

Some Issues in Contributory Patent Infringement in the EU & Bird & Bird

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Section 60(2) Patents Act 1977

- 60(2) Subject to the following provisions of this section,
 - a person (other than the proprietor of the patent) also infringes a patent for an invention if,
 - while the patent is in force and without the consent of the proprietor,
 - he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention
 - with any of the means,
 - relating to an essential element of the invention,
 - for putting the invention into effect
 - when he knows, or it is obvious to a reasonable person in the circumstances,
 - that those means are suitable for putting,
 - and are intended to put,
 - the invention into effect in the United Kingdom.
- Based, as with corresponding provisions elsewhere in Europe, on Article 26 CPC

Sections 60(3) and (6) Patents Act 1977

- 60 (3) Subsection (2) above shall not apply to the
 - supply or offer of a staple commercial product
 - unless the supply or the offer is made for the purpose of inducing the person supplied or, as the case may be, the person to whom the offer is made to do an act which constitutes an infringement of the patent by virtue of subsection (1) above.
- 60(6) For the purposes of subsection (2) above a person who does an act in relation to an invention which is prevented only by virtue of paragraph
 - (a)[done privately and for purposes which are not commercial],
 - (b)[done for experimental purposes relating to the subject matter of the invention] or
 - (c) [extemporaneous preparation in a pharmacy of a medicine ...]
 - of subsection (5) above from constituting an infringement of a patent for the invention
 - shall not be treated as a person entitled to work the invention, ...

Recent English case law on s 60(2) Patents Act 1977

- *Grimme v Scott* [2010] EWCA Civ 1110 as applied in *KCI Licensing Inc v Smith & Nephew plc* [2010] EWCA Civ 1260:
 - i) The required intention is to put the invention into effect. The question is what the supplier knows or ought to know about the intention of the person who is in a position to put the invention into effect – the person at the end of the supply chain.
 - ii) It is enough if the supplier knows (or it is obvious to a reasonable person in the circumstances) that some ultimate users will intend to use or adapt the “means” so as to infringe.
 - iii) There is no requirement that the intention of the individual ultimate user must be known to the defendant at the moment of the alleged infringement.
 - iv) Whilst it is the intention of the ultimate user which matters, a future intention of a future ultimate user is enough if that is what one would expect in all the circumstances.
 - v) ...

Recent English case law on s 60(2) Patents Act 1977

- *Grimme v Scott* [2010] EWCA Civ 1110 as applied in *KCI Licensing Inc v Smith & Nephew plc* [2010] EWCA Civ 1260:
 - i) – iv) ...
 - v) The knowledge and intention requirements are satisfied if, at the time of supply or offer to supply, the supplier knows, or it obvious to a reasonable person in the circumstances, that ultimate users will intend to put the invention into effect. This has to be proved on the usual standard of the balance of probabilities. It is not enough merely that the means are suitable for putting the invention into effect (for that is a separate requirement), but it is likely to be the case where the supplier proposes or recommends or even indicates the possibility of such use in his promotional material.

Recent English cases on s 60(2) Patents Act 1977

- *Grimme v Scott* [2010] EWCA Civ 1110 as applied in *KCI Licensing Inc v Smith & Nephew plc* [2010] EWCA Civ 1260:
 - Applying the above principles
 - There is no requirement that the ultimate users must have decided to use the means to put the invention into effect at the time they first take possession of the means. The relevant intention may be formed at a later time. But the supplier must know (or it must be obvious to him in all the circumstances) that some ultimate users will indeed form that intention.
 - Application of these principles to the facts as found by the judge at first instance and reversing him
 - S&N have infringed because it is probable that from time to time some medical personnel using the GO system have clamped the end of the inlet tube when changing the canister.
 - Further, it would have been obvious to a reasonable person supplying GO canisters that that this would be likely to occur.

