

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte SUNTJE SANDER-STRUCKMEIER, CLAUS RUDOLF STEINBORN,
MARTIN A. RUDMANN, DIETHARD SCHWANITZ
and FRIEDERIKE HENNIGES

Appeal No. 2005-1150
Application No. 09/953,450

HEARD: August 25, 2005

ELLIS, MILLS and GRIMES, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 of the examiner's final rejection of claims 1-7. Claims 8-11 have also been rejected by the examiner, but their rejection has not been appealed.

As a preliminary matter, we note the appellants' statement on page 5 of the Brief that the claims do not stand or fall together. The appellant states that claims 2 and 5 stand separately. Accordingly, we find that there are three groups of claims; Group I consisting of claims 1, 3, 4, 6 and 7; Group II consisting of claim 2 and Group III consisting of claim 5. Thus, for purposes of this appeal we have considered the issues as they apply to claims 1, 2 and 5. These claims read as follows:

1. A method of treating primary diabetes mellitus Type I in a larger mammal or human comprising administering to said mammal or human an effective amount of a pharmaceutical preparation comprising a physiologically acceptable enzyme mixture having lipolytic, proteolytic and amylolytic activity.
2. A method according to claim 1, wherein said pharmaceutical preparation comprises a physiologically acceptable enzyme mixture of microbially synthesized lipases, proteases and amylases.
5. A method according to claim 3,^[1] wherein said pharmaceutical preparation comprises pancreatin or a mixture of digestive enzymes containing pancreatin, and at least one microbial enzyme selected from the group consisting of lipases, proteases and amylases.

¹ Claim 3 reads as follows:

3. A method according to claim 1, wherein said pharmaceutical preparation comprises pancreatin.

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The references relied upon by the examiner are:

Fallis et al. (Fallis), "Observations on some metabolic changes after total pancreateoduodenectomy," Annals of Surgery, pgs. 639-667, 1948.

Delhaye et al. (Delhaye), "Comparative evaluation of a high lipase pancreatic enzyme preparation and a standard pancreatic supplement for treating exocrine pancreatic insufficiency in chronic pancreatitis," European Journal of Gastroenterology and Hepatology, vol. 8, no. 7, pgs. 699-703, 1996.

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Fallis in view of Delhaye.

We reverse, and set forth a new ground of rejection under 37 C.F.R. § 41.50(b) with respect to claims 1 and 3-7. Absent further action by the examiner, claim 2 stands free of the prior art.

Background

As indicated by the claims above, the present invention is directed to a method of treating primary diabetes mellitus Type I. The specification discloses that Type I diabetes is due to an insulin deficiency (pages 1 and 7); and Type II diabetes is due to reduced insulin effectiveness (page 1). Thus, the specification defines Type I diabetes as being insulin dependent; whereas Type II is non-insulin-dependent. Id. These

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definitions are consistent with the definitions set forth in the attachments to the appellants' brief.²

Insulin is a hormone, which is produced in the pancreas. Insulin acts to control the glucose levels in the blood by transporting it through cell membranes and into the cells. American Diabetes Association information attached as Appendix C to the Brief. In addition to its endocrine function (production of the hormones insulin and glucagon), the pancreas also has an exocrine function which involves the production of several

² The appellants have attached Stedman's Medical Dictionary, 26 Edition, Williams & Wilkins, Baltimore (1995) as Appendix B to the Brief. The dictionary defines Type I diabetes as an "insulin-dependent" and Type II as "non-insulin-dependent" disease. See, pp. 472-73. The dictionary discloses that

Of the 14 million Americans with diabetes, roughly 90% have Type II (non-insulin-dependent) and roughly 10% have Type I (insulin-dependent) disease [p. 473].

The appellants have attached information from the American Diabetes Association (<http://diabetes.org/about-diabetes.jsp>) as Appendix C to the Brief. The Association information states, inter alia, that

Type I diabetes

Results from the body's failure to produce insulin, the hormone that "unlocks" the cells of the body, allowing glucose to enter and fuel them. It is estimated that 5-10% of Americans who are diagnosed with diabetes have type I diabetes [page 1].

Type II diabetes

Results from insulin resistance (a condition in which the body fails to properly use insulin), combined with relative insulin deficiency. Approximately 90-95% (17 million) of Americans who are diagnosed with diabetes have type 2 diabetes [page 2].

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enzymes involved in digestion. These enzymes include the proteases trypsin and chymotrypsin, amylase and lipase. See, e.g., the Reply Brief, p. 4.

