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**Datasheet for the decision  
of 28 June 2016**

**Case Number:** T 2349/14 - 3.3.07  
**Application Number:** 09793326.1  
**Publication Number:** 2344129  
**IPC:** A61K9/00, A61K47/02,  
A61K31/4375, A61K31/47,  
A61K31/538  
**Language of the proceedings:** EN

**Title of invention:**

AEROSOL FLUOROQUINOLONE FORMULATIONS FOR IMPROVED  
PHARMACOKINETICS

**Applicant:**

Raptor Pharmaceuticals Inc.

**Relevant legal provisions:**

EPC Art. 123(2), 83, 84, 111(1)

**Keyword:**

Amendments - appeal proceedings  
Claims - clarity after amendment (yes)  
Appeal decision - remittal (yes)



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Case Number: T 2349/14 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 28 June 2016**

**Appellant:** Raptor Pharmaceuticals Inc.  
(Applicant) 7 Hamilton Landing  
Suite 100  
Novato, CA 94949 (US)

**Representative:** HGF Limited  
1 City Walk  
Leeds LS11 9DX (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 15 July 2014  
refusing European patent application No.  
09793326.1 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** D. Boulois  
**Members:** R. Hauss  
I. Beckedorf

## Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division, pronounced on 19 May 2014 and posted on 15 July 2014, refusing European patent application No. 09 793 326.1.
- II. In the decision under appeal, the examining division found that claim 1 of all pending requests failed to comply with the requirements of Articles 83 and 84 EPC. This was due to the feature: "*... to achieve a maximum lung sputum concentration ( $C_{max}$ ) of at least 1200 mg/L and a lung sputum area under the curve (AUC) of at least 1500 h·mg/L*" which was present in claim 1 of all requests.
- III. The applicant (appellant) lodged an appeal against that decision. With the statement setting out the grounds of appeal the appellant submitted a main request (identical to the main request examined in the decision under appeal) and fourteen auxiliary requests.
- IV. The appellant later withdrew auxiliary requests 1 to 13 and submitted new auxiliary requests 1 to 7.
- V. In a communication issued in preparation for oral proceedings and advising the appellant of the board's preliminary opinion, the board raised objections under Article 123(2) EPC against the main request and the first to seventh auxiliary requests, and under Article 84 EPC against the main request and first to third auxiliary requests. The board added that if it found one of the appellant's requests to meet the requirements of Articles 123(2), 83 and 84 EPC, it would be inclined to remit the case, since the examining division had not yet decided on novelty and inventive step.

VI. In reply to the board's communication, the appellant filed an amended main request and six amended auxiliary requests.

VII. Oral proceedings before the board took place on 28 June 2016. In the course of the oral proceedings, the appellant submitted a new amended main request (hereinafter: main request) and new first and second auxiliary requests to replace all requests previously filed during the written proceedings.

The claims of the main request read as follows:

"1. An aerosol of an aqueous solution comprising levofloxacin or ofloxacin and a divalent or trivalent cation for use in the treatment of a pulmonary infection in a human, wherein the solution consists essentially of from 80 mg/ml to 120 mg/ml levofloxacin or ofloxacin and from 160 mM to 220 mM of a divalent or trivalent cation, wherein the solution has a pH from 5 to 7 and an osmolality from 300 mOsmol/kg to 500 mOsmol/kg.

2. The aerosol of claim 1, wherein the solution consists essentially of a levofloxacin concentration of 90 mg/ml to 110 mg/ml, a magnesium chloride concentration of 180 mM to 220 mM, a pH of 5 to 7, an osmolality of 300 mOsmol/kg to 500 mOsmol/kg, and lacks lactose.

3. The aerosol of claim 1, wherein the pulmonary infection is associated with a disorder selected from the group consisting of cystic fibrosis, chronic obstructive pulmonary disease, chronic bronchitis, bronchiectasis, pneumonia and asthma.

