

PATENT ENTITLEMENT

YEDA RESEARCH AND DEVELOP- MENT COMPANY LIMITED V RHÔNE-POULENC RORER INTERNATIONAL HOLDINGS INC AND OTHERS

LUKE KEMPTON AND JANINE HARBORNE

Wragge & Co LLP

Synopsis

Patent entitlement cases are on the rise. The commercial value of patents has never been so widely recognised in the biotech community and entitlement proceedings can be bitterly contested. Case law on entitlement to patents in the United Kingdom has recently undergone a radical change. Until 2007, in order for party A to prove his entitlement to a patent which had been granted to party B, party A had to prove not only that he was entitled to apply for the patent but also that there was some other rule of law such as breach of contract or confidence which could be invoked to establish his entitlement. The House of Lords has finally removed this additional requirement in its judgment in the case of *Yeda Research and Development Company Limited v Rhône-Poulenc Rorer International Holdings Inc and others* ('the Yeda case').¹

Why all the Fuss?

It is no news to the life science industry that research and development is a time-consuming and costly activity with

rewards that can be few and far between. The very rationale behind patent law is to incentivise investment in research and development by protecting inventions once they arise. Patents can be highly valuable profit-generating assets in the right hands, yielding licensing revenue and boosting a company's profile and reputation for innovation. It is a hard blow to a business to discover that another organisation claims rights to a valuable patent.

Loss of patent entitlement can have significant financial impact on a company. In 2006, the US Blackberry litigation resulted in payment by Research in Motion of over \$600 million for a perpetual licence of the patents in suit, which was apparently preferable to facing trial.

Perhaps even more than other litigation, patent entitlement cases are typically intensified by bad feeling between the parties. Whether an ex-employee has continued development of an invention at a new company or co-inventors have gone their different ways, the disintegration of the co-operative relationship which originally cultivated the invention is emotive. Additionally, the very nature of a 'proprietaryship' argument is personal and participants can feel no less cheated than if they had been mugged.

Businesses can of course take steps to reduce the likelihood of a patent entitlement challenge. All biotech companies should ensure that every research collaboration agreement, outsourcing or employment contract executed contains clear intellectual property provisions. This is an easy precaution to take with hindsight, but inventions arise in unpredictable circumstances and, even with preparation, it is not always possible to circumvent legal entitlement provisions.

The Basics of Entitlement

Patents are granted to the inventor (or joint inventors) of an invention or to persons otherwise entitled to the property in it in the United Kingdom (or such parties' successors in title).² The owner of a patent is the one with the right to prevent others from doing what is set out in the claims of the patent for as long as the patent is in force (generally 20 years). Entitlement gets complicated where there are multiple parties involved and the relevant question to ask is 'who contributed to the main inventive concept?' Even knowing the legal test does not produce a clear outcome in many cases. The applicant for a patent is presumed to be the person entitled to the grant of the patent unless it is proved otherwise.³ The first person to apply for the patent will almost certainly be named as inventor unless this is challenged.

1) [2007] UKHL 43.

2) Section 7 Patents Act 1977 see Box 1.

3) Section 7(4) Patents Act 1977.

In the case of employee inventors, the property in the patent belongs to the employer if the invention is made in the course of the employee's normal duties or specifically assigned duties, provided in each case that an invention might reasonably be expected to result from those duties.⁴ The employer will also own the property in the patent if the employee inventor owes the employer a special duty to further its interests, for example as a director. It is not possible for employees to 'contract out' of these provisions; however, job specifications can be drafted widely to encompass inventive duties.

Where an invention is owned by the employer but is of 'outstanding benefit' to the employer, there are legal provisions which may allow the employee inventor to recover compensation from the employer. Before the Patents Act 1977 ('the Act') was amended by the Patents Act 2004, such recovery was practically almost impossible. Previously, the benefit had to be from the patent rather than the invention, which was hard to establish where the patent was exploited by manufacturing rather than licensing. The Patents Act 2004 removed this distinction and allowed compensation where the invention or patent (or a combination of both) is of outstanding benefit. The value must still be 'outstanding' rather than simply good, and the employee bears the burden of proof of showing this. Only time will tell if the new provision makes employee compensation more achievable.

