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D E C I S I O N
of 10 January 2006

Case Number: T 1127/03 - 3.3.04

Application Number: 92907214.8

Publication Number: 0585242

IPC: A61K 39/395

Language of the proceedings: EN

Title of invention:
WOUND HEALING

Patentee:
Renovo Limited

Opponents:
01: Cambridge Antibody Technology Limited
02: GENZYME CORPORATION
03: Integra Life Sciences Corporation

Headword:
Wound healing/RENOVO

Relevant legal provisions:
EPC Art. 54, 56, 87-89

Keyword:
"Right to priority - main request, auxiliary request II - (no); auxiliary request VI - (yes)"
"Novelty - main request (no)"
"Inventive step - auxiliary request II (no)"
"Novelty, inventive step - auxiliary request VI - (yes)"

Decisions cited:
G 0005/83, G 0002/98, T 0133/87, T 0249/93

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1127/03 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 10 January 2006

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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 14 August 2003 revoking European patent No. 0585242 pursuant to Article 102(1) EPC.

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
R. Moufang

Summary of Facts and Submissions

I. The appeal was lodged by the Patent Proprietor (Appellant) against the decision of the Opposition Division, whereby the European patent No. 0 585 242, claiming priority from GB 9106678 (28 March 1991), was revoked according to Article 102(1) EPC.

The patent, which had been granted on the basis of claims 1 to 26, had been opposed by Opponents 01, 02 and 03 (Respondents I, II and III) under Article 100(a) EPC on the ground of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) EPC on the ground of lack of sufficient disclosure (Article 83 EPC).

Claim 1 as granted read:

"The use of an effective activity-inhibiting amount of at least one growth factor neutralising agent specific against only fibrotic growth factors selected from the group of TGF-ß1, TGF-ß2 and PDGF in the manufacture of a medicament for use in the treatment of wounds to inhibit scar tissue formation during healing."

II. The following documents are referred to in this decision:

(2) J. Invest. Dermatol., vol.92, 1989, pages 301 to 303

(4) J. Immunol., vol.145, 1990, pages 1415 to 1422

(7) J. Cell. Biochem., Suppl.15F, page 198, Abstract Q 423, 1 April 1991

(10) WO-91/10 727

(15) Lancet, vol.339, 25 January 1992, pages 213 to 214

III. Oral proceedings were held on 10 January 2006 in the presence of the Appellant and Respondents I and II. Respondent III, although duly summoned, did not attend.

The Appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of claims 1 to 25 of the main request or, alternatively, on the basis of claims 1 to 25 of auxiliary request II, both filed on 9 November 2005, or on the basis of claims 1 to 4 of auxiliary request VI or claims 1 to 3 of auxiliary request VII, both filed at the oral proceedings.

The Respondents I and II requested that the appeal be dismissed.

IV. Claim 1 of Appellant's main request was identical to claim 1 of the patent as granted (see section (I) above).

Claim 1 of auxiliary request II read as follows:

"The use of an effective activity-inhibiting amount of at least one growth factor neutralising agent specific against only fibrotic growth factors selected from the group of TGF-ß1, TGF-ß2 and PDGF in the manufacture of a medicament for use in the treatment of wounds to

inhibit scar tissue formation during healing wherein said medicament is for human treatment."

Claims 1 to 4 of auxiliary request VI read as follows:

"1. The use of an effective activity-inhibiting amount of a growth factor neutralising agent specific against only PDGF in the manufacture of a medicament for use in the treatment of wounds to inhibit scar tissue formation during healing.

2. The use of a growth factor neutralising agent according to claim 1, wherein the growth factor neutralising agent is a growth factor neutralising antibody.

3. The use of a growth factor neutralising agent according to any of the preceding claims in conjunction with a pharmaceutically acceptable carrier.

4. A composition for use in the treatment of wounds to inhibit scar tissue formation during healing, comprising an effective activity-inhibiting amount of at least one growth factor neutralising agent specific against only the fibrotic growth factor PDGF."

