



15 March 2012

PATENTS ACT 1977

BETWEEN

Berni Hambleton and Cold Spring Harbor Laboratory Claimant

Defendant

PROCEEDINGS

Application under section 72 of the Patents Act 1977 for revocation of patent EP(UK) 0665886B1

HEARING OFFICER

Peter Slater

PRELIMINARY DECISION

Background

- 1 EP0665886B1 ("the patent") entitled "Cyclin complex rearrangement and uses related thereto" was filed 18 October 1993 in the name of Cold Spring Harbor Laboratory ("the defendant"). The patent claims priority from two earlier US applications 07/963,308 and 07/991,997 filed on 16 October 1992 and 17 December 1992 respectively. The patent was granted on 11 June 2003.
- The patent provides a method of identifying a transformed or abnormally proliferating cell by determining the subunit composition of a complex and comparing it to the equivalent complex in normal cells. It claims a purified and/or recombinant polypeptide known as *p16* (including the amino nucleic acid sequences thereof). It also claims antibodies to the proteins and diagnostic test kits comprising the same.
- An application under section 72(1)(a) of the Patents Act 1977 for revocation of the patent was filed by Berni Hambleton of Sterling IP ("the claimant") on 31 December 2010. The application was accompanied by a statement of grounds alleging that the invention as claimed lacks an inventive step. The application follows an earlier request by the claimant for an opinion under section 74(A) of the Act in relation to the validity of the patent which was issued on 17 November 2010 (Opinion Number 13/10).

- The defendants filed their counterstatement on 28 April 2011, and a hearing date was set for 9 February 2012. The claimants filed evidence-in-chief on 29 August 2011, and the defendants filed their evidence on 10 October 2011. The claimants took the opportunity to file evidence-in-reply on 22 November 2011.
- The defendants in a letter dated 13 December 2011, have objected to the admissibility of the claimants evidence-in-reply, and in particular have asked that the additional documents D8 to D11 contained therein are not entered into the proceedings.
- The parties were then given the opportunity to file further submissions on the admissibility of the evidence-in-reply by 19 January 2012. Subsequently, both parties have declined the opportunity to be heard on this matter and have agreed that I should decide the issue on the basis of papers currently on file.

Arguments and analysis

- The defendants evidence in support of their counterstatement consisted of extracts from the European prosecution file including the European Patent Office ("EPO") examination report dated 24 April 1998. The claimants in their evidence-in-reply have filed an additional four documents D8 to D11 which the defendants contend should not be admitted as they are not strictly in reply for the reasons set-out in their letter dated 13 December 2011.
- In essence, the defendants argue that the claimant was aware of the contents of the EPO examination report from the outset, as for example, it is referred to in their statement of grounds at page 3, paragraph 2, and that the additional documents which the claimant now seeks to enter into the proceedings could easily have been submitted at an earlier stage. On that basis, the defendants consider these documents to be inadmissible.
- The claimants maintain that the additional documents supplied with their evidence of 22 November 2011 are intended to address issues arising from the EPO examination report which forms the basis of the defendant's evidence, and as such are strictly in reply.
- 10 It is agreed practice, that in revocation proceedings, the third round of evidence i.e. the claimant's evidence-in-reply should be just that, and must be "**strictly**" in reply, and that any supplementary evidence which could (and should) have been included in their evidence-in-chief may be struck out as inadmissible.
- 11 So, was the claimants evidence "*strictly*" in reply, and should it have been filed earlier in the proceedings? It is clear to me that the claimant believes that the additional documents are required to address comments made by the EPO examiner in their examination report which forms the basis of the defendant's evidence and as such prima-facie the evidence is in reply. It is also true to say that the claimants were aware of the examination report when filing their statement of grounds and could have addressed this matter then. However, they could not have anticipated the extent to which the defendant would rely on the EPO examination report until the defendant had filed their evidence on 10 October 2011. I think therefore that it is

entirely appropriate, on this occasion, to allow the documents filed by the claimants into the proceedings.

Conclusion

I have found the claimants evidence-in-reply to be admissible, and in accordance with defendant's request in their letter dated 18 January 2012, I think it only right in the interests of fairness to give them an opportunity to respond. I therefore allow the defendants an additional four weeks from the date of this decision to file any further submissions they feel necessary to address issues arising from the claimants evidence-in-reply.

Costs

13 The question of costs has not been raised in this context.

Appeal

14 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

P R SLATER

Deputy Director acting for the Comptroller