

This opinion is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte OSI PHARMACEUTICALS, INC.

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Appeal 2007-4007  
Application 90/006,954  
Technology Center 1600

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Decided: September 20, 2007

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Before FRED E. McKELVEY, *Senior Administrative Patent Judge*, and  
ADRIENE LEPIANE HANLON and RICHARD TORCZON,  
*Administrative Patent Judges*.

TORCZON, *Administrative Patent Judge*.

DECISION ON APPEAL

The invention on appeal broadly relates to the use of an effector for a dipeptidyl peptidase (DP) IV enzyme to increase the capacity of insulin producing cells in an animal. Claim 3 stands rejected under 35 U.S.C. §§ 102(a) and 103. The appellant (OSI) seeks review of the rejections. We affirm.

CLAIM 3

Claim 3 is the sole claim on appeal. It defines the invention as follows (Amended Appeal Brief (Br.) 11 (claim appendix)):

A method for increasing the capacity of insulin producing cells in an animal comprising repeatedly administering to said animal a therapeutically effective dose of at least one DP IV enzyme activity effector and causing cells present in the pancreas to differentiate into insulin producing cells.

We are obliged to construe a claim as broadly as is reasonably possible in view of the disclosure. We understand the express step of the method to require the repeated dosing of a patient with an effective amount of at least one DP IV enzyme activity effector. We further understand the result of this regimen to be, *inter alia*, the differentiation of some pancreas cells into insulin-producing cells such that the collective cellular insulin-producing capacity of the patient increases. The claim is not limited to any specific dosage or rate of administration.

#### THE REJECTIONS

After the final rejection, OSI limited the claims under consideration to claim 3. Consequently, we take the final statement of the rejections from the Examiner's Answer (Ans. 7-14). Claim 3 stands rejected for being directed to an invention that was anticipated by a published German application (Probiotdrug):

Probiotdrug Gesellschaft für Arzneimittelforschung, *Neue Effektoren von Dipeptidylpeptidase IV*, DE 299 09 210 U1 (pub'd 9 September 1999)

We rely on the English-language translation in the record.

Claim 3 stands rejected for being directed to an invention that was anticipated by a Villhauer published application.

Edwin B. Villhauer, *N-substituted 2-cyanopyrrolidines*, WO 98/19998 (pub'd 14 May 1998)

OSI has not pointed us to evidence that would antedate or otherwise call into question the availability of these publications as prior art under §102(a).

Claim 3 also stands rejected for being directed to subject matter that would have been obvious to a person having ordinary skill in the art in view of a third reference. Since we affirm the anticipation rejections, we do not reach the obviousness rejection.

*Anticipation by the Probiодrug published application*

The Probiодdrug publication discloses the use of dipeptide compounds to treat a variety of conditions, including diabetes mellitus. The invention is (Probiодdrug 1, ¶¶1-2)—

a simple method of lowering the blood sugar concentration in mammals with the aid of dipeptide compounds as activity-reducing effectors (substrates, pseudosubstrates, inhibitors, binding proteins, antibodies etc.) for enzymes having activity comparable to or identical to the enzymatic activity of the enzyme dipeptidyl peptidase IV.

We note that mammals are animals. Administration of effectors for the DP IV enzyme is said to lower mammalian serum glucose concentration below the level characteristic of hyperglycemia (Probiодdrug 8, ¶2).

Probiодdrug contemplates the use of the method as a long-term treatment of diabetes mellitus (Probiодdrug 5, ¶4). Long-term treatment would require repeated administration of the effectors. Probiодdrug even discusses a daily dosing regimen (Probiодdrug 9, ¶3).

OSI argues (Br. 5:2-10) that—

While DE 29,909,210 U1 [the Probiодrugs application] utilizes a DP IV inhibitor to treat diabetes mellitus, it is specifically silent as to the use of the DP IV inhibitor mechanism to facilitate the conversion of epithelial cells in the pancreas to insulin producing cells. Instead, DE 29,909,210 U1 utilized a DP IV inhibitor to lower the blood sugar concentrations (page 1) by suppressing the undesired enzyme activity (page 2, paragraph 1) as a simple alternative acute treatment of symptoms. (page 2, paragraph 2) The result is a temporary decrease in the reduction in GLP-1 [glucagon-like peptide-1], whereas in the present invention the method, as a result of maintaining the extended presence of GLP-1, causes cells present in the pancreas to differentiate into insulin producing cells.

OSI is correct that Probiодrugs does not teach the use of the effectors to facilitate the conversion of epithelial cells in the pancreas to insulin-producing cells. It does, however, teach administering the same DP IV enzyme-specific effectors to the same group of patients as therapy for the same conditions. Although OSI argues that Probiодrugs teaches an "acute treatment", we find the reference makes clear that it also contemplates daily, long-term therapy. Indeed, OSI's argument does not really deny as much since "maintaining the extended presence of GLP-1" would require avoiding even short-term "reduction in GLP-1".

Claim 3 and the Probiодrugs reference differ not in the actual method, but rather in what is said to be the result of the method. We must start with the premise that both the Probiодrugs reference and the disclosure underlying claim 3 are enabled. Thus, we presume the method of repeatedly treating a diabetes patient with DP IV effectors will have both therapeutic effects (i.e., both the benefits disclosed in Probiодrugs and the benefits now claimed). In the absence of evidence to the contrary, we find that the benefit that now

serves to distinguish claim 3 from the daily therapy of Probiодrugs was, in fact, an inherent benefit of that therapy.

We find the anticipation rejection over the Probiодrugs publication to be supported by a preponderance of the evidence of record on appeal.

*Anticipation by the Villhauer published application*

Villhauer is also interested in regulating the inactivation of GLP-1 by regulating dipeptidyl peptidase IV (which Villhauer labels DPP-IV) in mammalian systems to treat diabetes and related conditions. Villhauer calls the DPP-IV effectors "inhibitors" since their effect is to inhibit DPP-IV (Villhauer 1). Villhauer also contemplates daily doses, beginning with a small dose that is increased until an optimal dosing level for the patient is determined (Villhauer 19-20).

OSI again stresses the difference in the effect disclosed in Villhauer versus the effect now claimed. OSI also again urges that Villhauer teaches an acute treatment. We again find the reference is not so limited. Villhauer expressly describes a program of repeated doses of the inhibitor in a mammal. Villhauer also describes therapeutic effectiveness in treating diabetic symptoms.

Although the Villhauer publication describes a different biological mechanism for the benefits it describes, we cannot read the reference to exclude other biological effects, including those now claimed. Again, Villhauer teaches inhibitors targeting the same enzyme (DP IV) in the same pathway (GLP-1 inactivation) in the same patients to relieve diabetes-related symptoms. In the absence of any evidence to the contrary, we find that the inhibitors must inherently have the same effect that is now claimed for them.

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We find the anticipation rejection over the Villhauer publication to be supported by a preponderance of the evidence of record on appeal.

HOLDING

The rejection of claim 3 is—

AFFIRMED

VW

Michael J. Rafa,  
OSI PHARMACEUTICALS, INC.  
41 PINELAWN ROAD  
MELVILLE, NY 11747