

Negotiating International R&D and Technology Transfer Agreements - IPRs, Valuation and Dispute Resolution

“Co-Ownership, Consequences for Breach of Contract and Dispute Resolution – an English law perspective”



WIPO / KOWI
November 12 , 2010, Brussels

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Relevant Provisions of the European Patent Convention [EPC]

- **Entitlement to file a European patent application: Art. 58 EPC**

An EP application may be filed by any natural or legal person, or anybody equivalent to a legal person by virtue of the law governing it.

- **Multiple applicants: Art. 59 EPC**

An EP application may also be filed either by joint applicants or by two or more applicants designating different Contracting States.

Relevant Provisions of the European Patent Convention [EPC] (2)

- **Right to a European patent: Art. 60 EPC**
 - The right to an EP may belong to the inventor or his successor in title.
 - If the inventor is an employee the right to the EP shall be determined in accordance with the law of the State in which the employee is mainly employed.
 - If the State in which the employee is mainly employed cannot be determined, the law to be applied shall be that of the State in which the employer has his place of business to which the employee is attached.
 - If two or more persons have made an invention independently of each other, the right to the EP shall belong to the person whose EP application has the earlier date of filing.

Relevant Provisions of the European Patent Convention [EPC] (3)

- **EP applications by persons not having the right to an EP:
Art. 61 EPC**

Where there has been a successful challenge to the right to an EP, the successful challenger may within 3 months from the decision in his favour - provided the EP has not been granted - in those designated Contracting States in which the decision has been taken or recognised

- prosecute the application as his own application in place of the applicant;
- file a new EP application in respect of the same invention; or
- request that the application be refused.

Relevant Provisions of the European Patent Convention [EPC] (4)

- **Right of the inventor to be mentioned: Art. 62 EPC**

The inventor shall have the right, vis-a-vis the applicant for or proprietor of an EP, to be mentioned as such before the European Patent Office [EPO].

- **Rights conferred by an EP: Art. 64 EPC**

- Subject to below, an EP shall confer on its proprietor from the date of publication of the mention of its grant, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State.

- If the subject matter of the EP is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.

- Any infringement of an EP shall be dealt with by national law.

Relevant Provisions of the European Patent Convention [EPC] (5)

- **Law applicable: Art. 74 EPC**

The EP application as an object of property shall, in each designated Contracting State and with effect for such State, be subject to the law applicable in that State to national patent applications.

Relevant Provisions of the European Patent Convention [EPC] (6)

■ **The laws of the designated Contracting States**

An EP, although centrally granted, issues as a bundle of national patents for the designated Contracting States. Consequently, the national court (applying its own laws and procedures) shall determine the following:

- disputes between persons as to who has actually made the invention; i.e. who is entitled to the patent;
- who, as between an employee and his employer, is entitled to ownership of the patent;
- infringement of the patent;
- other than the post grant EPO opposition and appeal procedure, validity of the patent;
- dealing with the patent, for example by assignment or licensing or otherwise by contract.

Entitlement Disputes under the United Kingdom Patents Act 1977 (as amended)

- **The person(s) entitled**
 - The person entitled shall be the inventor or joint inventors.
 - That is subject to any contract between the inventor(s) and or a third party [for example, an employment contract] whereunder the third party has become entitled.
 - “Inventor” means the actual deviser of the invention.

Entitlement Disputes under the United Kingdom Patents Act 1977 (as amended) (2)

- **Determination of entitlement pre-grant: section 8**
 - At any time before grant any person may claim entitlement, or joint entitlement and such claim is decided by the UK Intellectual Property Office.
- **The Comptroller may**
 - order that the application shall proceed in the name of the challenger, either solely or jointly with that of any other applicant, instead of in the name of the applicant;
 - where the challenge was made by two or more persons, order that the application shall proceed in all their names jointly;
 - refuse to grant a patent on the application or order the application to be amended so as to exclude any of the matters in respect of which the question was referred;
 - make an order transferring or granting any license or other right in or under the application.

