). The examiner concludes that this reference (Naito) teaches the equivalence between H and -OH groups, "motivating one of ordinary skill in the art to substitute art-recognized equivalent moieties" to screen for greater antibacterial potency (answer, pages 7 and 11).

The examiner states that "the courts have consistently held that if the claimed invention is structurally similar to the prior art compound, non-obviousness can exist only if this novel structure produces results unexpectedly different from those of the prior art" (answer, page 7).

Contrary to this assertion by the examiner, the court has held that, irrespective of any close structural similarity, it is essential that the prior art applied by the examiner disclose or

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render obvious a method for making the claimed compounds. As stated by the court in *In re Hoeksema*<sup>3</sup>:

Thus, upon careful reconsideration it is our view that if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public [footnote omitted]. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds.

See also *In re Payne*, 606 F.2d 303, 314-15, 203 USPQ 245, 255 (CCPA 1979), and *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964). References relied upon to support a rejection under 35 U.S.C. § 103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public. *In re Payne*, 606 F.2d at 314, 203 USPQ at 255.

Appellants argue that there is no known way to make the substitution proposed by the examiner (brief, page 7). Appellants cite evidence from Carter II and U.S. Patent No. 5,077,277 (of record) that the proposed methods of preparing the claimed compounds, as suggested by the examiner, would not result in the claimed compounds (see page 8 of the brief).

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<sup>3</sup> 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968).

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The examiner concludes that "preparing the claimed invention is considered to be within the purview of the skilled artisan because hydroxylation of the compound disclosed by Carter (II) would yield the claimed compound" (answer, page 11). The examiner further concludes that "[A]ssuming arguendo, that this synthetic route is not feasible the method of preparing appellant's compound does not impart patentability to the compounds because both the claimed and prior art compounds are obtained by the fermentation of the same *Streptomyces lydicus* sp." (answer, page 11). The examiner has not established that, at the time appellants' invention was made, the prior art disclosed or rendered obvious a method for making the claimed compound (either chemically or by fermentation). As seen from *Hoeksema*, the method of preparation is essential if the reference is relied upon to support a rejection under section 103.

The examiner argues that isolation and purification techniques are considered "to be within the purview of the skilled artisan" and that Carter II teaches the purification and isolation of the alpha and beta compounds (answer, page 11). However, Carter II does not teach or suggest the **further** isolation and purification to produce the Gamma compound as per appellants' procedure on page 13 of the specification. Carter

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II, in producing alpha and beta, does not employ the same method as appellants, using a different nutrient system, a different number of fermentations, purifying certain fractions, etc. (compare page 1511 of Carter II with pages 10-13 of the specification).

Naito does not cure the deficiency in the enablement of Carter II. Naito is directed to a different family of antibiotics prepared by a totally different semi-synthetic method.

Given the disclosures of Carter II and Naito, we hold that compound Gamma was not placed in the possession of the public at the time appellants' invention was made. Accordingly, the rejection of claims 1, 4 and 5 under 35 U.S.C. § 103 as unpatentable over Carter II in view of Naito is reversed.

*B. The Rejection under 35 U.S.C. § 102(b)*

The examiner has rejected appealed claim 1, directed to the Gamma compound, as being anticipated by Carter since "[T]he instant compound is obtained from the same strain, by the same process and as such is inherently present in the prior art concentrate" (answer, page 6).

Appellants' response to this new ground of rejection is that the law is clear that for a rejection based upon inherency to be

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sustained, the inherency must be an inevitable result and not merely a probability or possibility (reply brief, page 2). Appellants argue that Carter has no teaching or suggestion that materials other than alpha and beta were produced.

For a reference to anticipate a claim, "the disclosure need not be express, but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art." *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047, 34 USPQ2d 1565, 1567 (Fed. Cir. 1995), *cert. denied*, 116 S. Ct. 516(1995). As correctly stated by appellants, the inherency must be an inevitable result and not merely a possibility. See *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).

As noted by appellants on page 2 of the reply brief, the process of preparing compounds alpha and beta of Carter is markedly different than the process of preparing Gamma disclosed by appellants (as specifically set forth on pages 10-13 of the specification). Appellants' process does not use the same nutrient medium as Carter nor the same air flow rate. Appellants' process does not use a silica column purification as set forth by Carter at column 8, lines 31-42, and uses further purification with a reverse phase column that Carter neither recognizes or employs (see the specification, page 13).

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The examiner concludes that "inherency is a certainty" because both the prior art and the instant process use the identical microorganism strain and "subject it [to] substantially identical fermentation procedures" (examiner's response to reply brief, page 1). However, it is clear from the above comparison of the processes of Carter and appellants that the fermentation and purification procedures are not "substantially identical" and it has not been shown by the examiner that it is inevitable that the same products would be produced by each process. Therefore, the examiner has not shown that the compound of appealed claim 1 is inherently produced by the prior art process.

