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PATENT OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

This opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAMES B. PINSKI

Appeal No. 94-0030
Application 07/849,764¹

HEARD:
October 10, 1995

Before WINTERS, WILLIAM F. SMITH, and ELLIS, *Administrative Patent Judges*.

ELLIS, *Administrative Patent Judge*.

DECISION ON APPEAL

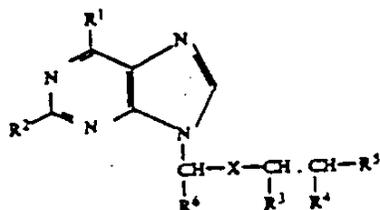
This is an appeal of the final rejection of claims 1 through 23, which are all the claims pending in the application.

¹ Application for patent filed March 12, 1992.

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Claims 1, 20, and 22 are illustrative of the subject matter on appeal and read as follows:

1. A method of treating a viral infection manifested in a human as at least one of warts, premalignancies, carcinomas, cancer of the cervix, human papilloma virus, Bowenoid papulosis or epidermal dysplasia verruciformis, said method comprising the step of administering a dosage of between about 1,500 mg/day and about 15,000 mg/day of a substituted purine of formula (I)



wherein X is selected from the group consisting of sulphur and oxygen; R¹ is hydroxy; R² is amino; R³ is selected from the group consisting of hydrogen, straight chain alkyl, branched chain alkyl, cyclic alkyl, hydroxyalkyl, benzyloxyalkyl and phenyl; R⁴ is selected from the group consisting of hydrogen, hydroxy, and lower alkyl; R⁵ is selected from the group consisting of hydrogen, hydroxy, amino, alkyl, hydroxyalkyl, benzoyloxy, benzoyloxyalkyl, benzyloxy, sulphamoyloxy, phosphate, carboxypropionyloxy, and acetoxy; R⁶ is selected from the group consisting of hydrogen, alkyl, hydroxyalkyl and a pharmaceutically acceptable salt thereof.

20. A method of treating a viral infection manifested in a human as at least one of warts, premalignancies, carcinomas, cancer of the cervix, human papilloma virus, Bowenoid papulosis and epidermal dysplasia verruciformis, which comprises the step of administering a dosage of between about 1,500 mg/day and 15,000 mg/day of 9-(2-Formyloxyethoxymethyl) guanine or a pharmaceutically acceptable salt thereof.

22. A method of treating a viral infection, according to claim 20, wherein said viral infection is warts and said dosage is between about 2,500 mg/day and about 10,000 mg/day.

The reference relied on by the examiner is:

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Schaeffer

4,199,574

Apr. 22, 1980

The claims were rejected as follows:

I. Claims 1 through 8, 10, 11, 14 and 16 through 23 stand rejected under 35 U.S.C. § 101 as being inoperative for treating all the human cancers recited therein.

II. Claims 1 through 23 stand rejected as unpatentable under 35 U.S.C. § 103 over Schaeffer.

Having carefully studied the record of this application, which includes the Appellant's Brief, the Examiner's Answer, and the declarations of Drs. Pinski, Rivers, and Kunimoto, we affirm the rejection under 35 U.S.C. § 101 and reverse the rejection under 35 U.S.C. § 103.

DISCUSSION
Rejection I

The present invention is directed to a method of treating several categories of viral infections which include warts, premalignancies, carcinomas, cancer of the cervix, human papilloma virus, Bowenoid papulosis and epidermal dysplasia verruciformis, using a broad range of substituted purines.

In the case before us, the examiner has taken the position that claims 1 through 8, 10, 11, 14, and 16 through 23 lack patentable utility by articulating on p. 3 of the Answer that "there is insufficient evidence of record demonstrating [sic,

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demonstrating] that appellant's compounds are effective for treating cancer in humans." The examiner's concern appears to be directed at the fact that the specification merely describes the structure of several substituted purines, but lacks any data related to treatments of the viral infections recited in the referenced claims.