Entitlement Disputes under the United Kingdom Patents Act 1977 (as amended) (3)

- **Licenses granted under the application; section 11**
 - Where the application proceeds in the name of one of the original applicants, existing licenses remain in place.
 - But, if the original applicant is replaced by, the challenger, existing licenses lapse.
 - If the original applicant or his licensee made *bona fide* effective and serious preparations to work the invention before an order replacing the original applicant by the challenger as the person entitled to the patent, they shall be entitled to a non-exclusive license to continue to work the invention, such license to be granted for a reasonable period and on reasonable terms. The Comptroller shall be the arbiter of what constitutes a reasonable period and reasonable terms.

Entitlement Disputes under the United Kingdom Patents Act 1977 (as amended) (4)

- **Determination of entitlement post grant; section 37**
 - The powers of the Comptroller mirror those in relation to pre-grant challenges.
 - But, a challenge to entitlement will be time barred if not brought within 2 years from the date of grant of the patent.
 - The exception to that 2 year limitation period is where the challenger can show that the person registered as proprietor knew at the time of the grant that he was **not** entitled to the patent.
 - The same provisions for existing licensees apply (under s. 38) as apply for pre-grant challenges (under s. 11 above)

Entitlement Disputes under the United Kingdom Patents Act 1977 (as amended) (5)

- **Co-Ownership of patents: section 36**

- subject to any agreement to the contrary, each co-owner shall be entitled to an equal undivided share in the patent.
- Again, subject to any agreement to the contrary, each co-owner shall be entitled to work the invention.
- **But**, the consent of all co-owners is required for
 - any amendment to the patent, or
 - granting a license, or
 - assigning or mortgaging a share in the patent.
- A third party supplying one of the co-owners with an essential element for putting the invention into effect shall not thereby infringe the patent.
- One of co-owners may sue for infringement. **But**, if the other co-owner(s) does not join as co-claimant / plaintiff, such other co-owner(s) shall be made a defendant.

Entitlement Disputes under the United Kingdom Patents Act 1977 (as amended) (6)

- **A twist on co-ownership: the employee inventor's right to compensation: sections 40 – 41**
 - In common with law of many EP Contracting States, the United Kingdom provides that, even where by terms of employment an employee invention belongs to the employer, the employee may (in certain circumstances) apply for compensation additional to his regular remuneration.
 - To qualify for such compensation the following must apply
 - the employee has made an invention for which a patent has been granted;
 - having regard, *inter alia*, to the size and nature of the employer's undertaking, the invention or the patent for it (or the combination of both) is of outstanding benefit to the employer; and
 - by reason of those facts, it is just that the employee should be awarded compensation by the employer

Entitlement disputes under the United Kingdom Patents Act 1977 (as amended) (7)

- When assessing the fair share to be paid to the employee, the following factors are taken into account;
 - 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;
 - the effort and skill which the employee has devoted to making the invention;
 - 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; and
 - the contribution made by the employer to the making, development 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.

A case study of entitlement: the ERBITUX case [*Yeda v Rhone Poulenc Rorer and ImClone, Incorporated* [2007] UKL 43]

■ **The Facts**

- The patent claims related to the billion dollar a year treatment for colorectal cancer, ERBITUX. This is sold in the Americas by ImClone [now, a subsidiary of Eli Lilly] and in Europe by Merck KGaA of Darmstadt.
- The patent claims a combination of a novel monoclonal antibody [cetuximab] with a known anti-neoplastic agent [irinotecan].
- The antibody was discovered by Schlessinger, an eminent researcher in the anti-cancer field. He was employed at the time by Meloy a subsidiary of Rhone Poulenc Rorer, now Sanofi-Aventis.
- Schlessinger was a former Professor at The Weizmann Institute in Israel. Yeda is the licensing arm of The Weizmann

A case study of entitlement: the ERBITUX case [*Yeda v Rhone Poulenc Rorer and ImClone, Incorporated* [2007] UKL 43] (2)

