

#### **PATENTS ACT 1977**

**BETWEEN** N Nazareth Claimant and Secretary of State for Defence Defendant **PROCEEDINGS** 

Application for revocation under Section 72 in respect of of patent numbers EP 1080178, EP 0942781 and GB 2333250

HEARING OFFICER

J Elbro

# **DECISION**

#### Introduction

- 1 An application for revocation of patent numbers GB2333250 ('250), EP094278 ('781), and EP1080178 ('178; collectively, "the patents") in the name of The Secretary of State for Defence ("the defendant") was made by Mr. Nelson Nazareth ("the claimant") on 7th March 2007.
- 2 GB2333250 was filed on 14 January 1999, claiming priority of 16 January 1998, and was granted on 5 June 2002. The claims relate to a reaction vessel using electrically conducting polymer ("ECP") with a container and cap member which projects into the container. EP0942781 was filed on 20 November 1997, claiming earliest priority of 6 December 1996, and was granted 26 October 2005. The claims relate to an apparatus for effecting reactions using ECP to heat reagents through a series of different temperatures. EP1080178 was filed on 17 May 1999, claiming priority of 23 May 1998, and was granted on 7 December 2005. The claims relate to a system for culturing biological materials with ECP, power supply and control means.
- 3 In July 2008 the defendant requested that the cases brought against them in respect of each patent be struck out, or alternatively decided summarily in their favour. This came before me at a hearing on 29 October 2008 and I issued a

preliminary decision on this matter on 29 December 2008 (BL O/343/08). In my decision I found that the statement of claim did not provide reasonable grounds for bringing a revocation claim. However, I did not find it appropriate to strike out the claim and instead offered the claimant the opportunity to file an amended statement of claim, bearing in mind the deficiencies I had outlined in his first filing.

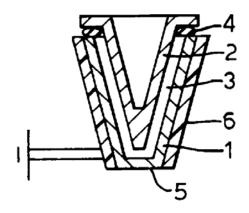
- Following my decision the claimant filed what appears to be revised statements of claim on 18 February 2009, followed by further revised statements on 17 July 2009. The defendant responded by arguing that the claim has no chance of succeeding at full trial and requesting summary judgment.
- Both parties have agreed to a decision being taken on the papers and to all three patents being considered together.

#### The inventions

The inventions claimed in the patents are closely related to each other. Each claims a vessel which comprises an electrically conducting polymer ("ECP"). It is apparent from the text of the patents that one of the key uses of these vessels (at least when they were conceived) was as (part of) a thermal cycling device in DNA amplification methods such as polymerase chain reaction (PCR).

# The '250 patent

The '250 patent relates to a reaction vessel, primarily for use in biochemical reactions which require heating. The figures reproduced from the patent below show one form the vessel might take. The reaction vessel (1) has an ECP material (6) arranged so as to heat the reagents contained within the vessel when current is supplied to the ECP material, and a cap member (2). The cap member is designed to project into the vessel so that it reduces the capacity of the vessel and creates a space (3) within the vessel that has 'substantially consistent proportions'. This means that the space in which the reagents are situated within the vessels is of substantially similar cross-section throughout.



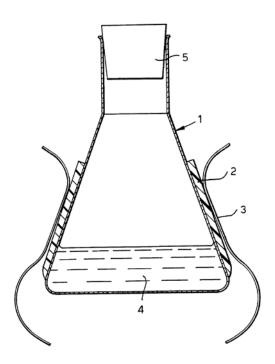
8 Claim 1 of '250 reads as follows:

A reaction vessel according to the present invention comprises a container, a cap member, and an electrically conducting polymer which is arranged so as

to heat reagents in the reaction vessel when current is supplied to said polymer, the cap member being formed so as to project into the container to reduce the capacity thereof and to create a space there between of substantially consistent proportions.