V. The submissions made by the Appellant, as far as they are relevant for the present decision, may be summarised as follows:

The claims of the actual requests were entitled to the priority date. Should the Board in this point come to a different decision, the disclosure in document (15), which then would belong to the state of the art

according to Article 54(2) EPC, was considered to be novelty destroying for the subject-matter of claim 1 of the main request (Article 54 EPC).

However, document (15), whose disclosure corresponded to the disclosure of the priority document, did not contain a teaching which could have been used by a skilled person to arrive at the subject-matter of claim 1 of auxiliary request II in an obvious way. Reaching a different decision would only be possible if the disclosure in document (15), and thus in the priority document, was not interpreted consistently when deciding on the right to priority and on the question of inventive step (Article 56 EPC).

The subject-matter of claims 1 to 4 of auxiliary request VI was novel and inventive over the disclosure in the cited prior art documents (Articles 54 and 56 EPC). In detail, claim 4 referring to the first medical use of a PDGF-neutralising agent, was novel over the disclosure in document (2), which did not mention medical compositions. Remittal of this request to the department of first instance would effect an undesirable delay of procedure.

VI. The submissions made by the Respondents, as far as they are relevant for the present decision, may be summarised as follows:

None of Appellant's pending requests was entitled to the claimed priority date. Consequently, claim 1 of the main request lacked novelty over document (15) (Article 54 EPC).

Document (15) represented the closest prior art when deciding upon inventive step of claim 1 of auxiliary request II. The problem to be solved, namely the provision of a medicament for human treatment, would be arrived by a skilled person in an obvious way by combining the teaching in the closest prior art with the disclosure in document (4) (Article 56 EPC).

The claims of auxiliary request VI should be remitted to the department of first instance, as they were not considered in the decision under appeal. Claim 4, which was not exactly in the form as accepted by the Enlarged Board of Appeal for claiming the first medical use of a known substance, was not novel over the disclosure in document (2) (Article 54 EPC).

Reasons for the decision

Priority - Articles 87 to 89 EPC

Main request

1. Claim 1 takes the form accepted by the Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985,64) for claims to the second or further medical use of a substance known per se.

The claim relates to the use of at least one neutralising agent specific against only fibrotic growth factors selected from the group of TGF-ß1, TGF-ß2 and PDGF for the manufacture of a medicament for the treatment of wounds. The treatment has the effect that scar tissue formation during healing is inhibited.

2. Knowledge of the potential targets, namely of the growth factors that have to be neutralised by the active substance(s) of the manufactured medicament, is essential for carrying out the invention according to claim 1.

3. The application as originally filed discloses that a number of soluble growth factors are fibrotic, which means that they induce neovascularisation, leukocyte chemotaxis, fibroblast proliferation and migration and deposition of collagen and other extracellular matrix molecules within wounds (page 2, line 21 to page 3, line 6). Among the group of growth factors that have been isolated and identified to have these characteristics are "...transforming growth factor beta (TGF-ß1, TGF-ß2, TGF-ß3 etc), platelet derived growth factor (PDGF), ..." (page 3, lines 10 to 12).

On page 4, last paragraph it is described that the TGF-ß growth factor family is believed to have a particularly important regulating role in wound repair. While the application as filed refers to three members of the TGF-ß growth factor family only (TGF-ß1, TGF-ß2, TGF-ß3), other documents disclose that five different TGF-ß members are known (document (10), page 2, lines 18 to 19).

4. On page 5, lines 5 to 8, the application as filed reads:

"However, it is now found that not all TGF-ß growth factors are fibrotic and that suppressing the activity of TGFß-3 in particular is counter-productive".

5. Thus, neutralisation of TGF-ß3, which is identified as not being a fibrotic growth factor, would be counterproductive for the technical effect of the invention, namely the inhibition of scar tissue formation during healing.

6. According to Article 87(1) EPC, a right of priority during a period of twelve months from the date of filing of the first application shall be enjoyed for the purpose of filing a European patent application in respect of the same invention.

The Enlarged Board of Appeal in decision G 2/98 (OJ EPO 2001, 413) concluded that the requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.

