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W 09/86

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PCT/GB 86/00028

Veröffentlichungs-Nr. / Publication No / N<sup>O</sup> de la publication :

Bezeichnung der Erfindung:

Prostaglandins

Title of invention:

Titre de l'invention :

Klassifikation / Classification / Classement:

C 07 C 177/00

ENTSCHEIDUNG / DECISION

vom / of / du

11 August 1986

Anmelder / Applicant / Demandeur :

National Research Development

Corporation

Patentinhaber / Proprietor of the patent /

Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

Thromboxane Antagonists / NRDC

EPÜ / EPC / CBE

PCT Rule 40.1

"Lack of Unity - Requirement to state reasons

in Invitation to pay, not elsewhere"

#### Leitsatz / Headnote / Sommaire

- I. The reasons why an International Application does not comply with the unity requirements must be communicated to the Applicant in the Invitation pursuant to Article 17(3)(a) PCT. It is not sufficient if reasons could be found in the files only (decisions W 04/85 and W 07/86 followed).
- II. An intention to raise a-posteriori unity objections cannot justify departing from the aforementioned principle.

Europäisches Patentamt

Beschwerdekammern

European Patent Office

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Chambres de recours

Case Number: W 09 /86

International Application No. PCT/GB 86/00028



DECISION
of the Technical Board of Appeal 3.3.1
of 11 August 1986

Applicant :

National Research Development Corporation

101 Newington Causeway

London SE1 6BU United Kingdom

Representative :

Gerald F. Stephenson Patent Department 101 Newington Causeway

London SE1 6BU

Subject of the Decision: Protest according to Rule 40.2(c) of the Patent

Cooperation Treaty made by the applicants against

the invitation (payment of additional fee) of the

European Patent Office (branch at The Hague)

dated 10 April 1986

Composition of the Board :

Chairman: K. Jahn

Member : F. Antony

Member : R. Schulte

# Summary of Facts and Submissions

- I. The Applicants filed International patent application PCT/GB 86/00028 with the United Kingdom Patent Office on 16 January 1986. The EPO was the designated office in the sense of Art. 2(xiii) PCT.
- II. On 10 April 1986, the EPO acting as International Searching Authority (ISA) sent to the Applicants an Invitation to pay 21 additional search fees, in accordance with Art. 17(3)(a) and Rule 40.1 PCT. The Invitation indicated that the ISA considered that the above-referred application does not comply with the requirements of unity of invention, specifiying 22 different subjects, as follows:

### Claims 1,2,5

A compound having thromboxane antagonist activity for use in the manufacture of a medicament for use in the treatment of hormone-dependent neoplasias, and a composition comprising such a compound

### Claims 6-25

A compound, according to Claim 1 or 5, having formula I, in so far as  $XC_2H_2$  represents a bicyclo (2,2,1) heptane ring system

#### Claims 6-24

A compound, according to Claim 1 or 5, having formula I, in so far as  $XC_2H_2$  represents a bicyclo (2,2,1) hept-2Z-ene ring system

#### Claims 6,8-21

A compound, according to Claim 1 or 5, having formula I, in so far as  $XC_2H_2$  represents a 7-oxa-bicyclo (2,2,1) heptane ring system

# Claims 6,8-21

A compound, according to Claim 1 or 5, having formula I, in so far as  $CX_2H_2$  (correctly:  $XC_2H_2$ ) represents a 7-oxabicyclo (2,2,1) hept-2Z-ene ring system

### Claims 6-24

A compound, according to Claim 1 or 5, having formula I, insofar as  $XC_2H_2$  represents a bicyclo (2,2,2) octane ring system

# Claims 6-24

A compound, according to Claim 1 or 5, having formula I, insofar as  $XC_2H_2$  represents a bicyclo (2,2,2) oct-2Z-ene ring system

# Claims 6,8-21

A compound, according to Claim 1 or 5, having formula I, insofar as  $CX_2H_2$  (correctly:  $XC_2H_2$ ) represents a 6,6-dimethyl-bicyclo (3,1,1) heptane ring system

### Claims 6,8-21

A compound, according to Claim 1 or 5, having formula I, insofar as XC2H2 represents a cyclohexene ring system

### Claims 6,8-21

A compound, according to Claim 1 or 5, having formula I, insofar as  $XC_2H_2$  represents a cyclohexane ring system

#### Claims 6,8-21

A compound, according to Claim 1 or 5, having formula I, insofar as XC<sub>2</sub>H<sub>2</sub> represents a hydroxycyclopentane ring system

Claims 26-29,32 and partly 35-37 as far as dependent from Claims 26 and 32:

A product comprising a thromboxane antagonist compound and one or both of a hormonal therapy agent and a cytotoxic agent for simultaneous, separate or sequential use in the treatment of hormone-dependent neoplasias, a pharmaceutical composition and a kit, comprising such a product

# <u>Claims 33-34</u> and <u>partly 35-38</u>:

A product according to subject 12, in which the compound has the formula I as defined in subject 2

# Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 3

# Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 4

# Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 5

#### Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 6

### Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 7

# Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 8

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### Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 9

### Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 10

### Claims 33-34 and partly 35-38:

A product according to subject 12, in which the compound has the formula I as defined in subject 11

Additional fees in the total amount of £ 13,209.00 were said to be required; however, the Invitation did not specify the reasons for its afore-said findings.