Jurisdiction for Entitlement Proceedings

At any time before a UK patent is granted, any person may refer the question of whether he is entitled or has any right under any patent granted to the Comptroller of Patents ('the Comptroller') under section 8(1)(a) of the Act. The Comptroller may make an order governing the name in which the application should proceed, refuse to grant the patent, or otherwise order amendment of the patent to remove claims covering the applicant's inventions.

After grant of a UK patent, there is a similar provision to refer an entitlement claim to the Comptroller under section 37 of the Act. Under section 37(5),⁵ no order transferring the patent into another name can be made if the reference was made after the end of the period of two years beginning with the date of the grant of the patent.

In each case, the Comptroller may decline to deal with the entitlement claim if it appears to be more suitable for determination by the court. Alternatively, either party may request transfer to the High Court, and this is likely to be

appropriate if there are arguments relating to breach of confidence or contract. Parties should be aware of the cost implications for making this decision. In comparison to the £500,000 cost of a typical High Court action, costs awarded in proceedings before the Comptroller are guided by a standard published scale. Whilst this is an advantage for a company which is uncertain of winning, a confident party should be aware that at best it will probably only recover a fraction of its costs from proceedings before the Comptroller.

Entitlement disputes over a European Patent Convention ('EPC') patent application can be decided by the courts or other authority with jurisdiction in a single EPC Member State in which the patent applicant has his residence or place of business (or, if the applicant is based outside the EPC Member States, in the country of residence or business of the claimant for entitlement). The matter gets more complicated once the patent is granted because an EPC patent is effectively a bundle of national patent rights. Entitlement proceedings must therefore be brought separately before the courts or other authority with jurisdiction in each designated country.

The Old Entitlement Law

In its judgment of *Markem v Zipher*⁶ in 2005, the Court of Appeal held that:

a person (A) who claims to be entitled to a patent which has been granted to someone else (B) could not succeed merely by proving that he had been the inventor and B had not ... A must be able to show that in some way B was not entitled to apply for the patent, either at all or alone. It follows that A must invoke some other rule of law to establish his entitlement⁷

The examples given of reliance on other rules of law were breach of contract or a duty of confidence.

There was no statutory reference to the requirement for breach of some other rule of law to justify the patent applicant being deprived of all or part of their rights to the invention, nor were there any similar requirements in the EPC. In practice, entitlement claims are likely to be brought where there has been breach of an independent rule of law (although, as discussed below, that may in fact have no bearing on entitlement). Nonetheless, the judgment in *Markem* restricted the situations in which all patent

4) Sections 7(2)(b) and 39 Patents Act 1977.

5) See Box 2.

6) *Markem Corporation and Markem Technologies Limited v Zipher Limited* [2005] EWCA Civ 267.

7) Words of Jacob LJ as paraphrased and explained by Lord Hoffmann in *Yeda*.

entitlement claims could be made and it was much criticised on this basis. For two years, the legal advice given out to many would-be claimants was that evidence of breach of some other independent rule of law was necessary.

The *Yeda* case finally provided a suitable factual scenario to put the *Markem* judgment to the test.

Factual Background to the Yeda Case

In 1988, a group of scientists employed by the Weizmann Institute of Science in Israel was working on different forms of treatment for cancer. Professor Schlessinger, who worked for the Meloy Laboratories in the United States, subsequently to become part of Rhône-Poulenc Rorer International Holdings Inc ('RPR'), provided the Weizmann scientists with two antibodies, which he and his team had developed. The Weizmann scientists conjugated these antibodies to an anti-neoplastic drug but also used a mixture of unconjugated antibodies and drug as a control. They unexpectedly found that this mixture gave a better result than the conjugated drug and wrote the results up in an article in spring 1988. The Weizmann scientists sent a draft of the article to Professor Schlessinger.

RPR applied for a US patent for the treatment of cancer as described in the draft article. The patent named Professor Schlessinger and some of his team as the inventors. Yeda Research and Development Co Ltd, the assignee of the rights of the Weizmann scientists, alleged that the discovery was made by the Weizmann scientists rather than by RPR.