In response, the appellant submitted four declarations, two by Dr. Pinski, and one each by Drs. Rivers and Kunimoto, as evidence that substituted purines are effective against one type of viral infection; i.e., warts. The two declarations of Dr. Pinski and the singular declaration of Dr. Rivers attest to the "medication covered U.S. Patent No. 4,199,574;" i.e., the Schaeffer patent, as producing "good results" in patients having warts.² However, we note that the declarations failed to disclose which, amongst the numerous substituted purines disclosed in the patent, were found to be effective. During the oral hearing the appellant's representative clarified this omission and indicated that the only effective compound for the treatment of warts is the 9-(2-Formyloxyethoxymethyl) guanine recited in claims 20 through 23. In addition, counsel acknowledged that (i) to date, the data had only demonstrated the

² Dr. Pinski's declaration, submitted September 30, 1992 in Paper No. 9, paragraphs 32-37; Dr. Pinski's second declaration submitted March 11, 1993, in Paper No. 16, paragraphs 25-30. Dr. River's declaration, submitted October 8, 1992 in Paper No. 11, paragraphs 46-50.

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effectiveness of this compound in treating a single viral infection; i.e., warts, and (ii) the appellant was not having good results treating any of the additional categories of viral infections recited in the claims with said compound. Consequently, counsel affirmed the statement on p. 40 of the Brief that the appellant is willing to withdraw the claims directed to a method of treating viral infections other than warts and, in addition, to limit the claims to the compound set forth in claim 20. However, an offer to cancel or limit claims is not sufficient to overcome the rejection, we can only consider the claims as they are presented to us on appeal. Therefore, on these facts, we affirm the rejection of claims 1 through 8, 10, 11, 14 and 16 through 21.

In view of the aforementioned admissions, and the lack of any position by the examiner with regard to the operability of the invention with respect to treating warts, it would appear that the § 101 rejection is not sustainable over claims 22 and 23 which are specifically limited to a method of treating warts with 9-(2-Formyloxyethoxymethyl) guanine. However, in reviewing the declarations submitted by Drs. Rivers and Kunimoto we found them to be inconsistent with the statement made by counsel at the oral hearing. The declarants have attested to their receiving a research grant from Burroughs Wellcome Pharmaceutical Co., the assignee of Patent No. 4,199,574, to investigate the use of

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Acyclovir, 9-[(2-hydroxyethoxy)methyl] guanine,³ for the treatment of recalcitrant viral warts,⁴ not the 9-(2-Formyloxyethoxymethyl) guanine indicated by counsel. Therefore, in view of this inconsistency, the record is not clear as to which of the substituted purines is effective for treating warts. Under these circumstances, we will sustain the rejection over claims 22 and 23 since the evidence of record suggests that none of the claims are directed to the treatment of warts with an effective composition.

Moreover, in view of the appellant's admission that only a single composition was effective in treating a single viral infection; i.e., warts, it is not clear why the examiner did not extend the § 101 rejection to include claims 9, 12, 13 and 15. On these facts, we find that it is reasonable to conclude that the successful treatment of warts using a single composition; i.e., 9-(2-Formyloxyethoxymethyl) guanine or 9-[(2-hydroxyethoxy)methyl] guanine, is not predictive of the efficacy of the range of compositions in the treatment of the broad categories of viral infections as required by the claims. *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974). Accordingly, we

³ The Merck Index, Tenth Edition, Merck & Co., Rahway, N.J. (1983), p. 22.

⁴ The declarations are both marked as being submitted on October 8, 1992 in Paper No. 11. See para. 43 of the Rivers declaration and para. 19 of the Kunimoto declaration.

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direct the appellant's attention to the rejection under 37 C.F.R. 1.196(b), *infra*.

Rejection II

Turning to the § 103 rejection, we find that the Schaeffer patent describes all of the substituted purines recited in the present method claims. The teachings of Schaeffer differ from the present methods of treatment in only one significant aspect--the present claims are directed to the treatment of different viral infections.

The examiner has argued on pp. 2-3 of the Answer that the Schaeffer patent:

clearly teaches appellants compounds as anti-viral agents for treating viruses broadly (note claims 23-31 and col. 1, lines 21-44) including "activity against various classes of DNA and RNA viruses both in vitro and in vivo" (col. 1, lines 35-37) in humans in the claimed ranges of 17,500 mg/day (250 mg/kg times 70 kg man - note col. 7, lines 23-78). In view of this one skilled in the art would be motivated to treat any DNA or RNA viral infection in man including warts, a DNA virus.

