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Datasheet for the decision of 28 September 2020

Case Number: T 1553/15 - 3.3.01

Application Number: 03770855.9

Publication Number: 1557171

IPC: A61K35/12, A61K35/36, A61P25/04, A61P29/00

Language of the proceedings: EN

Title of invention:
RABBIT SKIN COMPRISING BIOLOGICAL ACTIVE SUBSTANCE AND ITS USE

Applicant:
VanWorld Pharmaceutical (Rugao) Company Limited

Headword:
Rabbit skin extract/VANWORLD (RUGAO)

Relevant legal provisions:
EPC Art. 53(a)

Keyword:
Exceptions to patentability - (yes) animal suffering not commensurate with benefit for mankind

Decisions cited:
T 0019/90

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1553/15 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 28 September 2020

Appellant: (Applicant)	VanWorld Pharmaceutical (Rugao) Company Limited 139 Pu Qing Road - Rugao Jiangsu 226500 (CN)
Representative:	Isarpatent Patent- und Rechtsanwälte Behnisch Barth Charles Hassa Peckmann & Partner mbB Postfach 44 01 51 80750 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 20 March 2015 refusing European patent application No. 03770855.9 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	P. de Heij
	T. Sommerfeld

Summary of Facts and Submissions

I. The appeal lies from the examining division's decision refusing European patent application No. 03770855.9, published as EP 1557171 in accordance with Article 158(3) EPC on the basis of the international application published as WO 2004/060381.

II. The examining division's decision is based on the set of claims of the main request which was filed by letter of 29 April 2014, and on auxiliary requests 1, 2, 3 and 4 filed by letter of 24 November 2014. A further auxiliary request, designated auxiliary request 1' and filed during oral proceedings on 27 November 2014, was not admitted into the proceedings.

The examining division decided that none of the requests on file met the requirements of the EPC, in particular Article 53(a) EPC (main request and auxiliary request 1), Article 84 EPC (auxiliary requests 1 and 2), Article 56 EPC (main request and auxiliary requests 1, 2 and 4) and Article 83 EPC (all requests).

III. The applicant (appellant) lodged an appeal against the examining division's decision, requesting that the decision be set aside and that a patent be granted according to the main claim request or, alternatively, according to one of auxiliary requests 1 to 4, all filed with the statement of grounds of appeal dated 29 July 2015.

The **main request** comprises 10 claims, claim 1 of which reads as follows:

"1. A pharmaceutical preparation comprising an extract of nucleic acids and amino acids from rabbit skin and pharmaceutically acceptable adjuvants, wherein the extract is obtainable by a method comprising the steps of:
a) providing a rabbit skin possessing kallikrein production inhibition activity;
b) extracting the rabbit skin with organic solvent;
c) processing with an acid and alkali; and
d) absorbing, eluting and concentrating the extract;
wherein the rabbit skin is obtained by the process of vaccinating rabbit skin tissues with vaccinia virus by injecting subcutaneously 0.1-0.4 ml solution containing 10^6-10^9 viruses/ml at each site, to 100 to 250 sites per rabbit weighing 1.5-3 kg, feeding the vaccinated rabbit, killing the rabbit when its skin tissues are inflamed enough, peeling the rabbit, and freezing the rabbit skin at -18°C for storage, wherein the said vaccinia virus is Ikeda strain, Dairen strain, or EM-63 strain."

Claim 1 of **auxiliary request 1** is identical to claim 1 of the main request.

In **auxiliary request 2**, claim 1 reads as follows:

"1. An extract of nucleic acids and amino acids from rabbit skin for use as a medicament that possesses kallikrein production inhibition activity,
wherein the extract is obtainable by a method comprising the steps of:
<steps as in claim 1 of the main request>"

Claim 1 of **auxiliary request 3** is identical to claim 1 of auxiliary request 2.

In **auxiliary request 4**, claim 1 reads as follows:

"1. The use of an extract of nucleic acids and amino acids from rabbit skin for the manufacture of a medicament for treating symptomatic neuralgia, lumbago, acute pains from wound, burn and scald, and pains in surgery or post-surgery,
wherein the extract is obtainable by a method comprising the steps of:
<steps as in claim 1 of the main request>"

IV. As an annex to the summons to oral proceedings, the board issued a communication pursuant to Article 15(1) RPBA, providing a detailed preliminary opinion in relation to Articles 56 and 53(a) EPC.

V. By letter dated 12 March 2020, the appellant submitted a new auxiliary request 5.

Auxiliary request 5 is based on auxiliary request 4, with subject-matter of dependent claim 3, namely the feature "wherein the rabbit is a Japanese white rabbit", having been introduced into claims 1 and 2.