On 26 March 2004, Yeda initially applied to have the European patent derived from the US patent transferred into its joint name and for three of the Weizmann scientists to be named as co-inventors. Yeda claimed that the relevant practical work using the antibodies provided by Professor Schlessinger was carried out by the Weizmann scientists.

The application was made under section 37 of the Act using Form 2/77. About a year later, the Court of Appeal made its critical ruling in *Markem v Zipher*.

On the basis of the *Markem* judgment, Yeda applied to amend its Form 2/77 statement to refer to some other rule of law to establish its entitlement. Yeda also sought to allege that the Weizmann scientists were the sole inventors and that the European patent should be transferred into Yeda's sole name. The application for these amendments came after the two-year limitation period set out in section 37(5) of the Act.

The Comptroller allowed both sets of amendments, but they were disallowed on appeal by the High Court and Court of Appeal. Yeda made a final appeal to the House of Lords.

Outcome of the Case

Giving the Lords' leading judgment, Lord Hoffmann ruled as follows.

What does a person claiming entitlement have to prove?

Section 7(2) and (3) of the Act amount to an exhaustive code for determining who is entitled to the grant of a patent. The first step in any dispute over entitlement must be to decide who the inventor of the claimed invention was. A patent should be granted 'primarily to the inventor or joint inventors', who would be the 'actual deviser of the invention'. Therefore, if the invention was made by the Weizmann scientists, Yeda would be entitled to the invention on the basis that it was successor in title to a company with an enforceable right under a contract with the inventors to own the invention. Likewise, if the invention was discovered by Professor Schlessinger, RPR would be entitled.

Although Yeda had the burden (under section 7(4)) of proving sole inventorship, there was no justification for the rule in *Markem*. There was no need for Yeda to prove that Professor Schlessinger was in breach of some other rule of law, as the statute did not require anything more than proof of inventorship. The first set of amendments sought by Yeda was unnecessary.

The discretion to allow a transfer of the patent enables the Comptroller to consider factors such as delay on the applicant's part or the hardship of any RPR licensees. These factors do not affect inventorship, which is to be determined solely under the provisions of section 7.

After expiry of the two-year limitation period, could Yeda amend its claim for joint entitlement to one for sole entitlement?

The High Court judgment found that the application amounted to a new cause of action after the expiry of the limitation period. This decision was based, at least in part, on the wording of the Community Patent Convention (which has never come into force) and the finding was supported by the Court of Appeal. The House of Lords in contrast held that no inference could be drawn that a claim to sole entitlement was a different right to a claim to joint entitlement.

The potentially different consequences for licensees did not take the Lords beyond this finding to justify a conclusion that part and sole entitlement should be regarded as different rights.

The commencement of proceedings under section 37(1) ('a reference') was not analogous to the issue of a claim form under CPR 16.2. Yeda was not asserting a cause of action in the sense contemplated by the Limitation Act 1980 or the Civil Procedure Rules. All that the Patent Rules require is that the person making the reference identifies the statutory provision under which the reference is made. Yeda identified sections 37(1)(a) and 37(1)(c) (who is or are the true proprietor or proprietors of the patent and whether any right in or under the patent should be transferred or granted to any other person or persons). These questions cover both sole and joint proprietorship and therefore the amendment of the statement of facts would not make the reference a new reference.

Rule 100 of the Patent Rules 1995 gave the Comptroller a very broad discretion to allow Yeda to amend its statement. The question of entitlement was already before a Hearing Officer and it was difficult to see how such an amendment could be seen as a different reference. The Hearing Officer was entitled to decide that it would cause no prejudice to RPR if Yeda was allowed to assert full entitlement. The decision of the Hearing Officer to this effect was restored.

Comment

The additional rule in *Markem* was subject to much questioning by patent practitioners and the House of Lords' sensible approach to its abolition is welcome.