- When the antibody showed promise *in vitro*, Schlessinger sent it to his former colleagues at The Weizmann for trials *in vivo* in mice. Schelssinger was aware that they had well established animal tests.
- When the *in vivo* tests reported looked promising, Schlessinger / Meloy filed a patent application, which granted in the United States, Europe, Japan and elsewhere.
- RPR did not pursue research in that field and licensed the patent to ImClone.
- ImClone developed the product, which eventually obtained FDA and EMEA approval and became a billion dollar drug.
- Weizmann / Yeda then brought entitlement proceedings claiming sole ownership / entitlement, alternatively joint ownership / entitlement.

A case study of entitlement: the ERBITUX case [*Yeda v Rhone Poulenc Rorer and ImClone, Incorporated* [2007] UKL 43] (3)

- Cases were filed in the Southern District Court for the District of New York: London: Paris: Munich and Vienna. Yeda then sought to extend the case filed in Paris to cover the remaining 9 designated European Contracting States where Yeda was time barred by reason of failing to file an entitlement claim within either 2 or 3 years (depending on the country).
- In New York, Yeda succeeded in gaining sole ownership of the US patent. That judgment was on appeal when the litigation settled worldwide.
- None of the European cases reached trial before settlement. However, in Munich Yeda's claim was restricted to one of joint ownership. In the United Kingdom a preliminary pleading issue went through 3 courts until it reached the House of Lords (now, the Supreme Court) in 2006.

A case study of entitlement: the ERBITUX case [*Yeda v Rhone Poulenc Rorer and ImClone, Incorporated* [2007] UKL 43] (4)

- Prior to settlement, the Court of Appeals for the Federal Circuit in Washington DC mandated mediation. A 3 day mediation involving the three parties in Paris failed to produce agreement but did set in motion a dialogue which produced settlement some 8 months later.
- To complete the picture, the European entitlement cases caused stay of EPO opposition proceedings brought by Amgen and other parties.
- Finally, SPCs were obtained in a number of designated Contracting States. However, the SPC in The Netherlands was eventually rejected by the Dutch Supreme Court. The English High Court in October 2010 referred questions to the Court of Justice in Luxembourg in relation to the UK SPC application.

A case study of entitlement: the ERBITUX case [*Yeda v Rhone Poulenc Rorer and ImClone, Incorporated* [2007] UKL 43] (5)

■ What did the House of Lords say?

- Who is the “actual deviser of the Invention”?
 - It means the actual person who came up with the inventive concept.
 - It is not enough that someone contributed to the claims, because they may include non-patentable integers derived from the prior art.
 - The contribution must be to the formulation of the inventive concept.
 - Consequently, deciding upon inventorship will involve assessing the evidence adduced by the parties as to (1) the nature of the inventive concept and (2) who contributed to it.

A case study of entitlement: the ERBITUX case [*Yeda v Rhone Poulenc Rorer and ImClone, Incorporated* [2007] UKL 43] (6)

- The person who seeks to be added as a joint inventor bears the burden of proving that he contributed to the inventive concept underlying the claimed invention.
- The person who seeks to be substituted as sole inventor bears the additional burden of proving that the inventor named in the patent did not contribute to the inventive concept.
- There is no rule by which a former employer (here, The Weizmann) can claim entitlement to an invention made after that employee has left his employment simply because he has used the knowledge of prior art which he gained with them and has included some of that prior art in his claims.
- Entitlement to a patent should not be confused with the validity of a patent. Novelty only comes into play where two people independently make the same invention. The first to file prevails. This is subject to whether A communicated information to B in confidence, but B was the first to file a patent application using A's confidential information.

A case study on employee compensation *Kelly v GE Healthcare Ltd* [2009] EWHC Civ. 181 (Pat.)

