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# Datasheet for the decision of 15 October 2020

Case Number: T 1786/15 - 3.3.04

Application Number: 06735151.0

Publication Number: 1858541

IPC: A61K38/17, A61K47/48,

A61K39/395, A61P3/02, A61P7/06

Language of the proceedings: ΕN

#### Title of invention:

Use Of BMP Antagonists To Regulate Hepcidin-Mediated Iron Metabolism And Treat Iron Deficiency

# Patent Proprietor:

The General Hospital Corporation

### Opponent:

Eli Lilly and Company

#### Headword:

BMP Antagonists/GENERAL HOSPITAL CORPORATION

#### Relevant legal provisions:

EPC Art. 56, 87

#### Keyword:

Priority - transfer of priority right (no) Inventive step - (no)

# Decisions cited:

T 0472/92

Catchword:



# 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 1786/15 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 15 October 2020

Appellant: The General Hospital Corporation

(Patent Proprietor) 55 Fruit Street

Boston, MA 02114 (US)

Representative: Abel & Imray

Westpoint Building James Street West Bath BA1 2DA (GB)

Respondent: Eli Lilly and Company
(Opponent) Lilly Corporate Center
Indianapolis, IN 46285 (US)

Representative: O'Connor, David

Eli Lilly and Company Limited

8 Arlington Square West Downshire Way Bracknell, Berkshire RG12 1PU (GB)

Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 22 July 2015 revoking European patent No. 1858541 pursuant to

Article 101(3)(b) EPC.

#### Composition of the Board:

Chair G. Alt

Members: A. Chakravarty

R. RomandiniO. LechnerP. de Heij

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# Summary of Facts and Submissions

- I. European patent No. 1 858 541, entitled "Use Of BMP Antagonists To Regulate Hepcidin-Mediated Iron Metabolism And Treat Iron Deficiency" was opposed by a single opponent under Article 100(a) EPC in conjunction with Articles 54 and 56 EPC and under Articles 100(b) and (c) EPC 1973. The opposition division decided to revoke the patent.
- TT. The opposition division considered a main and two auxiliary requests. It held that the invention claimed in the set of claims of the main request did not meet the requirements of Article 83 EPC. In connection with the subject-matter of auxiliary request 1, it held inter alia that "the requirements under US law for a valid assignment of the right of priority based on D1 from the inventors to P [the patent proprietor] appear not to have been fulfilled before the filing date of the opposed patent" (see point 8.39 of the decision under appeal) and that "it has not been sufficiently proven that P was the beneficiary of the assignment of the rights to the invention, including the priority right. Thus, it has not been sufficiently proven that before the filing date P has become a valid successor in title of the priority right claimed by the opposed patent from D1. [...] Therefore, the priority claim based on US 60/653,479 (16.02.2005) is considered invalid and the effective date of the patent is the filing date of 16 February 2006" (see points 8.48 and 8.49 of the decision).
- III. As a consequence of the above, the opposition division then decided that the subject-matter of claim 1 of auxiliary request 1 lacked an inventive step over the

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disclosure in document D8 alone, while the subjectmatter of claim 1 of auxiliary request 2 lacked an inventive step over the disclosure in document D8 when considered in the light of the disclosures in documents D9 or D24. In particular, in point 13 of the decision under appeal, the opposition division held that:

"Document D8 is regarded as closest prior art. [---], the document itself does not justify any doubt on the suitability of the disclosed compound for in vivo treatment.

Claim 1 differs in that a fusion protein with Fc is used.

The problem to be solved is the provision of alternative or more stable treatments for anemia therapy.

The advantages of fusion proteins are well known to the skilled person and established in the art (documents D9, D24).

Hence, the corresponding modification of the molecule of document D8 is obvious and claim 1 lacks inventive skill."

IV. The patent proprietor (appellant) filed an appeal against this decision. The opponent is respondent to this appeal. With the statement of grounds of appeal, the appellant maintained the set of claims of the main request considered by the opposition division (filed at oral proceedings before the opposition division) and auxiliary requests 1 and 2 considered by the opposition division.

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

D1: US Provisional Application No. 60/653,479 (the priority claimed by the patent in suit).

D2: WO2006/088972 (the international application underlying the patent in suit).

D8: Lin L. et al., Blood, 5 July 2005, Vol. 106, No.8, 2884-2889

D9: Samad T.A. et al., The Journal of Biological Chemistry, 8 April 2005, Vol. 280, No. 14, 14122-14129: Published: JBC Papers in Press, 25 January 2005.

