

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BO HOFMANN, PARUNG NISHANIAN and JOHN L. FAHEY

Appeal No. 1996-0729
Application No. 07/859,572¹

HEARD: September 14, 1999

Before KIMLIN, OWENS, and SPIEGEL, *Administrative Patent Judges*.
SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 7, 12 through 14, 20 and 21. The final rejection of claims 22 and 23, which are the only other remaining claims pending in this application, has been withdrawn by the examiner (answer, page 3). Claims 1, 7 and 12 are illustrative and read as follows.

¹ Application for patent filed March 27, 1992.

Appeal No. 1996-0729
Application No. 07/859,572

The claims are rejected as follows:

I. Claims 1, 12 through 14, 20 and 21 stand rejected under 35 U.S.C. § 101 as lacking patentable utility (answer, pages 3-4 and 9-12).

II. Claim 7 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Legrand II (answer, pages 5 and 12-13).²

III. Claim 7 stands rejected under 35 U.S.C. § 103 as being unpatentable over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II (answer, pages 7-9 and 14-15).

IV. Claims 1 and 12 through 14 stand rejected under 35 U.S.C. § 103 as being unpatentable over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II (answer, pages 5-7 and 13-14).³

We *sustain* rejections II and III and *reverse* rejections I and IV for reasons which follow.

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's answer (Paper No. 26, mailed

²Our decision is based upon consideration of Legrand II which, according to the examiner, is the full length article underlying Legrand I (answer, page 3).

³The rejection of claims 20 through 23 under 35 U.S.C. § 103 over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II has been withdrawn by the examiner (answer, page 3).

Appeal No. 1996-0729
Application No. 07/859,572

February 17, 1995) for the examiner's reasoning in support of the rejections, and to the appellants' brief (Paper No. 24, filed November 16, 1994) and the appellants' reply brief (Paper No. 28, filed April 19, 1995) for the appellants' arguments thereagainst.

BACKGROUND

According to appellants, HIV components, and therefore HIV infections, inhibit T-lymphocyte proliferation by elevating the PKA/cAMP pathway in affected lymphocytes. Appellants' invention is directed (1) to methods using a known inhibitor, i.e., 2',5'-dideoxyadenosine, of an essential component of the PKA/cAMP pathway, i.e., adenylate cyclase, to inhibit elevation of the PKA/cAMP pathway thereby restoring normal T-lymphocyte proliferation and function (claim 1) and treating a subject infected with HIV (claim 12) and (2) to pharmaceutical compositions comprising 2',5'-dideoxyadenosine and a pharmaceutically acceptable excipient (claim 7). [Brief, pages 2-3.]

OPINION

I. Rejection of method claims 1, 12-14, 20 and 21 under 35 U.S.C. § 101 for lack of utility.

With respect to the utility rejection, claims 1, 12-14, 20 and 21 stand or fall together (reply brief, page 2). We, therefore, direct our attention to the broadest claim, claim 1, which is generic to both *in vitro* and *in vivo* methods.

Appeal No. 1996-0729
Application No. 07/859,572

According to the examiner, claims directed to affecting a biochemical pathway are absent utility unless the claims recite specific therapeutic regimens producing some therapeutic benefit (answer, pages 4 and 11). To support this rejection, the examiner cites “Splendor form Brassiere, Inc v Rapid-American Corp., 187 USPQ 158 (CCPA 1975)” (answer, page 4). No such case is found at that volume and page. However, a case styled in that manner is found at 187 USPQ 151. The decision reported therein is that of a United States District Court, not the Court of Customs Patent Appeals as stated by the examiner. In that case, the district court raised on its own motion a question of utility under 35 U.S.C. § 101 stating, 187 USPQ at 156: “if a patented invention fails to achieve the one advantage over the prior art which the patent specification asserts for it, it can hardly be said to be ‘useful’ as required by 35 U.S.C. § 101.” If in fact, this is the case the examiner intended to cite, it is not at all clear what relevance it has to the subject matter and issues at hand.

We also find the examiner’s argument that *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985) and *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980) support the position “that claims directed to mediating a biochemical pathway, absent an established nexus between the pathway modification and therapeutic benefit are devoid [of] utility and properly rejected under 35 USC 101” (answer, page 10) not well taken.

