Response to UK IPO Research Exception Consultation

Submission by the Intellectual Property Lawyers' Association (IPLA) on the UKIPO Patent Research Exception Consultation

This is a response to the UKIPO Consultation "The Patent Research Exception: A Consultation".

The Intellectual Property Lawyers' Association ("IPLA") acts as a representative body for law firms in England and Wales with intellectual property practices, who wish to lobby for improvements to IP law. Over 50 firms are members of IPLA, and the vast majority of patent and other litigation and transactions work relating to intellectual property rights in England and Wales is conducted by these member firms. Because of the international nature of patents, member firms are also familiar with how things operate in many other countries across Europe and in the United States of America. Members act for a wide range of clients, from major multi-national groups of companies to SMEs and technology start-up companies, as well as universities and private inventors and investors. As a group, IPLA probably has unparalleled experience of how existing IP systems work in practice in the UK.

The Gowers Review on Intellectual Property

This consultation has been prompted by Recommendation 1 of the Gowers Review of Intellectual Property ("Gowers"), which is "to clarify the research exception". It is accordingly appropriate at the outset to make some observations about the apparent basis for this recommendation especially as in certain respects it unfortunately perpetuates fundamental misconceptions about the present state of the law.

In so far as relevant to this consultation Gowers addressed two separate points. The first is a specific issue as to the overlap as between patent rights and plant breeders rights. The second concerns the scope of the research exception.

As to the first point, relating to the concerns originally expressed by the Royal Society of Plant Breeders, Gowers states at paragraph 4.9:

4.9 Even if the second generation plant does not infringe the scope of the patent, the research that created that plant might be found to have infringed the patent. This can act as a powerful disincentive to experiment on patented plants. This was recognised in the Biotechnology Directive, which provided that compulsory licences should be available for those new plants that demonstrate a technical advance. However, the British Society of Plant Breeders reports, that this provision is "ineffective in the UK at least", because to prove advance the product must actually be created, thereby infringing the patent. The [IPI] notes its concern that "the UK law on research exemption does not clearly allow plant breeders to make a cross with a variety with a patented gene sequence in it and to develop a new variety without that gene in it". Germany and France have introduced an exception as part of their implementation of the Biotechnology Directive, which prevents breeders being sued for development of new varieties.

We accept that this issue of overlap exists[1], and that the current UK patents legislation, and in particular the research exception at Section 60(5)(b) Patents Act, does not address it. If it

should be thought to be a problem in practice, as evidently the Royal Society of Plant Breeders so consider, then we agree that there should be legislation to make its clear that it does not infringe, along the lines already legislated for in France and Germany when they implemented the Biotechnology Directive.

As to the second point, namely the scope of the research exception, Gowers states at paragraphs 4.10 through 4.12:

4.10 The requirement that research is "private" is problematic; it is no longer sufficient for universities because they are increasingly conducting research in collaboration with private organisations. Furthermore, there is concern that if only research that is "non-public" is exempt, then publicly funded research that is, as a condition of funding, disclosed may also not qualify for the research exception.

4.11 The experimental use exception should be clarified to enable researchers to examine, learn from and improve upon inventions. The Swiss research exception, which was recently changed, provides a good example of a clearer exception.

4.12 The Review believes that clarifying the research exception along Swiss lines will foster research without damaging the interests of rights holders."

However, by suggesting, in paragraph 4.10, that research, to fall within the exception, must be private, and that the nature of the funding has a bearing on this, Gowers displays a fundamental misconception as the scope of the research exception[2] and therefore perpetuates the very myth that it then suggests requires "clarification" – instead, and as the Consultation correctly notes, section 60(5)(i) has been held capable of covering experimental work which has a commercial purpose. Indeed the purpose is irrelevant to the analysis, which is only as to whether or not the work is for experimental purposes, and whether it is in relation to the subject matter of the invention." Admittedly, and as recognised by the German Federal Supreme Court in *Clinical Trials II* there are experiments "carried out with the purpose of hindering the inventor's distribution of his product" or "undertaken in such proportions as to no longer allow justification on research grounds" that do not fall within the corresponding (identically worded) German exception, but these are extreme and limiting cases.

In those circumstances, it cannot be doubted, despite the suggestion implicit in paragraph 4.11 of Gowers to the contrary, that Section 60(5)(b) already allows "researchers to examine, learn from and improve upon inventions."