■ The Facts

- The patent related to a radio-active heart imaging agent, sold by Amersham (now, GE Healthcare) under the trademark MYOVIEW.
- The judge put a value of £50 million on the patents.
- Based on that valuation of £50 million, the two inventors were awarded additional compensation of £1.5 million between them.

A case study on employee compensation *Kelly v GE Healthcare Ltd* [2009] EWHC Civ. 181 (Pat.) (2)

- **The factors the Judge took into account**

- The patents were of outstanding benefit to Amersham. The total R&D costs for development of MYOVIEW were £2,414,000.00. By comparison, the first year's sales in 1996 were £4,473,000.00, producing a gross margin of £4,205,000.00.

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

- Dr Kelly was a senior Research, Scientist in charge of extra mural research [EMR] a pioneer group at Amersham aimed a work relevant to current R&D goals within the Company **but** going beyond the scope of current in-house activities. He was later appointed Manager of the Pharmaceuticals R&D Division of Amersham. Amersham was at the time behind DuPont in the race to produce a Technetium agent for heart imaging.

- Dr Chiu was a research scientist working with Dr Kelly. The total time he was employed at Amersham was just over 2 years.

A case study on employee compensation *Kelly v GE Healthcare Ltd* [2009] EWHC Civ. 181 (Pat.) (3)

- The patents did not expire until 2008 and the revenue from MYOVIEW – described as a blockbuster radio pharmaceutical – enabled Amersham to expend and acquire other businesses.
- Amersham argued for an *ex ante* approach to calculating the value of the invention. Namely, to calculate its worth at the point when the inventors ceased to make a contribution and the Company took over commercialisation. This approach, which valued the patents at £7.63 million was rejected by the Judge.

A case study on employee compensation *Kelly v GE Healthcare Ltd* [2009] EWHC Civ. 181 (Pat.) (4)

- The inventors argued for an *ex post* approach, in which a royalty is negotiated on the basis of an established product. This calculation put a value of £700 million on the patents, two orders of magnitude greater than Amersham's *ex ante* approach! The Judge also rejected this approach.
- Overall sales of MYOVIEW up to 2007 exceeded £1.3 billion. The Judge attributed £50 million “as the absolute rock bottom for the benefit from the patents”. He went on to say:

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”.
- At the relevant time (1987 – 1989) Dr Kelly's remuneration was between £23m and £27m p.a.
- Dr Chiu was paid between £12K and £15K p.a.

A case study on employee compensation *Kelly v GE Healthcare Ltd* [2009] EWHC Civ. 181 (Pat.) (5)

- Dr Kelly's success with the invention led to promotions within Amersham. By the date of his retirement in 2003 his annual salary was £71.5K, he received a pension of £34K p.a., and he also received *ex gratia* payments on retirement totalling £167.5K.
- The Judge found that the effort and skill contributed by Drs Kelly and Chiu exceeded those which would normally be expected from research scientists in their respective positions.
- The contribution from the 3 other co-inventors – two from academia – were also taken into account by the Judge.
- The Judge also took into account the resource committed by Amersham downstream to developing the invention into a blockbuster radio pharmaceutical and the risk inherent in the industry balancing the successful with the unsuccessful products.

A case study on employee compensation *Kelly v GE Healthcare Ltd* [2009] EWHC Civ. 181 (Pat.) (6)

- Amersham contended that fair compensation should be £100K to Dr Kelly and £60K to Dr Chiu.
- The Judge chose 5% of the value of the benefit from the patents [£50 million] as appropriate for the two claimant inventors, which he described as “a very conservative figure”.
- He then divided that as to 2% to Dr Kelly [£1 million] and 1% to Dr Chiu [£500K]. That sum represented about 0.1% of turnover.