Appeal No. 1996-0729
Application No. 07/859,572

In *Nelson*, the CCPA addressed the practical utility requirement in the context of an interference proceeding. Bowler challenged the patentability of the invention claimed by Nelson on the basis that Nelson had failed to sufficiently and persuasively disclose a practical utility for the invention, i.e., a class of synthetic prostaglandins modeled on naturally occurring prostaglandins. Naturally occurring prostaglandins are bioactive compounds which had a recognized pharmacological value (e.g., the ability to raise or lower blood pressure, etc.) at the time of Nelson's application. Nelson's specification included the results of tests demonstrating the bioactivity of his new substituted prostaglandins relative to the bioactivity of naturally occurring prostaglandins. The court concluded that Nelson had satisfied the practical utility requirement in identifying the synthetic prostaglandins as pharmacologically active compounds.

In *Cross*, the Federal Circuit affirmed a finding by the Board of Patent Appeals and Interferences that a pharmacological utility had been disclosed in the application of one party to an interference proceeding. The invention that was the subject of the interference count was a chemical compound used for treating blood disorders. Cross had challenged the evidence in Iizuka's specification that supported the claimed utility. The Federal Circuit relied extensively on *Nelson v. Bowler* in finding that Iizuka's application had sufficiently disclosed a

pharmacological utility for the compound. It distinguished the case from cases where only a generalized “nebulous” expression, such as “biological properties,” had been disclosed in the specification. The court held that such statements “convey little explicit indication regarding the utility of a compound.” *Cross*, 753 F.2d at 1048, 224 USPQ at 745.

Thus, *Cross v. Iizuka* and *Nelson v. Bowler* made clear that a showing of pharmacological activity, i.e., mediating a biochemical pathway, is sufficient to establish utility for a claimed compound. Here, the examiner has not challenged the patentability of the *compound* claims.⁴ Therefore, this argument is not well taken.

Rather, we find that the statement of the invention at page 4, lines 25-35 of the specification coupled with Figures 9-11 and its supporting data on pages 24-29 sufficient to satisfy the utility requirements of 35 U.S.C. § 101. The examiner has not articulated reasons why the skilled artisan would conclude that the asserted utility is not credible or explained why the evidence of record, e.g., at specification pages 24-29, that supports the asserted utility would not be persuasive to one of ordinary skill in the art.

Accordingly, we reverse the rejection of method claims 1, 12-14, 20 and 21 under 35 U.S.C. § 101 for lack of utility.

⁴The examiner admits that “[a]ppellants’ composition claims have numerous uses, not limited to the pathway modification herein claimed” (answer, page 11).

Appeal No. 1996-0729
Application No. 07/859,572

II. Rejection of composition claim 7 under 35 U.S.C. § 102(b) as being anticipated by Legrand II.

and

III. Rejection of composition claim 7 under 35 U.S.C. § 103 as being unpatentable over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II.

First, anticipation requires that all elements of the claimed invention be described, either expressly or under the principles of inherency, in a single prior art reference. *In re Paulsen*, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied* 465 U.S. 1026 (1984). Second, to be anticipatory, the reference need not teach the appellants' invention, it is only necessary that the claim language "read on" something disclosed in the reference. *Kalman v. Kimberly-Clark Corp.*, *supra*.

According to the examiner, Legrand II anticipates the composition of claim 7 because

Legrand et al teach 2' , 5' - dideoxyadenosine (page 1104, column 2, paragraph 3) in an aqueous buffer system (page 1104, column 1, paragraph 4). The skilled artisan would have seen the Legrand et al aqueous buffer as a pharmaceutical carrier or excipient. An active ingredient residing in a pharmaceutical carrier or excipient defines a pharmaceutical composition, thus, the Legrand et al teaching anticipates Appellants' claim 7. [Answer, page 12]

Indeed, the specification broadly defines acceptable excipients to include water containing buffering agents (para. bridging pages 9-10).

Appeal No. 1996-0729
Application No. 07/859,572

Appellants argue that pharmaceutical compositions are inherently limited to only certain uses based on only certain indications, e.g., a package insert describes the circumstances under which the pharmaceutical composition would be used (brief, pages 8-9 and reply brief, page 7).

While intended use recitations and other types of functional language cannot be entirely disregarded in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The directions in a package insert will not change the composition of the contents. Here, there is no indication that the “laboratory” composition disclosed by Legrand II, which can bring adenylate cyclase activity back to near basal levels (page 1104, col. 2, para. 3, last two lines), is any different from the claimed “pharmaceutical” composition.