## The '178 patent

The '178 patent relates to an incubation system for controlled heating of biological materials using an ECP. The biological materials may be animal cells, bacteria, viruses or similar materials that may need to be cultured for diagnostic or testing purposes. These are placed in an incubation vessel which is heated using an ECP to a controlled temperature. The figure below is taken from the patent specification. The ECP material (2) may be formed as part of the incubation vessel (1) or may be a coating on the surface of the vessel.



10 Claim 1 of '178 reads as follows:

The use of a system comprising an electrically conducting polymer, a power supply and control means therefore, as an incubation means for the culture of biological materials; wherein the polymer is in the form of a film which is either contiguous or integral with an incubation vessel or a coating on an internal or external surface of an incubation vessel, and wherein the control means is set to heat said polymer so that a predetermined culture temperature is reached and held within the incubation vessel.

## The '781 patent

11 The '781 patent relates to an apparatus for heating reagents, particularly for use in reactions requiring thermal cycling such as DNA amplification. The apparatus uses ECP material to provide the heat when an electric current is passed through it, the current being controlled so as to control the temperature to produce a sequence of different temperatures within the reagents held in the reaction

vessel.

12 Claim 1 of '781 reads as follows (reference numerals omitted):

Apparatus for effecting reactions, said apparatus comprising a reaction vessel suitable for holding reagents and comprising an electrically conducting polymer which emits heat when an electric current is passed through it, and control means for controlling supply of current to the polymer, said control means being arranged to supply electric current so as to produce a sequence of different temperatures in reagents held within the reaction vessel, the polymer being connectable to an electrical supply via the control means.

#### The law

- The Comptroller's powers to revoke a patent on the application of another person are set out in section 72(1) of the Patents Act 1977. This reads in part as follows:
  - 72 (1) Subject to the following provisions of the Act, the court or the comptroller may on the application of any person by order revoke a patent for an invention on (but only on) any of the following grounds, that is to say-
    - (a) the invention is not a patentable invention;
    - (b)...
    - (c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art.

. . .

- 14 The Patents Rules 2007 set out the criteria under which the Comptroller may strike out a claim or give summary judgment.
  - 83 (1) A party may apply to the comptroller for him to strike out a statement of case or to give summary judgment.
    - (2) If it appears to the comptroller that-
      - (a) the statement of case discloses no reasonable grounds for bringing or defending the claim;
      - (b) the statement of case is an abuse of process or is otherwise likely to obstruct the just disposal of the proceedings; ...

he may strike out the statement of case.

- (3) The comptroller may give summary judgment against a claimant or defendant on the whole of a case or on a particular issue if-
  - (a) he considers that -

- (i) that the claimant has no real prospect of succeeding on the case or issue, or
- (ii)...; and
- (b) there is no other compelling reason why the case or issue should be disposed of at a hearing.

#### Claimant's case for revocation

- The claimant's case as set out in his amended statement is not entirely straightforward or clear. But essentially it appears to be on the grounds of section 72(1)(a) that the claims are non-patentable as they lack an inventive step and section 72(1)(c) that the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art (I shall refer to this as 'insufficiency').
- Although the case has not yet progressed to the evidence rounds, Mr Nazareth has nonetheless accompanied his statements of claim with voluminous supporting documentation, which appears to be in the nature of evidence. I make reference to two patent documents provided in my discussion of inventive step below, but in large part for the purposes of this decision I have assumed Mr Nazareth can make good his allegations when considering whether the case for summary judgment is made out.

## **Application for summary judgment**

- 17 The defendant has requested summary judgment under Rule 83(3). He argues that while the option of striking out under Rule 83(2)(a) is available this is not appropriate at this time. The defendant further argues that the claimant has now had two attempts at making his case and that the patentee is entitled to assume that the he has put forward his best case possible. He also argues that the case presented has no chance of succeeding at full trial and therefore requests summary judgment to bring matters to a conclusion rather than leave open the possibility of the same material being presented again.
- In relation to the grounds for revocation the defendant argues that no independent information has been brought forward to support the allegation that the patents lack inventive step and neither of the documents cited in relation to '781 hint at the vessels of claim 1 of that patent. The defendant argues that the grounds of insufficiency repeat only what has been submitted previously.

## **Inventive step**

- In relation to the '250 and '178 patents Mr Nazareth simply asserts that 'the techniques taught in this specification would have been common general knowledge at the time of the disclosure'. The remainder of the statements with respect to section 72(1)(a) appear to relate to there being 'no industrial application', these do not go to the issue of inventiveness and appear to be related to the claim of insufficiency.
- 20 In relation to the '781 patent Mr Nazareth makes a similar assertion but also

refers to two documents as showing that certain aspects of the claims were known. The two documents referred to are US 5106538 and US 6106538. These documents merely show that ECP materials were known, they do not suggest any particular use in relation to the inventions of the claims under dispute. The claims of the '781 patent are directed towards a particular type of vessel. It is this claim that Mr Nazareth needs to show lacks inventive step. The patent does not seek to protect the ECP material itself, which the patent acknowledges is known (the Caliente material - paragraph 13). In summary, Mr Nazareth has asserted that the patents lack an inventive step on the basis that the ECP material used within them was known at the time of filing and all other matter contained within the specifications was part of the common general knowledge.

- In his statements Mr Nazareth has argued that the inventive step would have lain in the specification of the ECP material and the physical characteristics of the vessel. However, this is not what has been claimed. To succeed on these grounds Mr Nazareth would need to demonstrate that the invention as claimed would be obvious to the man skilled in the art. The "techniques" Mr Nazareth alleges as being obvious do not relate to the actual contribution allegedly made by the invention. Indeed, the flipside to this is that the defendant accepts, and in fact argues, that the techniques for making the flasks are known that is the basis of the defendant's rebuttal of the claimant's insufficiency arguments I consider below. It is readily apparent from the claims that what is allegedly new and inventive is the way the pieces have been put together and the claimant's arguments do not go to this.
- Mr Nazareth's arguments regarding inventive step are therefore misdirected as they do not go to the inventiveness of the actual claims. I therefore do not believe that the claim for revocation on the grounds of lack of inventive step has any reasonable prospect of succeeding.

## Insufficiency

- 23 Mr Nazareth has made a number of allegations in relation to the sufficiency of the patents. These are not entirely clear but, as far as I am able to understand them, fall within a number of areas where he believes there is insufficient detail for the skilled worker to put the invention into practice. I shall consider each of these issues in turn. However, I shall note at the outset that many of these claims simply link back to the first argument, that there is insufficient specification of the ECP material. This appears to be the cornerstone of Mr Nazareth's claim for revocation.
- 24 Mr Nazareth's submissions in this respect can be summarized as follows:
  - (a) Insufficient disclosure of the ECP material specification
  - (b) Insufficient disclosure of the thermal control and heating system
  - (c) Insufficient disclosure of the cooling systems ('250 and '781 only)
  - (d) Insufficient disclosure of the electrical contact method

- (e) Insufficient disclosure of the optical system ('781 and '250 only)
- (f) The presence of an electrical current will interfere with reactions in an ECP vessel making the process unreliable and incapable of industrial application.

