

These pages look at the statutory exceptions to patent infringement which exist in UK law and how they have been interpreted alongside similar provisions in some other European countries.

History of the Research Exception

1. The origin of the UK research and private-use exceptions lies in the Community Patent Convention (CPC) of 1975. Section 60(5)(a) and (b) of the Patents Act 1977 are almost identical to the equivalent provisions in Article 27 of the CPC.
2. The CPC was amended in 1989 by the Agreement relating to Community Patents¹. Annex II of the Agreement (Declaration of adjustment of national patent law) states that legislative proceedings have been completed in several member states with a view to eliminating as far as possible the differences between national patent law and the common law system of patents resulting from the said Convention.” However, neither the CPC Convention nor the amending Agreement has ever come into force. Member States are not currently required to harmonise their law on exemptions. For example, Belgium recently departed from the CPC wording when reformulating its research exception and Austria has no statutory exception.
3. The draft Community Patent Regulation and draft European Patent Litigation Agreement, which are still under debate in Europe, contain exceptions similar to those contained in Article 27 of the CPC.
4. Given this context, the European situation would need to be taken into account when assessing the extent of clarification needed in UK law. Any domestic clarification or amendment of the research exception would need to consider whether Europe-wide clarification or change is necessary. The experience of other European states may offer guidance. For example, as detailed above, Belgium has recently moved away from the European norm, introducing an exception covering research tools, and both Italy and Germany have broadened their research exceptions in order to implement the new European law on regulatory-review. Switzerland, which is not a member state, has formulated a brand new set of exceptions to infringement, as well as provisions for compulsory licensing of research tools. Adoption of an Agreement on the European Union Patent Judiciary which is currently under discussion by the EU and which contains its own research exception² could also impact on the interpretation of national research exceptions.

Case Law

5. The two limitations imposed by the Section 60(5)(b) exception are that acts must be both for “experimental purposes” *and* “related to the subject-matter of the invention”.

¹ 89/695/EEC

² [Article 14e Draft Agreement on the European Union Patent Judiciary: Working Document 9124/08](#)

6. In *Monsanto v Stauffer*,³ the English Court of Appeal noted that the specific limitation of Section 60(5)(a) to “private and non-commercial” purposes implied that section 60(5)(b), which does not have such a limitation, would extend to experiments with both commercial and non-commercial ends in view.
7. The Court concluded that “experimental purposes” would include trials carried out “in order to discover something unknown, or to test an hypothesis, or even in order to find out whether something which is known to work in specific conditions ... will work in different conditions”. The emphasis is on acts which generate new knowledge.
8. However, trials conducted in order to demonstrate to a third party (be it a customer or regulator) that a product works as claimed would not be considered to be done for “experimental purposes”.
9. In *Auchincloss v Agricultural & Veterinary Supplies Ltd*, the Court of Appeal reached a similar conclusion. It held that making and experimenting merely for the purposes of getting an official approval would not fall within the exception. However, if samples produced during the course of “genuine experiments” were sent to a regulatory authority, they would benefit from the research exception.
10. The meaning of the phrase “relating to the subject-matter of the invention” was elucidated in *Smith, Kline and French v Evans Medical*.⁴ The Patents Court asked whether a company seeking to investigate a chemical patent for the purposes of improving upon it or challenging its validity – actions falling within the research exception – would be able to carry out the patented process by using a reagent, also patented, from a third party. The answer?

In my view [it] cannot. I believe that in the circumstances outlined the experimental purposes relate to the chemical patent and not to the reagent patent. A contrary conclusion would, in practice, deprive the words “relating to the subject-matter of the invention” of any meaning.

11. This judgment would appear to mean that so-called “research tools”, which are accomplices to, but not the subject of, an experiment, do not fall within the exception.
12. What comprises the subject matter of the invention, according to *Auchincloss v Agricultural & Veterinary Supplies Ltd*, “must be ascertained from the patent as a whole”.⁵
13. From this case law, it appears that the exception is limited to research *into* or *on* a patented invention, as opposed to research *with* or *using* a patented invention. However, the distinction between research *into* and research *with* an invention may not always be clear. It may be difficult to determine the

³ [1985] RPC 675

⁴ [1989] FSR 513

⁵ [1997] RPC 649 (Patents Court); [1999] RPC 397 (Court of Appeal)

subject matter of the invention or the extent to which an experiment is related to that subject matter. Under UK law the research exception would not appear to extend to acts which do not seek to gain new knowledge, such as demonstrating to a third party the efficacy or safety of a patented product.