4. The aerosol of claim 1, wherein the pulmonary infection comprises one or more bacteria selected from

the group consisting of *Pseudomonas aeruginosa*,  
*Pseudomonas fluorescens*, *Pseudomonas acidovorans*,  
*Pseudomonas alcaligenes*, *Pseudomonas putida*,  
*Stenotrophomonas maltophilia*, *Aeromonas hydrophilia*,  
*Escherichia coli*, *Citrobacter freundii*, *Salmonella*  
*typhimurium*, *Salmonella typhi*, *Salmonella paratyphi*,  
*Salmonella enteritidis*, *Shigella dysenteriae*, *Shigella*  
*flexneri*, *Shigella sonnei*, *Enterobacter cloacae*,  
*Enterobacter aerogenes*, *Klebsiella pneumoniae*,  
*Klebsiella oxytoca*, *Serratia marcescens*, *Morganella*  
*morganii*, *Proteus mirabilis*, *Proteus vulgaris*,  
*Providencia alcalifaciens*, *Providencia rettgeri*,  
*Providencia stuartii*, *Acinetobacter calcoaceticus*,  
*Acinetobacter haemolyticus*, *Yersinia enterocolitica*,  
*Yersinia pestis*, *Yersinia pseudotuberculosis*, *Yersinia*  
*intermedia*, *Bordetella pertussis*, *Bordetella*  
*parapertussis*, *Bordetella bronchiseptica*, *Haemophilus*  
*influenzae*, *Haemophilus parainfluenzae*, *Haemophilus*  
*haemolyticus*, *Haemophilus parahaemolyticus*, *Haemophilus*  
*ducreyi*, *Pasteurella multocida*, *Pasteurella*  
*haemolytica*, *Helicobacter pylori*, *Campylobacter fetus*,  
*Campylobacter jejuni*, *Campylobacter coli*, *Borrelia*  
*burgdorferi*, *Vibrio cholera*, *Vibrio parahaemolyticus*,  
*Legionella pneumophila*, *Listeria monocytogenes*,  
*Neisseria gonorrhoeae*, *Neisseria meningitidis*,  
*Burkholderia cepacia*, *Francisella tularensis*, *Kingella*,  
*Moraxella*, *Bacteroides fragilis*, *Bacteroides*  
*distasonis*, *Bacteroides* 3452A homology group,  
*Bacteroides vulgatus*, *Bacteroides ovalus*, *Bacteroides*  
*thetaitaomicron*, *Bacteroides uniformis*, *Bacteroides*  
*eggerthii*, and *Bacteroides splanchnicus*,  
*Corynebacterium diphtheriae*, *Corynebacterium ulcerans*,  
*Streptococcus pneumoniae*, *Streptococcus agalactiae*,  
*Streptococcus pyogenes*, *Streptococcus milleri*;  
*Streptococcus* (Group G); *Streptococcus* (Group C/F);

*Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus saprophyticus, Staphylococcus intermedius, Staphylococcus hyicus subsp. hyicus, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus saccharolyticus, Clostridium difficile, Clostridium perfringens, Clostridium tetini, and Clostridium botulinum, Mycobacterium tuberculosis, Mycobacterium avium, Mycobacterium intracellulare, Mycobacterium leprae, Chlamydia pneumoniae and Mycoplasma pneumoniae."*

VIII. The appellant's arguments can be summarised as follows:

*Amendments - main request*

The definition of claim 1 of the new main request was based on paragraphs [0007] and [0008] of the description as filed. Dependent claim 2 was supported by paragraph [0078], and claims 3 and 4 found support in paragraph [0090] of the description as filed.

*Clarity and sufficiency of disclosure - main request*

Since the amended claims did not contain any technical feature relating to the *in-vivo* parameters  $C_{\max}$  and AUC, the objections raised under Articles 83 and 84 EPC in the decision under appeal no longer applied. With regard to the term "an aerosol of a solution", claim 1 was directed to nebulised droplets of the solution for use in the treatment specified. The presence of an aqueous solvent and of anions was implicit in the definition of the solution according to claim 1.

IX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of one of the sets of claims filed as new main request and as new first and second auxiliary requests.

## Reasons for the Decision

1. Amendments - main request
  - 1.1 The solution as defined in claim 1 of the main request is disclosed in paragraph [0008] of the application as filed. Administration in aerosol form for the treatment of a pulmonary infection is generally disclosed in paragraph [0007] and taught throughout the application. It is also apparent that, above all, administration to human patients is envisaged (see paragraphs [0008], [0009], [0033], [0103], examples 4 to 8). The composition defined in dependent claim 2 is based on paragraph [0078] as filed. Thus the subject-matter of claims 1 and 2 finds adequate support in the application as filed.

Claims 3 and 4 find support in paragraphs [0035], [0038] and [0090] of the description as filed. It is evident from the general teaching of the application (see for instance paragraphs [0007], [0032], [0033] [0035] and [0038]) that the intended indication is the treatment of pulmonary infection, and that such infection may be associated with certain disorders, as mentioned in amended claim 3.
  - 1.2 As a consequence, the board finds that the claims of the present main request meet the requirements of Article 123(2) EPC.
2. Clarity and sufficiency of disclosure - main request
  - 2.1 The objections which were discussed in the decision under appeal under Articles 83 and 84 EPC related to the requirement, present in claim 1 of all then pending requests, that certain lower limits of the *in-vivo*

parameters  $C_{\max}$  and AUC be reached. That technical feature is no longer present in the amended claims of the current main request.

2.2 The board has no doubt that a solution as defined in claims 1 or 2 can be prepared and that it can be aerosolised. Based on the teaching of the application, including the examples, it is also credible that the aerosol, containing the antibacterial drug levofloxacin or ofloxacin, can be used in the treatment of pulmonary infection. Thus the board sees no reason for objections under Articles 83 or 84 EPC.

3. Remittal

3.1 The decision under appeal concerns only objections raised under Articles 83 and 84 EPC.

3.2 Since an amended request was filed which meets the requirements of Articles 123(2), 83 and 84 EPC, and since the examining division has not yet decided on novelty and inventive step, the board finds it appropriate to remit the case, in accordance with the appellant's request (Article 111(1) EPC).



## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of the new main request filed during the oral proceedings.

The Registrar:

The Chairman:



G. Rauh

D. Boulois

Decision electronically authenticated