

**OPINION UNDER SECTION 74A**

Patent	GB2439562 C
Proprietor(s)	Medilec Limited
Exclusive Licensee	
Requester	Richard Saumarez
Observer(s)	Medilec Limited
Date Opinion issued	18 April 2016

**The request**

1. Richard Saumarez (the requester) has asked for an opinion on whether either of the instruments described in Annex 1 and 2 accompanying the request infringe claims 3, 23 or any claim dependent on either one of 3 or 23 of GB2439562 C (the patent).

**Observations**

2. Observations were received from Medilec Limited (the observer) arguing that the Opinion should not be issued for reasons discussed below. The observer also argues that the instruments described in the annexes infringe under Section 60(2) of the Act

**Observations in reply**

3. Observations in reply were received from the requester countering the arguments made by the observer.

**Should the request be refused**

4. The Patents Act 1977 provides in section 74(A)(3) that

*The comptroller shall issue an opinion if requested to do so under subsection (1) above, but shall not do so –*

*(a) in such circumstances as may be prescribed, or*

*(b) if for any reason he considers it inappropriate in all the circumstances to do so.*

5. The prescribed circumstances are set out in Rule 94 which reads as follows:

*94(1) The comptroller shall not issue an opinion if-*

*(a) The request appears to him to be frivolous or vexatious; or*

*(b) The question upon which the opinion is sought appears to him to have been sufficiently considered in any relevant proceedings.*

6. The observer here asserts that there is insufficient evidence to issue an opinion in relation to Section 60(2) and so the requested opinion in relation to infringement in general cannot be given. However after carefully considering all the material before me I am satisfied that there is sufficient information for me to give an opinion although as with all opinions, that is based solely on the information before me.
7. The observer has also argued that the requester's evidence includes confidential material in which copyright is owned by the observer. No consent has been given to the requester to publication or distribution and so, the observer argues, the opinion should be refused. In the observations in reply, the requester claims ownership of the copyright as the author and has provided an email chain and letter purporting to show this.
8. I would note first that Rule 53(2)(b) provides that the comptroller must refuse any request to treat as confidential any document filed in relation to an opinion request. Hence even if the observer is requesting that certain documents be treated as confidential then that request must be refused. But that does not mean that the comptroller could not still determine that the circumstances were such that it would be inappropriate for him to give an opinion. In this instance I do not believe it would be inappropriate. The observer has not in my opinion clearly demonstrated any breach of copyright or confidence. The documents in question are also now in the public domain. It is of course open to either party to take appropriate action elsewhere on these matters but for the purpose of this request I am satisfied that the circumstances are not such that I should refuse to give an opinion.
9. One further point to note is that the request asks for an opinion, listing the infringing acts to be considered. All these acts relate to (substantive) infringement under section 60(1). There is no specific request for an opinion relating to (contributory) infringement under section 60(2). However, the observations and observations in reply both argue the case in relation to section 60(2). Therefore I consider it appropriate to issue an opinion regarding section 60(1) and section 60(2) infringement.

### **The patent**

10. The patent was filed on 29 June 2006 with no claim to priority. It was granted on 4 March 2011 and is still in force. The patent was corrected and a C specification issued on 1<sup>st</sup> July 2015. Revocation proceedings were initiated by the requester on 24 April 2015 and in response, the proprietor (observer) requested a post grant amendment. The proposed amendment, which has not yet been accepted, limits claim 1 to include the features of claims 2 and 3, cancels claim 14 and creates a new independent claim based on claims 1, 18 and 23. The opinion request refers to the claim numbering as found in the corrected version GB2439562 C.

11. The patent relates to a system for analysis of electrograms. The system comprises an input electrode for applying stimulating signals to the heart and at least one output electrode for recording corresponding electrical signals after conduction of the stimulating signals through the heart. The recorded signals are processed and analysed to generate a parameter value which may indicate one of a plurality of physiological cardiac conditions.

12. Claims 1 to 3 of the patent read as follows:

1. *A system for use in analysis of electrograms, the system comprising:*

*a signal generator for generating an input signal;*

*an input electrode for applying an input signal to a driving region of a heart organ;*

*an output electrode for receiving an output signal at a driven region of the heart organ, so as to record a value thereof;*

*a processing system arranged to receive signals indicative of said recorded value from the output electrode for analysing conduction paths through the heart organ,*

*wherein the signal generator is arranged to generate an input signal comprising a plurality of pulses, individual said pulses being spaced from each other by a pacing interval;*

*and wherein the processing system is arranged to identify signal delay between the input signal and the output signal on the basis of the signal received by the output electrode in relation to the plurality of pulses,*

*characterized in that the processing system is arranged to identify a rate of variation in signal delay over a range of values of pacing interval.*

2. *A system according to claim 1, wherein said processing system is arranged to identify first and second rates of variation in signal delay within the range of values of pacing interval.*

3. *A system according to claim 2, wherein said processing system is further arranged to compare the first and second rates of variation in signal delay so as to generate a parameter value indicative of a difference in said first and second rates of variation in signal delay.*

13. Claims 18 and 23 read as follows:

18. *A system according to claim 1, wherein the plurality of pulses comprises a first set of pulses, a second set of pulses and a third set of pulses, individual ones of the first set of pulses being spaced from individual ones of the second set of pulses by a first pacing interval, and individual ones of the first set of pulses being spaced from individual ones of the third set of pulses by a second*

*pacing interval.*

23. *A system according to any of claims 18 to 22 wherein the processing system is arranged to identify a rate of variation in signal delay over a range of values of the first pacing interval and the second pacing interval so as identify a rate of variation in signal delay over a range of values of the first pacing interval and the second pacing interval.*

## **The law on infringement**

14. Section 60 of the Act states that:

*(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say-*

- (a) Where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;*
- (b) Where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;*
- (c) Where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.*

*(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.*

15. In order to determine whether the instruments described in annex 1 and 2 infringe the claims of the patent under section 60(1), I must first construe the claims and then determine whether the instruments have all the features of the claims so construed. If not, I will then consider whether there is infringement under section 60(2).