The specification discloses that “[p]ancreatin is a known enzyme mixture with lipolytic, proteolytic and amylolytic activity which is available for example, under the trade name Creon®.” Specification, p. 4.

Discussion

The examiner relies primarily on the teachings of Fallis and the disclosure therein of the use of pancreatin to treat patients who have diabetes as a result of having a total pancreatoduodenectomy. Answer, p. 4. The examiner contends that “[b]ecause the pancreas has been [surgically] removed ... [in these patients], the diabetes being treated is analogous to Type I diabetes.” Id. The examiner acknowledges that “Fallis does not teach that another lipase, amylase or protease is additionally administered with the pancreatin to the patient having diabetes . . . [or] that the additional enzyme comes from a microbial source.” Id., p. 5. The examiner relies on Delhaye to make up for these shortcomings. To that end, the examiner argues that “Delhaye teaches that lipase is administered to a patient having diabetes associated [sic, associated] with chronic pancreatitis . . . [and] that a bacterial lipase could be used in their treatments.” Id. The examiner concludes that “[i]t would have been obvious to one of ordinary skill in the art to administer not only pancreatin but also an enzyme such as lipase with the pancreatin to a patient with diabetes since Fallis teaches administering pancreatin to a

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patient having diabetes and since Delhaye makes it clear that lipase is routinely administered along with pancreatin to patients with chronic pancreatitis.” Id.

Although the examiner has made several excellent points with respect to the applied prior art, we find the rejection fails primarily for two reasons.

First, we find the examiner’s reliance on Fallis to be misplaced. Patients having a total pancreatoduodenectomy must receive treatment to replace both the lost endocrine and exocrine functions of the pancreas. Patients with Type I diabetes, as set forth in the claims, primarily lack only the endocrine function of the pancreas. Thus, we disagree with the examiner that the condition of the patients taught by Fallis is analogous to patients having Type I diabetes.

Second, in making a prima facie case of obviousness, it is the examiner’s responsibility to show that some objective teaching or suggestion in the applied prior art, or knowledge generally available [in the art] would have led one of ordinary skill in the art to combine the references to arrive at the claimed invention. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). As discussed above, we do not find that the treatment group taught by Fallis is analogous to patients having Type I diabetes. Rather, Fallis treats patients lacking a pancreas and, therefore, the endocrine and exocrine functions associated therewith. Delhaye discloses treating patients having both exocrine pancreatic insufficiency and Type I diabetes. The common ailment between the patients in the applied prior art is exocrine insufficiency, not diabetes. Thus, we do not find that the teachings therein

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would have suggested to one of ordinary skill in the art that the references should be combined to arrive at the claimed treatment of diabetes Type I.

Nevertheless, we note that during the prosecution of the application, and up until the Answer was submitted, the examiner had rejected the claims under 35 U.S.C. 102(b) as being anticipated by Delhaye. It is not clear to us why the examiner dropped this rejection. We hereby reinstate the 102(b) rejection, but because the rejection was withdrawn by the examiner we do so as a new ground of rejection pursuant to 37 C.F.R. § 41.50(b).

New Ground of Rejection

Claim 1

Claims 1, 3, 4, 6 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Delhaye.

We find that Delhaye discloses treating twelve (12) patients having insulin-dependent diabetes with pancreatin having lipolytic, amylolytic and proteolytic activity. Delhaye, p. 700, col. 1, para. 5 and col. 2, paras. 3-5. Specifically, Delhaye discloses treating said patients with pharmaceutical preparations comprising a physiologically acceptable enzyme mixture of “25,000 European Pharmacopoeia Units (EPU) lipase, 22,500 EPU amylase and 1250 EPU protease” (Pancrease HL capsules) or “8,000 EPU lipase, 9,000 EPU amylase and 450 EPU protease” (Creon capsules). *Id.*, col. 2, paras. 3-5. According to the specification and the Appendixes attached to the Brief, diabetes mellitus Type I is insulin-dependent diabetes. Thus, we find that Delhaye

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discloses the treatment of the same patients with the same pharmaceutical preparation recited in representative claim 1. Accordingly, we find no difference between the method recited in claim 1 and the method taught by Delhaye.

We point out that under such circumstances when the prior art teaches a compound or method which is similar to the claimed compound or method, it is reasonable to shift the burden to the appellants to demonstrate a difference between the prior art and that which is claimed. In re Best, 562 F.2d 1252, 1254-55, 195 USPQ 430, 433 (CCPA 1977). As stated in Best, 562 F.2d at 1254-55, 195 USPQ at 433, quoting In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (1971):

[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on [58 CCPA at 1031, 439 F.2d at 212-213, 169 USPQ at 229.] This burden was involved in In re Ludtke, 58 CCPA 1159, 441 F.2d 660, 169 USPQ 563 (1971), and is applicable to product and process claims reasonably considered as possessing the allegedly inherent characteristics [emphasis added].

