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PATENTS ACT 1977

IN THE MATTER OF an application under Section 27 of the Patents Act 1977 by The Minister of Agriculture, Fisheries and Food to amend Patent No 2090598B
and
IN THE MATTER OF an opposition thereto by IQ(Bio) Limited

DECISION

Specification No 2090598A was published on 14 July 1982 and was based on Application No 8137243 filed on 10 December 1981 claiming priority from an earlier United Kingdom application 8039742 dated 11 December 1980. The patent was granted on 21 March 1984 and relates to a method of competitive enzyme immunoassay of a hapten contained in a biological fluid.

An application to amend the patent under Section 27 was filed by the patentee on 21 March 1986, the reason for seeking amendment being given as:-

> "The description and claims have been amended to distinguish the present invention from matter disclosed in Hosoda et al, Chem Pharm Bull 27(9), 2147-2150 (1979) and Chem Pharm Bull 28(10), 3035-3040 (1980)"

I shall subsequently refer to these documents as the "Hosoda prior art". Following correspondence with the Patent Office, which led to a revision of the amendments proposed, the revised form of the amendments was advertised and formal opposition thereto was entered by IQ (Bio) Limited, their reasons being provided in an initial statement of case filed on 8 October 1987. There then followed a dispute over the adequacy of the opponent's statement of case which resulted in a preliminary hearing before Mr M F Vivian on

23 January 1989. The patentee appealed against the decision of the Superintending Examiner to allow the opponent one month to correct certain omissions from his statement of case, but the appeal was dismissed by Aldous J in the Patents Court on 19 July 1989.

After further discussion between the opponent and the Patent Office an amended statement of case, which appeared to meet the conditions laid down in the preliminary decision of Mr Vivian, was lodged on 17 November 1989 and the patentee, in his turn, was allowed to file an amended counterstatement on 26 March 1990. At this point in the proceedings the opponent was invited to file evidence in support of his allegations. This he failed to do within the time limits set and in a letter to the Comptroller dated 21 September 1990 the opponent declared that it was his intention not to file evidence nor to take part in any substantive hearing but went on to say that:-

> "They do not seek to withdraw from the opposition. They merely wish to stand on the case so far presented, and the facts admitted by the Patentee".

The Comptroller then decided that it was proper that certain matters, which I shall discuss later, should be pursued in the public interest and the patentee was invited to file evidence, which he duly did and, in a further letter to the Comptroller dated 27 June 1991, the patentee also stated that he did not seek a hearing. It appears that both sides accept that under Section 27, as with revocation proceedings under Section 72, if the opponent withdraws at any stage the matter is pursued in the public interest and proceedings may only be terminated by a formal decision by the Comptroller.

According to his statement, the grounds on which the opponent says that the amendments should not be allowed are:-

> 1. The subject matter of the Claims as proposed to be amended are not sufficiently clearly distinguished from the matter disclosed in the prior art referred to in the proprietors' request to amend, and thus do not cure the defect for which the amendment was sought.

2. The Claims of the Patent as granted were covetous in that the Patentee knew them to be broader than justified by the prior art, at least when the application was filed, and knew or should have known them to be broader than was justified by the prior art, when the Patent was granted. Further, the proprietors have sought to enforce the Patent, by extracting money from the opponent by way of licence fees, whilst representing to the opponents that the scope of the Patent was broader than was justified by their knowledge of the prior art.

3. The Patentees have delayed unduly in requesting amendment of the Patent, from the time at which they first knew of the need to amend.

4. In particular with regard to paragraph 3 above, the proprietors have on their own admission been aware of the prior art referred to in the application to amend for a substantial period of time, and at least since 25 November 1981 only two weeks before Patent Application no 8137243 was lodged, and yet made no application to amend until March 1986. In their amended Counterstatement dated 27 September 1988, the proprietors admit that despite the knowledge of the Chem Pharm Bull article only two weeks before the filing date of application 8137243, the application was nevertheless filed with Claims which both the Proprietor and his agent knew, or should have known to be invalid.

5. The applicants were reminded of the relevance of the Chem Pharm Bull article in October 1984, when it was drawn to their attention by the opponents in their letter of 18 October 1984, and again in their letter of 1 October 1985. Despite this, no attempt was made to amend the patent until March 1986.

6. The conduct of the proprietors in their failure to disclose to the Comptroller at the outset all the relevant circumstances surrounding the request for amendment, including the date on which the Patentee first knew of the relevant prior art, and further in putting forward misleading statements in its counterstatement in these proceedings, is such that the Comptroller should not now exercise discretion in favour of the Patentee to permit the amendment now sought.

Thus the grounds of the opposition may be summarised as lack of novelty and/or obviousness, covetousness, undue delay in seeking the amendment and failure to disclose all relevant matters.