7. The priority document GB 9106678, like the application as filed, refers to the role of specific soluble growth factors in the process of wound healing and identifies several growth factors as being fibrotic, among them TGF-ß and PDGF (pages 2 to 3). However, with regard to this characteristic, the priority document does not make a distinction between the different members of the TGF-ß, but, on the contrary, considers all members of the family to be fibrotic. The document, when referring to TGF-ß, either does not indicate any specific member of the family (see pages 9, 10 and 20 to 23), or

specifies TGF-ß1, TGF-ß2 and TGF-ß3 without giving any hint that they might differ in their fibrotic activity (see pages 8 and 25). On page 8, lines 20 to 25, it is stated that an antibody neutralising only one growth factor involved in the formation of scar tissue during wound healing may be sufficient to prevent scarring. The examples given for such growth factors on page 8, line 23, are "TGF-ß1,2,3 or PDGF". Thus, also in this passage the entire TGF-ß family is addressed, without suggesting any difference between its individual members.

The passage wherein it is explicitly stated that TGF-ß3 is not fibrotic and its neutralisation has to be avoided (page 5, lines 5 to 8 of the application as filed; see point (4) above), is not contained in the priority document.

8. The priority document, starting on page 12, contains the description of illustrative examples. This description is identically contained in the application as filed. The examples refer to the test of five growth factor neutralising antibodies in an animal model (adult, male, Sprague-Dawley rats) for their ability to inhibit scar tissue formation during wound healing.

One of the tested antibodies, which all are said to be commercially available and to be of known neutralising potency, is described on page 19, lines 15 to 17 as being a "TGF Beta neutralising antibody (raised in rabbit against native porcine platelet TGF-ß1 - neutralises both TGF-ß1 and TGF-ß2) - Dose 50 microgm/injection."

9. The Board does not agree with the Appellant that the disclosure of one antibody, which is described in the priority document as being specific for targets explicitly mentioned in claim 1 of Appellant's main request enables a skilled person to derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the priority document.

The application as filed differs from the priority document in so far, as the target for the active compounds contained in a pharmaceutical composition for use in the treatment of wounds has been redefined.

The priority document does not contain any disclosure that would prompt a skilled reader to assume that a specific member of the TGF-ß family is fibrotic while another one is not. On the contrary, the skilled reader must come to the conclusion that all members of the TGF-ß family are involved in scar tissue formation during wound healing. As a consequence all neutralising agents specific to any member of the family would be considered to be suitable for inhibiting scar tissue formation during wound healing. This group of neutralising agents, which the skilled person after having read the priority document would consider to be suitable to achieve the desired effect, includes the specific antibodies used in the examples of the priority document, but also agents which neutralize TGF-ß3. As disclosed in the application as filed, their use would have a counterproductive effect, which the Board interprets to mean that scar tissue formation during wound healing would be increased.

10. Consequently, the Board comes to the conclusion that a skilled person from reading the priority document does not know the target to be neutralised, i.e. those members of the TGF-ß family which are fibrotic. He/she cannot directly and unambiguously derive from the priority document the invention according to claim 1, which therefore is not entitled to the claimed priority date.

11. The relevant date for defining the state of the art according to Article 54(2) EPC with regard to Appellant's main request is therefore the date of filing, which is 30 March 1992. Thus, document (15), published on 25 January 1992, belongs to the state of the art according to Article 54(2) EPC.

Auxiliary request II

12. Claim 1 of this request also refers to the use of at least one growth factor neutralising agent specific against only fibrotic growth factors selected from the group of TGF-ß1, TGF-ß2 and PDGF in the manufacture of a medicament for use in the treatment of wounds (see section (IV) above.

For the same reasons as given above for claim 1 of the main request, the claim is not entitled to the claimed priority date. Document (15) belongs to the state of the art according to Article 54(2) EPC also for this request.

