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Recent developments in patent law

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Pierre-André Dubois and Catherine Schreier Kirkland & Ellis International LLP

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Recent developments in patent law

The past year has seen some key legal developments in the patent field. In the first-ever UK decision on this issue, the High Court ruled on the employee compensation scheme for patented inventions under the Patents Act 1977, resulting in a successful claim by two employees against their former employer. The House of Lords (replaced since October 1 2009 by the Supreme Court) clarified the applicable law as to insufficiency, the subject of its earlier ruling in *Biogen*. Finally, the Court of Appeal considered the criteria to apply to a commercial success defence when dealing with an attack based on obviousness.

Compensation for employee inventions

In *Kelly v GE Healthcare*, the High Court made an award of £1.5 million in compensation to two former employees of GE Healthcare under Section 40 of the Patents Act. This was the first time such a claim has made it to the High Court.

Section 40 of the Patents Act provides that an employee may seek compensation if:

- the employee has made an invention belonging to the employer for which a patent has been granted;
- having regard to, among other things, the size and nature of the employer's business, 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 to be paid by the employer.

The two claimants had been employed as research scientists at Amersham International plc (which then became GE Healthcare). The case concerned two patent families relating to a compound forming part of a radioactive imaging agent that became a highly successful product for GE Healthcare. The court concluded that the following rules should apply in deciding a claim under Section 40 and assessing whether an invention has been of outstanding benefit to the employer:

- The patent, and not the invention protected thereby, must be of outstanding benefit (however, the Patents Act has since been amended so as to make compensation payable when the invention and not just the patent has been of outstanding benefit. This amendment applies only to inventions made after January 2005).
- Compensation can be available only to actual inventors, not to those who merely contribute to the invention.
- There is no definition of 'outstanding benefit' in the Patents Act. However, the word 'outstanding' denotes something special and requires the benefit to the employer to be more than substantial or good. This benefit is more than what would be expected through remuneration for the employee's employment.
- In order to assess such benefit, it is necessary to compare what 'would have been' as opposed to 'what was'. That is, the court should try to form an estimate of how the employer would have fared in the absence of the patented invention (or now, the invention).
- The correct question for the court to ask itself is whether the patent in question was a cause of the benefit in question and, if this is the case and there is a direct causal relationship, how much of that benefit can be attributed to the patent (or now, the invention).
- If these factors have been satisfied, the court must still assess whether it would be just to award compensation. This will be a question of fact in each case.

The court concluded that the patents had been of outstanding benefit to GE Healthcare. First and foremost, the patents had protected GE Healthcare's business against generic competition and reduced profits after the expiry of regulatory data exclusivity. The court considered that without the patents, the threat from generic entry would have been "a crisis" for GE Healthcare. In addition, the fact that GE Healthcare

had a patented 'blockbuster radiopharmaceutical' was a major factor in achieving successful corporate deals and resulting profits over the years. The evidence showed that GE Healthcare's total sales of patented radiopharmaceuticals between 2002 and 2007 amounted to some £1 billion. The court noted the difficulties in apportioning the value of the benefit of the patents, but determined that the "absolute rock bottom figure for the benefit from the patents" to GE Healthcare was £50 million. On that basis, in principle the share due to the inventors could be anything from nil to 33 per cent and beyond. Taking into account the level of remuneration already paid to the employees, the effort and skill devoted by the employees to making the invention, and the contributions made by others and by the employer itself to making, developing and working the invention, the court awarded the claimants 2 per cent (£1 million) and 1 per cent (£500,000) respectively.

Whether the decision will open the floodgates for claims for compensation remains to be seen. However, it is clear that employers have to acknowledge this risk and attempt to mitigate it through their research and development policies, favourable employment terms and constant monitoring of the value and benefits of their patent and invention portfolio. Further, in the context of mergers and acquisitions, investment deals or licensing agreements, purchasers, investors and licensees should carefully conduct due diligence with respect to possible compensation claims and assess any potential material expense.

Insufficiency: *Biogen* revisited

In *Biogen Inc v Medeva plc*, decided in 1997, the House of Lords reached a key decision on insufficiency. In that case, which dealt with a claim for a DNA molecule defining the product partly by what it did and partly by the way it had been made, with only one method of making the product described, the House of Lords held that a claim for a class of products was properly enabled only if a skilled person could work the invention in respect of all members of the class. Otherwise, the patent was invalid for insufficiency.

In 2009, the House of Lords revisited the *Biogen* insufficiency rule in *Generics v H Lundbeck A/S*. The case concerned a claim to a product patent owned by H Lundbeck A/S. The patent was for the (+) enantiomer of escitalopram, an anti-depressant compound which is a combination of two types of molecule. Prior to the Lundbeck patent, it was not known how to separate the (+) and (-) enantiomers of citalopram; however, once Lundbeck devised a means of separating the enantiomers, it was discovered that it was the (+) enantiomer which has the desired anti-depressant effect, and that the (-) enantiomer actually inhibited the therapeutic effect. It was accepted that Lundbeck was entitled to patent protection for the process that it had discovered to separate the (+) and (-) enantiomers of citalopram. The dispute surrounded the sufficiency of the patent to cover escitalopram as a product.

At first instance, the trial judge rejected the attack on the patent by Generics for lack of novelty and obviousness, but agreed with the attack based on insufficiency. The trial judge reasoned that a patent that effectively covered all ways of making a product would be disproportionate and said: "The first person to find a way of achieving an obviously desirable goal is not permitted to monopolise every other way of doing so."