VI. Oral proceedings took place as scheduled. At their conclusion, the chairman announced the board's decision.

VII. The documents cited in the examination and appeal proceedings include the following:

D18 Instruction leaflet of Analgecine®
D23 Instruction/label and package of Analgecine®
D23a English translation of D23

VIII. The appellant's arguments, in so far as they are relevant to the present decision, may be summarised as follows:

The patentability exclusion pursuant to Article 53(a) EPC had been applied very rarely and only in such cases where the invention, or its commercial implementation, was so abhorrent that the grant of patent rights would be inconceivable. This was not the case for the application, which was directed to pharmaceutical preparations and medical uses.

The examining division had argued that the suffering of the rabbit could not be balanced by the benefit to mankind. However, as set out by decision T 19/90, animal suffering had to be weighed up against usefulness to mankind, which was a broader test than the one used by the examining division.

The pharmaceutical composition produced had analgesic, anti-allergic, anti-ulcer and sedative effects, and was different from other analgesics. It was useful for treating a given group of diseases. Thus the medical benefit of the invention was apparent.

The activity was disclosed in the application in paragraph [0010] in terms of specific SART activation and inhibition of kallikrein protease activity, which were methods, known from the prior art, for measuring activity of extracts (paragraphs [0018] and [0020]). The mechanisms of action were indeed already known, and there were alternative compounds on the market, but not the compound of the application.

Suffering of the rabbits was reduced as far as possible. The use of rabbits in medical research was a well-accepted standard method.

The suffering of the animals was thus clearly balanced considering the usefulness to mankind. There was no other way to produce the claimed pharmaceutical composition, so the process was necessary and could not be replaced by alternative processes.

The yield was not as low as it would appear because, as shown in Example 12 and evidenced by D18 and D23/D23a, the obtained extract was a stock solution that was further diluted to a volume of 300 ml to prepare an injection solution, which was then packaged into 3 ml ampoules to be administered once or twice daily, amounting to a total of 100 administrations.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or, alternatively, one of auxiliary requests 1 to 4, all filed with the statement of grounds of appeal dated 29 July 2015, or auxiliary request 5, filed with the letter dated 12 March 2020.

Reasons for the Decision

1. The appeal is admissible.

2. Main request: Article 53(a) EPC

2.1 Claim 1 is a product-by-process claim, being directed to a pharmaceutical composition comprising an extract

of nucleic acids and amino acids from rabbit skin and pharmaceutically acceptable adjuvants, the extract being further defined by the process to obtain it, which includes vaccinating rabbit skin tissues with vaccinia virus and killing the rabbit when its tissues are inflamed enough (for the complete wording of the claim, see section III).

2.2 According to the examples, the vaccinia-virus-infected rabbit was fed for four days (example 1) or for three days (examples 2 to 10) and sacrificed sometime afterwards when the skin was "inflamed enough", as defined above. Example 11 then teaches how the extract of bioactive substances is prepared from the rabbit skins. It is apparent from this example that 200 g rabbit skin yields a volume of 5 ml extract solution. The weight of the skin obtained from each sacrificed rabbit varies between 176 g (Example 3) and 349 g (Example 1). Examples 12, 13 and 14 then provide the formulas for preparing an analgesic injection, an analgesic tablet and a health food, respectively. According to these examples, 5 ml extract solution (i.e. corresponding to the 200 g rabbit skin) is used to prepare a volume of around 305 ml analgesic injection solution (Example 12), and 50 ml extract solution (i.e. corresponding to the skin of roughly 6 to 11 rabbits!) is used to prepare an analgesic tablet (Example 13) or to prepare a volume of around 1050 ml of "health food" (Example 14). It is not clear from the application how many "doses" are comprised in each of these formulations: according to the appellant, the 300 ml analgesic injection solution is packaged in 3 ml ampoules, each corresponding to an administration dose, hence the 300 ml solution would comprise 100 administration doses. Whatever the case, it is nevertheless apparent that the yield is quite low, and

that many rabbits will have to undergo this painful procedure and be sacrificed for the commercial exploitation of the invention.

2.3 Regardless of whatever analgesic effects - not shown in the application - these extracts may have in patients, it is considered that the amount of suffering caused to the animals is incommensurate with any benefits, or usefulness to mankind, that the invention may have. In this assessment "benefit" and "usefulness" are regarded by the board as synonyms. The claimed pharmaceutical preparation does not have different mechanisms of action or target different pathways from other widely available compounds of the prior art: there are thus plenty of alternative medicaments on the market which achieve the same or a comparable therapeutic effect without involving the same amount of animal suffering. Therefore the board considers that the subject-matter presently claimed does fall under the exclusion of Article 53(a) EPC.

