Neutral citation number: [2009] EWHC 181 (Pat)

Case No: HC07C01131

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 11/02/2009

Before :

THE HON MR JUSTICE FLOYD

- -

Between :

(1) JAMES DUNCAN KELLY
(2) KWOK WAI CHIU — **Claimants**

- and -
GE HEALTHCARE LIMITED — **Defendant**

- -
- -

Iain Purvis QC and **Will James** (instructed by **Marks & Clerk Solicitors**) for the **Claimants**
Henry Carr QC and **Andrew Lykiardopoulos** (instructed by **Bristows**) for the **Defendants**

Hearing dates: 3rd-5th, 8th-11th, 15th-16th December 2008

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Judgment

Mr Justice Floyd :

Introduction

1. This judgment is divided into the following sections:

2. Duncan Kelly and Kwok Wai ("Ray") Chiu, the claimants in this action, were two research scientists at Amersham International Plc ("Amersham"). They were involved with the first synthesis of a compound called P53, which later formed the basis of a patented radioactive imaging agent which was a highly successful product for their employers. It was sold under the trade mark Myoview. By this action they seek an award of compensation from their employer under Section 40 of the Patents Act 1977. They are claiming a share of the benefit which they say has been derived by their employer from the patents.

3. Since the time when the invention was made, Amersham has been taken over by General Electric Company and is now called GE Healthcare Limited, the defendant in the action. It is common ground that the relevant undertaking to consider for the purposes of the legislation is the healthcare division of Amersham, which continued to exist under different names after the acquisition. For that reason, when I refer to "Amersham" or "the employer" I am referring to that division.

4. There are two patents (or more accurately patent families) involved in the action. The first, European Patent (UK) No 0311352 ("352") has a claimed priority date of 6th October 1987. The second, European Patent (UK) No 0337654 ("654") has a claimed priority date of 11th April 1988. Broadly speaking, the first family of patents expired in 2008 and the second in 2009, although the precise expiry dates are not the same everywhere. Patent protection continues in the United States until February 2010. Three Amersham employees are named as inventors in respect of both patent families: Duncan Kelly, Ray Chiu and a Dr Ian Latham. Dr Latham has not participated in the present claim. In addition, two external academics are named as inventors in respect of 352: Professor Vaughan Griffiths of Keele University and Professor Peter Edwards of Cardiff University. These external academics cannot claim under section 40, as their employers, the Universities, did not obtain the patents. The position of the Universities has been regulated by contracts entered into after Myoview became a success, and the academic inventors have benefited through schemes operated by the Universities themselves.

The Law on inventor compensation

5. Section 40 (1) of the Act provides as follows

> "**Compensation of employees for certain inventions**
>
> 40(1) Where it appears to the court or the comptroller on an application made by an employee within the prescribed period that the employee has made an invention belonging to the employer for which a patent has been granted, that the patent is (having regard among other things to the size and nature of the employer's undertaking) of outstanding benefit to the employer and that by reason of those facts it is just that the employee should be awarded compensation to be paid by the employer, the court or the comptroller may award him such compensation of an amount determined under section 41 below.
>
> (2) Where it appears to the court or the comptroller on an application made by an employee within the prescribed period that -
>
> (a) a patent has been granted for an invention made by and belonging to the employee;
>
> (b) his rights in the invention, or in any patent or application for a patent for the invention, have since the appointed day been assigned to the employer or an exclusive licence under the patent or application has since the appointed day been granted to the employer;
>
> (c) the benefit derived by the employee from the contract of assignment, assignation or grant or any ancillary contract ("the relevant contract") is inadequate in relation to the benefit derived by the employer from the patent; and

> (d) by reason of those facts it is just that the employee should be awarded compensation to be paid by the employer in addition to the benefit derived from the relevant contract;
>
> the court or the comptroller may award him such compensation of an amount determined under section 41 below. ”

6. The section has been amended by the Patents Act 2005 so as to make compensation payable when the invention (and not just the patent) has been of outstanding benefit. The amendments only affect patents applied for after 1st January 2005. So it is the unamended section which applies here.

7. With or without the amendment the section presents difficulties of interpretation and application. There is no reported case of a successful contested award made under it, although there are known to have been some settlements. It is perhaps justifiable to note in passing that in the passage of the Bill through the House of Lords, Lord Nelson of Stafford is recorded in Hansard as saying that:

> "I have never seen such a collection of vague terms in my life. What compensation, who is responsible, what is outstanding benefit, what value is to be put on this and what on that?" and
>
> "Who is to be the Solomon who will sort out all these vaguenesses at the end of the day and adjudicate on compensation when a claim is made, I hesitate to think."

8. With that introduction, I turn to consider the disputes which have arisen.

“Invention belonging to the employer”

9. The first matter which the applicant for compensation has to establish is that he has made an invention belonging to the employer for which a patent has been granted.

10. The inventor is the “actual deviser of the invention”: see Patents Act 1977, section 7(3). In *Yeda Research v Rhone-Poulenc Rorer* [2007] UKHL 43; [2008] RPC 1 Lord Hoffmann said at [20]:

> “The word “actual” denotes a contrast with a deemed or pretended deviser of the invention; it means, as Laddie J said in *University of Southampton’s Application* [2005] RPC 11, [39], the natural person who “came up with the inventive concept”. It is not enough that someone contributed to the claims, because that may include non-patentable integers derived from the prior art: see *Henry Brothers (Magherafelt) Limited v Ministry of Defence* [1997] RPC 693, 706; [1999] RPC 442. As Laddie J said in the *University of Southampton* case, the “contribution must be to the formulation of the inventive concept”.

11. It must follow that section 40 was enacted in the knowledge that it would provide the possibility of compensation to actual inventors, but not to those who merely contribute to the invention. The same point emerges from section 41 (reproduced below) which expressly contemplates that there will be contributions from employees

who are not joint inventors. This is important, as it is an important part of the employer's case to suggest that it is unjust to compensate inventors, whilst leaving others who contribute to the invention uncompensated.

12. It is not in dispute here that Drs. Kelly and Chiu were properly named as inventors on the patents in question here.

13. Section 39 deals with ownership of inventions as between employer and employee. Section 39(1) and (2) provide:

> **"Right to employees' inventions**
>
> (1) Notwithstanding anything in any rule of law, an invention made by an employee shall, as between him and his employer, be taken to belong to his employer for the purposes of this Act and all other purposes if—
>
> (a) it was made in the course of the normal duties of the employee or in the course of duties falling outside his normal duties, but specifically assigned to him, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his duties;
>
> (b) the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his duties and the particular responsibilities arising from the nature of his duties he had a special obligation to further the interests of the employer's undertaking.
>
> (2) Any other invention made by an employee shall, as between him and his employer, be taken for those purposes to belong to the employee"

14. "In the course of the normal duties of" is not limited to the "day to day work of" the employee. So an invention may still belong to the employer even if it represents a departure from what he is expected to be working on. In *LIFFE Administration & Management v Pinkava* [2007] RPC 30, Jacob LJ said:

> "As between the employer and employee the primary source of a duty are the terms of the contract. What is it that he is employed to do must be the key question. That is not the same thing as was suggested by Mr Tritton—what is his day-to-day work? Take for instance a research chemist working on a cancer cure for the last 10 years. Suppose he came up with a cure for arthritis. He could not seriously contend that he owned the invention because he was day-to-day working on a cancer cure. His duty as a research chemist is clearly wider than his day-to-day work."

15. It is not in dispute that by virtue of Section 39(1), the inventions made by Drs Kelly, Chiu and Latham vested in their employer.

16. In circumstances outside section 39(1), the invention belongs to the employee – see section 39(2). However, even in such cases, the employee may have a claim for compensation if he assigns the invention, and the right to apply for a patent, to his employer. Such cases fall within section 40(2).

"Outstanding benefit"

17. The most significant difference between the subsections (1) and (2) of section 40 is that it is only under section 40(1) that the employee must show "outstanding benefit". Under section 40(2) the employee need only show that the benefit received from the contract of assignment is "inadequate" in relation to the benefit derived by the employer from the patent.

18. Beyond saying that the benefit must be in "money or money's worth" – see section 43(7) – the Act contains no definition of "outstanding benefit". In *Memco-Med Ltd's Patent* [1992] RPC 403, Aldous J (as he was then) said at page 414 lines 7-10:

> "The word 'outstanding' denotes something special and requires the benefit to be more than substantial or good. I believe that it is unwise to try and redefine the word 'outstanding'. Courts will recognise an outstanding benefit when it occurs.**"**

19. I agree that it is not advisable to redefine the word "outstanding". In *Memco Med* Aldous J said that he did not disagree with a statement by the Superintending Examiner in *GEC Avionics Limited's Patent (Ellis' Application)* [1992] RPC 107, to the effect that the rationale for the use of the word outstanding was that the employee had already been compensated for the invention through remuneration for his employment. The superintending examiner in that case had said:

> "It is for this reason that the section (section 40) uses the word 'outstanding' to qualify the benefit which would make it just that the employee should receive compensation. Moreover it is noted that the word 'outstanding' is used rather than 'significant' or 'substantial' or other such term. It must be something out of the ordinary and not such as one would normally expect to arise from the results of duties that employee is paid for. It is, I think, for this reason that reference is made to the size and nature of the employer's undertaking, and that the benefit (to the employer) must be looked at in the total context of the activities of the employer concerned to see whether it is outstanding."

20. Aldous J also did not disagree with a statement made by a superintending examiner in *British Steel PLC's Patent (Monks' Application)* [1992] RPC 117 in which it was said that:

> "While Mr Tritton was plainly correct in describing 'outstanding' as a comparative term, I would regard it as going further than that, implying a superlative."

21. Quite apart from the problem of a term being both a comparative and a superlative, Aldous J's summary, which I have already set out, does not suggest that he read the

statement in *Monks' Application* as meaning that the benefit has to be "superlative" in the sense that the benefit is one that could not have been improved upon in some way. There can hardly be a case where the benefit from a patent would satisfy such a test, and I do not believe that the legislator can have intended to create one.

22. Section 40 does not require the Court to value the benefit precisely. The test is a qualitative one, although, as we shall see, in a case where outstanding benefit is shown, section 41 requires the court to secure for the employee "a fair share of the benefit which the employer has derived from the patent". In those circumstances it will obviously be necessary to have an idea of the value of the benefit.

23. As a number of decisions have pointed out, it is the benefit of the patent which must (under the section prior to amendment) be outstanding, rather than the benefit of the invention or the benefit of sales of products made in accordance with the invention: see e.g. *Memco-Med* at 413 lines 14-15. Equally, the notion of outstanding benefit has nothing to do with how inventive the employee was, although the employee's effort and skill are matters which fall to be considered in deciding on the quantum of an award.

24. In *Memco-Med* Aldous J said that, in determining whether the patent has been of benefit to the employer:

> "it is likely to be useful to assume that the patent was never granted due to some failure by the Patent Agents and thereafter to decide what would have been the position of the employer. It will then be possible to ascertain the benefit from the patent by comparing the position of the employer with the position he would have been in if the patent had not been granted"

25. The enquiry thus called for involves a comparison with what "would have been" as opposed to "what was". The problem of quantification thus caused is not an unfamiliar one: see for example the discussion of the problem in relation to estimating damages for patent infringement in *Gerber v Lectra* [1995] RPC 383 at 395. The court must try to form an estimate of how the employer would have fared in the absence of patent protection.