D24: Samad T.A. et al., The Journal of Neuroscience, 25 February 25 February 2004, Vol. 24, No. 8, pp. 2027-36.

D31: MGH Intellectual Property Policy, 2002

D40: Invention Disclosure Form

D51: Ownership reallocation policy, as applicable to The Massachusetts General Hospital, dated 18 September 2002.

D58: Declaration of Christopher Clark dated 6 November 2015.

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VI. The arguments of the appellant are summarised as follows:

Admissibility of the appeal

The appeal was admissible. The section 1.1 of the statement of grounds set out on pages 6 to 9 the reasons why the appellant believed it was the owner of the legal title to the invention and the priority rights prior to the filing date of the application by virtue of document D31. It was implicit from the submissions on pages 5 and 6 of the statement of grounds of appeal that "the conclusion [that D31 does not include the language of conveyance which could lead to an assignment of the priority right by the inventors to P before the filing date] is incorrect" and "it is submitted that MGH also had legal title of the invention as soon as it was conceived because the rights in the invention were automatically transferred in accordance with D31" that the appellant believed that the opposition division came to the wrong conclusion on the basis of the evidence before it. The arguments provided over the following three-and-a-half pages set out the reasons why the appellant believed that document D31 did amount to an assignment of future rights (and implicitly therefore why the opposition division was wrong).

Entitlement to priority of document D1 (Article 87 EPC)

The patent proprietor was the successor in title to the invention at the time of filing of the priority application (document D1) and accordingly, to the priority right. Under US law, the right to priority was

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transferred together with the right to the invention itself.

The inventors named in document D1 were employees of "The General Hospital Corporation" and each was bound by the "Intellectual Property Policy 2002" (document D31) that was in effect for "Partners-Affiliated Hospitals and Institutions" (of which the patentee/appellant was one). In accordance with this "Intellectual Property Policy", inventions conceived during the course of employment were owned by the employer unless determined otherwise by the criteria set out therein.

In the Invention Disclosure Form (document D40), the inventors detailed their invention and "agree[d] to assign all right, title and interest in this invention to The General Hospital Corporation d.b.a Massachusetts General Hospital in accordance with the Intellectual Property Policy ('the IP Policy' (D31)) and the Intellectual Property Acknowledgement".

Document D31 demonstrated that (i) all ownership of intellectual property rights - including future priority rights - were transferred by the inventors to 'The Massachusetts General Hospital', the parent company of 'The General Hospital Corporation' and (ii) this allocation of ownership could, pursuant to paragraph 2.4, be changed any time.

Paragraph 2.4 stated that the "Partners Professional and Institutional Conduct Committee" ("the Committee") was entitled inter alia to "approve mechanisms under which ownership are transferred to different institutions in order, for example, to facilitate the administration of IP rights". This clause allowed the

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Committee to operate a reallocation of future or existing rights without involvement of any inventor(s).

Document D51, in turn, showed that a reallocation with respect to the invention at issue and the priority right based on document D1 had occurred. This reallocation was possible without any further involvement of the inventors, since they had agreed to such a reallocation by virtue of 2.4 of document D31. Document D51 confirmed, that "The Massachusetts General Hospital (the "MGH") owns all Intellectual Property created by Members with Professional Staff appointments at the General Hospital, or otherwise made at or under the auspices of MGH", as provided for by the Intellectual Property Policy (document D31)."

Even if the opposition division's decision that document D31 concerned a desired future legal effect rather than an immediate conveyance were accepted for the sake of argument, MGH undoubtedly held at least equitable title in the invention from its conception. Under US law, where there is a valid and enforceable promise to assign in the future all the rights in an invention that does not yet exist, the promisee holds equitable title in the invention. Upon the invention being made, the promisee is entitled to demand the transfer of the legal title and to compel the same by way of civil proceedings.

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VII. The arguments of the respondent are summarised as follows:

Admissibility of the appeal

The appeal was not admissible because the statement of grounds of appeal did not address all of the grounds on which the contested decision was based.

