

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 33

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YUKIO SHIMAZAKI, MIYUKI KAWASHIMA,
MASHAIKO ISHIBASHI, RYO TANAKA,
KIYOSHI SAKAI and HISAHIRO ISHIWARI

Appeal No. 95-4691
Application 08/021,652¹

ON BRIEF

Before KIMLIN, WEIFFENBACH and ELLIS, *Administrative Patent Judges*.

WEIFFENBACH, *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 1-17, which are all of the claims in the application. We affirm.

¹ Application for patent filed February 22, 1993. According to appellants the application is a continuation of Application 07/580,913, filed September 12, 1990, now abandoned.

The Claimed Subject Matter

The claims on appeal are directed to a thrombolytic composition containing tissue plasminogen activator having improved solubility in aqueous solutions, including body fluids of humans. Claim 1 is representative of the claimed subject matter and reads as follows:

1. A thrombolytic composition comprising tissue type plasminogen activator or a derivative thereof, an anionic polymer or a salt thereof and an amine compound or a salt thereof, said thrombolytic composition providing improved t-PA solubility in solutions over a broad range of salt concentrations.

References of Record

The following references of record are relied upon by the examiner as evidence of obviousness:

Dussourdd'Hinterland et al. (Dussourdd'Hinterland)	4,083,961	Apr. 11, 1978
Pâques (EP 198321) ²	EP 0 198 321	Oct. 22, 1986
Duffy et al. (Duffy)	4,898,826	Feb. 6, 1990
Isaacs et al. (Isaacs)	4,980,165	Dec. 25, 1990

²We did not find a translation of this document in the file. Accordingly, the patent has been translated and a copy is attached to this decision. Any reference to EP 198321 in this opinion is a reference to the complete English language translation of the patent. We note that the examiner has considered U.S. Patent Nos. 4,818,690 and 5,015,583 as translations of EP 198321 because the U.S. patents claim foreign priority to the same German patent application as in EP 198321. This is a false presumption. Unless there is evidence of record that the U.S. patents and the European patents are identical, and there is none in this case, we will not presume that the U.S. patents are translations of the European patent. If the examiner intended to rely on the disclosures of the U.S. patents, then she should have the U.S. patents, and not the European patent, in making her rejection.

The Rejections

Claims 1, 3, 5, 6, 8, 9 and 11-17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention.

Claims 1-17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Duffy and Isaacs combined with Dussourdd'Hinterland and EP 198321.³

Opinion

We have carefully considered the respective positions advanced by appellants and the examiner. For the reasons set forth below, we will affirm the examiner's rejection.

The examiner rejected claims 1, 3, 5, 6, 8, 9 and 11-17 under the second paragraph of 35 U.S.C. § 112 as being indefinite because the expression "broad range of salt concentrations" in claim 1 renders the claims vague and indefinite. According to the examiner, "it is unclear what range of salt concentrations is encompassed by the term 'broad' and it is unclear as to what range of salt concentrations Appellants consider to be within the metes and bounds of their invention" (answer: p. 3).

The legal standard for indefiniteness under the second paragraph of 35 U.S.C. § 112 is whether a claim reasonably apprises those of skill in the art of its scope. *See Amgen Inc. v. Chugai Pharmaceuti-*

³This rejection included another reference, Kakimoto et al (U.S. Patent No. 4,837,022, issued June 6, 1989). The examiner withdrew the reference from the rejection (answer: p. 9).

Appeal No. 95-4691
Application 08/021,652

cal Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir.), *cert. denied sub nom., Genetics Inst., Inc. v. Amgen, Inc.*, 112 S.Ct. 169 (1991). On the record before us, the examiner has not presented an analysis of the teachings of the prior art and the application disclosure as it would be interpreted by a person having ordinary skill in the pertinent art to establish that such a person would have found the claim indefinite in scope. Taking the ordinary meaning of the term “broad,” namely, covering a wide scope.⁴ We find that a person having ordinary skill in the art would have a reasonable understanding of the ranges as exemplified in Tables 1-4 of appellants’ specification. Accordingly, we reverse this rejection.

The examiner rejected claims 1-17 under 35 U.S.C. § 103 over Duffy, Isaacs, Dussourdd’-Hinterland and EP 198321. We have carefully reviewed the respective positions presented by appellants and the examiner. In so doing, we find ourselves in agreement with appellants that the applied prior art fails to establish a *prima facie* case of obviousness of the claimed subject matter. Accordingly, we will not sustain the examiner's rejection for essentially those reasons advanced by appellants, and we add the following primarily for emphasis.

Before we can consider the prior art, the metes and bounds of the claimed subject matter must be ascertained. The claims are interpreted in light of the specification as it would be interpreted by one of ordinary skill in this art, *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir.

⁴*The American Heritage Dictionary*, 2nd College Edition, Houghton Mifflin Company, Boston, Mass., p. 210 (1982).