Case Law in Other EU Member States

14. As many European countries provide research exceptions which have a common origin in the CPC,⁶ it is also helpful to look at the decisions of European courts when considering the exception in the UK. The most notable European decisions are the two *Clinical Trials* cases, from Germany.
15. In *Clinical Trials I*,⁷ the German Federal Supreme Court concluded that the German research exception, which was identical to the UK exception, “in principle exempts all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention”, including research into “possible new uses hitherto unknown”. It did not matter whether the experiments were used to check statements in the patent or to obtain further research results. An experiment was “any (planned) procedure for obtaining information, irrespective of the purpose which the information gained is eventually intended to serve”.
16. It would appear that the use of a patented invention as a “research tool”, or “technical aid”,⁸ would fall outside the exception. However, acts performed to gain information would continue to be exempt if they were also performed for “further purposes” such as to support an application to a regulatory authority.
17. The German Federal Court took a similar view in *Clinical Trials II*.⁹ An act would be exempt if oriented towards “clearing up uncertainties” or “bringing out new discoveries” about the invention. The Court emphasised that this was true irrespective of any commercial intention that might be served by the research, and that such experiments should be allowed so as to facilitate the development of new technologies.

The unlimited protection of the patent is not justified in a case where the further development of the technology is hindered.

18. The Court confirmed that it made no difference if such a test also “achieves the aim of obtaining data for legal pharmaceutical permissions”.
19. The Court also found that, while “experimental purposes” were to be broadly construed without being limited to non-commercial purposes, large-scale trials might be held not to be experimental, when trials on a smaller scale could equally gain information to the required degree.¹⁰ Trials must not be carried

⁶ Hereafter, the “CPC exemption”
⁷ *Klinische Versuche (Clinical Trials) I* [1997] RPC 623
⁸ *Klinische Versuche (Clinical Trials) I* [1997] RPC 623
⁹ *Klinische Versuche (Clinical Trials) II* [1998] RPC 423
¹⁰ *Ibid.*

out on too large a scale, or carried out with the intention of disturbing or interfering with a patentee's marketing of a patented product.¹¹

20. Other courts have since applied the principles developed in the Clinical Trials cases. Notably, in the French case *Wellcome Foundation v Parexel International and Flamel Technologies*¹² the Tribunal de Grande Instance de Paris agreed that experiments which sought to find new information about a patented substance should be exempt from infringement, even if those experiments were directed towards known principles in new conditions.

... deciding otherwise would equate to depriving researchers of the possibility of experimenting with the use of known and protected active principles in new conditions ... and thus would prejudice the development of advanced patents, by giving a de facto monopoly to the holders of initial patents.

The Regulatory-review (“Bolar”) Exemption

21. In 2004 the EU introduced legislation¹³ that exempts from infringement activities such as bioequivalence and stability testing performed for the regulatory approval of generic drugs, which is necessary under European law.¹⁴
22. The result of the UK implementation of Directive 2004/27/EC, which had to be implemented throughout the EU by 30 October 2005, was Section 60(5)(i) of the Patents Act. This closely follows the wording of the Directive, and is considered to be a narrow implementation, although some Member States have introduced broader exceptions. For example, the French implementation covers all marketing authorisations required in the EU, not only abridged applications, and the German implementation covers all market authorisations required by any country, not only within the EU.¹⁵ The Spanish and Italian governments have implemented the Directive by incorporating acts required for regulatory approval into their pre-existing research exceptions, so departing from the wording of the CPC.
23. Article 30 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) states that countries have the right to provide exceptions to patent rights, as long as such exceptions are “limited”, “do not unreasonably conflict with a normal exploitation of the patent”, and do not “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”. Each of these conditions must be fulfilled for an exception to be allowed. In 2000, a panel of the WTO

¹¹ Klinische Versuche (Clinical Trials) II [1998] RPC 423

¹² Tribunal de Grande Instance de Paris, 20 February 2001, *Wellcome Foundation v Parexel International & Flamel & Créapharm* (PIBD 2001, 729, III-530)).