Court v Arbitration / Mediation

- **Disputes between potential co-owners as to entitlement**
 - Unless one court is able to adjudicate entitlement at the pre-grant stage, the risk is that the parties will find themselves in a multi-jurisdiction litigation with absolutely no guarantee that each Court will reach the same conclusion. The options are (i) the challenger's claim totally fails; (ii) the challenger succeeds in becoming a co-owner with the applicant / registered proprietor; (iii) the challenger succeeds in becoming the sole owner; or (iv) the ownership does not change but the claims are amended to remove the contribution made by the challenger.
 - What happens to the innocent third party Licensee, who may – as in the ImClone ERBITUX case – have made a massive investment in developing a commercial product based on the patent? Again, different national courts may produce different results.

Court v Arbitration / Mediation (2)

- How long will the multi-jurisdiction litigation take to resolve? In the ImClone ERBITUX case, 3 years to a First Instance decision in the US but in Europe not one claim even had a trial date appointed after 3½ years of procedural decisions. As it was, settlement was only reached less than 3 years before patent term expiry, subject to Supplementary Protection Certificates which – as noted – were not obtained in all Contracting States.
- So, we have uncertainty of outcome with potentially incompatible decisions, years of litigation in a fiercely competitive market where the blockbuster of one year can easily be supplanted by a competitor product overnight, very significant legal costs, considerable in-house resource tied up and the reputations of world-class scientists on public display.

Court v Arbitration / Mediation (3)

- **Is there an alternative?**

First stop, mediation. What is lost if unsuccessful? Four to six weeks and modest legal fees. The upside is the potential of a speedy and interest-based solution for all parties. **And**, if unsuccessful, arbitration. Private / confidential, expeditious; no appeal; award enforceable in the 144 New York Convention countries; dramatically less costly than multi-jurisdiction litigation and a panel of arbitrators with relevant IP / technical experience vs preponderantly, non-specialist national court judges.

- **The mechanics**

Always use an experienced administering authority and Rules appropriate to the subject matter of the dispute. The WIPO Mediation and Arbitration Center provides both

- ***Co-ownership / Entitlement: is it a real issue?***

In recent years, entitlement disputes have suddenly mushroomed. As Jacob L.J. said in the *IDA v University of Southampton* case in 2006:

“No one really knew why this jurisdiction (which in my time at the Bar was moribund) has recently come alive.”

Court vs Arbitration / Mediation (4)

After then suggesting possible reasons, for example, increases in joint ventures and in the appreciation of the significance of patents, he went on to conclude:

“This sort of dispute is particularly apt for early mediation. Such mediation could well go beyond conventional mediation (where the mediator facilitates a consensual agreement). I have in mind the process called “MedArb” where a “mediator” trusted by both sides is given the authority to decide the terms of a binding settlement agreement.”

- As an illustration of the recent rash of entitlement cases, set out below are recent United Kingdom reported decisions in addition to the ImClone “case study” already summarised.

Court vs Arbitration / Mediation (5)

- ***IDA Ltd et al v. University of Southampton* [2006] EWCA Civ. 145**
Patent for a cockroach trap filed by the University. Held, sole ownership by the Claimant, IDA Ltd.
- ***Statoil ASA v University of Southampton* [BL 0/24/05]**
Patent relating to a technique for subsea oil exploration filed by the University. Held, sole ownership by the Claimant, Statoil.
- ***Markem Corporation v Zipher Ltd* [2005] EWCA Civ. 267**
Patents relating to thermal transfer printing obtained by former Markem employees and filed in the name of the Defendant, Zipher. Judgment for Zipher.
- ***Cinpres Gas Injection Ltd v Melea Ltd* [2008] EWCA Civ. 9**
Patent related to a method for making hollow plastic containers by former employee of Cinpres. Judgment for Cinpres.

Court vs Arbitration / Mediation (6)

- **Employee compensation: another candidate for mediation / arbitration**

In the GE Healthcare case, Sir Richard Sykes – the former CEO of GlaxoSmithKline – gave evidence for the defendant deprecating the threat which employee compensation claims raises in R&D industries, such as those in the life sciences / pharmaceutical area. His views were not adopted by the Court.

Again, perhaps a clear indicator as to why an ADR approach should be considered for disputes of this nature.