On appeal, the Court of Appeal held that the trial judge had misinterpreted the rule in *Biogen*. The court held that the *Biogen* insufficiency principle was not applicable in this case as the claims here were to a single product not defined by a class of processes of manufacture. The trial judge had extracted too broad a principle from *Biogen*, which dealt not with a simple product claim but with a 'product-by-process' claim, and in fact a claim to a wide class of such products.

The House of Lords heard the case on further appeal from Generics. In a unanimous decision the appeal was dismissed. The court agreed with the Court of Appeal that the trial judge had made a mistake in equating the "relevant technical contribution" with the patent's "inventive concept" (the process of making the product), and confirmed there was a distinction between the two. It agreed that, when considering the validity of a simple product claim, as here, it may be that concentrating on identifying the inventive step rather than the technical contribution can lead to error. As this was a simple product claim, the trial judge should have found that the novel and non-obvious enantiomer in itself was the technical contribution and not how it had been done. If the claim was for a process or (as in *Biogen*) included a process, the issue of how the alleged invention has been achieved was relevant.

Generics had contended that where a product was a known desideratum, the first person to make it could rely on the method of making it as support for a claim to that process, but not for a claim to a product. The court disagreed. The court acknowledged that although this meant that by finding one method of making a product, a person can obtain a monopoly for that product, this would be the case with any product claim; the fact that the claim related to a pharmaceutical compound should be no different.

This decision could have a far-reaching impact on the

pharmaceutical industry and allow more patents to survive challenges based on insufficiency. However, although this decision clarifies that it does not apply to simple product claims, the breadth of claims in between (ie, not a 'process-by-product-by-process' claim) still leaves room for uncertainty as to when the *Biogen* insufficiency rule will apply.

Commercial success in determining obviousness

Proving commercial success is often an element of a defence to an attack based on obviousness. In *Aerotel Limited v Wavecrest Group Enterprises Limited*, a case dealing with a patent for a system for making pre-paid telephone calls, the Court of Appeal provided useful guidance on what will be sufficient to establish commercial success.

Aerotel sued Wavecrest for infringement and Wavecrest countersued for revocation on numerous grounds, including obviousness. At trial, the court held that the patent was invalid for obviousness. Aerotel appealed against this finding on a number of grounds, including failure by the trial judge to consider the commercial success of the invention.

The Court of Appeal stated that commercial success "can indeed be a powerful indication of non-obviousness if it is shown that the alleged invention has led to commercial success". The question "why was it not done before?" is compelling if there is no adequate answer (eg, that the cited prior art is only just before the priority date, or that the success is due to marketing). However, the counter-question to this, "why was it not done after?", must also be asked. In this case, the court found that the answer should be "when the invention was made known absolutely nothing happened".

First, Aerotel made money principally by litigation and the threat of litigation against users. In considering the licences as evidence of commercial success, the court saw no reason why these licences were not entered into by third parties other than in contemplation of the considerable downside risk they would avoid from doing so. Second, although Aerotel could point to an increasing business in pre-payment telephone cards starting in 1994, it had failed to show that this was due to the potential inventions as many other factors may have influenced this.

The evidential burden lies with the patentee to prove that success of a product is down to its invention. The court stated: "If a patentee seeks to rebut an allegation of obviousness by an assertion of commercial success of his invention, it is down to him to prove that the success is due to the invention. Where a number of other factors may explain the success, unless he can show they were irrelevant or largely so, he will not have proved what he needs."

The court's conclusions of what needs to be proven for a finding of commercial success to save what would otherwise have been an obvious patent shows that it will continue to be rare for this to occur. It will need to be shown not only that the development of the subject of a patent has been commercially successful, but further that such commercial success is directly attributable to the technical merits of the development. A further point to note from this decision is that patent trolls with weak patents should be wary of the United Kingdom as a sympathetic venue, especially if the patentee is looking to prove commercial success through its licensing income stream.

Pierre-André Dubois
Partner, London
Tel +44 20 7469 2020
Email pierre.dubois@kirkland.com
Kirkland & Ellis International LLP
United Kingdom

Pierre-André Dubois heads the firm's UK and EU IP and competition group. He obtained a LLB (first class honours) in civil and common law from the University of Montreal in 1984. His practice covers all aspects of IP and IT law, as well as UK and EU competition law. PLC *Which Lawyer? Global 50* has named him as a leading lawyer every year since 2005, and he was named a leading lawyer by the *Legal 500* (UK edition 2003) and *Global Corporate Counsel* (2002).

Catherine Schreier
Associate, London
Tel +44 20 7469 2145
Email catherine.schreier@kirkland.com
Kirkland & Ellis International LLP
United Kingdom

Catherine Schreier is an IP associate in the London office of Kirkland & Ellis International LLP. She handles contentious and non-contentious IP and IT work. Her experience includes copyrights, design rights, trademarks, patents and data protection.

Kirkland & Ellis International LLP
30 St Mary Axe, London, EC3A 8AF,
United Kingdom
Tel +44 20 7469 2000
Fax +44 20 7469 2001
Web www.kirkland.com
Other offices Chicago, Hong Kong,
Los Angeles, Munich, New York, Palo Alto,
San Francisco, Shanghai, Washington DC

KIRKLAND & ELLIS
INTERNATIONAL LLP