Turning to the first ground of opposition, it is manifestly clear that the opponent has at no time given particulars of relevant passages in either of the two prior art documents in the name of Hosoda to demonstrate in what way the proposed amendments fail to meet the patentee's declared intention to distinguish the present invention from the said prior art. It would seem from a study of page 3 of Mr Vivian's preliminary Decision that it was the opponent's intention to demonstrate that the features which the patentee sought to introduce by way of amendment were conventional in the art and that evidence supporting this allegation would be filed in the form of a statutory declaration detailing common practice based on information from the opponent's factory. The Superintending Examiner warned the opponent against the introduction of further documents in support of an attack on validity of the type of "roving inquiry" which was condemned by Whitford J in Great Lakes Carbon Corporation Patent [1971] RPC 117. The first ground of opposition was therefore restricted to state that the proposed amendments do not cure the defect for which amendment was sought which is the type of pleading endorsed in James Gibbons Ltd Application [1957] RPC 158 and referred to in paragraph 27.28 of the Manual of Patent Practice. In the absence of evidence on behalf of the opponent to support this allegation it is not clear whether their intention may have been to mount a general attack on validity of a type which more properly should have been dealt with as a revocation under Section 72. Nevertheless, even without the assistance which such evidence might provide, I think that it is incumbent upon me to consider whether the proposed amendments overcome the admitted defect.

I will deal with the matter quite briefly because with regard to novelty I am satisfied that the present method claims, as amended and which are restricted to a competitive enzyme immunoassay of a hapten in a biological fluid in which the hapten may only be progesterone, are clearly distinguished from the disclosures in the Hosoda prior art in which the hapten is testosterone. I am also satisfied that the other restricting features introduced

into the main claims render them inventive. The requirements of Section 76 also appear to be met, namely that the amendments do not result in the specification disclosing additional matter nor in extending the protection conferred by the patent.

The allowance of amendment sought under Section 27 is discretionary and there is a heavy onus on the patentee to demonstrate that he has acted with the utmost good faith. There are many judgements pertinent to the exercise of discretion in amendment proceedings and these are reviewed in Smith Kline & French Laboratories Ltd v Evans Medical Ltd [1989] FSR 561. At page 569 line 23 Aldous J sets out the principles which he distilled from his consideration of precedent cases as follows:-

> "First, the onus to establish that amendment should be allowed is upon the patentee and full disclosure must be made of all relevant matters. If there is a failure to disclose all the relevant matters, amendment will be refused. Secondly, amendment will be allowed provided the amendments are permitted under the Act and no circumstances arise which would lead the court to refuse the amendment. Thirdly, it is in the public interest that amendment is sought promptly. Thus, in cases where a patentee delays for an unreasonable period before seeking amendment, it will not be allowed unless the patentee shows reasonable grounds for his delay. Such includes cases where a patentee believed that amendment was not necessary and had reasonable grounds for that belief. Fourthly, a patentee who seeks to obtain an unfair advantage from a patent, which he knows or should have known should be amended, will not be allowed to amend. Such a case is where a patentee threatens an infringer with his unamended patent after he knows or should have known of the need to amend. Fifthly, the court is concerned with the conduct of the patentee and not with the merit of the invention."

I therefore have to study the patentee's conduct from the date when he became aware of the Hosoda prior art until the application to amend was filed with these principles in mind. The learned judge places great emphasis on the fact that the patentee must make full disclosure

of the facts and this leads me to conclude that, as in the present case, even if an opponent does not provide evidence in support of his allegations then, nevertheless, the court may still refuse to exercise discretion in favour of the patentee if he is unable to justify his actions.

It is quite clear from the statutory declaration of Dr Maurice J. Sauer that he and his co-inventor Dr. J. Foulkes were aware of the existence of one of the Hosoda papers, Chem Pharm Bull (1980) 28 page 3035, at least as early as 15 September 1981 which was almost three months prior to the filing date of the present application. It is also apparent from Dr Sauer's declaration however, that neither he nor Dr Foulkes believed in late 1981 that the Hosoda prior art would render their patent invalid and that the full significance of the publication was only brought to their attention by their Patent Agent in December 1985, that is only three months before the request to amend was filed. I accept Dr Sauer's statement that between September 1981 and December 1985 he was not aware of the need to amend to avoid the known prior art. But, generally speaking, the inventor depends upon his Patent Agent to advise upon the validity of the invention as claimed vis-à-vis relevant prior art, and consequently I regard the actions of the Patent Agent in the present matter to be of paramount importance.