2.4 As regards the appellant's arguments, the board agrees that exceptions to patentability must be construed narrowly. While the situation is clear for such rare and extreme cases as are so abhorrent that grant of patent rights would be inconceivable as it would infringe "ordre public" and morality (Guidelines G-II, 4.1), the board still considers that in all cases where animal suffering is involved the provisions of Article 53(a) EPC have to be assessed. The same conclusions seem to have been drawn in T 19/90, where the board stated, as cited by the appellant, that "The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks for the environment on the

one hand, and the invention's usefulness to mankind on the other" (Reasons 5). Although T 19/90 is specifically concerned with transgenic animals, it is nevertheless apparent from the decision's reasoning that special attention is given to the aspect of animal suffering, which in that particular case was linked to the insertion of an activated oncogene (Reasons 5).

2.5 Contrary to the transgenic mouse of T 19/90, which opened up new research avenues in the field of oncology at the cost of the suffering of a limited number of animals, the board considers that the benefit to mankind brought by the present invention is not such as to weigh up against the suffering of animals which is necessary to produce the claimed pharmaceutical composition. The new pharmaceutical composition does not open up new avenues in the treatment of the claimed diseases, and animal suffering is not limited to a given number of animals needed for testing - as argued by the appellant, a well-accepted standard method - but rather is always present and involves a considerable number of animals every time that the composition is produced.

2.6 As regards the appellant's argument that there was no alternative method to produce the claimed pharmaceutical composition, the board notes that, while this might indeed be the case, the fact is that there are alternatives to the claimed pharmaceutical composition. Again, the provision of the claimed pharmaceutical composition does not represent such a benefit to mankind as to justify the use of such a production method, for which there is no alternative, in order to obtain it.

3. Auxiliary request 1: Article 53(a) EPC

3.1 Claim 1 of auxiliary request 1 is identical to claim 1 of the main request. Hence, for the same reasons as set out above for the main request, auxiliary request 1 is also directed to subject-matter which is excluded from patentability under Article 53(a) EPC.

4. Auxiliary requests 2 and 3: Article 53(a) EPC

4.1 In auxiliary requests 2 and 3, claim 1 of the main request has been deleted, the new claim 1 being a first medical use claim, directed to an extract of nucleic acids and amino acids from rabbit skin for use as a medicament that possesses kallikrein production inhibition activity, the extract again being further defined by the method to obtain it (which is the same method as in claim 1 of the main request).

4.2 The board notes that claim 1 of the main request, while, as a product claim, not being restricted to any use, was nevertheless directed to a pharmaceutical preparation, which therefore already indicates at least the potential for a medical, therapeutic effect, and in fact the conclusions reached above in relation to the main request have taken such potential therapeutic effect into consideration. Hence, for the same reasons as set out above for the main request, the board still considers that claim 1 of auxiliary requests 2 and 3 relates to subject-matter which is excluded from patentability pursuant to Article 53(a) EPC.

5. Auxiliary request 4: Article 53(a) EPC

5.1 In auxiliary request 4, claim 1 of auxiliary request 3 has been deleted. New claim 1 is a second medical use claim, the therapeutic compound being the extract of nucleic acids and amino acids from rabbit skin, defined by the method to obtain it as in claim 1 of the main request, and the therapeutic indications being symptomatic neuralgia, lumbago, acute pains (sic) from wound, burn and scald, and pains (sic) in surgery or post-surgery.

5.2 The claimed therapeutic indications are all related to the analgesic effect of the pharmaceutical preparation of the invention, an effect which has already been taken into account above in relation to the main request. Hence, for the same reasons as given above for the main request, auxiliary request 4 is also considered to relate to subject-matter excluded from patentability under Article 53(a) EPC.

6. Auxiliary request 5: Article 53(a) EPC

6.1 Claim 1 of this request differs from claim 1 of auxiliary request 4 merely in that the rabbit to be used for the manufacture of the pharmaceutical preparation is further defined as being a Japanese white rabbit. This request was submitted in order to overcome objections under Article 56 EPC. In relation to Article 53(a) EPC, the appellant relied solely on its arguments regarding the higher-ranking requests. The board considers that the same arguments apply to this request as well. Hence, for the reasons given above, auxiliary request 5 is also considered to relate to subject-matter which is excluded from patentability under Article 53(a) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated