

# **PATENTS ACT 1977**

## **IN THE MATTER OF**

Patent Application GB9813433.1

in the name of Mercury Diagnostics Inc.

## **DECISION**

### **Introduction**

1. Patent application GB9813433.1 (the new application) was filed on 22 June 1998 in the name of Mercury Diagnostics Inc. claiming, under section 15(4), the filing date of 30 October 1997 and priority date of 30 October 1996 of patent application GB9811645.2 (the earlier application). The earlier application results from an international application entering the British national phase in accordance with section 89. The original application was published as WO98/19159.

2 In a letter dated 17 July 1998 the examiner objected that, since the claims in the new application were directed to a different invention from the single invention present in the earlier application, the new application disclosed matter extending beyond that disclosed in the earlier application, thus contravening the requirements of section 76(1), and that in consequence the new application could not proceed with the filing date of the earlier application unless the added matter was removed. In a letter dated 30 July 1998, Mercury Diagnostics' patent agents, Lloyd Wise, Tregear & Co, refuted the objection arguing that the test for entitlement of a later filed application to the filing date of an earlier application is whether the later application relates to matter contained in the earlier application, and not whether it relates to an inventive concept which was set out as being an inventive concept in the earlier application.

3 Further correspondence between agent and examiner failed to resolve the matter and consequently it came before me at a hearing on 2 March 1999. The applicant was represented

by Mr A Rackham and Mr S Howe and Mr R Clark attended as examiner.

### **The applications**

4 As filed the earlier application is identical in content to the international application which is entitled "Synchronized analyte testing system" and relates to a device for determining the presence or concentration of analytes in a sample, using a testing instrument and test strips. The "synchronising" in the title refers to the fact that the testing instrument is precalibrated or synchronized to the test strips with which it is supplied.

6. Under the heading "Field of the invention" it is stated :-

"The present invention relates to detection devices for determining the presence or concentration of analytes or biological agents in a sample, and more particularly, to systems using testing instruments to measure analyte activity on test strips impregnated with appropriate reagents."

7. The paragraph following the heading "Summary of the invention" reads as follows:-

"The invention overcomes the deficiencies of the prior art by providing a low cost testing instrument and single use test strips capable of reading small sample sizes, e.g. 3  $\mu$ L, and determining the amount of analyte in the small sample. The low cost nature of the testing instrument permits the packaging of the testing instrument and test strips together in a package, creating a synchronized system which may be used to perform a specific number of tests. The testing instrument is provided at no extra cost to the user, who benefits from having a fresh device with each package of test strips purchased. This eliminates the need for the patient to make an investment in test equipment to monitor a specific condition or therapy."

8. This is followed by :-

"In an alternate configuration, the device may be provided as part of a starter package including a sampling device and test strips. Replacement test strips

could be purchased separately without the device or sampler if longer testing instrument life is preferable. For example, the desire to include additional features such as data management capabilities could add cost which would favor(sic) a longer useful life for the testing instrument."

9. The only independent claim reads:-

A synchronized detection device for detecting the presence of an analyte in a sample based on a physically detectable reaction of the sample with a reagent, the device comprising:

a set of test strips each containing the reagent disposed thereon, each set containing at least one test strip;

a calibration means corresponding to the set of test strips and containing calibration information uniquely characteristic to the reagent in the set of test strips;

a housing having a docking portion for engaging at least one of the test strips;

a sensor disposed at least partially in the housing and adapted to generate an electrical signal responsive to the reaction of the sample with the reagent; and

a processor disposed at least partially in the housing and adapted operate in accordance with the calibration means to generate a detection signal representative of the presence of the analyte in the sample.

10. The new application is entitled "Test strip" and is directed to the strip shown in figure 1 of the earlier application. It has one independent claim, the claim to which objection has been made under section 76, and this reads as follows:-

A test strip for analysis of a bodily fluid sample and for reading in a test instrument comprising:

a strip having an opening with a test pad positioned in the opening and impregnated with a reagent system for reading in the test instrument and a handle extending from the surface of the strip on the opposite side from the opening and containing a channel for transferring the fluid sample to the test pad.

## **The law**

11. Section 15(4) reads:

Where, after an application for a patent has been filed and before the patent is granted, a new application is filed by the original applicant or his successor in title in accordance with rules in respect of any part of the matter contained in the earlier application and the conditions mentioned in subsection (1) above are satisfied in relation to the new application (without the new application contravening section 76 below) the new application shall be treated as having, as its date of filing, the date of filing the earlier application.

12. The relevant part of section 76 reads:

- (1) An application for a patent which-
- (a) is made in respect of matter disclosed in an earlier application, or in the specification of a patent which has been granted, and
  - (b) discloses additional matter, that is, matter extending beyond that disclosed in the earlier application, as filed, or the application for the patent, as filed,
- may be filed under section 8(3), 12, or 37(4) above, or as mentioned in section 15(4) above, but shall not be allowed to proceed unless it is amended so as to exclude the additional matter.

## **General principles and authorities considered**

13. It was agreed that, for the purposes of determining whether or not section 76 is contravened, comparison should be made between the original PCT application and the application in suit.

14. Mr Rackham referred to the CIPA guide at page 660, 76.13 where general principles for determining whether matter has been added are laid down. In particular he drew my attention to the test laid down in *Bonzel v Intervention (no 3)* [1991] RPC 553 at page 547, viz:

- (1) to ascertain through the eyes of the skilled addressee what is disclosed, explicitly and impliedly in the original application;
- (2) to do the same in respect of the patent as granted: and
- (3) to compare the two disclosures and decide whether any subject-matter related to the invention has been added whether by addition or deletion, this comparison being strict in the sense that subject-matter will be added unless such matter is clearly and unambiguously disclosed in the application either explicitly or implicitly.

This is followed by a statement that the court is concerned with "what is disclosed, not with what might have been described".

Mr Rackham also referred to the statement by the Comptroller in *Van der Lely's Application* [1987] RPC 61 that :-

"the fundamental principle in determining additional subject-matter is to decide whether any document presents the informed reader with information relevant to the invention which the other document does not."

15. Further guidance is given in *Southco Inc v Dzus Fastener Europe Ltd.* [1990] RPC 587 particularly at page 616 line 5, page 616 at line 36 and page 618 at line 23. In the first passage it is stated :-

"There is no definition in the Act of what is meant by the word "matter" and I believe that this word is wide enough to cover both structural features of the mechanism and inventive concepts."

The second passage reads :-

"It appears to me that when amendment has been made pre-grant it is not material whether that amendment has the effect of widening or narrowing the monopoly claimed. The Act contemplates that amendments to claims will be made and therefore the ambit of the claims will be altered. What the Act is seeking to prevent is a patentee altering his claims in such a way that they claim a different invention from that which is disclosed in the application. Thus, provided the invention in the amended claim is disclosed in the application when read as a whole, it will not offend against section 76."

The third passage reads :-

"I believe that section 76 is there to prevent the patentee disclosing either by deletion or addition any inventive concept which was not disclosed before but not to prevent a patentee claiming the same invention in a different way."

16. *LB (Plastics) Application* (Office Decision O/90/86) and *Plantronic's Inc Application* (SRIS C/96/85) were considered. Both these cases relate to applications in which a later filed case was not allowed to proceed under section 15(4) with the filing date of the earlier case. In *LB (Plastics)* the claims in the later application were directed to a glazing bead which, in the application as originally filed, was described in terms of a particular construction of frame component to which the original claims were directed. It was held, following the reasoning in *Glatt's application*, that the invention claimed in the later case was not "within the contemplation of the invention as described in the originally filed specification". In *Plantronic's* the claims in the later filed application were directed to a post-auricle capsule including an electret microphone which was shown in one of the figures but they were not restricted to the shape of capsule claimed in the earlier application. On appeal from the Office decision it was held that "it would be quite impossible to consider that there has been therein a disclosure of an invention other than that which relates to a post-auricle headset to be contoured as described".