According to the statutory declaration of Mr W J Gunning, Assistant Director of Patents at the Ministry of Defence with overall responsibility for the Patent Agent, Dr S R James, who was actually prosecuting the case at the date of filing in December 1981, the 1980 Hosoda publication and another document were drawn to his attention at the end of November 1981 and he goes on to say that Dr James "expressed his concern that the application would require critical review in the light of their disclosures". The filing of the application on 10 December 1981 was consequently only authorised on the understanding that such a review would be effected on issue of the UK search report. The patentee's Agents have claimed that the period of two weeks between the date when copies of the publications were received in their Office and the date by which the application had to be filed in order to preserve its claimed priority date was insufficient for proper consideration to be given by the Agents and the inventors to the publications. The evidence here does not lead me to the inevitable conclusion that the patentee's Agents knew for certain that amendment of the application was necessary to avoid the Hosoda prior art but that here were two documents to which serious

consideration should be given with respect to patentability. The fact that the Agents considered that there was inadequate time in December 1981 to allow for such a consideration would not appear to be wholly unreasonable although, with hindsight, it has led to unfortunate consequences.

Having briefly minuted the file to the effect that a review of the application should be carried out when the search report was received, Mr Gunning's evidence indicates that, due to an oversight, no review of the Hosoda publication was conducted during the prosecution of the application to grant despite the fact that the search report listed two relevant documents (not the Hosoda publications) and these were formally cited under Section 1(1)(a) and 1(1)(b) in the substantive examination report. The Agent's inaction in the matter in question during this period of the prosecution of the application appears to me to amount to a lack of due care rather than deliberate prevarication.

Finally we come to the evidence of Mr R W Beckham, the Patent Agent who was responsible for initiating the review of the Hosoda documents in late 1985 which led to the application to amend the patent. Mr Beckham acknowledges that the patentee's Agents received a letter dated 18 October 1984 from the opponent's Agents relating to the Hosoda prior art but that no action was taken until the receipt of a further letter dated 1 October 1985.

I do not have the benefit of any evidence from the opponent to throw light on the form which these letters took or to explain the inaction of the patentee's Agent. In paragraph 5 of his amended statement of case of 17 November 1989 the opponent states that the applicants "were reminded (my emphasis) of the relevance of the Chem Pharm Bull article (ie Hosoda) in October 1984". On the other hand in paragraph 5.1 of his counterstatement of 26 March 1990 the patentee refutes the assertion that the opponent's letter was a reminder, as it was the first time IQ (Bio) had written, and goes on to say that "the letter did not give any opinion on the precise relevance of the prior art and was not cast in a form which would have drawn the patent proprietor's attention to the importance of the document and in particular to its precise relevance to the claims" ...

Since I have not had sight of the opponent's letter of 18 October 1984, I am inclined to the view that the benefit of the doubt must rest with the patentee and that not until their receipt of the opponents' letter of October 1985 did the patentee have a bona fide awareness of the necessity to amend. It must be said that, subsequently, the patentee acted promptly to file the application to amend.

However the opponent has failed to persuade me that the patentee studied the publications in question and appreciated fully their significance before October 1985, which was 19 months after the date of grant and I have concluded that his allegation that the claims of the granted patent were covetous because the patentee knew at the date of filing and at the date of grant that they were broader in scope than was justified by the prior art is unsubstantiated.

The opponents also base their attack on the ground of covetousness on the fact that the patentee ought to have known that his claims were too broad. I find myself unable to accept this contention if it is founded merely upon the patentee's admission that he was "aware" of the relevant documents but had accidentally failed to study them sufficiently to form a conclusion in relation to his own invention. Thus Graham and Whitford J J sitting en banc in the case of Imperial Chemical Industries Ltd (White's Patent) [1978] RPC 11 observed at line 38 on page 22:-

> "... a charge of covetousness, if it is to be successful, must involve proof that the patentee has knowingly and deliberately obtained claims of unjustified width."

Strong circumstantial evidence would therefore be required to uphold such an allegation such as was demonstrated in the case of Bentley Engineering Co Ltds Patent [1981] RPC 361 wherein the patentees failed to amend their UK application even though they were aware of a relevant document cited by the Examiner in proceedings in the corresponding US application. Similarly, in Autoliv Development AB's Patent [1988] RPC 425, evidence showed that the patentees had ignored action which restricted the scope of the claims in their corresponding German application. In both of these cases the patentees' misconduct resulted in the court refusing to exercise discretion to allow the amendments sought.