As to paragraph 4.12 of Gowers the Swiss defence here referred to (which in fact only became law in the course of 2008) states:

9(1) The effects of a patent do not extend:
(a) …
(b) to acts undertaken for experimental and research purposes in order to obtain knowledge about the object of the invention, including its possible utilities; in particular all scientific research concerning the object of the invention is permitted.
…

We can see no basis for suggesting that this is in fact any different in scope than Section 60(5)(b) Patents Act 1977 which states:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if:
(a) …
(b) it is done for experimental purposes relating to the subject matter of the invention
(c) …

We accept however that it could be said that the Swiss defence is expressed in terms which may perhaps make it more comprehensible on its face to the layman. But against this it should be said that the UK formulation in Section 60(5)(b), based as it is on the language of the Community Patent Convention, has the great advantage that it is the same as that in most of the rest of Europe[3], and in particular Germany, enabling reliance to be placed on jurisprudence in such other jurisdictions. Indeed in their leading decisions in *Clinical Trials I* and *Clinical Trials II*, the German Federal Supreme Court drew on the decisions of the English Court of Appeal in *Monsanto v Stauffer*, and in turn UK practitioners have placed reliance on these decisions of the German Federal Supreme court in advising their own clients as to the position in the UK.

Response to Questions Posed in the Consultation

With that background, we turn to the questions posed in the Consultation. We have no evidence on which to base answers to the last two questions, both concerning "research tools"[4] but we comment on the first two questions together, namely:

Q1 Is the research exception in need of clarification? Do you have any evidence to support your view?

Q2 If you consider that the research exception does need clarification, how would you like to see this done?

Subject the one point set out below we do not believe that the research exception is in need of clarification, as clear advice on its scope can be given in most real life situations. What we do however believe is required is better education, and less incorrect and misleading commentary on the issue such as that set out in paragraphs 4.10 and 4.11 of Gowers, and we would hope that the UKIPO could assist in educating people properly as to this.

One problematic area on which some of us have however been asked to advise on occasion is that of comparative clinical trials, where the comparator is a compound patented by a third party but the patentee is not its source. It requires a broad interpretation of "the subject matter of the invention" to include such use within the scope of the exception. Other countries in Europe, such as France, Germany, Italy, Spain (and indeed Switzerland, even though of course not mandated so to do) have dealt with this by expressing their "Bolar" exceptions more widely than mandated by the 2004 Community medicines legislation and as been done in the UK. Although we appreciate that the scope of the Bolar exception does not form part of the Consultation, we feel it unrealistic to separate the two issues, and would urge that the UK "Bolar" exception be amended along the lines for example of the German implementation of the defence.

A further point which is not one of clarification, because we do not believe it falls within the scope of the exception, but which we think merits attention, is the "overlap" point made

Royal Society of Plant Breeders and discussed above in the context of paragraph 4.9 of Gowers.

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[1] It is explained more fully in the 2006 IPI Report referred to in the Consultation - *A European Perspective as to the Extent to which Experimental Use and Certain Other Defences to Patent Infringement apply to Differing Types of Research* - but reflects essentially the fact that the plant variety rights system has, in addition to a research exception, a breeding exception, that has no parallel in the patent law. This disparity has only become significant as developments in patent law (including those reflected in the Biotechnology Directive) have brought about areas of overlap between the patent system and the plant variety rights system.

[2] Gowers seems to confuse two of the distinct exceptions to infringement set out in section 60(5). Subsection (a) exempts acts which are private and non-commercial and subsection (b) exempts work done for experimental purposes relating to the subject matter of the invention. The English Court of Appeal made it clear in *Monsanto v Stauffer* that subsection (a) must mean that subsection (b) relates to research that is other than private and non-commercial.

[3] Notable exceptions apart from Switzerland, which never had such a law till it introduced one in 2008, are the Netherlands, which has always had a more narrowly drawn exception (qualified by the word "exclusively"), and Belgium which has recently amended its exception to widen it in effect to remove the "relating to the subject matter of the invention" aspect. We consider the Dutch exception to be too narrow, and the Belgian one as amended to be far too wide, as it in effect removes all research tool use from the scope of patent protection, and may well be contrary to TRIPs.

[4] Namely "Q3 Do you have any evidence of research being hindered by patents on research tools, or of the current law working effectively?" and "Q4 If you consider that research has been hindered by patents on research tools, how do you think this could best be overcome, or has research been able to continue?"