The "but for" argument

26. The test propounded by Aldous J in *Memco-Med* could be described as a "but for" test for determining whether benefit has been derived from the patent. Mr Carr QC, who appeared for the employer, submitted that a "but for" approach to determining whether the benefit derives from the patent is not enough. He described "but for" as a blunt tool when it came to discriminating between multiple causes. At best, he said, it functions as an exclusionary test, to exclude truly irrelevant causes. He pointed out that, in the case of a pharmaceutical product, the entire profit could be attributed on the "but for" basis to a whole variety of matters, such as regulatory approval, or the obtaining of other necessary patent licences. The correct test, so Mr Carr submitted, was whether the patent was the effective or dominant cause of the benefit – the *causa causans.*

27. Mr Carr relied on what Hoffmann J (as he then was) said in a different context in *Performing Right Society Ltd v British Entertainment and Dancing Association Ltd* [1993] EMLR 325 at page 329:

> "The PRS scheme was rejected on the ground that there was an insufficient causal relationship between the musical works [played in a discotheque] and the gross receipts. It was true that one could not very well operate a disco without music, but then one could not operate it without electricity and many other things either. It could not be suggested that it would be fair for the suppliers of such utilities to have a percentage of the gross receipts."

28. I think the analogy with this case needs to be treated with caution. Hoffmann J was not faced with a question about whether the music played in a discotheque was of benefit or outstanding benefit to the operator: he was concerned with determining a reasonable royalty for use of copyright.

29. In my judgment Mr Purvis is right when he says that it has to be assumed that the draftsman of the section understood that a patent for an invention is just that. It does not earn benefits on its own: a product has to be manufactured and promoted, and if it is a pharmaceutical, licensed. There will inevitably be multiple causes for the benefits derived from a patent. Even where the patent is licensed to others, the extent of the benefit will be due in part to the skills of the negotiators. As we shall see, the contributions of others are to be fully taken into account in assessing the fair share of the benefit under section 41.

30. I think it is implicit in this that a patent may be of benefit to the employer even where there are multiple causes for the profits under consideration. The existence of multiple causes is not a reason for disregarding a given benefit altogether, although it may prevent the benefit of the patent alone from being outstanding. Where outstanding benefit is shown, the presence of other causes may have a significant impact on the share of the benefit which the employee may claim.

31. I think the correct question for the court to ask itself is whether the patent in question was *a cause* of the benefit in question. There may be cases where it is possible to say that the benefit was too remote from the existence of the patent, or no genuine causal relationship existed. But where there is a causal relationship, the next question is how much of that benefit can be attributed to the patent. This may require an apportionment of the benefit, and may raise difficult questions. The court should then go on to consider whether that benefit is outstanding.

Meaning of "patent" in section 40

32. Section 43(4) provides an expanded definition of the term "patent" in section 40. It provides that references in section 40:

> "to a patent and to a patent being granted are respectively references to a patent or other protection and to its being granted whether under the law of the United Kingdom or the law in force in any other country or under any treaty or international convention."

33. There is no dispute that this provision means that the benefit of foreign patents may be taken into account, provided these are identified. The expanded definition has, however, given rise to an argument about what is meant by "other protection". In particular, are the regulatory data exclusivity (RDE) regimes enjoyed by new chemical entities properly to be treated as "other protection"?

34. In order to obtain registration of a new pharmaceutical for sale, its promoters have to generate safety and efficacy data to satisfy the regulator that it is appropriate to grant registration. This is a costly and time consuming exercise, and those who generate the data understandably regard it as their confidential information. Generic competitors are generally reluctant to repeat the work performed by the originators when making their own applications for registration of the same pharmaceutical. There is therefore a tension between the rights of the owner of the data, and the promotion of competition. The resulting balancing exercise has resulted in regimes in most countries which allow for a determinate period of data exclusivity. During that period, if a generic company wishes to enter the market, it will have to generate its own data. After the period of exclusivity has expired, the regulator is free to refer to the originator's data during the application process: the generic company need only show that his product is the same in all material respects as that of the originator. Reliance on data in this way is sometimes referred to as "piggy-backing".

35. The employer argues that RDE is not "other protection". Accordingly, absent the patents, the product would still have enjoyed this alternative form of regulatory protection. So applying Aldous J's analysis, the benefit of the patent, at least during the period of regulatory protection, is limited accordingly.

36. Mr Purvis QC, who appeared for the employees, submitted that RDE is "other protection". Plainly RDE protection is not absolute protection, but neither, so he argues, is patent protection which has exceptions in favour of private and non-commercial use, and experimental use. Thus, when considering the benefit derived from the patent, one takes into account the benefit of RDE as well. Likewise when applying Aldous J's analysis, one considers, by way of comparison, the position where there is neither patent nor RDE.

37. It is common ground that the protection in question must, given the context, be protection for the invention. Mr Carr, for the employer, submits that RDE does not protect the invention: as its name suggests, it only protects the data.

38. I prefer the submissions for the employer on this issue. I will assume in the employees' favour, without deciding, that RDE is "granted under the law…". However, there is, as it seems to me, a fundamental distinction between a form of protection which grants a monopoly in respect of the manufacture and sale of a product or use of a process (such as a patent or utility model); and a form of "protection" which merely makes it more difficult for a competitor to enter the market (as in the case of a product where the generic competitor has to generate his own safety and efficacy data).

39. It is not necessary to determine the precise outer limits of the reference to "other protection". In my judgment "other protection", in the context of this statute, means "other monopoly protection". It does not extend to RDE which is a quite different type of intellectual property right, and one which does not give monopoly rights, or really any rights in the invention at all.

"by reason of those facts it is just.."

40. Section 40 also requires that "by reason of those facts" it should be "just" that the employee be awarded compensation. The only facts expressly referred to in the section are (a) that the employee has made an invention belonging to the employer for which a patent has been granted, and (b) that patent had been of outstanding benefit

having regard among other things to the size and nature of the employer's undertaking.

41. In my judgment, section 40 requires the court to come to a conclusion on the factual issues it recites. If it is satisfied that those matters are established, it must go on to consider whether an award is just. Those words are there to ensure that the court does not proceed mechanically to the assessment of compensation. The consideration of whether it is just cannot have been intended to be confined to the facts already taken as established: if so the words would add nothing. It is not desirable or sensible to seek to categorise the types of situation where an award may be unjust. The court will recognise such situations when they arise.

The use of the word "compensation"

42. Mr Carr stressed the fact that the court is supposed to be awarding the employee "compensation". He points to the explanation of the usual sense in which the term "compensation" is used in *Halsbury's Laws* Volume 12.1:

> "pecuniary recompense which a person is entitled to receive in respect of damage or loss which he has suffered, other than as a result of an actionable wrong."

43. Mr Carr submits that this indicates that section 40 might apply where an employee has made an invention of particular merit in circumstances where the employee, because of inequality of bargaining power, has not received the level of salary and benefits that the market rate for such responsibilities would suggest. In such a case the section would be rectifying an injustice or loss to the employee, brought about by inequality of bargaining power, and ensuring that the employee's remuneration package meets an acceptable level. He draws attention to the fact that section 40 is excluded where there is in place a "relevant collective agreement": see section 40(3) and (6). He says that this recognises that where a trade union has negotiated such an agreement for compensation for inventions, the court assumes that the inequality of bargaining power is eradicated and the need for section 40 removed.

44. Mr Carr also points to section 40(2) which deals with the case where an invention or patent originally belonging to the employee is assigned to the employer. It makes compensation payable when:

> "the benefit derived by the employee from the contract of assignment … is inadequate in relation to the benefit derived by the employer from the patent"

45. Mr Carr suggests that this is another example of remedying, after the event, a contract which operated unfairly against the employee who has equally sustained a loss.

46. An alternative situation in which Mr Carr suggests that the use of the word compensation might be appropriate is the case referred to by Jacob LJ in *LIFFE* (in the quotation I have included in paragraph 13 above) where the invention falls within the normal duties of the employee but not his day to day work, so the employee can be regarded as having done work beyond the call of duty. He says that, before one can move on to Section 41, which is concerned with quantum, one must establish that the case is one where compensation in this sense is actually due.

47. Mr Purvis submits that what underlies the use of the word "compensation" is the fact that it is the employer and not the employee who is drawing all the benefit from a patent brought into existence by the intellectual effort of the employee. He draws attention to the Report of the Committee to Examine the Patent System and Patent Law (the Banks Committee). That Committee considered, but did not recommend, the introduction of a system of employee compensation: Parliament decided otherwise and introduced one anyway. Prior to the 1977 Act, inventions made by an employee in the course of employment were generally owned by the employer. The Banks Committee considered the case for a change in that position, based largely on a suggestion that the "master and servant" concept was not in line with "modern views on industrial relations". At paragraph 459 the Committee reported the view that had been presented to it that the present law:

> "operates unfairly against the employee in that, while in general inventions made as part of an employee's work are automatically assumed to be the property of the employer, the employee has no legal right to claim any reward in respect of such an invention, even if it was so outstanding that it could be said to have been made beyond the call of duty and if its use resulted in substantial profits to the employer. This was regarded as inequitable and to provide no encouragement to inventive employees."

48. The contrary view presented by industry was said to be "unanimously against the introduction of any statutory obligation on employers to reward employee inventors". At paragraph 461 the Report summarises industry's position in this way:

> "They considered that such an obligation would have an inhibiting effect on the organisation and effectiveness of a research and development department. It would cause difficulties in the assignment of staff to those types of work which were less likely to result in patentable inventions. Secrecy between members of staff could develop. There might be the further problem when deciding on awards that, since research today is so much a matter of team work, it might prove difficult, if not impossible, to identify the real inventor. Many employees make important contributions to the well-being of a firm which are not patentable inventions and which therefore would not then qualify for a special award set up under any legislation relating to patentable inventions. Legislation relating solely to patentable (and presumably preferably only to patented) inventions would discriminate in favour of only one of the many types of employees' contributions. The view was expressed that the system of rewarding work by salary increases, promotion and special bonuses is capable of catering satisfactorily for all forms of meritorious work carried out by employees whether the work is patentable or not."

49. In rejecting industry's view and enacting a statutory scheme for the compensation of employee inventors, Mr Purvis submits that Parliament must have been recognising, at least to some extent, the need to compensate the employee for the unfairness inherent in the fact that the law takes the invention away from the employee and gives

it to the employer. Mr Carr submits in response that the 1977 Act left ownership of employee inventions where it had been before: with the employer. So there was no change in the relationship for which the employee had to be compensated.

50. I do not think these passages from Banks serve as more than general background. They do, I think, focus attention on the fact that Parliament has now chosen to make such awards possible based only on the notion of "outstanding benefit" to the employer, rather than any notion that the invention was made "beyond the call of duty". They also focus attention on the fact that Parliament must be taken to have been aware of the arguments about potential unfairness of rewarding inventors but not other types of contributor. I think it may be dangerous to read too much into deliberations of this sort, particularly when the Committee's recommendations were rejected.

51. There are, I think, three important considerations. Firstly, and most importantly, I think that, if the underlying purpose of compensation were the remedying of loss, then one would expect the section which determined the amount of compensation to be expressed in such terms as to secure for the employee compensation for such loss. But the amount of compensation payable under section 41 is such as will secure for the employee "a fair share … of the benefit". The employee's loss is not sensibly to be regarded as a function of the benefit to the employer: yet the employee's compensation under the statute is expressly made so.

52. Secondly, I think "compensation" has a wider meaning in this context than that attributed to it by the extract from *Halsbury*'s *Laws.* What is being compensated for by both limbs of section 40 is the disparity between the benefits received by the employee and the benefits received by the employer. In the section 40(2) case this is particularly clear – one benefit is "inadequate in relation to" the other. The inadequacy has arisen after the event, and in the light of the disparity between the benefit to the employer and the benefit to the employee. There may have been nothing unfair about the contract assigning the patent at the time it was made: but with the benefit of hindsight it has become so. In section 40(1) the concept of compensation would be expected to be, and in my judgment is, the same: what is different is that it will only be awarded in a case where the invention is of outstanding benefit, that is to say in a case where, again with the benefit of hindsight, the disparity in benefit between employer and employee is extreme.