Admissibility of new lines of argument on priority (Article 12(4) RPBA 2007)

Even if the appeal as a whole were considered admissible, the completely new argument that "The Massachusetts General Hospital" (MGH) held at least equitable title in the invention from its conception and that this was sufficient to make MGH the successor in title for the purpose of validly claiming priority should not to be admitted into the appeal proceedings. The appellant had had every opportunity to make a complete case during the first instance proceedings. The framework for an appeal could not be extended at will by the appellant to issues which were not discussed during the first instance proceedings to which the present appeal relates (see R 10/09, point 3.2 of the reasons).

Entitlement to priority of document D1 (Article 87 EPC)

The inventors designated in the patent in suit filed the application from which priority was claimed (document D1) under US law, while they filed the PCT application, WO2006/088972 (document D2), on which the patent in suit was based, together with the patent proprietor, The General Hospital Corporation, now the appellant. Thus, the PCT application designated the

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inventors of document D1 as applicants for the US, while the appellant was designated as applicant for all Designated States except the US.

However, the appellant had not provided evidence that a transfer of the priority right from the inventors to the appellant had taken place at a point in time before the filing date of the PCT application.

In particular, there were serious doubts about the authenticity of document D51 which was used to show that the right to priority from document D1 had been transferred to the appellant. Document D51 had not been signed; therefore, its binding character and its evidential value were questionable. The appellant had to prove beyond reasonable doubt that document D51 had been adopted at the relevant time. In the absence of any other evidence, the opposition division was correct in deciding that it has not been sufficiently proven that the appellant was the beneficiary of the assignment of the rights to the invention, including the right to claim priority from document D1.

VIII. The board issued a summons to oral proceedings and subsequently, a communication pursuant to Article 15(1) RPBA in which it informed the parties, inter alia, that it was "of the provisional opinion that the evidence on file is not sufficient to prove - beyond any reasonable doubt - that the appellant has acquired automatic and immediate ownership of the priority right without the need for a separate or additional transfer" and set out the reasons for this view.

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- IX. With the agreement of the parties, the oral proceedings before the board were held as scheduled, by means of videoconference. At the end of the proceedings, the Chair announced the decision of the board.
- X. The appellant requested that the decision under appeal be set aside and that the patent be maintained based on the set of claims of the main request. Alternatively, it was requested that the patent be maintained on the basis of the set of claims of one of the first, or second auxiliary requests.

The appellant also requested *inter alia* that the following be admitted into the appeal proceedings:

- document D51, not admitted by the opposition division;
- the submissions made with the letter dated 6 July 2016 pursuant to the provisions of Article 13(1) RPBA.
- XI. The requests of the respondent were that
  - the appeal be held inadmissible or alternatively, that the appeal be dismissed;
  - the appellant's new line of argument on priority that The Massachusetts General Hospital held at least equitable title in the invention not be admitted into the appeal proceedings.

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#### Reasons for the Decision

Admissibility of the appeal

- 1. The respondent argued that the appeal of the patent proprietor was not admissible. The board did not agree and held the appeal to be admissible

  (Articles 106 to 108 and Rule 99 EPC).
- 2. In view of the decision of the board (see point 21.), the reasons for this need not be set out here.

Admission of documents (Article 12(4) RPBA)

- 3. The board admitted document D51 into the proceedings after the request not to admit it had been withdrawn (see minutes). However, in view of the decision of the board (see point 21.), the reasons for its admission are moot and need not be given here.
- 4. The requests of the parties regarding the admission or otherwise of other documents are moot, since they played no role in the board's decision.

Entitlement to priority of document D1 (Article 87 EPC)

- 5. In the proceedings before the opposition division, the opponent (now respondent) challenged the patent proprietor's entitlement to claim the priority stemming from document D1 (see Section VII., above)
- 6. The opposition division agreed with the opponent's objection and consequently considered that document D8, published in the priority interval, was prior art and decisive in assessing the patentability of the subjectmatter of claim 1 of auxiliary requests 1 and 2.

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- 7. In appeal, the appellant challenged this point of the decision, arguing that the priority was validly transferred. In view of this, the first question to be answered is whether or not the patent can validly claim the priority of document D1.
- 8. It was common ground between the parties that:
  - (i) the EPO is entitled to examine whether or not an applicant can claim the priority of a previous filing;
  - (ii) the applicant can only claim the priority of document D1 if a transfer from the inventors to the applicant occurred before the filing date of the PCT application, document D2;
  - (iii) the question of whether such transfer
     occurred should be determined according to
     national law;
  - (iv) the relevant national law, in the present case is US law: federal law where the effect of the assignment is concerned, state law where the construction of the contract is concerned.
- 9. For the purpose of the present decision, the board does not, ex officio, challenge any of the above points of consensus between the parties. Instead, it will address the main point of disagreement between the parties, being the question of whether or not documents D31 and D51 demonstrate, according to the applicable standard of proof (see point 13., below), that the appellant acquired ownership of the priority right created with

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the US filing of document D1 before the date of filing of the PCT application, without the need for any separate additional transfer.