Accordingly, absent evidence to the contrary, we find that the teachings of Delhaye anticipate the subject matter of representative claim 1.

We note the appellants' argument that Delhaye discloses "the use of a high lipase pancreatic enzyme preparation to treat exocrine pancreatic insufficiency in patients with chronic pancreatitis." Brief, p. 9; Reply Brief, p. 4. The appellants contend that Delhaye "contains no discussion of treating diabetes and likewise no evaluation of

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patient parameters relating to diabetes.” Brief, p. 9; Reply Brief, p. 5. We find these arguments unpersuasive.

First, as discussed above, Delhaye discloses treating patients having insulin dependent diabetes. Since the specification defines diabetes mellitus Type I as being insulin dependent diabetes, absent evidence to the contrary, we find that the publication teaches the method described in representative claim 1.

Second, it is immaterial that the patients treated in Delhaye also had an exocrine pancreatic insufficiency. We point out that claim 1 does not exclude the presence of additional diseases or disorders. To that end, attention is directed to dependent claim 7 which is directed to a method of treating patients having both Type I diabetes and exocrine pancreatic insufficiency.³ Since claim 7 is dependent on claim 1, it further limits claim 1. 37 C.F.R. § 1.75(c).⁴ Therefore, claim 1 manifestly encompasses the treatment of Type I diabetes patients suffering from exocrine pancreatic insufficiency as described in Delhaye.

³ Claim 7 reads as follows:

7. A method according to claim 1, wherein said larger mammal or human is a patient suffering from diabetes mellitus accompanied by exocrine pancreatic insufficiency.

⁴ 37 C.F.R. § 1.75(c) states, in relevant part, that:

(c) One or more claims may be presented in dependent form, referring back to and further limiting another claims or claims in the same application. . . . Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.

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Third, that Delhayé does not evaluate “patient parameters relating to diabetes,” is immaterial. Representative claim 1 does not require that any particular effect be achieved by the method described therein. It is only directed to the treatment of Type I diabetes patients, which Delhayé does. Accordingly, the appellants’ argument does not address a limitation present in the claims.

Accordingly, pursuant to 37 C.F.R. § 41.50(b), we find that claim 1 is unpatentable under 35 U.S.C. § 102(b) as being anticipated by Delhayé. As discussed above, claims 3, 4, 6 and 7 fall with claim 1.

Claim 5

We agree with the examiner that the subject matter of claim 5 is unpatentable under 35 U.S.C. § 103 in view of Delhayé. However, because our reasons differ from those of the examiner, we set them forth as a new ground of rejection pursuant to 37 C.F.R. § 41.50(b).

As discussed above, Delhayé discloses the treatment of humans having primary diabetes mellitus Type I with a pharmaceutical preparation comprising a physiologically acceptable enzyme mixture with lipolytic, proteolytic and amylolytic activity. Delhayé, p. 700, col. 1, para. 5 and col. 2, paras. 3-5. Delhayé further discloses that bacterial lipases are “more resistant to acid inactivation than porcine lipase” and, thus, are more stable in vivo. Id., p. 702, col. 2. Given the teachings of Delhayé with respect to the greater stability of microbial lipases compared to porcine lipase, we find that it would

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have been obvious to one of ordinary skill in the art to include a microbial lipase in the pharmaceutical preparation used to treat the diabetes patients. Accordingly, we hold that the method set forth in claim 5 is unpatentable under 35 U.S.C. § 103 in view of Delhayé.

Claim 2

Claim 2 stands on a different footing. The method described therein requires the use of an enzyme mixture of microbially-synthesized lipases, proteases and amylases. Although Delhayé teaches the advantages of using a microbially-synthesized lipase in vivo, the publication is silent with respect to the other microbially-synthesized enzymes recited in the claim. Upon return of the application to the corps, the examiner may wish to perform an additional search of the prior art to determine whether microbially-synthesized pancreatic amylases and proteases were known in the art and, if so, whether these enzymes were also known to be more resistant to acid inactivation in vivo. Assuming, arguendo, that the examiner finds such teachings, he may wish to consider whether said teachings, in combination with Delhayé, would have rendered the method recited in claim 5 obvious to one having ordinary skill in the art.

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

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37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED, 37 C.F.R. § 41.50(b)

Joan Ellis
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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