It is relevant at this point, I think, to consider the comments of Graham J. in Matbro Ltd v Michigan (Great Britain) Ltd [1973] RPC 823 where at page 834 line 4 he compares the actions of the patentees in the case of Bristol Myers Co v Manon Frères Ltd [1973] RPC 836 and Van der Lely v Bamfords Ltd [1964] RPC 55 in the following terms:-

> "I think these cases do support what I have said above in regard to delay and detriment and also draw a clear distinction between instances where a patentee knows of prior art which he genuinely, and quite properly in the circumstances, thinks is irrelevant, and other instances where, though he learns of or has been warned of objections which are available against his patent as a result of prior art, yet he takes no steps or, still worse, knowingly persists in retaining it in the unamended and suspect form. In the latter cases delay is culpable because potential defendants and the general public are entitled to plan their activities on the assumption that the patentee, though warned, has decided not to amend. If the patentee, by his conduct, lulls the public into a false sense of security he cannot thereafter be allowed to change his mind and ask for amendment, or at any rate without adequate protection being granted to the public".

To my mind the actions of the patentee in the present case lie somewhere between the circumstances contrasted by Graham J. and I have concluded that the element of culpability is missing and that the opponent's attack on the ground of covetousness fails.

However, that does not dispose of the matter concerning the delay in seeking amendment of the patent. Even if I accept that the behaviour of the patentee was not unreasonable in failing to take account of the Hosoda prior art in December 1981, he had nonetheless been alerted to the need to give it serious consideration. While Mr Gunning gave instructions that this prior art should be reviewed on receipt of the UK search report, this did not happen and I have been offered no explanation of why it could not have been reviewed at any time before the grant of the patent. Again, even if the opponent's letter of 18 October 1984 was not as strong a warning as he would have me believe, there does not seem to be any dispute that it included at least a further reference to the Hosoda prior art which was ignored by the patentees.

The outcome of this is that a period of 4½ years elapsed between the date when the inventors first became aware of the Hosoda prior art and the date when the formal application to amend the patent was made which suggests to me a lack of care and diligence on the part of the patentee which amounts to a failure to satisfy the third of the principles expounded by Aldous J. to which I have referred earlier. There is no indication in seeking to excuse the delay that the public interest was taken into account nor is there any suggestion that the patentee had reasonable ground for believing that amendment was not necessary; indeed, to the contrary, the patentee was aware at an early stage that the Hosoda prior art merited critical review.

The final ground upon which the opponent relies is that the patentee failed to disclose to the Comptroller all of the relevant circumstances.

When the request to amend the patent was eventually filed, the patentee must have been aware of the delay which had occurred since the initial consideration of the Hosoda prior art towards the end of 1981 but, apart from the need to distinguish from Hosoda being given as a reason, no other information was furnished. Furthermore, during the consideration of the amendments in the Patent Office prior to their advertisement, no details of the length of time during which the patentee had been aware of the prior art was volunteered to the Comptroller. Failure to provide such information, in my view, is not easily reconciled with the patentee seeking the exercise of the Comptroller's discretion in his favour, a view it would seem which is shared by Aldous J. according to his judgement on the appeal from the Preliminary Decision on the present case where he said at line 1 of page 7:-

> "These are amendment proceedings in which the patentees seek an indulgence and are under a duty to place before the Comptroller all matters which would be relevant in the exercise of his discretion. Thus such matters as the date when the patentees first became aware of the prior art should have been supplied by the patentees to the Comptroller."

This endorses the long-standing principle which was stated, for example, in the judgement in Chevron Research Co Patent [1970] RPC 580 that there is a heavy onus on the patentee to put the whole story before the court or, as in this case, the Comptroller. Since the Comptroller did not specifically request such information prior to advertisement of the amendments, it was not until opposition proceedings had commenced that details were given on 28 September 1988, in response to a request from the Comptroller, and the patentee finally divulged when he first knew of the Hosoda prior art. There appears to have been a marked reluctance on the part of the patentee to make such an admission and it seems to me that the failure of the patentee to bring vital information to the attention of the Comptroller of his own volition at an early stage of the section 27 proceedings has compounded the current situation wherein an opponent who had a licence to work the invention initiated an opposition, but was unable to furnish satisfactory evidence.

In summary, therefore, I am not satisfied that the patentee has met the criteria set out by Aldous J. in that he failed to provide the relevant information at an early stage in these proceedings and has not shown reasonable grounds for the delay and, accordingly, I refuse to allow the request to amend the patent.

Finally, I will deal with the matter of an award of costs which both sides have sought and in respect of which they have put in written submissions. Although the opponent has succeeded on two of the grounds pleaded, he has not filed any evidence nor attended a Hearing. Taking all of these matters into account I consider that the opponent, IQ(Bio) Limited is entitled to an award of costs of £100 and I direct that this sum be paid by the patentee, The Minister of Agriculture, Fisheries and Food.

Signed this 6 day of February 1992

P J HERBERT
Superintending Examiner acting for the Comptroller

THE PATENT OFFICE