### **Application to the case in suit**

17. Mr Howe indicated descriptive passages which he considered would signify to the skilled man that the test strip was an inventive concept in its own right. He admitted that the main problem set out in the PCT application, *viz* that of ensuring that the test strips are calibrated to give accurate results was not addressed by the test strip but was solved by the association of the test strip and testing instrument as claimed in the earlier application. However he argued that this was not the only problem set out, drawing my attention particularly to two aspects, the desirability of producing (1) a low cost system and (2) a system using smaller fluid samples (3  $\mu$ L instead of 10 $\mu$ L). He considered that both these problems were solved by the test strip which formed the subject matter of the new application and not by the combination of testing instrument and strips. In respect of the first he argued that there is a high cost in the combination

of a meter and a set of test strips because the meter must be more expensive than the test strip. In respect of the second he asserted that it was the wicking action of the handle of the test strip that enabling the device to operate with a small size sample. He also argued that the paragraph quoted at 8 above indicated quite clearly that the test strips were intended to be sold as items in their own right and that it was in fact the norm for test strips to be sold separate from the testing instrument. He placed much reliance on the statement on page 12 at lines 18,19 that the test strip 11 of this invention differs from current test strips in multiple ways, considering that this was a clear indication that the test strip was new and inventive.

18. Mr Rackham considered that this application was distinguished from the precedent cases of *LB (Plastics)* and *Plantronics* since in both these cases there was no suggestion in the earlier applications that the individual components for which protection was subsequently sought in the later applications were new or useful in their own right. He contrasted this with the application in suit where the test strips were of general applicability, having their own life separately from the combination originally claimed.

## **Conclusions**

19. In my opinion the main thrust of the applicant's argument for allowability of the earlier date is based on the view that a skilled addressee reading the original specification would realize that the test strip should be recognised as a separate entity of general applicability, firstly because the original specification posed problems of cost and sample size which were solved by the test strip alone, secondly because the test strip was designed to be sold as a separate entity and thirdly because there was a passage in the original description indicating that the strip differs from current test strips in multiple ways.

20. Taking these in turn, in my opinion the proposition that the problem of cost is solved primarily by the test strips is not supported by the disclosure of the earlier application. In the paragraph following the heading "Summary of the invention" (paragraph 7 above), it is stated that the testing instrument is provided at "no extra cost to the user". Then in the second paragraph on page 7 there is a reference to an advantageous feature being the provision of a

simple low cost testing instrument and a complementary reagent test strip. Paragraph 1 on page 12 refers to the ever decreasing cost of computing power and constructing multiple optical systems at very low cost and on page 14 it is stated that the kit of testing instrument and a specific number of synchronized test strips provides a cost-effective test method. Consequently, whilst I agree that it is acknowledged that cost is a problem with prior art systems, it seems to me that the whole tenor of these statements in the original PCT disclosure is that the solution to this problem comes about primarily because of the low cost of the testing instrument and secondly by the combination of the testing instrument and test strip in the invention as claimed, viz a synchronised detection device.

21. Likewise I do not consider that there is support for the second proposition. The small sample size is referred to in paragraph 3 on page 5 in the following terms:-

"In addition, a system which requires a smaller fluid sample would be attractive to many patients. There has been a trend toward smaller sample sizes, but most devices still require about 10  $\mu$ L of blood. Many patients have difficulty routinely applying an adequate sample to the strips or electrodes. Inadequate sampling can cause erroneous results or may require that the user discard an expensive test strip and repeat the sample application procedure."

It is also mentioned as one of several advantageous features on page 7 where it is stated :-

"An advantageous feature in accordance with the invention is the use of a small sample sizes (sic), e.g., about 3  $\mu$ L, which is a fraction of the volume required for most blood glucose tests and could be more readily obtained from patients."

However on page 19 in a paragraph beginning "The subject invention provides improvements over existing technology " it is stated that:-

"The use of lens based optics permits the system to focus on small reaction area which reduces the size of the test pad. The resulting small test pad reduces the cost of the matrix employed and the quantity of expensive reagents needed to conduct an accurate assay using an oxidase and peroxidase chemistry. With a smaller test pad a smaller sample volume is adequate. The system conserves the energy used and minimizes the amount of light require by the system to determine the color (sic) change."

This seems to me to be a clear indication that one factor in operating with a smaller sample size



is the lens based optics of the testing instrument and that therefore any advantage in this area comes from the combination of this optical system with the test pad.

22. Consequently I do not accept that the original specification either implicitly or explicitly discloses that reduction in cost and operation with a smaller sample size were solved by the test strip alone.