## **Claim construction**

16. In construing the claims I shall use the standard principles of claim construction as set out in *Kirin-Amgen and others v Hoechst Marion Roussel Limited and others* [2005] RPC 9. I must put a purposive construction on the claims, interpret them in light of the description and drawings, as instructed by Section 125(1) of the Act and take account of the Protocol to Article 69 of the European Patent Convention. Put

simply, and as emphasised by Hoffmann LJ in that judgment, I must decide what a person skilled in the art would have understood the patentee to have used the language of the claims to mean.

17. The claims appear generally straightforward to construe and there has been no argument from either side as to their meaning. I note that the copy of claim 1 recited in the request has some minor differences to claim 1 of the published C specification. However I do not think these differences have any bearing on the outcome of this opinion. I have taken claim 1 above from the C specification as the correct version.

### **Do the instruments of Annex 1 and 2 infringe under section 60(1)?**

18. Annex 1 describes a system for stimulating the heart and for recording, processing and analysing the resulting electrograms. It comprises the same hardware as that of claim 1, namely a signal generator, input and output electrodes and a processing system (comprising a computer). The input signal is also the same as claimed in claim 1.
19. The requester argues that the instrument processes and analyses the signals in a different way to claim 3 (dependent on claims 1 and 2) and claim 23 (dependent on claim 1 and 18). This has not been disputed by the observer and I agree that according to the evidence this appears to be the case. The instrument of annex 1 does not therefore infringe claim 3, 23 or any of their dependent claims under section 60(1).
20. The instrument of annex 2 comprises the same hardware as the instrument of annex 1 but adds a number of processing steps to reduce noise in the electrograms before they are processed and analysed using the methods described in annex 1. The requester argues that the instrument of annex 2 does not include all of the features of claim 3 or 23. Again this has not been disputed by the observer and I agree that according to the evidence this appears to be the case. The instrument does not therefore infringe claim 3, 23 or any of their dependent claims under section 60(1).

### **Do the instruments of Annex 1 and 2 infringe under section 60(2)?**

21. The observer argues that the only difference between the instruments of annex 1 and 2 and the claimed invention is the way in which the signals are processed. Since the processing is achieved by a suitably programmed computer, then the instrument could also be programmed to perform the processing recited in the claims. Thus section 60(2) infringement is relevant. The observer applies the assessment set forth by the Court of Appeal in *KCI Licensing Inc & Ors v Smith & Nephew Plc & Ors* [2010] EWCA Civ 1260 in which it was held:

*“There is no requirement that the ultimate users must have decided to use the means to put the invention into effect at the time they first take possession of the means. The relevant intention may be formed at a later time. But the supplier must know (or must be obvious to him in all the circumstances) that some ultimate users will need form that intention”*

22. The observer argues that it would be obvious to the requester that the ultimate users

of the instruments would form the intention to put the claimed invention into effect (in order to identify certain cardiac conditions identified in the patent, but then goes on to state that there is insufficient information for an opinion in relation to section 60(2).

23. In the observations in reply, the requester states that the invention lies in software running on known hardware and to reprogram the instruments would require substantial effort by a skilled programmer. The requester also argues that existing systems in use before the filing date of the patent could be reprogrammed in this way, meaning that the patent could be infringed by the sale of many existing systems or even a desktop computer with nothing other than factory operating system installed.
24. The requester and observer appear to be in agreement that the only difference between the invention of claims 3 and 23 and the instruments of annex 1 and 2 is the software used to process and analyse the electrical signals from the heart. According to the requester and the background discussion in the patent, the hardware was known before the priority date of the invention. So in light of this do the instruments infringe under section 60(2)?
25. I am not convinced by the observer's assertion that it would be obvious to the requester that an ultimate user of the instruments would form the intention to adapt the instruments to put the claimed invention into effect. Firstly, to reprogram the instruments to carry out the invention is not a simple task. It would require specialist skills beyond most users. It is not a case of replacing a part with another readily available part. Secondly, if the observer is correct then the supply of conventional hardware would also infringe. It would seem entirely wrong that a new method of processing (embodied in software) should render supply of such hardware an infringing act. There is no evidence to show that conventional hardware has been programmed to carry out the invention. So if conventional hardware has not been used to infringe then there is no reason to believe that the instruments in question would be so used.
26. Therefore I do not consider the instruments described in annex 1 and 2 to infringe under section 60(2).

## **Conclusion**

27. I conclude therefore that the instruments described in annexes 1 and 2 do not infringe claims 3 or 23 of the patent or any claim dependent on either claim 3 or 23.

## **Application for review**

28. Under section 74B and rule 98, the proprietor may, within three months of the date of issue of this opinion, apply to the comptroller for a review of the opinion.

GARETH GRIFFITHS  
Examiner

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**NOTE**

*This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.*