# <u>Insufficient disclosure of the ECP material specification</u>

- In relation to all three patents Mr Nazareth argues that there is insufficient specification of the ECP material for the skilled worker to be able to put the invention into practice. He asserts that the skilled worker would be unable to produce the invention claimed as there is inadequate specification of the ECP material used. His primary argument is that it is difficult to reproduce the exact same effect for mass production as the properties of the ECP material will vary. This, in his view, makes the inventions of the patents unworkable as it will be impossible to maintain identical results for every vessel or system produced.
- Whilst it might be undesirable to have inconsistent results (and I do not decide whether there are indeed difficulties in achieving mass production at a commercially acceptable level of quality) these arguments, even if proven, do not lead to the claims being insufficient. The claims merely require the skilled worker to select an ECP, which will produce heat when an electric current is passed through it, and apply this in the manner described to produce the vessel and systems claimed. It is clear to me that the specifications are sufficient to enable the skilled worker to make the invention claimed. If the claimants arguments are proven then this would point to the apparatus not working particularly well to achieve its desired result and manufacturers having difficulties in making consistently performing apparatus in significant quantities. However, this does not show that the invention as claimed cannot be put into practice or that it will not work at all.
- All that is required by the claim 1s is that the ECP material chosen is suitable for producing heat and being deposited as a film on the reaction vessel. Mr Nazareth does not contest that such an ECP could have been made by one skilled in the art. Therefore, even if his assertions on reproducibility were proven, Mr Nazareth would not succeed in having the patent revoked on grounds of insufficient disclosure of the ECP material. I therefore find that this ground has no real prospect of success.

## Insufficient disclosure of the thermal control and heating system

- The claimant alleges that there is insufficient disclosure of the thermal control system and the heating and cooling systems. However, the argument is somewhat confused and in fact seems to be returning to the same arguments relating to the ECP material.
- In his amended statements Mr Nazareth appears to be arguing not that there is insufficient disclosure of the thermal control systems but that it is simply not possible for the temperature of the systems to be controlled due to the lack of specification of the ECP material, and the variations that occur within ECP material. Mr Nazareth argues that it is not possible to consistently produce ECP

material having identical properties. This, in his view, means that individual vessels would not have absolutely consistent temperature throughout and that it would not be possible to use the vessels in a testing environment as they would not perform consistently.

- Mr Nazareth's arguments here seem to relate to the reliability of the results that would be obtainable if the equipment is used in a diagnostic environment. His argument is that the ECP material is not specified in sufficient detail so as to give identical results in every vessel every time. He claims that in a diagnostic application it would be essential for each and every vessel to give exactly the same results in every case and that the lack of specification of the ECP means it will not be possible to maintain exactly the same temperature in every situation, thereby giving unacceptable variance in the results of the diagnostic.
- Even if Mr Nazareth proves these allegations they do not point to the patent being insufficient. The main claims make only very basic requirements regarding these features, which are clearly met by statements in the specification. To demonstrate insufficiency he must be able to show that the skilled worker would not be able to put the claimed invention into practice. If proven, Mr Nazareth's allegations would at most show that if the inventions were made using ECP material of differing properties, they are likely to produce different results in a diagnostic testing environment, and these differences would be (commercially) unacceptable. These arguments point towards the inventions not working as well as would be desired, but they do not appear to come close to demonstrating that the invention cannot be made to work at all. I therefore find that this ground has no real prospect of success.

# Insufficient disclosure of the cooling systems

- This is claimed in respect of only the '250 and '781 patents, although it is specifically discussed only within the statements of claim for '781. It is not clear which claims Mr Nazareth intends to attack on this basis as none of the claims appears to require the presence of a cooling system. It may be that Mr Nazareth is aiming to argue that a cooling system is inherently necessary to the working of this system and the lack of specification means the invention cannot be made to work.
- The patent specification mentions, as Mr Nazareth quotes, that the reaction vessel may be subjected to artificial cooling; possibly using a water bath or fan arrangement. Mr Nazareth argues that this will not work as it would be essential for the vessels to all be cooled in exactly the same manner, and this is not specified.
- The allegation, however, again goes to whether the invention would work particularly well on a commercial scale, rather than the question of whether it works at all. I therefore find that this ground has no real prospect of success.

# Insufficient disclosure of the electrical contact method

Mr Nazareth claims, again, in relation to the required 'electrical contact' that there is insufficient detail within the specifications for the skilled worker to put the

invention into practice.

- First, I note that this argument is directed at claim 1 of the '781 patent but only against later claims of the '250 and '178 patents. So in relation to the '250 and '178 patents appears to have no impact on the potential validity of the main claims, but is directed at showing that the specification is insufficient in relation to some of the later claimed inventions. Second, I note that this argument again appears to lead back to the argument that the ECP is not adequately specified.
- Mr Nazareth appears to be arguing that the specification is insufficient as it does not tell the reader exactly how the contact should be made, allowing for variables such as the size and electrical resistance of the item being heated. He also argues that the vessels will have entirely different heating properties if the electrical contact is not made in the same way each time.
- Mr Nazareth appears to take the view that the patent must specify every detail of every aspect of the apparatus in order for the specification to be considered sufficient. This is not the case. The specification needs to describe the apparatus in sufficient detail for the skilled worker to be able to make it. The skilled worker would not require details of standard features such as the choice of electrical contact methods available to him to be able to work the claimed invention. The claims Mr Nazareth appears to be directing these arguments against make only basic requirements that an electrical contact is made. The disclosure is certainly sufficient in respect of the requirement for an electrical contact.
- Mr Nazareth may well (I do not decide) be correct in his allegation that a set of vessels will produce differing results if the electrical contact is made differently in each one. However, this will not assist him in showing that the specifications are insufficient in this respect. The skilled worker would be informed that an electrical contact is required and, if he is aiming for consistent results, he would not implement different forms of electrical contact in different vessels.
- A claim of insufficiency of the disclosure on the electrical contact method is bound to fail. The claims make minimal requirements in respect of the contact and there is certainly sufficient disclosure within the specifications for this feature in the claims. Even if proven to be true, the allegation that making the vessels with differing electrical contacts would result in differing results would not assist Mr Nazareth on these grounds. I therefore find that this ground has no real prospect of success.

# Insufficient disclosure of the optical system ('781 and '250 only)

- This allegation is made against only two of the three patents and is directed towards certain inventions defined by within the later claims, namely claim 18 of the '781 patent and claims 15 and 21-23 of the '250 patent. These claims make minimal requirements regarding the specification of an optical system.
- 42 Mr Nazareth states that the patents refer to the PCR method which entails the use of optical dyes present in the reaction which when visualized can reveal the amounts of analyte present, and the claims require a monitoring (or observing)

system. The skilled worker would understand this to be an optical interrogation system to visualize the fluorescence associated with the presence of an analyte. Mr Nazareth states that these were known in the art at the relevant time but were either for examining individual vessels serially or required a significant period of time (over ten seconds) to detect the signal where a plurality of vessels were being analysed. He therefore claims that the skilled worker would need to invent an optical system, suitable for use in the claimed invention, which could monitor a plurality of vessels rapidly. He then states that the patentee is seeking protection for an optical monitoring system that has to been described.

- 43 Mr Nazareth's argument is that the specific type of monitoring, that he believes the skilled worker would consider the specification to be suggesting he use, used for PCR reactions would not be suitable for monitoring a large number of vessels within very short timescales.
- 44 This argument cannot succeed. The claims require a monitoring system, referred to in the claims as a 'means adapted to observe the development of signals' and 'means for detecting a signal from a sample in a reaction vessel'. They do not require any more that this, and there is certainly sufficient disclosure within the specifications for these requirements. Mr Nazareth argues that the system described in the '781 patent would not be suited for monitoring a plurality of vessels as they were used for monitoring single vessels, or took time to analyse a number of vessels. However, the claim puts only minimal requirements on the optical monitoring. The dependent claims are all linked to a main claim requiring the use of a single vessel, although other claims also have plural vessels. The requirement is that the vessel of the earlier claims can be monitored, and in the case of the '250 patent can be monitored using the known fluorescent monitoring device. The patents provide sufficient disclosure for the skilled person to make the device and provide a monitoring system. Mr Nazareth may (I do not decide) be correct in his assertion that the use of a single monitoring system for a plurality of vessels will be slower than desired in analyzing, but this again points to the invention not working as well as it possibly could, rather than not working at all. It is also possible for each vessel to be monitored separately; this might be undesirable for commercial and practical reasons but would be a workable alternative within the scope of the claims.
- The allegation that the patentee is seeking protection for an optical monitoring system that he has not disclosed cannot succeed. The claims that include the optical monitoring feature are all dependent on main claims to the reaction vessel. The patentee is clearly claiming protection for the vessel and its use, which include using the vessel in a system with a monitoring apparatus. I therefore find that this ground has no real prospect of success.
  - The presence of an electrical current will interfere with reactions in an ECP vessel making the process unreliable and incapable of industrial application.
- This is included in Mr Nazareth's statements under the titles 'invalid claims and nonworking embodiments' and 'fundamental flaw leading to non-enablement', here the claimant essentially repeats the allegations made in his original statement, that the presence of an electrical current will render any reactions taking place unreliable. The argument appears to be that the electrical current