Rejection for anticipation requires, as noted above for section 103 rejections, that a reference must describe the applicants' claimed invention sufficiently to have placed a person of ordinary skill in the art in possession of it, i.e., the reference must contain an enabling disclosure. See *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). However, the examiner has not presented any evidence that a skilled artisan would have expected any compounds other than

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alpha and beta to be produced by the method of Carter, much less know how to isolate and purify a compound such as Gamma. See *In re LeGrice*, 301 F.2d 929, 936, 133 USPQ 365, 372 (CCPA 1962)(A reference anticipates a claim if it discloses the claimed invention "such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.", emphasis in original).

Even assuming *arguendo* that the Gamma compound was produced by Carter, there was no recognition by Carter that any fraction contained a useful product other than the alpha and beta compounds in fractions 7 and 11-13, respectively (see column 8, lines 47-49). Carter does not recognize or appreciate that there was a 4-hydroxy derivative of alpha, that it was produced by the Carter process, or how to isolate and purify any such compound if present.

The examiner states that "unrecognized and unappreciated co-production of a chemical by a process does not bar a patent on the later invention of the same product", citing *Silvestri v. Grant*<sup>4</sup>, but limits this principle of law to duplications of an invention that are "both accidental and unappreciated" (emphasis

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<sup>4</sup> 496 F.2d 593, 596, 181 USPQ 706, 708 (CCPA 1974).

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examiner's, answer, page 6). The examiner concludes that the production of the claimed Gamma compound, though unappreciated, is "by no means accidental", and the complex of compounds was clearly intended to be made (answer, page 6).

Contrary to the examiner's interpretation, any production of Gamma by Carter would be considered accidental and unappreciated. Carter never recognized that 4-hydroxy derivatives of alpha existed or how to isolate and purify them. As conceded by the examiner, any production of Gamma by Carter was unappreciated (answer, page 6). This result may also be considered "accidental", i.e., not intended and not appreciated. See *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 43 S. Ct. 322 (1923). A prior achievement of a product may be considered accidental if it was a consistent though unintended or incidental consequence of what was deliberately intended<sup>5</sup>. It is clear that any production of Gamma by Carter was unintended or incidental to the deliberate production of alpha and beta.

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<sup>5</sup> *Chisum on Patents*, Vol. 1, § 3.03[2], p. 3-37 (Matthew Bender, 1997).

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For the foregoing reasons, the rejection of claim 1 under 35  
U.S.C. § 102(b) as anticipated by Carter is reversed.

*REVERSED*

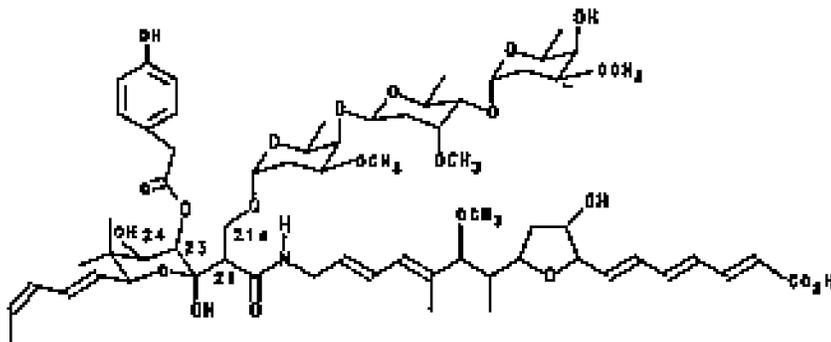
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|-----------------------------|---|-----------------|
| SHERMAN D. WINTERS          | ) |                 |
| Administrative Patent Judge | ) |                 |
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| ANDREW H. METZ              | ) | BOARD OF PATENT |
| Administrative Patent Judge | ) | APPEALS         |
|                             | ) | AND             |
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| THOMAS WALTZ                | ) |                 |
| Administrative Patent Judge | ) |                 |
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APPENDIX

1. A compound LL-E19020 Gamma comprising  
(a) the structure



- (b) an elemental analysis: C 62.22; H 7.77; N 0.92;
- (c) a molecular weight of 1241 (FABMS = M/Z 1264 corresponding to [M+Na]<sup>+</sup>);
- (d) a specific optical rotation:  
 $[\alpha]_{D}^{26E} = 7E(1.001, \text{MeOH})$
- (e) a characteristic ultraviolet absorption spectrum as shown in Figure I of the attached drawings;
- (f) a characteristic infrared absorption spectrum as shown in Figure II of the attached drawings;
- (g) a characteristic proton nuclear magnetic resonance spectrum as shown in Figure III of the attached drawings;
- (h) a characteristic carbon-13 nuclear magnetic resonance spectrum as shown in Figure IV of the attached drawings.

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