- 10. In the appellant's view, document D31 demonstrates that:
  - (i) all ownership of intellectual property rights - including future priority rights were transferred by the inventors to 'The Massachusetts General Hospital', the parent company of The General Hospital Corporation.
  - (ii) this allocation of ownership could, pursuant to paragraph 2.4 of document D31, be changed at any time.
- 11. The appellant submitted that document D51 showed that a reallocation with respect to the invention at issue and the priority right based on document D1 actually occurred and that this transfer was possible without any further involvement of the inventors, since they had agreed in principle to this reallocation by virtue of paragraph 2.4 of document D31. On the other hand, the respondent contested that document D51, the 'Policy Reallocating Ownership of Intellectual Property', had been adopted at the relevant date.
- 12. The board notes that the appellant, having been the applicant, bears the burden of proof for demonstrating that the reallocation of ownership of the priority right took place in 2002.
- 13. The appropriate standard of proof to be applied in this factual situation is not the balance of probabilities.

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Indeed, in cases where all evidence supporting a specific statement of fact (for instance a public prior use) is within the power and knowledge of one party, the Boards of Appeal apply a stricter standard of proof, namely the standard "beyond reasonable doubt" (see decision T 472/92, OJ EPO 1998, 161, point 3.1 of the reasons and Case Law of the Boards of Appeal, 9th edition, 2019, III.G.4.(b), with further references to the case law). In the case at hand, all evidence for the possible transfer of the priority right claimed is in the hands of the appellant.

- 14. The board notes that document D51 is the key piece of evidence that purports to demonstrate that the right to claim priority from document D1 had been transferred to the appellant. However, in the board's judgement, document D51 does not demonstrate to the required standard of proof that a reallocation of priority rights, had taken place by the filing date of document D2, 16 February 2006. This is because document D51 is unsigned and therefore it cannot provide conclusive evidence that the reallocation policy, set out therein, was in fact adopted.
- 15. Document D58, a declaration of an employee working for a company affiliated with the appellant, does not fill the gap in the evidence highlighted above. It does mention the date on which document D51 was allegedly adopted, however this is not corroborated by any evidence contemporary with document D51. For this reason, also document D58 does not represent sufficient evidence to meet the standard of proof required.
- 16. Finally, the appellant brought forward a line of argument according to which the applicant had at least equitable title in the invention before the filing

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date. However, at the oral proceedings, after the board communicated to the parties that it considered the transfer of the priority based on document D1 to The General Hospital Corporation had not been proven beyond reasonable doubt by documents D51 and D31, the appellant accepted that the same applied to the transfer of the equitable title. Transfer of the equitable title has therefore not been proven to have taken place for the reasons as explained above. The question whether such a transfer would be sufficient to accept the validly of the priority right therefore need not be considered.

17. As the priority claimed by the patent cannot be acknowledged, the board considers the documents published in the 12 months following the priority date and, in particular, document D8 to be prior art pursuant to Article 54(2) EPC.

# Inventive Step (Article 56 EPC)

- 18. In the decision under appeal, the opposition division held that the subject-matter of claim 1 of auxiliary request 2 lacked an inventive step over the disclosure in document D8 when considered in the light of the disclosures in document D9 or D24.
- 19. The board notes that claim 14 of the main request and of auxiliary request 1 are identical to claim 1 of auxiliary request 2 and therefore any finding of lack of inventive step for claim 1 of auxiliary request 2 must also apply to claim 14 of the higher ranking claim requests.
- 20. The appellant made no substantive submissions in the appeal arguing why the above mentioned decision of the

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opposition division on inventive step of the subject-matter of claim 1 of auxiliary request 2 (see Section III., above) was wrong. The board sees no reason to depart from said decision and holds that the claimed subject-matter lacks an inventive step.

21. No claim request meets the requirements of the EPC.

# Order

# For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



I. Aperribay

G. Alt

Decision electronically authenticated