Appeal No. 95-4691
Application 08/021,652

1997); *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). We are of the view that appellants' claims encompass only a tissue type plasminogen activator (t-PA) or a derivative thereof. Appellants point out at page 1, lines 12-16 of the specification that "t-PA has become the object of such attention as a novel plasminogen activator for pharmaceutical use, because, unlike conventionally known urokinase, t-PA has strong affinity to fibrin and high thrombolytic activity and, in particular, single-chain t-PA cause fewer side effects." In the brief, appellants state that "urokinase is an entirely different protein from t-PA" (brief: p. 11). While the scope of the claim as to the derivatives of t-PA is uncertain and the subject of a new ground of rejection under the provisions of 37 CFR § 1.196(b), *infra*, we find a person having ordinary skill in the art would have considered appellants' claims are limited to tissue type plasminogen activators and would not include other plasminogen activators such as urokinase.

The Duffy and Isaacs patents disclose enhancing the solubility of a t-PA by combining a citrate salt and an amine such as an arginine salt with t-PA. EP 198321 discloses a pharmaceutical drug consisting of t-PA and a polysulfate ester of a saccharide for the treatment of thromboses and emboli. According to the patentee, "[i]t has surprisingly been found that [tissue] ... plasminogen activators ... have a high affinity for polysulfate esters of saccharides ... and that the activity of PA is balanced in the presence of a polysulfate ester of a saccharide ..." (translation, p. 2). Dussourdd'Hinterland discloses a pharmaceutical composition comprising a urokinase, plasminogen activator, and an anionic polymer such as polysaccharide sulphate (dextran). Neither EP 198321 nor Dussourdd'Hinterland teach or suggest adding an amine to the plasminogen activator composition. According to the examiner:

Appeal No. 95-4691
Application 08/021,652

The prior art shows that of the three components Appellants include in their tissue plasminogen activator composition, both the amine compound and the acid are conventionally added to such composition for the purpose of improving the solubility of the tissue plasminogen activator. Of the third component, the anionic polymer, one of ordinary skill in the art would be motivated by the prior art to include an anionic polymer for the purpose of increasing the activity of the tissue plasminogen activator. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a tissue plasminogen activator composition with known excipients well recognized in the art for improving the solubility and activity of the tissue plasminogen activator.

We cannot agree with the examiner's conclusion for obviousness. First, the Dussourdd'Hinterland reference is not directed to t-PA. Second, the examiner has not explained why a person having ordinary skill in the art would have been motivated to add the polysulfate ester of EP 198321 to the compositions of either Duffy or Isaacs based on increased activity disclosed in EP 198321. The suggestion to combine t-PA, an amine and an anionic polymer must flow from the prior art, not from appellants' disclosure. In essence, we consider the examiner's obviousness conclusion to be based upon impermissible hindsight derived from the appellants' own disclosure rather than a teaching, suggestion or incentive derived from the applied prior art. To the extent that the examiner considers that it would have been obvious to combine the compositions taught by each of the references in accordance with *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), we cannot agree. On this record, the examiner has not taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the same purpose, in order to form a third composition which is to be used for the same purpose.

Accordingly, for the reasons given above, the rejection of claims 1-17 under 35 U.S.C. § 103

Appeal No. 95-4691
Application 08/021,652

over Duffy, Isaacs, Dussourdd'Hinterland and EP 198321 is reversed.

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new grounds of rejection. Claims 1-17 are rejected under 35 U.S.C. § 112, first and second paragraphs, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention and because the specification, while enabling for t-PA, does not reasonably provide enablement for derivatives of t-PA. Claims 1 and 2, from which all remaining claims depend, recite the plasminogen activator as being a "tissue type plasminogen activator or a derivative thereof." Applicants have not defined or provided by way of examples what constitutes a derivative of t-PA which can be combined with an amine and an anionic polymer to improve the solubility of t-PA in solution over a broad range of salt solutions. Thus, the meaning of the claims is in doubt. *Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d at 1217, 18 USPQ2d at 1030. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with claims 1-17. Applicant has not provided any guidance as to what derivatives of t-PA are intended and how the solubility of such derivatives would be affected by the addition of an amine and an anionic polymer. We find that as to the derivatives of t-PA, the specification lacks any teaching or guidance as to how to formulate the claimed compositions without undue experimentation. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1367, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997).

Appeal No. 95-4691
Application 08/021,652

Conclusion

For the foregoing reasons, the examiner's rejections of claims 1-17 under 35 U.S.C. §§ 103 and 112 are reversed, and claims 1-17 are subject to a new ground of rejection under 37 CFR § 1.196(b).

37 CFR § 1.196(b) also provides that the appellants, 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 proceedings (37 CFR § 1.197(c)) as to the rejected claims:

- (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
- (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should the appellants elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), 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.

Appeal No. 95-4691
Application 08/021,652

If the appellants elect 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 the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

REVERSED
37 CFR § 1.196(b)

EDWARD C. KIMLIN)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
CAMERON WEIFFENBACH)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
JOAN ELLIS)	
Administrative Patent Judge)	

Appeal No. 95-4691
Application 08/021,652

CW/sld

Nixon and Vanderhye
1100 North Glebe Road
8th Floor
Arlington, VA 22201-4714