We agree with the examiner's description of teachings of the patent, but not with his conclusion as to the obviousness of the present invention over those teachings. We do not find that one skilled in the art would read Schaeffer as teaching that the substituted purines disclosed therein would be effective against all viruses or a panacea for all viral infections, just as the

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appellant has found that these compounds are not effective against all the presently claimed viral infections. As correctly pointed out by the appellant in the Brief, Schaeffer does not teach or suggest the use of any substituted purine, including 9-(2-Formyloxyethoxymethyl) or 9-[(2-hydroxyethoxy)methyl] guanine, for the treatment of the viral infections recited in the present claims. Given that there are innumerable RNA and DNA viruses which are potentially capable of infecting all forms of life from simple procaryotes through the highest mammalian species, there must be some suggestion in the Schaeffer patent as to the use of the disclosed substituted purines in the present methods of treatment, in order to establish a *prima facie* case of obviousness. That is, since Schaeffer discloses the virtually infinite genus of a method of treating all RNA and DNA viruses, absent a specific suggestion, such a broad teaching does not necessarily render obvious a method of treating any viral species which it happens to encompass, especially in an unpredictable art such as treating viral infections.

It is well settled that the examiner has the initial burden of establishing that the teachings of the applied prior art would have suggested to one of ordinary skill in the art that they should perform the claimed method, and that such a person would have a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). However, in the case

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before us, we find that the examiner has failed to provide any evidence of such a suggestion, either in the applied prior art, or on the basis of knowledge generally available to one of ordinary skill at the time the present application was filed. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

In response, the appellant has provided declarations which attest to the nonobviousness of the claimed methods of treatment. However, since we find on these facts, that the examiner failed to make a *prima facie* case of obviousness, the burden did not shift to the appellant to make such a showing. Accordingly, it is not necessary for us to consider the merits of the appellant's rebuttal evidence at this time.

For the foregoing reasons, the rejection is reversed.

The decision of the examiner is affirmed-in-part.

New Ground of Rejection

Under the authority of 37 C.F.R. § 1.196(b), we make the following new ground of rejection.

Claims 1 through 5 and 16 through 19 are rejected under 35 U.S.C. § 112, second paragraph, as being misdescriptive and confusing.

In claims 1 and 16, "R⁶" is written as a Markush group, however, the appellant's inclusion of "a pharmaceutically acceptable salt thereof" within said group is improper. The

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salts are not members of the Markush group. Inserting a conjunctive between "alkyl" and "hydroxyalkyl" will obviate this rejection for claims 1 through 4 and 16 through 19.

Similarly, in claim 5, the phrase "and a pharmaceutically acceptable salt thereof" must be distinguished from the hydrogen atoms of R³, R⁴, and R⁶.

Claims 9, 12, 13 and 15 are rejected under 35 U.S.C. § 101 as the appellant has failed to establish that the present compositions are effective for treating the viral infections recited therein.

As discussed *supra*, the facts of record in this case, which include the appellant's admission that successful results have been achieved for the treatment of warts with only one substituted purine, and not with additional compounds, or for other viral infections, we are obligated to extend the § 101 rejection to cover all the claims.

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date hereof (37 CFR 1.197).

With respect to the new rejection under 37 CFR 1.196(b), should appellant elect the alternate option under that rule to prosecute further before the Primary Examiner by way of amendment or showing of facts, or both, not previously of record, a

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shortened statutory period for making such response is hereby set to expire two months from the date of this decision. In the event appellant elects this alternate option, in order to preserve the right to seek review under 35 U.S.C. 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to us for final action on the affirmed rejection, including any timely request for reconsideration thereof.

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

AFFIRMED-IN-PART; 37 CFR 1.196(b)

Sherman D Winters

SHERMAN D. WINTERS)
Administrative Patent Judge)

William F. Smith

WILLIAM F. SMITH)
Administrative Patent Judge)

Joan Ellis

JOAN ELLIS)
Administrative Patent Judge)

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