The House of Lords has confirmed that the question of entitlement is based on identifying the inventor. He or she is primarily entitled to the patent. In some cases under section 7(2)(b) other persons are entitled to the patent, namely employers where the invention is made by an employee, or a company where the invention is created by a contractor working for it and the agreement between them provides that all inventions made by the contractor are owned by the commissioning company. In *Markem*, the Court of Appeal held that breach of confidence was another such rule of law, but Lord Walker in *Yeda* pointed out that breach of confidence is not a basis for entitlement. If party A, the true inventor, discloses his invention to party B under obligations of confidence and party B files a patent application in breach of such obligations, then the reason why party B is not entitled to the patent is, quite simply, because party B is not the inventor. The issue can be decided straightforwardly under section 7(1) of the Act without any recourse to the law of confidence.

Finally, the House of Lords commented that automatic grant of the right to a patent to the inventor in entitlement proceedings could be unfair to the patentee who applied for the patent believing he was entitled to do so and had placed reliance on this belief. The House of Lords identified that the solution to this problem lay in the broad discretion of the Comptroller as to what order to make as a result of an entitlement finding. The Comptroller is entitled to consider issues as wide as equitable proprietary estoppel in determining the order to be made.

Box 1

The statutory rules of entitlement are set out in section 7 of the Patents Act 1977 as follows:

7. (1) Any person may make an application for a patent either alone or jointly with another.
- (2) A patent for an invention may be granted –
 - (a) primarily to the inventor or joint inventors;
 - (b) in preference to the foregoing, to any person or persons who, by virtue of any enactment or rule of law, or any foreign law or treaty or international convention, or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was or were at the time of the making of the invention entitled to the whole of the property in it (other than equitable interests) in the United Kingdom;
 - (c) in any event, to the successor or successors in title of any person or persons mentioned in paragraph (a) or (b) above or any person so mentioned and the successor or successors in title of another person so mentioned; and to no other person.
- (3) In this Act 'inventor' in relation to an invention means the actual deviser of the invention and 'joint inventor' shall be construed accordingly.
- (4) Except so far as the contrary is established, a person who makes an application for a patent shall be taken to be the person who is entitled under subsection (2) above to be granted a patent and two or more persons who make such an application jointly shall be taken to be the persons so entitled.

Box 2

Section 37:

- (1) After a patent has been granted for an invention any person having or claiming a proprietary interest in or under the patent may refer to the Comptroller the question –
 - (a) who is or are the true proprietor or proprietors of the patent,
 - (b) whether the patent should have been granted to the person or persons to whom it was granted, or
 - (c) whether any right in or under the patent should be transferred or granted to any other person or persons;and the Comptroller shall determine the question and make such order as he thinks fit to give effect to the determination.
- (2) Without prejudice to the generality of subsection (1) above, an order under that subsection may contain provision –
 - (a) directing that the person by whom the reference is made under that subsection shall be included (whether or not to the exclusion of any other person) among the persons registered as proprietors of the patent;
 - (b) directing the registration of a transaction, instrument or event by virtue of which that person has acquired any right in or under the patent;
 - (c) granting any licence or other right in or under the patent;
 - (d) directing the proprietor of the patent or any person having any right in or under the patent to do anything specified in the order as necessary to carry out the other provisions of the order.
- (4) Where the Comptroller finds on a reference under this section that the patent was granted to a person not entitled to be granted that patent (whether alone or with other persons) and on application made under section 72 below makes an order on that ground for the conditional or unconditional revocation of the patent, the Comptroller may order that the person by whom the application was made or his successor in title may, subject to section 76 below, make a new application for a patent –
 - (a) in the case of unconditional revocation, for the whole of the matter comprised in the specification of that patent; and
 - (b) in the case of conditional revocation, for the matter which in the opinion of the Comptroller should be excluded from that specification by amendment under section 75 below;and where such new application is made, it shall be treated as having been filed on the date of filing the application for the patent to which the reference relates.
- (5) On any such reference no order shall be made under this section transferring the patent to which the reference relates on the ground that the patent was granted to a person not so entitled, and no order shall be made under subsection (4) above on that ground, *if the reference was made after the end of the period of two years beginning with the date of the grant*, unless it is shown that any person registered as a proprietor of the patent knew at the time of the grant or, as the case may be, of the transfer of the patent to him that he was not entitled to the patent.