53. Thirdly, questions of the remuneration of the inventor and the efforts the inventor made in making the invention are expressly listed as factors under section 41 in determining a fair share. It would be a little surprising therefore if establishing inadequate remuneration, or efforts beyond the call of duty were threshold requirements of obtaining any award under section 40.

54. I therefore reject Mr Carr's submission that the notion of compensation is restricted by reference to remedying some loss in his restricted sense.

Section 41 – assessing the compensation

55. Section 41(1) provides:

> "An award of compensation to an employee under section 40 (1) … above in relation to a patent for an invention shall be such as will secure for the employee a fair share (having regard

> to all the circumstances) of the benefit which the employer has derived, or may reasonably be expected to derive, from the patent …."

56. I think this section makes it clear that the valuation of the benefit must be in the light of all the available evidence as to what the patent has achieved, and may reasonably be expected to achieve. It is not a hypothetical valuation exercise to be performed at the date the invention was made, and before the profits had been earned. This is the dispute about whether valuation should be *ex-post* or *ex-ante* which I discuss below.

57. Section 41 (4) provides:

> "In determining the fair share of the benefits to be secured for any employee in respect of a patent for an invention which has always belonged to an employer, the court or the controller shall, among other things, take the following matters into account that is to say:
>
> (a) the nature of the employee's duties, his remuneration and the other advantages he derives or has derived from his employment or has derived in relation to the invention under this Act;
>
> (b) the effort and skill which the employee has devoted to making the invention;
>
> (c) the effort and skill which any other person has devoted to making the invention jointly with the employee concerned, and the advice and other assistance contributed by any other employee who is not a joint inventor of the invention; and
>
> (d) the contribution made by the employer to the making, developing and working of the invention by the provision of advice, facilities and other assistance, by the provision of opportunities and by his managerial and commercial skill and activities.

58. As I have said, it seems to me that this is the proper place for consideration of matters such as the level of remuneration paid to the employee and whether the invention involved effort and skill beyond the call of duty.

59. The amount of compensation is to be determined in accordance with section 41 so as to secure a just and fair reward to the employee, neither limiting him to compensation for loss or damage, nor placing him in as strong a position as an external patentee or licensor.

Summary of the law

60. Drawing this material together:

i) Section 40 is available to an inventor in the sense of the "actual deviser" of the invention, but not to those who merely contribute to the invention without being joint inventors;

ii) Section 40 is available to an employee who makes an invention (which is subsequently patented by the employer) in the ordinary course of his employment or in the course of duties specifically assigned to him;

iii) Under the section prior to its amendment, it is the patent (as opposed to the invention) which must be of outstanding benefit to the employer, having regard to the size and nature of the employer's undertaking;

iv) "Outstanding" means "something special" or "out of the ordinary" and more than "substantial", "significant" or "good". The benefit must be something more than one would normally expect to arise from the duties for which the employee is paid;

v) On the other hand it is not necessary to show that the benefit from the patent could not have been exceeded;

vi) Section 40 is not concerned with whether the invention is outstanding, although the nature of the employee's contribution may fall to be considered at the section 41 stage, if it is reached;

vii) It will normally be useful to consider what would have been the position of the company if a patent had not been granted, and compare this with the company's position with the benefit of the patent;

viii) The patent must have been a cause of the benefit, although it does not have to be the only cause. The existence of multiple causes for a benefit does not exclude the benefit from consideration, although the benefit may have to be apportioned to isolate the benefit derived from the patent;

ix) "Patent" in section 40 does not include regulatory data exclusivity. Thus the scenario without patent protection is one where RDE nevertheless exists;

x) It must be "just" to make an award: the consideration of what is just is not limited to the facts set out in section 40;

xi) It is not a requirement of obtaining compensation that the employee can prove a loss (for example by reference to inadequate remuneration for his employment) or by the expenditure of effort and skill beyond the call of duty. These are nevertheless factors to take into account under section 41;

xii) The valuation of any benefit is to be performed *ex-post* and in the light of all the available evidence as to benefit derived from the patent: not "*ex-ante"*;

xiii) Where the employee shows that the invention has been of outstanding benefit, the amount of compensation is to be determined in the light of all the available evidence in accordance with section 41 so as to secure a just and fair reward to the employee, neither limiting him to compensation for loss or damage, nor placing him in as strong a position as an external patentee or licensor.

Technical background

61. A summary of the relevant technical background is attached to this judgment as a Technical Appendix. I confess that the summary borrows heavily from the agreed

Primer prepared by Drs. Kelly and Chiu, but I have endeavoured to restrict it to the main points.

The making of the inventions

The setting up of the Pioneer Section and the Heart Project

62. The work of Professor Deutsch at the University of Cincinnati (see Appendix paragraphs 226-228) sparked interest amongst a variety of commercial concerns including DuPont, Mallinckrodt, Squibb and Medi-Physics. Professor Deutsch's patents were assigned to Research Corporation Technologies (RCT), who subsequently offered licences to any interested company on non-exclusive terms. Amersham took such a licence in due course.

63. In April 1982, scientists working at Harvard/MIT filed a patent on the use of Tc-99m isonitrile complexes as heart imaging agents.

64. In October 1983 Amersham entered into licensing and research agreements with the University of Missouri with the aim of commercially exploiting the university's technology in the field of propylene amine oxime (PnAO) complexes of technetium-99m. These were complexes that had shown some promise for brain imaging and, to a lesser extent, heart imaging. Heart imaging agents based on PnAO complexes would fall into the "technetium non-essential" category (see Appendix paragraphs 222-225).

65. A research and development programme to exploit this technology was set up within the Pharmaceutical Division under the overall direction of Dr Rudi Neirinckx, Manager of Pharmaceuticals Research & Development. Dr Neirinckx's arrival from the USA coincided more or less exactly with the signing of the Missouri agreement.

66. Amersham's initial research effort was devoted to finding a brain imaging agent. This research resulted in the identification of a compound known as Pn26, eventually developed into Amersham's brain imaging agent called Ceretec. Ceretec was launched in January 1986.

67. In 1983 Dr Kelly was in charge of extra-mural research (EMR). In that capacity he began collaboration with Dr Vaughan Griffiths at Keele University.

68. In April 1984, Dr Neirinckx considered establishing a Pioneer Section at Amersham. He thought Dr Kelly would be suitable to lead the group. He wrote in Dr Kelly's appraisal for that year:

> "The job could be integrated with a kind of a "new venture" group within the company and Duncan can be considered for heading this up. No manpower is yet available for this group that would evaluate new ideas both theoretically and practically and would lay extensive contacts with the outside."

69. The new group was to do work relevant to current R&D goals within the company but went beyond the scope of current in-house activities.

70. The Pioneer Section idea was activated in June 1985, under the leadership of Dr Kelly. By comparison with the resources of pharmaceutical companies, the funding of this group was modest.

71. It was at around this time that the Heart Project got going in earnest. It initially concentrated on technetium non-essential cations. The leadership of the project had been given to Dr Nowotnik. Amersham was behind DuPont in the race to produce a Technetium heart agent. DuPont's product Cardiolite was launched in 1991, some three years before Myoview. Both products were licensed under the Deutsch/RCT patent.

72. The technetium non-essential group had five PhD chemists, each with a technical/ lab assistant and two graduates.

73. The Pioneer Section under Dr Kelly had no specific remit, but it was expected that the Section would support the Heart Project amongst other potential areas. The Heart Project was the greatest research goal within Amersham at the time. The amount of effort which the Pioneer Section put into the Heart Project, and in particular to product-oriented research work, was nevertheless a matter for Dr Kelly.

The Padua Symposium

74. In September 1985 Drs Kelly, Neirinckx and Nowotnik along with a Dr Nechvatal, all attended the 2nd international Symposium on Technetium chemistry in Padua. One of the main points of interest that the group noted after the conference was that most of the other research groups attending the conference were concentrating on Tc-essential cations for heart imaging. Arene, isonitrile and mixed phosphine complexes had all been discussed as potential areas of research. The group jointly concluded that:

> "there is still a lot of potential in pursuing Tc-essential cations as heart agents…"

75. Following the Padua conference, Dr Kelly decided that the activities of the Pioneer Section should focus on Tc-essential cations, as he put it:

> "having regard to the efforts and progress of our competitors highlighted at the Padua conference."

Recruitment of Drs Chiu and Latham

76. In the latter part of 1985 Dr Kelly commenced recruitment for the Pioneer Section. He recruited Ray Chiu and Ian Latham. Ray Chiu came with the highest of commendations. An excerpt from Ray Chiu's reference by his former research supervisor at Imperial College, the Nobel laureate Sir Geoffrey Wilkinson read:

> "Ray has the ability to complete an experiment in the time that other people are gathering together their apparatus, or even their thoughts."

77. Ray Chiu joined Amersham in November 1985 to work in the Pioneer Section. Dr Latham was recruited to the Pioneer Section in January 1986.

Phosphine research

78. Of the three potential areas of research discussed at Padua, isonitriles were closed off to Amersham by DuPont's exclusive licence under the Harvard/MIT patents. Dr Kelly was aware of this obstacle at the time.

79. Dr Chiu's PhD was in phosphine chemistry (see Appendix paragraphs 229-230). During his first month Dr Kelly discussed with Dr Chiu the possibility of synthesising phosphines with functional groups attached. They discussed one of Professor Deutsch's papers on technetium phosphines. In November 1985 Drs Chiu and Kelly discussed functionalised phosphines (*ibid* 231-232) with Dr Edwards at Cardiff University, because he was known to have an interest in phosphine synthesis.

The synthesis and testing of P11

80. The first phosphine made by Ray Chiu, in January or February 1986, was P11 (see appendix 238), a compound he had previously made at Imperial College. By August 1986 the P11 technetium complex had been made and screened and shown to have good heart uptake in an animal model. However, when it was later tested in humans in November 1986 it failed to show any heart uptake at all.

81. The failure of P11 in man raised the doubts of a number of researchers at Amersham as to whether the phosphine path was the one to follow. Dr Nowotnik was amongst those who expressed these views. Dr Kelly still believed it held promise.

82. Before the human results on P11 were available, Dr Kelly was pressing for synthesis of chemical analogues of P11. Synthetic efforts to create these analogues, including ether analogues, failed because the 1-carbon bridge structure proved an unsuitable vehicle on which to build a range of functionalised molecules (see Appendix paragraphs 231-232).

Ether-functionalised ligands and P30

83. In June 1986 DuPont published some promising results on ether analogues of isonitriles. Whilst ether analogues were amongst those targeted by Dr Kelly from at least January 1986, it was not until after publication of the DuPont results that the Heart Project focussed particularly on ether analogues. Dr Kelly accepted that the Du Pont work influenced the Heart Project in favour of ethers. However it by no means follows that functional groups which work for isonitriles will work for phosphines. The Heart Project carried on investigating ethers well into the second half of 1986.

84. At the same time as attempting the syntheses of analogues in house, Dr Edwards at Cardiff had successfully attempted the synthesis of an ether functionalised diphosphine having an ethylene (2-carbon) bridge. This was P30 (see Appendix paragraph 239).

85. Ray Chiu first prepared the 'tris' complex of P30, which was then tested in rats and guinea pigs. The results showed that P30 was an improvement over the analogous alkyl diphosphine, DMPE. Ray Chiu reported in April, 1987:

> "P30 shows good heart uptake and retention in rat as well as in G.P. Rapid blood clearance and colder liver are the advantage over Tc(I) dmpe"

86. P30 led to the filing of the first patent family, in October 1987. The family includes P53 within its scope.

Beyond P30 – tetrakis ethers and P53

87. The discovery of P30 led to a desire to synthesise ethylene (2-carbon) linked diphosphines. These were known as the 'tetrakis' ethers – diphosphines bearing four identical ether functions.

