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Comments by John Richards Esq. of Ladas & Parry LLP

Ladas & Parry is an American law firm specializing in intellectual property law.

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There are a number of points in the survey of Overseas Experience contained in the Issues Paper on which I feel it is worthwhile making comments:

1) The pieces of equipment that were the subject of the decision in Madey v. Duke University in the United States were research tools (an electron gun and a laser oscillator) Allowing free use of such equipment would have destroyed the value of the patents since allowing Duke University to continue to use the equipment would have resulted virtually any one else wishing to use similar equipment "for research".

2.) The Japanese Supreme Court in Ono vs. Kyoto did not really need to use the experimental use exemption in Japanese law to reach its conclusion. Its basis was simply that once a patent expired the public should be free to obtain the claimed product so that steps during the life of the patent which facilitated this should be permitted in order that the patentee should not be allowed to extend its period of exclusivity. The Tokyo High Court decision which was reviewed by the Supreme Court had gone one step further with this line of reasoning taking the view that since the patentee was entitled to an extension of its patent term to compensate for delays in obtaining marketing approval before putting its product on the market, it would be granting the patentee two bites at the cherry to allow it to delay the attempts by a generic manufacturer to obtain its necessary marketing approval.

3) You state that Judge Fysh has indicated in an article that there isan implicit "and" between subsections (a) and (b) of Section 60 of the UK Patent Act. This was not the conclusion of the German Supreme Court in considering the same language in the German statute (in both countries the language derives from the proposed Community Patent Convention - Article 29 of the 1989 version). In Clinical Trials II the German Supreme Court concluded that to qualify under subsection (a) the use must not be commercial but that one could succeed with a defence under subsection (b) even if the use was commercial.[1998] RPC 423 at p. 433.

4) It is worth noting that in Monsanto v. Stauffer, the only trial that were enjoined were those carried out elsewhere than in the defendants green houses or on its own experimental farm. Both of the latter were permitted. Also in SKF v. Evans the court found that the exemption covers "acts done for experimental purposes including experiments with a commercial

end in view, but the purposes must relate to the claimed subject matter of the patent in suit in the sense of having a real and direct connection with that subject matter."

5) The point made at the end of the above quote from SKF ties in with the problem that the German Supreme Court had in reaching its conclusion in Clinical Trial I [1997] RPC 623 that a use testing a patented compound for new uses was an experimental use of the patented invention (as is required for the exemption to apply). It resolved the difficulty in concluding that where the invention was a new compound research into "the invention" could include any use of it since all such uses fell within the claim.

Turning now to your section "Formulating an Experimental Use Exemption", I have the following thoughts:

1) It may be desirable to draw a distinction between the situation where any permitted experimental use will effectively destroy the value of the invention to the original inventor (as may be the case when the patent is for a research tool) and where the experiments do not have this effect, for example as a result of their being into the basic science underlying the invention or in attempts to improve on it or even to assist in designing around the patented invention.

2) Although both Clinical Trials I in Germany and the SKF case in England tried to use the "research into the invention" rather than "research using the invention" test to achieve the objective set out in comment 1, the problems that the German Supreme Court experienced may indicate that the "into the invention" rather than "of the invention" distinction may not be the best way to achieve the objective.

3) Attempting to draw a distinction based on whether or not there are commercial overtones to the use is fraught with difficulty because, as Madey v. Duke made clear, almost everything can have a commercial overtone (In Madey the Federal Circuit found that good research at a university improves the image of the university and so encouraged applications and was therefore "commercial".

4) It seems very difficult to draw a clear line between what is "fair" to the patentee and what is in the best interests of society in promoting further research, which is after all the basic reason for the patent system. It seems therefore that the only viable approach is likely to be to give a trier of facts as to whether a use should be excused as being "experimental" guidelines that should be followed in order to make such a determination and trust that he or she will use good judgment in the application of them.

5) Three of the criteria used for judging fair use in copyright cases in the United States may provide a useful starting point for setting out such guidelines. They are:
a) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
(b) the nature of copyrighted work; and
(c) the effect of the use upon the potential market for or upon the value

of the copyrighted work.
Substitution of the words "patented invention" for"copyright work"
in this test would cover most of the issues that would need
to be considered when making an assessment of what should be permitted and, if it were felt desirable to provide for compensation to the owner of the patent for the experiments carried the basis on which such compensation should be awarded. The situation in which compensation might be appropriate are, however, those relating to research tools and provision of a compensation regime in this area is perilously close to deeming such inventions subject to compulsory licensing, which might be a breach of TRIPS Article 27(1)'s requirement that patent rights should be enjoyable without discrimination based on the field of technology involved.

Respectfully submitted

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