will retard the growth of the desired organisms, possibly destroying them, as there is no electrical insulation of the reagents within the vessel from the ECP material. This seems to point to the current making the reactions less efficient than is possibly desired, he states that the presence of 'an electrical current *can* prevent biological organisms from being cultured' but not to the result that the device cannot work as a reaction vessel at all.

Further, it is clear to me that at least one embodiment of the '781 patent would be sufficiently insulated to overcome this problem. This is described in column 3, lines 26-29, 'a polymer sheath can be used to adapt apparatus using pre-existing reaction vessels, In particular, a strip of flexible polymer film can be wrapped around a reaction vessel of various different sizes and shapes'. It is therefore not possible to show that the patent is insufficient in its disclosure of this aspect. This same arrangement is also described in the '250 patent (page 5 lines 17-26) and the '178 patent (column 3 lines 21-26). This was in fact conceded by Mr Nazareth at the earlier hearing in this case (paragraph 25 of my decision). I therefore find that this ground has no real prospect of success.

#### Conclusion

On each of the grounds Mr Nazareth has raised I have found that he has no real prospect of succeeding in his claim. I further agree with the defendants that he has now had ample opportunity, including that afforded by my preliminary decision, to make his best case. I therefore see no compelling reason why this case should nonetheless proceed. In accordance with Rule 83(3), I therefore give summary judgment against Mr Nazareth.

### Costs

- The usual rule in *inter partes* cases before the Comptroller is that the winning side is entitled to a contribution to its costs based on the published scale.
- The defendant has argued that Mr Nazareth's conduct throughout the proceedings has caused unnecessary delays and therefore costs. In particular they point to the fact that the claimant made numerous attempts to file statements of case early in the proceedings before finally submitting the version that was considered at the preliminary hearing. They then make the point that this version was wholly inadequate and that the decision on this issue fell only just short of complete strike out.
- It is true that the claimant has had a number of attempts at filing statements of claim and, despite my urging him to do so in my preliminary decision, he does not appear to have taken legal advice or rectified the deficiencies within his original statements. However, I do not think Mr Nazareth's actions have been deliberately aimed at increasing the costs or time of the proceedings and do not see this as reason to depart from the scale of costs.
- These proceedings commenced before 3 December 2007, therefore it is the scale published in TPN 2/2000 which applies. These proceedings have indeed been lengthy and not entirely straightforward, which is not entirely the fault of either party. There have been extensive rounds of correspondence. There has

already been one hearing, and a preliminary decision. Although there have been no evidence rounds, Mr Nazareth did file documents which amounted to evidence, and the defendant needed to consider these. An award at the higher of the scale does appear justified.

I therefore order that Mr Nazareth pay the Ministry of Defence the sum of £2000 to the defendant as a contribution towards their costs. This sum should be paid within seven days of the expiry of the appeal period below. Payment may be suspended in the event of an appeal.

# **Appeal**

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

## J Elbro

Divisional Director acting for the Comptroller