23. In respect of the reference to replacement test strips I believe that the skilled addressee would not be surprised to read that test strips could be purchased separately because, as Mr Howe pointed out, this is "the way it is normally done". Furthermore they are only referred to (page 6 paragraph 2) in the context of an alternate configuration in which, for example, a longer life for a more complex (and consequently more expensive) testing instrument is desirable. The strips still need to be calibrated to the specific testing instruments which suggests that these strips are not of more general applicability.

24. However even if it were possible to identify the test strip as a separate entity in the earlier application, in my view this would not in itself be sufficient. The first passage in *Southco* quoted above makes clear that added matter could include an added inventive concept, whilst the second refers to the Act preventing "a patentee altering his claims in such a way that they claim a different invention from that which was disclosed in the application". The third, at page 618, refers to "the patentee disclosing either by deletion or addition any inventive concept which was not disclosed before". The hearing officer in *LB Plastics* followed the reasoning in *Glatt's Application* [1983] RPC 122 that :-

"Third parties who, potentially, may be affected should not, it seems to me, have to face monopolies which were neither clearly sought nor founded by the inventor at the date of filing, but which were conceived later and claimed *post hoc*."

This was supported in the Patents Court in the following terms:-

"The Principal Examiner has come to the conclusion that [the claim] is not [supported by the description] and I think that he is quite right in reaching this conclusion upon this basis, that the applicants are putting forward as covering something which quite plainly, to my mind was never within the contemplation of the invention as described in the

specification."

The inventive concept of the new application is clearly a test strip of general applicability. It seems to me that, following these precedents, unless there is disclosure of such an inventive concept in the earlier application then matter would be added in the new application by its disclosure.

25. Section 125(1) reads:-

"For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly."

This section therefore makes clear that, unless the context otherwise requires, the invention in the earlier application is that specified in the claims.

26. Looking at the original specification it consistently describes the inventive concept as the testing system. It is so described in the title, the field of the invention, the summary of the invention and claims. None of the claims is for a test strip *per se* and none specify the features of the test strip now sought to be included in claim 1 of the new application. Furthermore all the advantageous features listed on page 7 indicate that the invention relates to a testing system comprising a testing instrument and test strips. Therefore, in my view, the context does not require the skilled addressee to look elsewhere for the invention.

27. It was however argued for the applicant that the most important thing the skilled addressee would see in the specification is the statement (the third paragraph on page 12) that the test strip 11 of this invention differs from current test strips in multiple ways and that the skilled person reading this sentence would see a very clear indication that this is new and inventive. I cannot agree with this argument. In my view, whilst the reader might see such an indication if he were reading the later application where the test strip alone is claimed, bearing in mind that the claims form part of the disclosure, in the earlier application the phrase "the test

strip of the invention" must mean the invention disclosed in the earlier application, where the test strip is part of a combined device consisting of a measuring instrument and a test strip. What we are concerned with here is not what the skilled reader might think could have been claimed but what was actually disclosed, and I cannot conceive the possibility that the repeated references to the combined device can be ignored. In my opinion the skilled addressee reading the earlier application would consider that only one inventive concept was clearly disclosed, *viz* a testing system comprising both a testing instrument and a set of test strips, both parts of the testing system being presented as essential integers of the invention.

28. Mr Rackham submitted that any doubt should be resolved in favour of the applicant. However the Bonzel test states that subject-matter is added unless such matter is clearly and unambiguously disclosed in the application either implicitly or explicitly. I consider that there is no clear disclosure in the earlier application of the inventive concept claimed in this application, i.e. a test strip *per se* and in particular a test strip of general applicability including features selected at will from the earlier disclosure. Thus the inclusion of such a claim results in the disclosure of matter extending beyond that disclosed in the earlier application as filed, contrary to section 76 and consequently the new application cannot proceed as a filing under section 15(4). I allow two months from the date of this decision for the filing of amended claims free of objection under section 76. If no amendments are proposed within that time the application will proceed with a filing date of 22 June 1998.

### **Appeal**

29. As this decision relates to a substantive matter, under the Rules of the Supreme Court any appeal must be lodged within six weeks of the date of this decision.

Dated this 17<sup>th</sup> day of March 1999

JACKIE WILSON

Deputy Director, acting for the Comptroller