88. In July 1987 Ray Chiu was spending most of his time attempting to prepare this compound by two different approaches. It proved very difficult. Dr Kelly also directed Dr Edwards in a letter of 16th July 1987 that

> "The primary objective will be the synthesis of tetrakis ether derivatives of 1,2- diphosphinoethane."

89. Ray Chiu's efforts continued for some months in the latter part of 1987. Dr Kelly reported in October 1987:

> "KWC has made monumental efforts to achieve the tetrakis methoxymethyl analogue of P30, and still has more tricks up his sleeve"

90. In September 1987 Rudi Neirinckx left Amersham. Barney Tyrwhitt-Drake, previously head of Marketing, was appointed as the new Manager of Pharmaceuticals Research & Development. During his first weeks, he conducted a review of the Heart Project which highlighted two principal deficiencies: (a) the lack of a relevant animal model (b) in part as a result of the above, a lack of direction and focus in the overall synthetic effort. In the early part of November 1987, when the review was complete, Barney Tyrwhitt-Drake decided to stop all work on technetium non-essential agents. The work on the phosphine-based technetium-essential agents being pursued by the Pioneer Section, was to continue. Dr Kelly became overall project leader of the Heart Project.

91. In December 1987 a meeting of the Heart Project was held at which timing and strategy was discussed. The meeting was informed that phosphine synthesis was due to be terminated in April 1988 unless a "sound and promising" lead had emerged by that date. By April 1988, as we shall see, P53 had emerged.

92. In November 1987 Ray Chiu succeeded in making the P53 ligand (see Appendix paragraphs 235-237). The first attempt to complex it with technetium was made by John Dudmesh, a gap year student working under Dr Chiu's supervision.

93. The screening results were poor: low heart uptake and unexpectedly high, undesirable liver uptake. These and other results gave rise to questions as to whether or not the entity tested was the desired compound. As Ray Chiu was going on holiday, he left John Dudmesh under Ian Latham's supervision with a schedule of work to be carried out. The investigation carried out by John Dudmesh showed that the previously tested entity had not been a genuine dioxo compound. Taking this finding into account, a repeated labelling attempt under modified conditions led to the genuine P53 dioxo complex.

94. The first stage screening tests, available in December 1987, of rat bio-distribution and human plasma protein binding compared favourably with the best DuPont compounds.

95. It is clear that the synthesis of P53 and subsequent testing and validation involved much effort on the part of those involved. Ray Chiu and Ian Latham in particular had

been responsible for these efforts. This was acknowledged by Barney Tyrwhitt-Drake in a memo to Duncan Kelly on 26 February 1988:

> "I have not failed to notice that the pioneering spirit has been alive and well in your section these last few weeks, particularly concerning the collaboration with Physiology on the heart agent programme. I particularly appreciate Ian's and Ray's early morning starts and the support they have had from Fong, John and Clinton please pass on my appreciation to them all. Well done."

Product Development

The animal model

96. Brian Higley had been given the responsibility to seek out more relevant animal models following the Tyrwhitt-Drake review at the end of 1987. He devised a tertiary screening protocol involving:

    i) a primary screen in rats and protein binding by size-exclusion chromatography;

    ii) a secondary screen using guinea pigs and human plasma binding; and

    iii) a tertiary screen in Vietnamese mini-pigs.

97. P53 had been synthesised and shown promise before this new screening protocol was introduced. It was nevertheless subjected to the protocol. Previous results had shown that early promise does not necessarily translate into success in humans.

98. The employees accept that the original animal screening in rats and guinea pigs could serve in principle to identify useful compounds and distinguish them from inactive ones. The new screening program was also important, as it increased confidence in taking a compound forward. Dr Kelly strongly supported a more rigorous animal screen. However the new screening program did not play any role in directing the team towards the synthesis of P53, which had occurred before the new screening program was introduced.

99. None of the screening programs was ever shown to be useful as a predictive tool. Attempts to correlate structure and activity even after the event showed no reliable correlation.

Clinical trials begin

100. The three promising compounds to emerge from the new screening process were P53, PL37 and PL46. PL37 and PL46 had been synthesised at Keele in April and June 1988. There was no clear cut efficacy margin between PL37 and P53, although both were better than PL46. P53 could however be complexed at room temperature, without a boiling step. It was this which led, in December 1988, to the recommendation to proceed to the development stage with P53. This room-

temperature complexing feature of P53 was an inherent feature of the ligand. In due course this gave Myoview an advantage over Cardiolite, which cannot be reconstituted at room temperature and requires boiling.

101. The human study of P53 was conducted at Northwick Park Hospital commencing in May 1988. Dr Kelly was one of the three human volunteers.

102. The second family of patents, covering P53, was filed in April 1988. Ian Latham took up a post in manufacturing in July 1988. Ray Chiu left Amersham in September 1988, but was retained as a consultant until April 1989.

103. Following the selection of P53 as the compound to be taken forward to development, Dr Kelly was appointed acting manager of the Pharmaceuticals R&D Division of Amersham.

The development phase

104. The development phase commenced in January 1989. The tasks embarked on under Dr Kelly's direction included:

a) the synthesis of sufficient quantities of P53 to begin product development;

b) investigation of the commercial procurement of P53;

c) in conjunction with Regulatory Affairs, identifying the Good Manufacturing Practice requirements for the commercial-scale supply of P53 ligand;

d) investigation of the formation of phosphonium salts of P53;

e) stability and formulation studies in order to design and develop excipients to make a robust and reliable cold kit (see Appendix paragraphs 243-245).

105. At the end of January 1989 Dr Kelly handed over the leadership of the Heart Project to Dr Alan Forster, who set up a Launch Team for Myoview. Dr Kelly ceased to have any further formal role in the development beyond that as Manager of the Pharmaceutical R&D Department, in which post he was confirmed in April 1990.

106. P53 had to be formulated into a suitable cold kit. There was significant work involved here, which was done under the direction of Dr Forster. There was a need to find a stable salt and make a freeze-dried formulation.

107. The employees accept that that those responsible for the development of the P53 kit did an excellent job. Dr Forster went as far in his witness statement as to suggest that further inventions were needed in order to arrive at the commercial product, but this claim is not justified. Nevertheless the substantial contribution of the development team is a very important factor for section 41 purposes.

Clinical trials, approval and launch

108. Phase I clinical trials on Myoview were completed in September 1990. Phase II studies were commenced in April 1991, and Phase III in December 1991. The

applications for regulatory approval were submitted in Europe in August 1992 and in the US in June 1993. Approval was granted in the UK and Europe in November 1993. Myoview was launched in the UK in January 1994. In the same month it obtained marketing approval in Japan for the non-conjugate form, and was launched in Japan in April 1994. The conjugate form was licensed in October 1996. FDA approval was granted in the United States in February 1996, and launch in the United States followed in April 1996.

109. The periods of RDE for Myoview vary country by country. In the United States RDE continued until February 2001. In Japan it continued until January 2000. In the UK it expired in November 2003.

Manufacturing

110. A Dr Canning was given the task of finding a manufacturer for Myoview. Unlike ordinary pharmaceuticals, the manufacture of P53 requires special skills and equipment. Amersham had difficulties in locating a suitable manufacturer, but Courtaulds eventually agreed to take on the work. A number of manufacturers were not prepared to take on the work.

Distribution

111. Most hospitals in the United States are not in a position to reconstitute the cold technetium kits themselves. Thus, in the United States, the product is reconstituted in a radiopharmacy and delivered to the hospital. Access to the United States market depended on selling the product into the radiopharmacies.

112. In the 1990s the largest network of radiopharmacies was owned by Syncor. Syncor controlled over 100 pharmacies. Syncor had an exclusive agreement with DuPont to distribute Cardiolite. This made it hard for a competitor product to break into that market.

113. Amersham, now under the leadership of Sir William Castell, had decided in the early 1990s to set up its own distribution network in the US in order to increase it sales there. This was initially to benefit Ceretec, but Myoview benefited from it as well. Amersham bought the first 18 pharmacies in 1990 and then bought about four a year thereafter. It also formed affiliations with independent pharmacies.

114. By 1995, the year before the launch of Myoview, Amersham had access to a network of 120 owned and independent pharmacies. The owned network accounted for 60% of sales, meaning that those sales were insulated from generic competition. The remaining sales, through independents, were less well insulated from generic competition. There was nothing in their agreements to prevent them from taking rival products.

115. Mallinckrodt also had a network of around 30-35 radiopharmacies. Their own attempt to produce a technetium heart-imaging agent, ‘furifosmin’, had failed at the clinical trials stage.

Sumitomo Joint Venture and Nycomed acquisition

116. In 1994 Amersham acquired a stake in Nihon Medi + Physics (“NMP”) as part of a joint venture arrangement with Sumitomo. The acquisition occurred in two stages,

with Amersham increasing its total stake in NMP to 50% in 1996. This was a significant acquisition for Amersham and followed from three years of talks with Sumitomo. Dr Kelly was involved in due diligence work in the run up to this deal.

117. There was no doubt that Myoview was an important facilitating factor in the deal with Sumitomo. The approval of Myoview by the Japanese regulatory authority was a condition precedent of the final joint venture deal, indicating that it was regarded as extremely important. Sir William Castell pointed to the fact that the management of NMP had reasons for preferring thallium as a product. I was not persuaded by his evidence that Myoview was a hindrance to doing the deal. To the contrary, I concluded that Myoview was a significant advantage for Amersham in pushing through the deal. The fact that it was patented must have helped.

118. The NMP deal established Amersham as a global player in the radiopharmaceuticals market. The Independent newspaper, reporting on Amersham's results in its Investment Column on 13 November 1996 said:

> "The figures received a one-off boost from the steady build up in the period of Amersham's stake in Nihon Medi-Physics, a Japanese radio-pharmaceutical joint venture with Sumitomo Chemical, which chipped in £4.3m in the half year. But things are going right for Amersham on several fronts. The £106m cost of the NMP holding now looks cheap. Last year's profits growth of over 20 per cent is impressive enough, but the combination of a ready- to-use version of Amersham's Myoview heart imaging product from January with NMP's marketing muscle opens up a Japanese market expected soon to be worth £40m. Meanwhile, the recent introduction of Myoview to the US launches it on to the largest market in the world, valued at around £75m and growing at 15 per cent a year. Myoview, which saw first half sales soar 126 per cent, is set to emerge as Amersham's lead product."

119. Amersham acquired Nycomed in August 1997. Shortly before the deal was concluded a question arose over whether Myoview infringed a Bracco patent. Amersham took the commercial decision to take a licence, although it was not clear that a licence was in fact required. Myoview was also a key factor underlying this deal. Sir William Castell accepted that there was no question but that this was the case, although he said there were other causes such as the earlier products Metastron and Ceretec.

120. There is no doubt that the fact that Amersham had a patented product in Myoview was a significant factor in achieving these deals. Without a patent for Myoview, Amersham would have looked rather different to partners such as NMP and Nycomed. The existence of patent protection is treated as a "given" in such deals. Although I had no direct evidence of this, Dr Kelly told me that it is likely that both NMP and Nycomed would have done due diligence assessments on the patent portfolio. Had Myoview been an unpatented product there is a substantial chance that the deals would not have been achieved, or at least not have been achieved on such favourable terms.