Application to medical use patents

- Above case law developed in context of mechanical patents
- How does it apply to process claims in Swiss form and use bound product claims?
- “Carve out” or “Skinny labels” permitted under Article 11 Community Code for human medicinal products:
 - “For authorisations under Article 10, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.”
- Adapting the language of *KCI v S&N* in such a case can it be right to say:
 - [Supplier of a generic drug] have infringed because it is probable that from time to time some medical personnel using the [generic drug] have [used it for a patented indication that has been omitted from the summary of product characteristics for the generic drug].
 - Further, it would have been obvious to a reasonable person supplying [the generic drug] that that this would be likely to occur.
- Especially an issue for oncology products that are often used off label

Schering v Teva (Hague DC 10 November 2010)

- Only case in Europe to have addressed efficacy of skinny labels in enabling suppliers of generic drugs to avoid infringement
- But only discussed in a direct, rather than contributory, infringement context
- Schering Swiss form claims concerning (as summarised by the Court)
 - the use of ribavirin for the preparation of a pharmaceutical composition for the treatment of chronic hepatitis C infection for the combined therapy of ribavirin with (peg-)interferon alpha, in which it must concern a specific category of patients and a specific treatment period, i.e.:
 - a) naive patients,
 - b) with a HCV genotype 1 infection and with
 - c) a (high) viral burden of over 2 million copies per ml of serum, and this
 - d) for a treatment period of 40-50 weeks.
- Teva MA to ribavirin with carve out the effect of which is to exclude from scope of MA
 - a) naive patients and
 - b) patients known to be infected with HCV genotype 1

Schering v Teva (Hague DC 10 November 2010)

- Held
 - Teva MA with carve out covers no more than what is already implied in the prior art.
 - The MA permits Teva to provide generic ribavirin destined for use in a known combined therapy in a known dosage scheme of 6 or 12 months,
 - but excludes the patient category specifically claimed by Schering (naive and with genotype 1 infection).
 - Therefore no infringement
- But also observed that might be different
 - If evidence had been provided that because of the clinical study described elsewhere in the SmPC and the conclusion drawn therefrom Teva's generic ribavirin would be prescribed for naive patients with HCV genotype 1 infection.
- Also contributory infringement not explored

Schutz v Werit

● Facts

- Claim to cage, bottle and pallet
- Invention resides in cage
- Action against
 - Delta who replace bottles in Schutz cages (“cross-bottling”)
 - Werit who supply Delta with bottles

● First Instance

- Held no direct infringement by Delta by “making”
 - Considered, as to when repair infringed, UK HoL decision in *United Wire v Screen Repair Services* [2001] RPC 24 and DE BGH decisions X ZR 48/03 *Impeller Flow Meter*, X ZR 45/05 *Wheel Tread*, X ZR 38/06 *Pipette System*
 - Did what was left when part in issue was removed embody the whole inventive concept of the claim?
 - Here when bottle was removed the part retained (the cage) embodies the whole of the inventive concept.
- Contributory infringement by Werit not fully argued or decided
 - As if direct infringement then bottle likely to be “means essential”
 - Assumed that if no making then supply of bottles cannot have been “intended to put the invention into effect “

Schutz v Werit

- Court of Appeal [2011] EWCA Civ 303
 - Contributory infringement not in issue
 - Held direct infringement by Delta by making
 - Product as claimed “ceased to exist when bottle is removed” and “what remained at that stage was merely an important component from which a new product as claimed could be made.”
- Further decision of BGH as to corresponding cases in X ZR 97/11 *Pallet Container II*
 - Relevance of
 - Expectations as to what would be replaced during life of a product
 - Extent to which technical effects of invention are reflected in the replaced parts
 - Prevailing market opinion as to whether repair (non infringing) or remanufacture (infringing)
 - Disagreed with UK CoA as to relevance of Delta describing what they did as “remanufacture”

Schutz v Werit

- Supreme Court [2013] UKSC 16
 - Contributory infringement not in issue
 - Concession recorded at [13] that if Delta [directly] infringes then Werit does so [as a contributory infringer]
 - As to direct infringement by Delta by “making”
 - Thoroughly considered BGH X ZR 97/11 *Pallet Container II*
 - [78] “Deciding whether a particular activity involves “making” the patented article involves, ... an exercise in judgment, or, in Lord Hoffmann’s words, it is a matter of fact and degree. In some such cases, one can say that the answer is clear; in other cases, one can identify a single clinching factor. However, in this case, it appears to me that it is a classic example of identifying the various factors which apply on the particular facts, and, after weighing them all up, concluding, as a matter of judgment, whether the alleged infringer does or does not “make” the patented article.”
 - Held no direct infringement by Delta by “making”
 - [78] “... given that (a) the bottle (i) is a freestanding, replaceable component of the patented article, (ii) has no connection with the claimed inventive concept, (iii) has a much shorter life expectancy than the other, inventive, component, (iv) cannot be described as the main component of the article, and (b) apart from replacing it, Delta does no additional work to the article beyond routine repairs, ...”

Thank you **& Bird & Bird**

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