Auxiliary request VI

13. Claim 1 defines the neutralising agent as being specific against only PDGF (see section (IV) above). Claim 2 defines the neutralising agent as being a neutralising antibody. Claim 3 refers to the use of the neutralising agent of any preceding claim in conjunction with a pharmaceutically acceptable carrier, and claim 4 relates to a composition for use in the treatment of wounds comprising a growth factor neutralising agent specific against only PDGF.

14. The priority document discloses at various passages that the use of an antibody or other agent having a neutralising effect in respect of only one growth factor selected from TGF-ß **or** PDGF is effective in reducing scar tissue formation during wound healing (see page 8, lines 20-25; page 9, lines 17 to 19; page 21, lines 15 to 18; page 25, lines 11 to 17). Pharmaceutical compositions comprising the neutralising agents in conjunction with a pharmaceutically acceptable carrier are disclosed on page 25, line 24 to page 26, line 17, of the priority document.

15. Accordingly, claims 1 to 4 of auxiliary request VI are entitled to the claimed priority date.

Main request

Novelty - Article 54 EPC

16. Document (15) is a scientific publication of the inventors of the patent in suit. It refers to control

of scarring in adult wounds by a neutralising antibody to TGF-ß.

Experimental tests using the rat model of the patent in suit are described on page 213, right column, second paragraph. Adult, male Sprague-Dawley rats were anesthetised and four incisions were made on the dorsal skin of the animals. The wounds were left unsutured to heal by secondary intention to produce the greatest amount of granulation tissue and scarring. In each animal one wound (control) was unmanipulated, one (sham control) was injected with an irrelevant antibody, one (positive control) was injected with TGF-ß1 and one was injected with a neutralising antibody to TGF-ß. This antibody is described as follows:

"(10 µg antibody neutralise 0.25 ng TGF-ß1,2; BDA1, British Biotechnology, Oxford)."

It is reported that the wounds treated with this antibody contained much less collagen and had a more normal, regenerative pattern of dermal architecture, when compared to the other wounds (page 214, left column).

17. The Appellant explicitly acknowledged at the oral proceedings (see section (V) above) that, should claim 1 not enjoy the right of priority, its subject-matter was anticipated by the teaching in document (15). The Board agrees. In view of the explicit acknowledgement no further reasoning will be given.

The subject-matter of claim 1 is not novel contrary to the requirements of Article 54 EPC.

Auxiliary request II

18. Claim 1 is distinguished from claim 1 of the main request in so far as it contains the additional phrase "wherein said medicament is for human treatment".

The Appellant argued that the antibody designated BDA1 (see point (15) above), which was used in the experiments of document (15), was a polyclonal antibody preparation. Since such preparations were recognised as being highly immunogenic, a person skilled in the field of pharmacology would have immediately recognised that they were not suitable for human treatment. Accordingly, the subject-matter of claim 1 was not anticipated by the disclosure in document (15) and was novel under Article 54 EPC.

19. The Respondents I and II argued that the subject-matter of claim 1 had no basis in the application as filed (Article 123(2) EPC and that the claim was not clear (Article 84 EPC). Moreover, they objected to the novelty of the claimed subject-matter on the basis of the disclosure in document (15).

20. In view of the findings on Article 56 EPC (see points (20) to (28) below) it is not deemed to be necessary to give a reasoned decision with regard to Articles 123(2), 84 and 54 EPC.

Inventive step - Article 56 EPC

21. In accordance with the problem and solution approach, the Boards of Appeal have developed in their case law

certain criteria for identifying the closest prior art which provides the best starting point for assessing inventive step. It has been repeatedly pointed out that this should be prior art relating to subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications (cf Case Law of the Boards of Appeal of the European Patent Office, 4th Edition 2001, chapter I.D.3).

22. The invention according to claim 1 aims at the objective to provide a medicament for human use for the treatment of wounds to inhibit scar tissue formation during healing.

This objective is met by the use of at least one growth factor neutralising agent specific against only fibrotic growth factors selected from the group of TGF-ß1, TGF-ß2 and PDGF in the manufacture of such medicament.