Accordingly, we sustain the rejection of claim 7 under 35 U.S.C. § 102 as being anticipated by Legrand II.

Moreover, since anticipation is the epitome of obviousness (*In re Fracalossi*, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982)), we will also sustain the examiner's section 103 rejection of claim 7 as unpatentable over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II. A discussion of Mitsuya, Ahluwalia, Herdewijn, Van Aerschot and Harmenberg is not necessary to our decision.

Appeal No. 1996-0729
Application No. 07/859,572

IV. Rejection of method claims 1 and 12 through 14 under 35 U.S.C. § 103 as being unpatentable over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II.

Mitsuya, Ahluwalia, Herdewijn, Van Aerschot and Harmenberg all disclose 2', 3' - dideoxynucleosides, e.g., 2', 3' - dideoxyadenosine and/or 2', 3' - dideoxyinosine, as antiviral agents which inhibit HIV infection. Legrand II has been discussed *supra*.

According to the examiner, these 2', 3' - dideoxynucleosides are positional isomers of 2', 5' - dideoxyadenosine and their known antiviral activity would have suggested that 2', 5' - dideoxyadenosine also possessed antiviral (i.e., anti-HIV) activity, thereby rendering the claimed methods obvious (answer, pages 5-6). However, the examiner has not rebutted appellants' arguments that these structural relationships are not sufficiently close in the context of deoxynucleosides to suggest a common activity (brief, pages 9-10). There is no evidence of record that 2', 3' - dideoxynucleosides inhibit adenylate cyclase and the specification explicitly states that "[i]n contrast to 2', 3' -adenosine analogs, ddAdo [i.e., 2', 5' -dideoxyadenosine] has no antiviral effect" (page 24, lines 31-32).

According to the examiner, the claims simply read on inhibiting the PKA/cAMP pathway and since "cited prior art," presumably Legrand II, teaches inhibiting this pathway by administering 2', 5' - dideoxyadenosine, claims to such as a use are obvious (answer, page 14).

Appeal No. 1996-0729
Application No. 07/859,572

Appellants admit that 2', 5' - dideoxyadenosine is known to inhibit adenylate cyclase (brief, page 11). Appellants argue (a) that none of the cited references disclose or suggest that inhibiting the PKA/cAMP pathway would counteract a major effect of cellular contact with HIV/HIV components and (b) that the examiner has failed to provide any motivation to combine the references (brief, page 12).

To establish a *prima facie* case of obviousness, there must be both some suggestion or motivation to modify the references or combine reference teachings and a reasonable expectation of success. Furthermore, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Here, we agree with appellants that the examiner has not established that one of ordinary skill in the art would have reasonably expected 2', 3' - dideoxynucleosides and 2', 5' - dideoxyadenosine to possess common biological activities so as suggest using a known adenylate cyclase inhibitor as an antiviral agent or *vice versa*. We also agree with appellants that the examiner has failed to provide a reason or motivation to combine the primary references with Legrand II. While Legrand II discloses inhibiting adenylate cyclase with 2', 5' - dideoxyadenosine, that is not the claimed invention. We find that the only incentive to use 2', 5' - dideoxyadenosine to prevent or reverse the functional deficiency induced in lymphoid cells during HIV infection or by exposure to HIV components or to treat a subject infected with HIV in this case is provided by appellants' disclosure.

Accordingly, we reverse the rejection of claims 1 and 12 through 14 under 35 U.S.C.

Appeal No. 1996-0729
Application No. 07/859,572

§ 103 as being unpatentable over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II.

CONCLUSION

To summarize, the decision of the examiner (I) to reject claims 1, 12-14, 20 and 21 under 35 U.S.C. § 101 as lacking patentable utility is **reversed**, (II) to reject claim 7 under 35 U.S.C.

§ 102(b) as being anticipated by Legrand II is **affirmed**, (III) to reject claim 7 under 35 U.S.C.

§ 103 as being unpatentable over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II is **affirmed**, and (IV) to reject claims 1 and 12-14 under 35 U.S.C. § 103 as being unpatentable over Mitsuya, Ahluwalia, Herdewijn, Van Aerschot, Harmenberg and applicants' admission in view of Legrand II is **reversed**.

Appeal No. 1996-0729
Application No. 07/859,572

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Appeal No. 1996-0729
Application No. 07/859,572

MORRISON & FOERSTER
2000 PENNSYLVANIA AVENUE, N.W.
SUITE 5500
WASHINGTON, D.C. 20006-1812