¹³ Directive 2004/27/EC

¹⁴ specifically, the abridged authorisation procedure of Directives 2001/82/EC and 2001/83/EC

¹⁵ Cook, T. “A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, Apply to Differing Types of Research”, Bird & Bird, a report for the Intellectual Property Institute.

Dispute Settlement Body found that the regulatory-review exception present in the Canadian Patents Act, which allowed the making of a patented product prior to the expiry of its patent, met these conditions.¹⁶ In reaching this conclusion, the panel highlighted the research exception as an exception based upon the legitimate interests of third parties – in this case scientists and society – to support the advance of science and technology through the disclosure and dissemination of new technical knowledge.¹⁷

24. The United States of America is notable for not having a statutory research exception, but has evolved a limited exception through case law. In 1813 Supreme Court Justice Story (in *Whittemore v Cutter*) opined:

“...it could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine to produce its described effects”.

25. In 1984, the US Court of Appeals for the Federal Circuit ruled in the landmark case *Roche v Bolar*¹⁸ that unauthorised use of a patented pharmaceutical in order to test a generic version for regulatory approval was not allowed under the US common law research exception. This ruling prevented manufacturers of generic medicines placing products on the market immediately following the expiry of relevant patents as they were unable to gain prior authorisation to do so from the regulatory authorities: extending the effective protection conferred by a patent beyond its expiry date. Following this case, US legislators introduced the “Hatch Waxman” Act¹⁹, which exempts from infringement acts “reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products”.

26. *Madey v Duke*²⁰ confirmed the view in *Roche v Bolar*²¹, that the US research exception was “truly narrow”, and “so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense”.

27. Japan has a research exception with similar scope to the European exception. It provides that “The effects of the patent right shall not extend to the working of the patent right for the purposes of experiments and research”. Though there is little case law to clarify the meaning of this exception, it is generally thought to have similar effect to the European research exception, exempting

¹⁶ World Trade Organization Panel Report *Canada - Patent protection of Pharmaceutical Products* WT/DS114/R (2000); available from http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf.

¹⁷ Ibid, at paragraph 7.69. Also see the Australian Advisory Council on Intellectual Property (ACIP) report on Patents and Experimental Use, October 2005, at pages 20 to 25 for further analysis of the TRIPS Agreement.

¹⁸ *Roche Products v Bolar Pharmaceuticals* 733 F.2d, 858, 1984.

¹⁹ Drug Price Competition and Patent Term Restoration Act 1984

²⁰ *Madey v Duke University* 307 F.3d, 1351, 2002

²¹ *Roche Products v Bolar Pharmaceuticals* 733 F.2d, 858, 1984.

only experimentation into the subject-matter of the patented invention. In *Ono Pharmaceuticals v Kyoto Pharmaceutical Industries*²² the Supreme Court placed a broad interpretation on what was meant by experimentation and research, ruling that tests such as bioequivalence tests, performed to gain regulatory approval for generic medicines, would fall within the exception.

28. Other countries, notably Australia, Canada and New Zealand have recently conducted their own studies into whether to introduce exceptions for research, which have led to changes in legislation. Both Australia and New Zealand chose to adopt a research exception with almost identical wording to the CPC exception. The Canadian Biotechnology Advisory Committee to the Government of Canada has also suggested introducing an exception which is similar to the CPC exception.

29. To conclude we can also note that the Gowers Review remarked on concerns that only “non-public” research is exempted, meaning that publicly-funded research that is disclosed as a condition of funding may not qualify for the research exception. This would appear to be referring to the “private use” exception, described above, rather than the research exception as such.

30. The Review recommended the (then) draft Swiss research exception as “a good example of a clearer exemption”:²³

Swiss research exception (Article 9 of the new Swiss Patents Act)²⁴

The effects of a patent do not extend:

- a) *to acts undertaken in the private sphere for non-commercial purposes*
- 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*
- c) *to acts necessary to obtain a marketing authorisation for a medicament according to the provisions of the law of 15 December 2000 on therapeutic products*
- d) *to the use of the invention for the purpose of teaching in teaching establishments*
- e) *to the use of biological material for the purposes of selection or the discovery and development of a plant variety*
- f) *to biological material obtained in the field of agriculture which was due to chance or which was technically unavoidable*

²² *Ono Pharmaceuticals v Kyoto Pharmaceutical Industries* (16 April 1999 - 30 IIC 448)

²³ See Gowers Report, page xx

²⁴ [In force 1st July 2008](#)