The Queen's Award for Technological Achievement 1998

121. On 21 April 1998, Amersham's Healthcare Division was awarded a Queen's Award for Technological Achievement for Myoview. It was the company's eighth award since 1967 for Technological Achievement. The fact that Myoview was patented was emphasised by Amersham through Mr Castell (as he was then) in his acceptance speech for the Queen's Award. This included the slide: "Myoview, protected by strong patents in all key markets for next 10 years". It also included a graph showing 'How Myoview has powered our nuclear imaging growth in the US.' In his speech, Mr Castell said, as noted by Ian Latham at the time:

> "Myoview has also enabled Amersham to do two significant things: Myoview was leveraged to give Amersham its 50:50 Sumitomo JV based on Myoview profit forecasts.
>
> Myoview was leveraged to purchase of Nycomed business where the underlying growth in profitability of Amersham came from Myoview. Whereas Nycomed profitability was in decline due to its imaging business suffering from Xray contrast media competition.
>
> Patent coverage is in place for next 10 years – expect good prospects for future growth of the product".

122. The financial section of the Queen's Award submission provided details of R&D expenditure and the time taken for this to be repaid out of profits. The company's response was

> "R&D costs were therefore covered by the profits generated from the gross margin in the first year of product launch, i.e., cumulative R&D costs were less than the gross margin of £4,205K in the first full year".

123. The total R&D costs for Myoview's development were £2,414,000. The first year's sales were given as £4,473,000. So, given the very high margins, Myoview's R&D costs were covered very comfortably indeed in the first year.

The importance of patents to Myoview and to Amersham

124. Sir William Castell was very clear in his evidence about the importance of patents to the Myoview project.

> "Q. At that time, you regarded the patent protection you had for Myoview as very important indeed, did you not?
>
> A. I think it is always important to take products to the market. If your product is a biomolecule, it is a chemical and anyone can copy it. If your product you are going to the market is a defined molecule, it can be copied by anyone and there is no point in developing generic markets. This product would not have been developed in the way it was if it did not have patent protection. If you had strong technology, like an aircraft engine, then you do not have to worry about your patents."

125. Sir William Castell also explained that Amersham had a major problem looking forward as to what to do once the patents for Myoview expired.

> "Q. Are you saying that that was your view at the time, that you would need something to replace Myoview when the patent expired in 2008?
>
> "A. Absolutely. When you plan a healthcare business, you are often looking out 10, 12, 15 years ahead. Mr. Purvis has referred to the fact that we have made claims that we had an interesting patented product portfolio. Actually, if I look at it today five years on, the patented products we had under development, one of them only has been licensed. So how one replaces the revenue flows when a product goes off patent and generic competition occurs is a major challenge. The biggest example of that is Pfizer and Lipitor. When Lipitor comes off patent, they lose $14 billion of revenue. How do you replace it? For our healthcare business in Amersham, replacing Myoview income stream and making sure you do not get that loss of profitability going all the way to the bottom line has been a preoccupation of mine since 2000.
>
> Q. Yes. And how would you rate that in terms of the issues you were facing in 2003?
>
> A. It would be one of the major issues."

The performance of Myoview

126. In 1991 Ceretec was generating sales of some £13 million a year, with a very high gross profit margin. Although its sales grew thereafter, they never exceeded £20 million a year. Metastron at that stage was achieving sales of £1.83 million a year with a lower margin: its sales also never much exceeded £20 million a year.

127. By contrast, Myoview reached sales of over £20 million in its third year, 1996/7. Thereafter it continued to grow, whilst maintaining a very high profit margin. The sales for 2005, 2006 and 2007 were, rounding to the nearest million, £175, £179 and £162 million respectively. Overall the sales to 2007 have exceeded £1.3 billion. As the precise figures for the gross profit margin of its products are treated as confidential information by Amersham, I have set them out in a confidential appendix.

128. Omnipaque and Visipaque were products that were acquired by Amersham as a result of the Nycomed deal. They are very successful products as well. But they are not of comparable benefit to Myoview. So to treat them is to ignore the fact that these were bought in products, with significant costs of acquisition. By contrast the in-house R&D for Myoview was extremely small, and recovered in profits inside the first year of sales.

What was the benefit of the patents to Amersham?

129. On any view Myoview was responsible for a large proportion of Amersham's profits. The employees' basic case was that with sales at the levels indicated and a very high

available gross profit margin, a monopoly in Myoview and related compounds was bound to be of outstanding benefit to Amersham. Amersham pointed to a number of factors as indicating cumulatively that the patents were of minimal benefit to Amersham. It submitted that the link between the patents and the profits of Myoview had not been established.

Are all the profits of Myoview benefits of the patents?

130. Mr Purvis submitted firstly that the evidence established that, without patent protection, the Heart Project would not have gone ahead at all, and that one can therefore ascribe all the profits of Myoview to the patents.

131. I think this argument, which even Mr Purvis was inclined to describe as "nihilistic", is bad. It fails to account for the fact that the patents were just one of the causes of Myoview's success, and fails to provide any basis for apportioning the profits between the multiple causes.

132. I think a much better way of isolating the actual benefit which it is possible to ascribe to the patents, as opposed to other causes, is to assume that Myoview has gone ahead, but unprotected by patents, and compare an estimate of how it would have performed with the actual profits.

Corporate deals

133. The employees also contended that much of Amersham's general success was a result of the patent protection enjoyed by Myoview. I have concluded that Myoview was an important factor in the NMP deal and the Nycomed acquisition. I do not think that the employees have established that without the patents the deals would have foundered. Nevertheless, I have no doubt that the fact that Myoview enjoyed patent protection contributed to the attractiveness of these deals to the opposite party. No party has attempted to quantify the financial benefit of these deals to Amersham, or apportion the benefit which is due to the patents. I am nevertheless satisfied that the fact of patent protection running many years into the future had the effect of strengthening Amersham's position in relation to these deals, which have been of enormous benefit to Amersham generally. It is appropriate to have that benefit in mind when assessing the overall benefit to Amersham.

134. Mr Carr submits that if anything or anyone can claim to be the effective cause of these deals, it is Sir William Castell. The witnesses were indeed full of praise for his efforts. But it would, in my judgment, be entirely wrong to hold as a result that the Myoview patents were of no benefit in achieving these favourable arrangements. In my judgment they are likely to have been of considerable benefit.

135. Mr Carr also submits that, far from the patents being the dominant cause, it was the deals with Sumitomo and Nycomed which gave Amersham the critical mass to develop a large presence in the hospital market with which to sell Myoview. Again, I accept that the deals strengthened Amersham. I also accept that the effort which Amersham made in order to achieve the deals is something which contributed to the success of Myoview, and of which account must be taken under section 41. I am, however, not persuaded that I should as a result ignore the benefit of the patents in

achieving the deals. It is something I should keep in mind in assessing the more direct benefits of the patent.

RDE would have kept competition out

136. Amersham contends that RDE would have prevented generic competition until the expiry of RDE. In the US this was February 2001. Even after RDE ends it may take time for the "piggy-back" application to be processed. Accordingly they submit that this takes the period of Myoview exclusivity to early 2002 in the US.

137. I think Amersham is right on this point. Although I have held that RDE is not "other protection" because it does not constitute an absolute monopoly, nevertheless it is clear as a practical matter on the evidence that competitors would be most unlikely to attempt to launch a competing product by doing their own animal testing. No witness could think of any case where this had happened.

Numbers of generic competitors

138. Amersham suggests that there are relatively few potential generic competitors. It accepts that Mallinckrodt was a potential competitor, but points to the fact that the first generic competitor is unlikely to have much of an impact on price. Mallinckrodt was indeed an obvious candidate. The evidence established that Mallinckrodt had an interest in entering the market with its own product furifosmin, but this had failed. It was a hybrid company, part generic part proprietary. It had a network of radio-pharmacies. It had something of a history of price cutting. Dr Dean said:

> "I can tell you this, that is if they [i.e. Amersham] came out and it was not patent protected, we would have had the same kit out there as fast as possible."

139. Of course, the employees are not obliged to identify the precise companies that would have launched on the market in the absence of patent protection. A number of witnesses, Sir William Castell included, assumed that there would be generic competition.

140. However, in my judgment, there were other companies that had the potential to enter the market as well. Syncor had a network of radiopharmacies. In due course they would have wanted a generic product as well. Bracco and CIS were potential entrants as well. It seems to me that, given the obvious commercial forces, it would be extraordinary if multiple generic competitors did not emerge at the end of the period of data exclusivity.

Manufacturing difficulties

141. Amersham pointed to obstacles which it alleged lay in the way of a generic company wishing to imitate Myoview.

142. Firstly, there were difficulties in identifying a contract manufacturer of P53. The precursor chemical in the manufacturing process was pyrophoric and volatile. But companies with suitable equipment did exist. The real problem encountered by Amersham was that the scale of production was small, and contract manufacturers were reluctant to set up special facilities for such a small amount of throughput. In the end Dr Forster of Amersham accepted:

> "if there were a determined generic competitor trying to make Myoview, sourcing the P53 sulfosalicylate probably would not have been their greatest of problems."

There were other difficulties encountered by Amersham as well, such as devising an appropriate vial closure. I think the evidence established that a determined competitor, particularly a determined US competitor, would overcome these difficulties.

143. Mr Carr submitted that the best evidence of the difficulties surrounding the manufacture of Myoview was that, to date, there has been no generic Myoview anywhere – even where there are no Myoview patents (save for one instance of attempted approval in China). Amersham led some oral evidence about the fact that at one point in Hungary and Greece generic Cardiolite came on the market in infringement of DuPont's rights, at a time when Myoview could have been sold without infringement, as there are no patents in those territories. I am unable to conclude from this evidence that the reason for generic Cardiolite coming on the market was difficulties of manufacture of Myoview. The evidence is far too sketchy for me to jump to this conclusion. Moreover I have no doubt that the reluctance of manufacturers to undertake small scale production could be overcome with an appropriate inducement on price.

Market access

144. Dr Dean, a witness called by the employees, said that the need to distribute through radiopharmacies acted as a kind of "double patent" for Amersham. It is true that access to a network of radiopharmacies was important, and that the owned radiopharmacies gave Amersham protection in the sense that they would not stock generic Myoview. But the same is not true of the independent radiopharmacies. What is more, Mallinckrodt had access to a network of radiopharmacies.

145. Despite the distribution difficulties, I am not persuaded that the market was such that it would not have allowed generic competitors who were prepared to cut prices to enter. By the time the period of RDE had expired in the US there were increasing numbers of independents, giving rise to a much more fragmented market. There would inevitably been a downward price spiral that, absent patent protection, Amersham would not have been able to prevent.

Cardiolite competitors

146. A number of companies are seeking to come on the market with generic Cardiolite. Covidien, formerly Mallinckrodt, are already on the market. Dr Smith suggested that the price had already dropped by 25%. Whilst I am prepared to accept that Cardiolite is coming down in price, I was not persuaded that Dr Smith had sufficient first hand knowledge for this to be an accurate figure.

Were the patents of outstanding benefit to Amersham?

147. In answering this question I am to have regard, amongst other things to the size and nature of the employer's undertaking. It is the patents and not the product on which the inquiry is focussed. It is a binary question.

148. I have come to the conclusion that the patents were of outstanding benefit to Amersham having regard to all the circumstances, including the size and nature of its

undertaking. The benefits went far beyond anything which one could normally expect to arise from the sort of work the employees were doing.

149. The first and most obvious contribution the patents have made to Amersham is in protecting the business against generic competition and reduced profits after the expiry of RDE. The expiry of the patents in about 2008 and the advent of generic competition was one of the major issues facing the company from 2000 onwards. If the patents had not existed in 2000, and Amersham had been facing the expiry of RDE in 2002, this would not simply have been a major issue, it would have been a crisis for Amersham.

150. The benefit of patent protection is not limited to profits from sales. As I have held, the fact that Amersham had a patented blockbuster radiopharmaceutical has been a major factor in achieving the corporate deals. In this way the patents have helped transform Amersham. Considering the totality of the evidence I had no difficulty in recognising that the patents were of outstanding benefit to Amersham.