23. The Board, in agreement with the opinion expressed by all parties, considers document (15) to represent the closest state of the art. It provides a composition for the control of scarring of wounds in a rat model, which composition contains a polyclonal antibody preparation neutralising TGF-ß1 and TGF-ß2.

24. Although the Respondents I and II did not agree that polyclonal antibody preparations are generally unsuitable for human use, the Board accepts the Appellant's argument that BDA1, the preparation used in document (15), is too immunogenic to be suitable for

human use. The problem underlying the present invention in the light of the disclosure in the closest prior art is therefore seen in the provision of a medicament for the intended purpose which is suitable for human treatment.

25. It is undisputed between the parties that a skilled person at the filing date of the patent in suit, when trying to replace a polyclonal antibody preparation having a defined binding specificity with a less immunogenic antibody for human use, would look for a monoclonal antibody having the same binding specificity.

26. The Appellant argued that the skilled person when reading document (15) did not get sufficient information with regard to the binding specificity of a monoclonal antibody suitable to solve the underlying problem. Document (15), like the priority document of the patent in suit, did not contain any disclosure that would have prompted a skilled reader to assume that a specific member of the TGF-ß family was fibrotic while another one was not. In fact document (15) speaking about TGF-ß in general terms only did not make a distinction between the different members of the TGF-ß family. Thus, the skilled person would not have got any hint to avoid monoclonal antibodies binding to TGF-ß3, which had been found by the present invention to be not fibrotic and whose neutralisation had turned out to be counterproductive for the intended purpose.

The Appellant put emphasis on the fact that the disclosure of document (15) did not go any further than the disclosure of the priority document, which was considered by the Board to be insufficient for claiming

priority for the subject-matter of claim 1. The same disclosure in document (15) could not possibly be used to show that the claimed subject-matter did not involve an inventive step.

27. The Board does not agree. The Appellant is right when saying that document (15) does not disclose that a monoclonal antibody suitable to solve the underlying problem must not neutralise TGF-ß3. (The same applies to the priority document, which therefore was found not to refer to "the same invention" (see points (1)-(11) above).) However, and this is important for the assessment of inventive step, the document shows that a polyclonal antibody neutralising TGF-ß1 and TGF-ß2 is suitable to achieve the desired effect in a rat animal model (see document (15), page 213, right column, second paragraph).

Thus, although the skilled person looking for an adequate monoclonal antibody would not explicitly search for one that does not neutralise TGF-ß3, he/she would have no reason to disregard a monoclonal antibody which neutralises TGF-ß1 and/or TGF-ß2 and whose neutralising activity with regard to TGF-ß3 is unknown.

28. Further, the skilled person in his search for a solution to the posed problem would also turn to document (4), which in table 1 on page 1417 discloses two TGF-ß-specific monoclonal antibodies. One, designated 2G7, neutralises TGF-ß1, TGF-ß2 and TGF-ß3, the other, designated 4A11, neutralises TGF-ß1 only. The exact neutralising activity of the two antibodies is indicated on page 1417, right column, end of last full paragraph).

29. The board is convinced that, in order to solve the technical problem underlying the present invention, a skilled person would combine the disclosure of document (4) with that of document (15) and thus simply replace the polyclonal antibody preparation BDA1, used in document (15), with the monoclonal antibodies disclosed in document (4). He/she would have to repeat the experiments described in document (15) with each of the two monoclonal antibodies described in document (4). When doing so it would immediately be apparent that one of the two prior art monoclonal antibodies, namely 2G7, does not give rise to the desired effect as it neutralises TGF-ß3, which according to the patent in suit is counter-productive. The other monoclonal antibody 4A11, however, neutralising TGF-ß1 only, represents an obvious solution to the underlying problem.

Accordingly, the subject-matter of claim 1 does not involve an inventive step contrary to the requirements of Article 56 EPC.

Auxiliary request VI

Remittal - Article 111(1) EPC

30. Remittal to the department of first instance is at the discretion of the Board (cf decision T 249/93 of 27 May 1998; point (2.2)).

The Respondents I and II based their request on the argument that the subject-matter of auxiliary request

VI had not yet been subject to a substantive discussion before the Opposition Division.