On 2 May 1986 a voucher for the settlement of all the III. additional International Search Fees identified in the above-referred Invitation was received from the Applicants, together with a protest in accordance with Rule 40.2(c) PCT. According to the reasons of this protest the claims on file are all directed to a single inventive concept, the various subjects specified in the Invitation being directed to particular embodiments of the one invention, rather than to different inventions. More particularly, the invention arises from the finding that any compound having thromboxane antagonist activity is also of value in the treatment of hormone-dependant neoplasias. The first subject identified in the Invitation claims this second medical use in different ways; the twelfth subject claims the same use in conjunction with the use of one or both of two additional agents; and the remaining subjects specify thromboxane antagonist compounds of particular interest for use in the invention, all belonging to one and the same class of compounds, defined by formula (I) of Claim 6.

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# Reasons for the Decision

- 1. Pursuant to Art. 154(3) EPC and Art. 9 of the agreement between WIPO and the EPO, the Boards of Appeal of the EPO are responsible for deciding on protests made by Applicants against additional search fees charged by the EPO under Art. 17(3)(a) PCT (OJ EPO 4/1978, 249). The protest is admissible under Rule 40.2(c) PCT because the Applicants have paid the additional fees under protest and have added to the protest reasons according to which the international application complies with the unity requirements.
- 2. The ISA has made clear in its Invitation that it considers the 22 subjects specified therein as a group of inventions not so linked as to form a single general inventive concept. Contrary to Rule 40.1 PCT, however, it failed to specify, in the Invitation, the reasons for its above finding.
- 3. This Board and another Appeal Board of the EPO have already decided (W 04/85 of 22 April 1986 and W 07/86 of 6 June 1986) that indicating of reasons in an Invitation pursuant to Art. 17, para. 3, lit. a, and Rule 40.1 PCT is an essential prerequisite for such an Invitation to be legally effective.
- 4. It is true that in the present case the file contains a detailed explanatory statement to the point of unity.

  However, Rule 40.1 PCI expressly states that "the Invitation ... shall specify the reasons ..." (emphasis added). It is thus insufficient if explanations (or even full reasons) are given in such a way that the Applicants have no opportunity to take note thereof before formulating their protest. In the Board's view, the requirement for the

ISA to give reasons does not, or at least not in the first line, serve the better understanding or convenience of the Board, but is essential for the Applicants so that they can form an opinion:

- (i) whether and to what extent any protest has a reasonable chance of success and is therefore at all worthwhile; and
- (ii) what arguments from their side might be suitable as reasons accompanying their protest so as to prevail over the ISA's reasons.

Explanations, however cogent, which the Applicants have no opportunity to see cannot help them in forming their opinion and are, therefore, not a sufficient substitute for the missing reasons in the Invitation.

- 5. On the basis of essentially the same considerations, the Board cannot agree with a practice of the ISA according to which, in the framework of the PCT system, the results of searches leading to a-posteriori unity objections are not communicated to the applicants. Such a practice clearly contravenes Article 113(1) EPC at least insofar as the Invitation pursuant to Article 17(3)(a) PCT contains no reasons. Entitlement to reasons is a fundamental right which therefore cannot be denied under the PCT system.
- 6. There being no reasons given in the Invitation, it remains to be seen whether the present case is an exceptionally simple one, in which the mere enumeration of subjects is sufficient to prove lack of unity:

- According to the Invitation the application comprises 22 different inventions. While the existence of patent applications with such a high number of separate, non-interrelated inventions cannot be ruled out completely, general experience teaches that this is extremely unlikely and thus rare. In cases where a provisional unity evaluation leads to such an unlikely result, this warrants particular care before issuing the Invitation.
- The problem of the invention as pointed out in the 6.2. introduction to the specification and which has to serve as the basis for the ISA's considerations, is to propose novel (additional) means to combat hormonedependant neoplasias. As a solution, Claims 1,2 and 5 propose - in differing terms - a second therapeutical use for certain compounds defined by a biological parameter. Claim 6 and the dependant Claims 7 to 25 are directed to a class of compounds defined by structural parameters and apparently falling in the category of the compounds whose use is claimed in Claims 1, 2 and 5. Certainly at this stage, in the absence of detailed reasons to the contrary, it cannot be seen why these compounds (thus Claims 6 to 25) could not contribute to the solution of the same problem as Claims 1, 2 and 5.
- 6.3. Even supposing that Claims 1, 2 and 5 should fall e.g. for lack of novelty it could not be seen, without detailed reasons to the contrary, why the class of compounds defined by Claim 6 could not solve one and the same problem, viz. that of providing improved compounds for combatting certain neoplasias. The structures represented by the symbol X in formula (I) of Claim 6 are not so different either that, absent detailed

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justification, they can be recognized as lacking unity. Thus, without detailed reasons, it cannot be seen why subjects 2 to 11 as specified in the invitation should lack unity relative to one another.

- 6.4. Subject 12 as specified in the Invitation relates substantially to the use claimed in Claims 1, 2 and 5 in conjunction with the use of one or two additional agents. Again, without detailed reasons to the contrary, it cannot be seen why the use of a first agent in conjunction with a second and/or third agent could not contribute to the solution of the same problem as the use of the said first agent alone.
- 6.5. To subjects 13 to 22 is applicable, <u>mutatis mutandis</u>, what has been said in sub-paragraph 6.3 above.
- 6.6. In summary, the Board fails to see a simple case in which the mere enumeration of subjects, wholly or in part, could sufficiently demonstrate lack of unity even in the absence of detailed reasons.
- 7. Accordingly, the Invitation lacks legal basis, because it contravenes Rule 40.1 read in conjunction with Rule 13.1 PCT, and thus cannot have any legal effect. Therefore the additional search fees cannot be retained.

#### Order

For these reasons, it is decided:

Refund of the additional search fees is ordered.

The Registrar:

DADaman

Jelin 5.9.86

The Chairman:

B.A. Norman

K. Jahn