Is it just to make an award to the employees?

151. Mr Carr submitted that:

i) It is appropriate under this heading to consider the extent to which the contribution of the employer goes beyond what is expected of him and the extent to which he has already benefited;

ii) The notion of just compensation requires the court to focus on the degree of risk the employer has assumed in embarking on the relevant research together with a consideration of the degree of compensation which the employee has already received.

152. The first of these submissions is based on the proposition that section 40 is only concerned with compensation in a very narrow sense. I have considered this submission when dealing with the law above.

153. In support of the second submission, and indeed a more general submission about whether it is just to award Drs Kelly and Chiu compensation, Mr Carr relied on the evidence of Sir Richard Sykes, a former CEO of Glaxo. He said that it was invidious to single out individual inventors for an award in the context of a truly corporate research effort.

154. Mr Carr also relied on the fact that neither inventor ever complained that they had been unjustly treated by Amersham: why then, he asks forensically, would it be just to award them compensation. Moreover, he points to the fact that neither inventor raised a claim under the Act until the end of 2003 – two months before Dr Kelly retired from Amersham. He only raised the claim then because he thought there was some requirement to do so while still employed. Had it not been for this misconception, he would have waited until after he had retired, and all due benefits had been paid to him. Amersham submits that Dr Kelly's decision to wait silently for so many years while collecting all due benefits, and then to claim, is not just.

155. As to Dr Chiu, Amersham point to the fact that he stayed for just over two years at Amersham, and his time at Amersham secured him benefits in later employment.

156. Finally Amersham point to the fact that neither employee took any of the risks: these were all Amersham's.

157. I see nothing in any of this to take the case outside the purview of section 40.

158. It is inherent in sections 40 and 41 that employees who have contributed to the invention and its development but who are not joint inventors will not receive an award. To the extent, as Sir Richard Sykes indicated, this can be described as invidious it is a consequence of legislation which Parliament has enacted. It cannot be a factor which renders it unjust to make an award.

159. As to Dr Kelly's timing in raising the claim, I do not consider this to be relevant. The statute allows the employee under to wait until the patent expires before raising any claim. The extent to which his remuneration has been low or high is a factor considered under section 41: not one which makes it just or unjust to make an award under section 40.

160. I consider that the present case is one where it is just to make an award of an amount to be determined under section 41.

Valuing the benefit

161. Several approaches to arriving at a value for the benefit of the patents were canvassed in argument and in the evidence.

Relief from royalty

162. Mr Bezant, the expert in forensic accounting instructed on behalf of Amersham proposed an approach to valuing the benefit of the patents based on relief from royalty. He takes an *ex ante* approach, that is to say an approach by reference to a royalty agreed before it is known whether the invention will make profits. This is to be contrasted with an *ex post* approach in which the royalty is negotiated on the basis of an established product. He also takes into account the royalties which Amersham had to pay to work the invention both to Bracco and RCT together with the amounts it had to pay to the Universities of Cardiff and Keele for their part in making the invention in the Patent. This results in a figure of £7.63 million before tax as the benefit attributable to the Patents up to 2007.

163. Nearly £5 million of the benefit attributed on this basis is for the years 2002-2007 inclusive, after US RDE had expired. Mr Bezant's royalty calculation is based on a royalty of 1 % of Myoview's actual revenues.

164. Mr Bezant justifies the *ex ante* approach by saying that it values the benefit of the patents at the point where the inventors cease to make a contribution. He recognised that his approach conflates to a significant degree the estimation of benefit and the estimation of fair share. He accepted that the employee was entitled to a larger proportion of the *ex ante* benefit than he would be of an *ex post* benefit.

165. I think the *ex ante* approach adopted by Mr Bezant is the wrong one. The benefit with which section 40 is concerned is the benefit of the patent to the employer. The benefit may, in principle, be benefit reasonably expected in the future or achieved in the past. But where actual benefits have been achieved from the patent, the proper approach must be to take those benefits into account. A royalty negotiated for the bare

invention does not take these benefits into account. A royalty negotiated in the knowledge that the invention has led to a successful product would be likely to be an order of magnitude higher than Mr Bezant's 1%.

Estimating the chances of reduced profits

166. Mr Purvis for the employees suggested that one could perform a calculation based on estimating the chances of reduced profits. By way of illustration, he said that if I came to the conclusion that there was an 80% chance of the profits on Myoview being reduced by 50% on a 50% sales volume, one could estimate that there was an 80% chance that the profits would have reduced to 25% of what was actually made. Equally there was a 20% chance that the profits would have remained as they were. The value of the patented versus the non-patented scenario was therefore 60% of gross profits. This calculation would yield a figure of some £700 million for the value of the patents: two orders of magnitude greater than Mr Bezant. He invited me to use figures I considered appropriate to perform a similar calculation.

167. Even taking into account the fact that we are in the realm of the hypothetical, I do not think the evidence provides a sound basis for making any calculation of this kind.

168. Nevertheless I have held that generic competition would have caused price cutting after the expiry of RDE. A significant part of Amersham's US sales would have been protected to some extent from generic competition, but other parts of their market would not. In my judgment the evidence justifies the conclusion that, at a minimum, generic competition would have caused the price of Myoview to drop by 10% (at least but probably a lot more) on about half of its sales.

169. Myoview sales from 2002 to 2007 were as follows:

	Myoview sales (£m)
2002	137.9
2003	151.1
2004	158.7
2005	175.2
2006	179.5
2007	162.5
Total	**964.9**

170. Taking a round figure of £1 billion, a price cut of only 10% on only half of Myoview's sales over that period would have reduced Amersham's revenues by £50 million. I consider that I have been very conservative in arriving at these figures. I think that prices would have fallen by much more than this over the course of the post RDE period.

What figure to take?

171. There is no doubt that both sides have adopted positions which overstate the strength of their cases. There are difficulties in upgrading Mr Bezant's approach to allow for the real benefit of the patent in the absence of clear evidence of what a licence for a proven product would cost. There are difficulties with downgrading the employees' profit estimates in the absence of more concrete evidence as to what would have happened.

172. I think I am justified in taking a figure of £50 million pounds as the absolute rock bottom figure for the benefit from the patents. This is ten times the post RDE benefit calculated by Mr Bezant on the basis of a 1% royalty. But Amersham paid 6% to Bracco and RCT for licences for mere freedom to operate. In qualitative terms I have no doubt that the real benefit to Amersham's business overall is very much greater: but this broader benefit is not really capable of quantification. By taking this low figure, which I do in fairness to Amersham, I am in no way casting doubt on my conclusion that the overall benefit was outstanding.

Share of the benefit

173. I consider first the various section 41 factors.

(a) The nature of the employee's duties, his remuneration and the other advantages he derives or has derived from his employment or has derived in relation to the invention under this Act

174. Dr Kelly's duties were to lead the Pioneer Section and direct its research. This included leading the team which worked on the Tc-essential part of the Heart project.

175. Dr Chiu was a much more junior employee. He was nevertheless a very able and productive synthetic chemist. His duties included making and labelling phosphine compounds.

176. Between 1987 and 1989 Dr Kelly was paid around £23,000 and £27,000 per annum. On retirement in 2003, his salary was just under £71,500. He received a tax free lump sum of just under £93,000 and a final salary pension which yielded £34,000 in 2005. On retirement he was given an *ex gratia* payment of £74,500. He also received some share options.

177. Dr Chiu was paid between £12,000 and £15,000 between 1987 and 1989.

178. Amersham point to a number of other advantages which accrued to the employees as a result of their work on P53. For example they contend correctly that Dr Kelly's success in producing the compound that was taken forward to development led to his appointment as acting manager of R&D (and later permanent manager) and entry into the management grade salary structure. The invention also gave Dr Kelly recognition outside Amersham. He became known generally throughout the world as one of the

inventors of the Myoview patents. In Dr Chiu's case, being named as an inventor on the patents helped him to negotiate a starting salary in his next job at around £30,000, double his salary at Amersham.

179. I think this factor is really directed to asking whether the employee has already received some recognition for making an invention of outstanding benefit. There is no suggestion that either employee was paid above or below industry rates for doing the sort of work which he did. I think the other advantages they received should exert some downward pressure on the share of the benefit.

(b) The effort and skill which the employee has devoted to making the invention

180. Amersham accept, as it had to, that Dr Kelly is clearly a very good chemist. Amersham submits, however, that Dr Kelly did no more than apply himself with the effort and skill expected of an employee in his position.

181. Amersham also accept that Dr Chiu was conducting skilful work. It submits, however, that it is the sort of work that many other competent research workers, (including other Amersham employees) were capable of performing.

182. I think the level of effort and skill which the employees devoted here was high. I have referred to those efforts, recognised at the time by Amersham in the "pioneering spirit" memorandum from Mr Tyrwhitt-Drake, above. Success in finding a viable candidate for development was by no means guaranteed. Dr Kelly directed the Project to a successful conclusion on a modest research spend, and under considerable pressure to produce results. Dr Chiu made monumental efforts in his own sphere of responsibility.

(c) The effort and skill which any other person has devoted to making the invention jointly with the employee concerned, and the advice and other assistance contributed by any other employee who is not a joint inventor of the invention

183. I must, of course, take into account the fact that there are other named inventors beside Dr Kelly and Dr Chiu. But it is not suggested that there are others, beyond the named inventors, who are entitled to be described as making the invention "jointly with them". I am concerned under this head, therefore with advice and assistance added by non-inventor employees. Amersham contends that the Heart Project which led to P53 was a team effort within Amersham. It contends that the relevant work included (i) the teams working on the Tc-non-essential and essential projects, (ii) the external university advisors and (iii) the biologists led by Dr Higley who undertook the screening of the complexes.

184. There is no doubt that the inventions were made in the course of a research project in which other employees were working. As with any such project, the inventors will have been assisted by the ability to interact with others in the research environment. There is no doubt that those involved in the technetium-essential group helped out those in the non-essential group and the other way around. There is also no doubt that Dr Kelly's decisions as to the way in which to direct the research were reached after, and were reinforced by discussion with colleagues. Dr Kelly also accepted that the decision to research ether functionalised phosphines as opposed to esters was influenced by Professor Griffiths at Keele University, who pointed out problems with esters. P30, first synthesised by Professor Edwards, was also fundamentally important

to the project. Dr Higley's animal model was an important tool, but it did not help give direction to the synthesis of P53.

185. The joint inventors apart, it is not in my judgment possible to single out any individual who contributed significant advice and assistance to the employees in making the inventions.

(d) The contribution made by the employer to the making, developing and working of the invention by the provision of advice, facilities and other assistance, by the provision of opportunities and by his managerial and commercial skill and activities

186. There is no doubt that the inventions were of such a character that they depended to a significant extent on the contribution of the employer. It was the employer who set up the Pioneer Section and the Heart Project, and provided all the facilities essential to the running of such research. It also provided high levels of external assistance from the Universities. Beyond this it took the project forward through the development and manufacturing phases.

187. I agree with Amersham that is very important not to underrate the contribution of the employer in these circumstances. Research in pharmaceuticals (which this is or to which it is closely analogous) involves a wide-ranging scattergun approach to discovering useful new agents. The work on successful agents has to be seen in the context of work on unsuccessful ones, and not isolated from it. To some extent the fact that an employee makes an invention can be a consequence of his being assigned a routine task at the right time. Nevertheless each case will depend on its own special facts.

188. In the present case I think the following are important factors favouring the employee:

i) the overall costs of R&D in the present case are extremely small in relation to the profits generated: some £2.4 million as reported in the Queen's Award document;

ii) neither Dr Kelly nor Dr Chiu were carrying out routine operations: their jobs involved significant thought and creativity.