It has been acknowledged in the jurisprudence of the Boards of Appeal that there is no absolute right of a party to have every aspect of a case examined in two instances (T 133/87 of 23 June 1988, point (2) of the reasons).

31. Independent claims 1 and 4 were contained in auxiliary requests II and III before the Opposition Division as claims 19 and 43, with the only difference that according to the present claims the growth factor neutralising agent is "... specific against **only** PDGF..." (emphasis added by the Board). In point (5.2) of the decision under appeal the Opposition Division explicitly stated that these claims were novel over the cited prior art documents (Article 54 EPC). The claims were also contained (as claims 1 and 25) in auxiliary request III filed by the Appellant with the grounds for appeal. The Respondents during the entire appeal procedure did not comment on this request.

In the present case, considering the structure and content of Appellant's auxiliary request VI, the Board comes to the conclusion that it is procedurally adequate not to remit the case to the department of first instance but to reach a final decision in this case.

Amendments - Article 123(2) and (3) EPC

32. Claims 1 to 4 are based on page 11, last paragraph and claims 1 to 3 of the application as filed. The scope of

protection conferred by the claims is reduced with regard to the claims as granted. Thus, the requirements of Article 123(2) and (3) EPC are met.

Novelty - Article 54 EPC

33. Claims 1 to 4 enjoy the right of priority (see points (12) to (14) above). Consequently, document (7), cited by Respondents I and II at the oral proceedings, does not belong to the state of the art according to Article 54(2) EPC.

34. Respondent I argued that claim 4 lacked novelty over the disclosure in document (2). He took the view that the claim was not worded as accepted by the Enlarged Board of Appeal for claiming the first medical use of a substance known per se. Instead of claiming a substance for use in a medical treatment, which use as such was excluded from patentability according to Article 52(4) EPC, the claim referred to a composition containing a pharmaceutically active component for use in a specific medical treatment.

35. The Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985, 64) held that claims directed to substances or **compositions** for use in any methods for treatment of the human or animal body are unquestionably directed to inventions which are susceptible of industrial application within the meaning of Article 52(1) EPC. This is expressly made clear in Article 52(4) EPC (see point (14) of the reasons).

Furthermore, in point (15), the Enlarged Board held that Article 54(5) EPC provides that the general rules

of law relating to novelty (Article 54(1) to (4) EPC) shall not exclude the patentability of any substance or **compositions**, comprised in the state of the art for use in a method referred to in Article 52(4) EPC, provided that its use for any such method is not comprised in the state of the art.

36. Thus, in order to anticipate the subject-matter of claim 4, a prior art document must disclose a composition comprising a neutralising agent specific only against PDGF for use in a medical treatment of the human or animal body.

Document (2) investigates the effect of different growth factors on scar formation. The appearance and localization of PDGF (and other growth factors) in sections of skin biopsies from patients are investigated using specific antibodies to human PDGF. The document comes to the conclusion that PDGF may play an important role in the pathogenesis of scleroderma (see abstract and page 303, left column, last paragraph).

The document, although it mentions the use of an anti-PDGF antibody for an analytical purpose, does not mention its use for medical treatment or a pharmaceutical composition containing the antibody. Neither does any of the other prior art documents on file.

Claim 4 is therefore novel under Article 54 EPC. The same applies to claims 1 to 3.

Inventive step - Article 56 EPC

37. The Respondents did not raise an objection under Article 56 EPC with regard to claims 1 to 4 of auxiliary request VI.

In the light of the disclosure in the prior art documents on file which do not disclose or suggest the use of neutralising agents specific against only PDGF in a medical treatment of the human or animal body in general, or specifically in the treatment of wounds to inhibit scar tissue formation during healing, the Board concludes that claims 1 to 4 involve an inventive step according to the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of the following documents:

   – Claims 1 to 4 of the auxiliary request VI as filed at the oral proceedings,

   – pages 2 to 9 of the amended description as filed at the oral proceedings.

Registrar: Chair:

P. Cremona U. Kinkeldey