

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GUNNAR FAGER

Appeal 2008-1956
Application 11/074,893
Technology Center 1700

Decided: June 17, 2008

Before EDWARD C. KIMLIN, CATHERINE Q. TIMM, and
KAREN M. HASTINGS, *Administrative Patent Judges*.

KIMLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 12-41. Claims 12 and 17 are illustrative:

12. A method of treatment of dialysis of a patient in need of such treatment which comprises subjecting said patient to dialysis using a dialyzing solution including a low molecular weight thrombin inhibitor having a molecular weight of below 2,000.

17. A dialyzing solution including a low molecular weight thrombin inhibitor.

The Examiner relies upon the following references in the rejection of the appealed claims:

Fourneir	FR 2,687,070	Aug. 13, 1993
Lundgren	WO 97/397770	Oct. 30, 1997
Grootenhuis	WO 97/30073	Aug. 21, 1997

Appellant's claimed invention is directed to a dialyzing solution and a method of treatment by dialysis wherein the solution comprises a low molecular weight thrombin inhibitor (claim 17), having a molecular weight of below 2,000 (claim 12).

Appealed claims 17, 18, 22, and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by FR '070. Claims 12-16, 19-21, and 24-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over FR '070 in view of WO '073 and WO '770.

Appellant has not separately argued any particular claim on appeal. Accordingly, the groups of claims separately rejected by the Examiner stand or fall together.

We have thoroughly reviewed each of Appellant's arguments for patentability, as well as the declaration evidence relied upon in support thereof. However, we find that the Examiner's rejections are well founded and supported by the prior art evidence relied upon. Accordingly, we will sustain the Examiner's rejections for the reasons set forth in the Answer, and we add the following primarily for emphasis.

We consider first the Examiner's § 102 rejection of claims 17, 18, 22, and 23 over FR '070. There is no dispute that the reference specifically

discloses a dialyzing solution comprising low molecular weight fragments of heparin, a thrombin inhibitor. The dispute arises over whether the low molecular weight fragments disclosed by the reference meet the presently claimed “low molecular weight thrombin inhibitor.”

It is Appellant’s position that the low molecular weight heparins disclosed by FR ‘070, having a molecular weight between 2,500 and 8,000, are not encompassed by claim 17 since the Specification assertedly defines a low molecular weight thrombin inhibitor as one having a molecular weight below 2,000. However, we agree with the Examiner that the relevant disclosure at page 7 of Appellant’s Specification fails to define the claimed low molecular weight thrombin inhibitor as including **only** compounds having a molecular weight below 2,000. The cited paragraph of Appellant’s Specification appearing at page 7 reads “[t]he term “low molecular weight thrombin inhibitor” will be understood by those skilled in the art. The term may **also** be understood to include any composition of matter . . . which possesses a molecular weight of below 2,000 . . . ” (emphasis added). Hence, while the claim language may **also** include compounds having a molecular weight below 2,000, it also embraces compounds having a molecular weight above 2,000 that would be considered low molecular weight by one of ordinary skill in the art. As explained by the Examiner, FR ‘070 provides substantial evidence that one of ordinary skill in the art would consider low molecular weight thrombin inhibitors to include compounds having molecular weights varying from 2,500 to 8,000. The opinion of the present inventor in the Declaration of record does not refute this clear, explicit teaching in FR ‘070.

Furthermore, FR ‘070 expressly discloses that “[o]ther anticoagulatory agents can be used in the dialysis bath if their molecular weights enable them to cross the membrane employed in haemodialysis sessions” (Translation 3, third para.). Accordingly, we find that FR ‘070 provides a clear description within the meaning of § 102 of other known low molecular weight thrombin inhibitors that fall within the scope of claim 17 which were known in the art, such as those disclosed in WO ‘073 and WO ‘770.

Concerning the Examiner’s § 103 rejection, we are in full agreement with the Examiner that WO ‘073 and WO ‘770 provide substantial evidence that it would have been obvious for one of ordinary skill in the art to employ thrombin inhibitors having a molecular weight below 2,000, including the presently claimed melagatran, in the dialyzing solution of FR ‘070. As set forth by the Examiner, WO ‘373 expressly teaches that the low molecular weight thrombin inhibitors “are more effective with lower dosages and

having [sic, have] fewer and less severe side effects, with use in extracorporeal circuit, dialysis or parenteral applications” (Ans. 6).

Furthermore, as noted by the Examiner, FR ‘070 provides ample motivation for using the low molecular weight thrombin inhibitors of WO ‘073 and WO ‘770 by expressly disclosing that “[t]he lighter molecular weights of these fragments therefore enable them to cross the membranes which are currently employed in haemodialysis” (Translation 3, second para.).

The Declarant’s statement that “there is no motivation provided by any of the three cited WO documents to substitute a low molecular weight thrombin inhibitor for sodium heparinate as taught by FR ‘070” (para. 7) is a bald assertion without the requisite explanatory analysis. Also, the

Declarant's statement is a legal conclusion which is outside the scope of the Declarant's expertise. See *Cable Electronic Products Inc. v. Genmark*, 770 F.2d 1015 (Fed. Cir. 1985); and *In re Grunwell*, 609 F.2d 486 (CCPA 1979).

Appellant contends that “[t]he Fager declaration describes experiments which demonstrate unequivocally that, by providing low a molecular weight thrombin inhibitor, such as melagatran, to the dialysing solution prior to and/or during dialysis, in accordance with the presently claimed method, not only can problems associated with standard prior art methodology . . . be solved, but also distinct and unexpected advantages are observed for such inhibitors when compared to the compounds and methodology described in the French ‘070 patent” (Principal Brief 11, second para.). However, we agree with the Examiner that Appellant has not established that the superior delivery of the low molecular weight thrombin inhibitor, melagatran, relative to inhibitors, such as unfractionated standard sodium heparinate and Fragmin, having higher molecular weights would be considered truly unexpected by one of ordinary skill in the art. *In re Merck & Co.*, 800 F.2d 1091, 1099 (Fed. Cir. 1986). The Declarant fails to set forth any reason why one of ordinary skill in the art would not have expected a lower molecular weight compound to permeate a dialysis membrane more readily than a higher molecular weight compound, especially in light of the cited prior art which teaches that low molecular weight fragments cross the membrane more efficiently. Also, the Declarant gives no reason why one of ordinary skill in the art would not have considered it obvious to use the lower molecular weight inhibitors of WO ‘073 and WO ‘770 in a conventional dialysis method of the type disclosed by FR ‘070.

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Accordingly, based on the foregoing and the reasons well stated by the Examiner, the Examiner's decision rejecting the appealed claims is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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