189. On the other hand the following factors help the employer:

i) Dr Chiu's and Dr Kelly's work was to a significant degree dependent on the opportunity provided by the employer to make inventions;

ii) the downstream work was well executed, and involved the solution of some problems: Dr Kelly's contribution to this was limited;

iii) the development of the market in the United States was also a major factor of assistance in working the invention;

iv) overall it was the employer who accepted the risk for the project.

Amersham's primary case on share

190. Amersham's primary case was that the factors taken as a whole called for nothing but a nominal award. Alternatively Amersham contended that a bonus by reference to the employee's annual remuneration in 1989 was all that was appropriate. A bonus of one

year's salary in 1989 scaled up for inflation to 2008 would result in a payment of about £100,000 for Dr Kelly and £60,000 for Dr Chiu.

Mr Bezant's fair share

191. Mr Bezant chose a figure of 5% in his first report as the share of the benefit. As I have indicated, in his report he applied an *ex ante* approach to the valuation of benefit. He recognised that a lower percentage would be necessary if one was looking at the benefit *ex post*. His 5% figure came from that recommended by the Biological and Biotechnology Sciences Research Council (BBSRC) under an industry scheme. The 5% is applied to exploitation income. In Mr Bezant's calculation he applies this 5% to his benefit figure of £7 million pounds.

192. By the time he came to make his second report, the BBSRC had raised its rates to 33.3%. This was done in order to bring its rates into line with universities, which typically pay their academic inventors a third of exploitation income. Not surprisingly he wished to disassociate himself from this as a comparable figure, and Ms Okikiolu, the accountant called by the employees, did not seriously suggest a figure in this region would be reasonable.

193. I do not think that the position of academic inventors is comparable with the position of the inventors in the present case. I suppose if an inventor in industry made an invention which created an entirely new product and income stream for his employer without any substantial input from the employer, a share in this region or even higher might be justifiable. But that would be a very different case.

194. Mr Bezant applies his 5% figure to the approximately £8 million pre-tax profit arrived at after deduction of the royalties paid to the Universities. This gives a figure of £400,000 up to 2007. This needs to be scaled down to represent only post RDE benefits: say £250,000 to share between the inventors.

The employees' fair share argument

195. The employees' main argument on fair share was to take as a starting point external licensing arrangements in the field.

196. The Bracco and RCT licences were all at 6% of turnover. The commercial background against which these licences were negotiated is very different. Mr Purvis recognised that the figure would require heavy discounting to take account of the section 41 factors, although not for the contribution of the employer in developing the invention once made, as such a royalty already takes account of that factor. He also accepts that the 6% would require to be discounted as well for the fact that these are employee inventors, not independent contractors. He suggested that the combined effect of the discounts which one would have to apply would by to reduce the rate to 1.5%. One would give two-thirds of this to the employees and deduct one third to allow for Dr Latham.

197. This calculation would result in £7 million for the employees to share: but it is not sufficiently evidence based for me to place reliance on it.

The Goldman agreements

198. In February 2000 Amersham entered into a consultancy agreement with a Professor Goldman. Inventions were to belong to Amersham. Under the agreement Professor Goldman was to receive an annual fee of 48,000 Euros and a potential royalty in the event of the commercialisation of any invention made by him. Royalties for technology involving "a minimal degree of innovation" were to be set at 0.25-1% and royalties for technology involving "a significant degree of innovation" are set in the range of 1-3%. Inventions involving new chemical entities were "more likely to fall in the second category".

199. This agreement was replaced in 2006 with a second agreement which was in similar terms, except that there was no provision for any royalty. The inventions still belonged to Amersham.

200. Despite the later removal of the royalty clause, I think this agreement is some indication of what a fair division of spoils might be between an employer and an employee in circumstances where the employee is receiving remuneration in any event for making the invention, and not carrying any of the commercialisation risk. It would require further discounting where the employer and other employees contribute to the making of the invention.

Universities of Cardiff and Keele and the Professors

201. Under its agreement with the University of Cardiff Amersham pay the University "a reasonable royalty .. based on the raw material value of the ligand". The resulting negotiations yielded an agreement under which Amersham pay Cardiff and Keele Universities 200% of raw material costs. These royalties, when translated into percentages of Myoview finished product sales represented roughly 0.5%. Under the arrangements between the Professor and the Universities, the Professors received approximately 30% of these amounts. The aggregate amount paid to the Universities to date is £5.7 million. The evidence suggested that this was an unusual arrangement, at least as far as Amersham were concerned.

Decision on fair share

202. I think, aside from the facts of this case, from the materials I have reviewed, the employee's share of the value of a patent might in principle lie somewhere in the broad range from nil to as much as 33% or beyond. In the present case I think the employee's share lies towards the bottom of the scale, having regard to the factors which I have considered at length above. I have taken a very conservative figure for the valuation of the benefit. Taking the same approach to the share of the benefit, I consider that 3% of the value of the benefit represents a just and fair award to the employee claimants.

203. As between the two inventor claimants, I think Dr Kelly should receive more than Dr Chiu. Dr Kelly should receive 2% and Dr Chiu 1% of the £50 million figure I have taken as the value of the patents. Thus Dr Kelly receives £1 million and Dr Chiu £500,000.

204. These combined figures represent about 0.1% of turnover. I am confident that none of the comparators show this figure to be unreasonable. Whilst it is far from perfect, the closest comparable is the Goldman licence. The lowest figure in the Goldman licence was 0.25% of turnover. Standing back, and looking at these sums in the light of all

the evidence I have heard, I consider them to be just and fair. It represents about three days' of the profits from Myoview at current rates.

205. Whilst I have had in mind the fact that the context of the award is employment, I have not thought it right to limit the award by reference to one year's salary. The benefit to Amersham has extended well beyond a single year.

206. Although the Act contemplates that the employee can make more than one application, I was invited to make a once and for all award, which is what I have done.

Conclusion

207. I have reached the following conclusions:

i) The patents have been of outstanding benefit to Amersham;

ii) It is just that the employees should receive an award of compensation;

iii) I have decided that the benefit of the patents is of the order of £50 million;

iv) A fair share for the employees is £1 million for Dr Kelly and £500,000 for Dr Chiu.

Direction

208. I will hand down this judgment at 10.30 on Wednesday 11 February 2009. There is no need for any party to attend. The parties should attempt to agree a minute of order to give effect to my judgment. In the event that there are matters which cannot be resolved by agreement or by submissions in writing for decision on paper, the matter should be restored for further argument. At the time of handing down I will adjourn any application (such as an application for permission to appeal) of which I have been notified by 4.30 pm on the previous day.

TECHNICAL APPENDIX

Medical imaging and radiopharmaceuticals

209. In medical imaging a radioactive substance is administered to a patient so as to create a source of radiation which can give rise to an image detectable with a camera. The radioactive substance is known as an imaging agent or radiopharmaceutical.

210. Radiopharmaceuticals are subject to the same form of regulation as conventional pharmaceuticals, including the need for trials to demonstrate efficacy and safety. The radiopharmaceuticals of relevance to this case are gamma emitting radioisotopes, such as technetium-99m and thallium-201.

Heart disease and the role of myocardial perfusion agents

211. This case is concerned with heart imaging agents, or myocardial perfusion agents. These are used to identify disease in heart muscle by revealing the areas of reduced activity in the image.

212. To provide a reliable image of perfusion, the radiopharmaceutical has to be able to enter living cells in proportion to the blood flow reaching them.

Thallium-201 and its limitations

213. Thallium-201 is a useful tracer of myocardial perfusion. Thallium-201 has some drawbacks. The energy of its gamma emissions is well below the optimal level for use with the gamma camera. Thallium-201 also has an isotopic half-life of three days, meaning that he patient is exposed to radiation for a much longer period than that required to conduct the imaging test.

214. Despite the disadvantages described above and the increased availability of Technetium-99m heart imaging agents, thallium-201 still has a usage in the marketplace. In 2005, thallium-201 had an estimated market share of 20% to 25% of the total worldwide market for thallium and technetium myocardial perfusion agents. Its use was not protected by patents and its price was accordingly much lower than patented agents.

Technetium as a radioactive label

215. Technetium (Tc) is a radioactive transition metal. It has a short-lived radioisotope: technetium-99m (Tc-99m). Technetium is only available from artificial sources. The half life of technetium-99m is 6 hours. Technetium is a metallic element which can form complexes.

The preference for technetium-99m as an imaging isotope

216. Technetium-99m is highly favoured for imaging applications. Several factors combine to make it the most widely used imaging nuclide:

    i) it is readily produced using a Tc-99m generator: these generators are generic products supplied to customers in hospitals and commercial pharmacies;

    ii) it has a low cost per unit of radioactivity;

iii) its 6-hour half-life is well suited to imaging applications, being long enough to establish physiological localisation and to take an image, but short enough to minimise radiation exposure to the patient;

iv) the energy of its gamma emissions is well-suited to optimal detection by a gamma-camera, the imaging device used in hospitals.

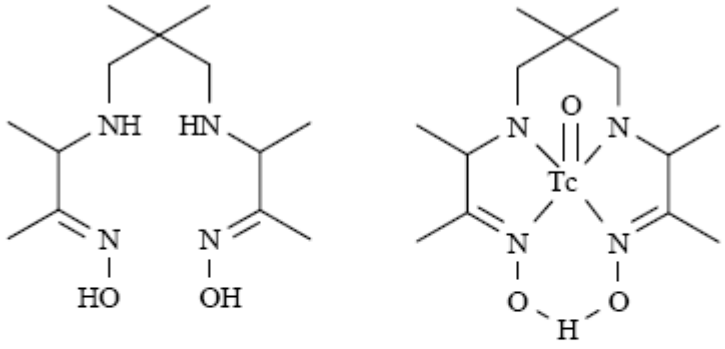
217. A further factor in the convenience of technetium-99m as an imaging isotope is the commercial availability of "cold kits". These are lyophilised (freeze-dried) formulations of non-radioactive product. They are registered pharmaceutical products, to which radioactive technetium-99m is later added to produce the imaging entity for injection into a patient. The word "cold" in this context is used to indicate that the material at that stage is not radioactive; once it is combined with the radioactive material it becomes "hot".

218. In-hospital and commercial radiopharmacies equipped to handle radioactivity are widespread. The cold kit is combined with technetium-99m from a generator to produce the imaging agent for administration to the patient.

Technetium Radiopharmaceuticals

219. In technetium radiopharmaceuticals technetium-99m forms a complex. The complex consists of a binding molecule (ligand) which combines with technetium to form a metal-ligand complex possessing the right biological properties to act as an imaging agent.

220. An example of a technetium complex is shown below. Amersham's brain imaging agent Ceretec is administered as a complex of a ligand and Tc-99m. The ligand alone is shown on the left and the complex is on the right.



HM-PAO ligand molecule **Labelled Ceretec molecule**

Figure 4: Technetium imaging agent: ligand and complex

221. The biological targeting characteristics of a technetium-99m radiopharmaceutical depend upon the species to which the technetium is attached.

'Technetium essential' and 'non-essential' imaging agents

222. Technetium imaging agents are classified by researchers into two main groups of molecule: technetium non-essential and technetium essential, based on the role of the species to which the technetium is attached.

223. A technetium non-essential agent has biological characteristics that are determined by the entity to which the technetium is bound, such that the entity already has bio-localising properties. The attached technetium-99m is instead required to have as little effect as possible on the bio-distribution of the "targeting molecule" (i.e. ideally functions only as a means of detection).

224. In a technetium essential agent, the biological properties do not parallel those of the entity to which the technetium is bound. Instead, they are governed by the characteristics of the technetium species as a whole, usually a technetium-99m metal complex. The technetium atom in the molecule plays an essential part in the biological activity of the complex; it is not functioning solely as a source of signal. Technetium-99m pertechnetate is probably the simplest example of a technetium essential agent.

225. The patents in suit cover the complex in Figure 7 (below). This complex forms the basis of Myoview injection as an imaging agent. When in the 'dioxo' complex form $[TcL_2O_2]^+$ (where L = the ligand 'P53'), the complex is a technetium essential cation with +1 charge. The overall cationic complex comprises two phosphine ligands (i.e. two P53 ligands) and a technetium atom with two oxygen atoms.

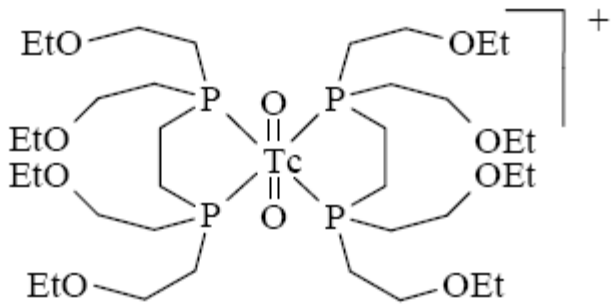


Figure 7: P53 Dioxo Complex – technetium essential cation (where 'Et' is ethyl (-CH_2CH_3))

Early work on technetium cations

226. Early work conducted at the University of Cincinnati by a research group led by Professor Edward Deutsch provided the basis for imaging using technetium cations. In 1980, Professor Deutsch found that cationic complexes of technetium-99m could show favourable uptake in the heart tissue of rats and dogs. In these prototype compounds the technetium atom combined with a member of one of two classes of ligand (arsines and phosphines) to form a lipophilic cation. The lipophilic cation diffuses across cell membranes.

227. One of the early examples of these lipophilic cations was $[Tc(dmpe)_2Cl_2]+$ from the ligand DMPE (1,2-bis(dimethylphosphino)ethane).

228. Deutsch and his co-inventor filed patents containing broad claims for the use of technetium-99m lipophilic cations which were "technetium essential cations" as heart imaging agents.

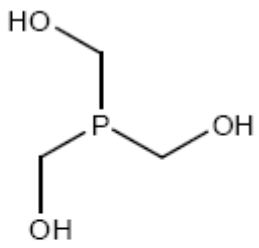
Phosphines

229. The phosphines are a class of phosphorus-containing organic chemical compounds of the general structure PR_3, in which the phosphorus atom (P) is bound to either hydrogen or the carbon of an organic group (R). They are named after the simplest example of the class, the specific molecule itself known as 'phosphine', PH_3.

230. Organic compounds with bonds between phosphorus and carbon are named as derivatives of phosphine; in primary, secondary, and tertiary phosphines, one, two, and three hydrogen atoms have been replaced by organic combining groups.

Functionalised and unfunctionalised phosphines

231. A simple functionalised phosphine is shown below:



Tris(hydroxymethyl)phosphine

Figure 10: A simple functionalised phosphine

232. In tris(hydroxymethyl)phosphine, the molecule contains three hydroxyl groups. Ligands such as phosphines are described as 'functionalised' when they incorporate functional groups other than hydrocarbons: that is, the functional groups contain 'hetero' atoms such as oxygen or nitrogen. When there are no hetero atoms, the ligand is 'unfunctionalised'.

Diphosphines and their role as ligands

233. Where the phosphine molecule contains just one phosphorus atom, it is termed a monophosphine. Where it contains two phosphorus atoms it is termed a diphosphine. An example of a diphosphine is DMPE (the phosphine ligand in the early studies by Deutsch et al and referred to above). DMPE is an example of an unfunctionalised diphosphine.

234. Diphosphines form complexes with technetium in which the diphosphine bonds to technetium through both of its phosphorus atoms. Acting alone or in combination with other ligands, such as the simple inorganic anions oxide, chloride or nitride, diphosphines can form a range of technetium-essential cations.

The diphosphine ligand P53, 'tetrofosmin'

235. P53 or "tetrofosmin" is 1,2-bis[bis(2-ethoxy-ethyl)phosphino]ethane. It can represented as follows:

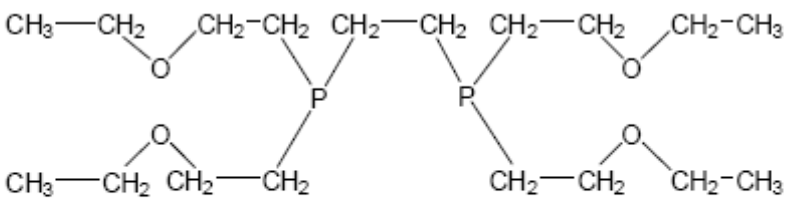


Figure 14: The molecular structure of tetrofosmin, P53

236. The four chains of atoms having the sequence $CH_3CH_2OCH_2CH_2$- are ether functions. The central chain of atoms >PCH_2CH_2P< makes the molecule a diphosphine with an ethylene (2-carbon) bridge. It is therefore an ether-functionalised diphosphine. Tetrofosmin is a "tetrakis" ether functionalised molecule, because it has four ethers.

237. Tetrofosmin (P53) is the Myoview ligand that, during reconstitution of the Myoview kit, combines with the radioisotope technetium (Tc-99m) to form the dioxo complex cation having the composition shown in Figure 7, above. It is this technetium complex that, when injected into the patient, highlights healthy heart tissue and has reduced uptake in unhealthy tissue.

The diphosphine ligands P11 and P30

238. P11 is an unfunctionalised diphosphine ligand containing four methyl (-CH_3) groups and two phosphine functions connected by a methylene (1-carbon) bridge:

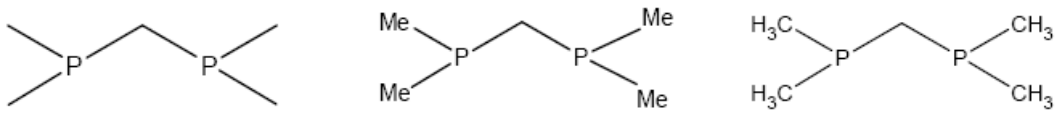


Figure 15: The molecular structure of P11

239. P30 is an ether-functionalised diphosphine ligand, having an ethylene (2-carbon) bridge between the phosphorus atoms. Each phosphorus atom (P) is attached to both a methyl (CH_3) and a methoxymethyl ether function, -CH_2OCH_3.

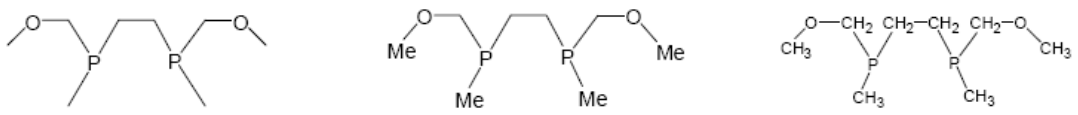


Figure 16: The molecular structure of P30

Technetium-99m "cold kit" technology

240. Typically, a "cold kit" contains two principal chemical constituents: (1) the ligand, which will both bind chemically to technetium and confer the biological properties of the

complex; and (2) a reducing agent, to reduce technetium from its +7 oxidation state in pertechnetate. The reducing agent is usually a stannous salt.

241. Other constituents such as stabilisers may be present. The constituents of the cold kit are preferably combined as a freeze-dried mixture, in an inert atmosphere, usually nitrogen gas, in a glass serum vial with a rubber closure.

242. Technetium-99m is produced in a saline solution from a technetium-99m generator in the chemical form of pertechnetate ion (TcO-4). The radioactive imaging agent is prepared by adding pertechnetate from the generator to the freeze-dried mixture by injection through the rubber closure. This is shown schematically in Figure 17. The chemical reactions of reduction and complex formation that then occur may take place at room temperature or may require heating at temperatures up to 100ºC, depending on the characteristics of the ligand (with Myoview the reaction takes place at room temperature).

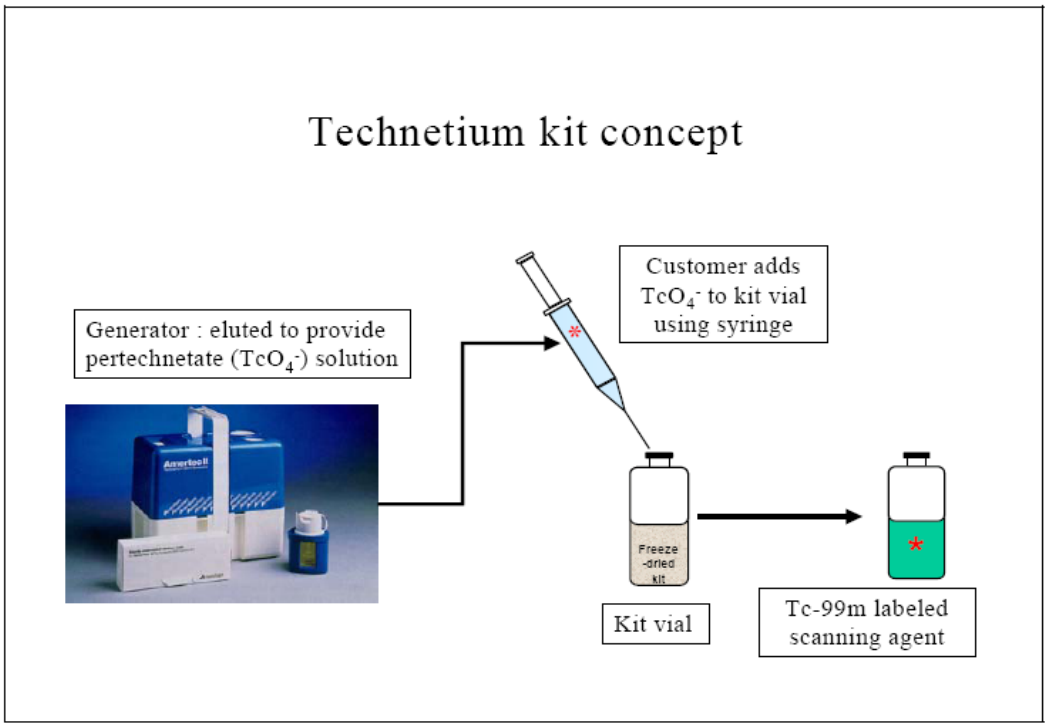


Figure 17: Technetium cold kit reconstitution

Stability of the technetium-tetrofosmin dioxo complex

243. In the presence of stannous reductant, as in the Myoview kit, the technetium tetrofosmin dioxo complex forms. In the absence of stannous reductant, as in labelling experiments, P53, like other diphosphines, can play a dual role as reductant as well as ligand, some P53 being itself sacrificially oxidised to the phosphine oxide.

244. In either case, the tendency for P53 to act as a reducing agent means that the dioxo complex can be fairly readily further reduced if there is too high a concentration of the P53 ligand. This is because lower oxidation states are favoured by metals when bound to phosphines. The P53 is present in considerable excess over the amount necessary to bind to the minute chemical quantity of technetium that is present. There are two phosphorus atoms per P53, and each can add an oxygen atom.

245. To avoid such unwanted reactions, the P53 concentration is kept to a minimum.

Manufacture of tetrofosmin

246. The immediate precursor of tetrofosmin is 1,2-bisphosphinoethane, (BPE). One molecule of BPE is combined with four molecules of ethylvinylether to produce tetrofosmin.

247. BPE is a colourless, volatile liquid with the very unpleasant odour characteristic of primary and secondary phosphines. It is toxic and spontaneously flammable in air. Manipulation must be carried out under a nitrogen atmosphere and caution should be exercised during the collection of the product because of its toxic and flammable nature. The subsequent reaction step to combine BPE with ethylvinylether entails the manipulation and reaction of BPE.

248. Tetrofosmin is a liquid which is moderately air sensitive at room temperature.