Questionnaire on Exceptions and Limitations to Patent Rights

The answers to this questionnaire have been provided on behalf of:
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Questionnaire answers to sections 7 and 9 updated 9 May 2014.

Questionnaire answers to sections 10 and 11 updated 15 May 2014.

Section 7: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(i) of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –
(i) it consists of -
(i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or
(ii) any other act which is required for the purpose of the application of those paragraphs.
Section 60(7) defines the terms used in s.60(5)(i):
60(7) In this section –
"Directive 2001/82/EC" means Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products as amended by Directive 2004/28 of the European Parliament and of the Council;
"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by Directive 2002/98/EC of the European Parliament and of the Council, by Commission Directive 2003/63/EC, and by Directives
2004/24/EC and 2004/27/EC of the European Parliament and of the Council.

Proposals to amend section 60(5) of the Patents Act are currently being considered by the UK Parliament. If Parliament agrees, this section of the Act will be amended to specify that activities relating to trials for human and veterinary medicines, as well as health technology assessment (HTA) are acts which fall within the scope of the existing research exception (section 60(5)(b)[1]).

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:
N/A

53. (a) What are the public policy objectives for providing the exception? Please explain:
Generic medicines should be in competition with patented medicines as soon as the relevant period of protection has expired

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

[1] Section 60(5)(b) Patents Act currently reads "An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if (b) it is done for experimental purposes relating to the subject-matter of the invention".

Section 60(5)(i) implements article 13 paragraph 6 of Directive 2001/82/EC on veterinary medicinal products and article 10 paragraph 5 of Directive 2001/83/EC on medicinal products for human use.

The underlying policy for the proposed changes to section 60(5)(b) is that the patent system should not prevent a company from meeting the requirements of the regulatory approval system for medicinal products, and that activities carried out to meet such requirements should be exempt from patent infringement. Section 60(5)(i) addresses this concern in relation to generic drugs and the proposed amendments to the Patents Act will address it in relation to innovative drugs. This should allow patients to have earlier access to new drugs.

54. Who is entitled to use the exception? Please explain:
Section 60(5)(i)(i) provides that the exception applies to those carrying out studies, tests and trials on generic medicinal products to show that the generic product is bioequivalent to an approved patented product where these acts are required to obtain marketing authorisation. Section 60(5)(i)(ii) provides that the exception also applies to any other act required for the purpose of such studies, tests and trials. This suggests that manufacturers and suppliers of materials for such studies, tests and trials would also be covered by the exception.

The proposed changes may be used by anybody seeking to obtain regulatory approval or carrying out health technology assessment for a medicinal product.

55. The exception covers the regulatory approval of:
_ any products
_ certain products. Please describe which products:
Veterinary medicinal products and medicinal products for human use which fall within the scope of the Directives mentioned in s.60(5)(i).

The proposed amended exception applies to medicinal products for human and veterinary use, as set out in Directives 2001/83/EC and 2002/82/EC.

56. Please indicate which acts are allowed in relation to the patented invention under the exception?
The following acts would appear to be allowed in principle if carried out for the purposes of a study, test or trial falling within the scope of s.60(5)(i):
_ Making
_ Using
_ Selling
_ Offering for sale
_ Import
_ Export
_ Other. Please specify:

Making and using a patented invention for the purposes set out in the proposed new exception are allowed. Making and using an invention for commercial activities are not in scope of the proposals.

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):
N/A

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

Proposed amendments are as set out above.

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

We are not aware of any significant challenges.

Section 9: Compulsory licenses and/or government use

Sections 48-59 of the Patents Act are concerned with the grant of compulsory licences, including government use which is considered to be a form of compulsory licence.

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

Sections 48-54 of the Patents Act are concerned with the grant of compulsory licences.

Also applicable is the EU Compulsory Licensing Regulation (Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems). Section 128A of the Patents Act sets out how certain provisions of the Act apply to EU compulsory licences and applications for such licences.

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

Under sections 48-54, the grounds that apply are dependent on whether or not the proprietor of the patent is a 'WTO proprietor' i.e. is a national of, or is domiciled in, a country which is a member of the World Trade Organisation, or has a real and effective industrial or commercial establishment in such a country. The grounds for patents owned by WTO proprietors and non-WTO proprietors are set out by s.48A(1) and s.48B(1) of the Patents Act respectively.
48A(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are:
(a) where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;
(b) that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms
(i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or
(ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
(c) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.
48B(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are:
(a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;
(b) where the patented invention is a product, that a demand for the product in the United Kingdom-
(i) is not being met on reasonable terms, or
(ii) is being met to a substantial extent by importation from a country which is not a member State;
(c) where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked
(i) where the invention is a product, by the importation of the product from a country which is not a member State,
(ii) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;

(d) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms-
(i) a market for the export of any patented product made in the United Kingdom is not being supplied, or
(ii) the working or efficient working in the United Kingdom of any other patented invention which makes a substantial contribution to the art is prevented or hindered, or
(iii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
(e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

The Compulsory Licensing Regulation provides for the availability of a compulsory licence for anyone who wishes to make a specific patented pharmaceutical product solely in order to export it to a developing country with a particular health problem.

_ Non-working or insufficient working of the patented invention *(s.48B(1)(a))*
_ Refusal to grant licenses on reasonable terms *(s.48A(1)(b) and s.48B(1)(d))*
_ Anti-competitive practices and/or unfair competition *(s.50A and s.51)*
_ Public health *(Compulsory Licensing Regulation)*
_ National security
_ National emergency and/or extreme urgency
_ Dependent patents *(s.48A(1)(b)(i) and s.48B(1)(d)(ii))*
_ Other, please specify: *See s.48A(1)(a), (c) and s.48B(1)(b)-(c), (e).*

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

Sections 48-54
The objective is to prevent the monopoly conferred by the patent working against the public interest. The Patents Act 1977 provides for the granting of compulsory licences as a way of correcting or remedying problems where certain conditions in the market are not being met or where licences are available but only under unreasonable terms.
It could also be argued that the existence of the compulsory licensing provisions acts as an incentive for parties to negotiate and agree voluntary licensing agreements rather than go through what is, essentially, inter partes litigation in order to attempt to obtain a compulsory licence. If so, it can be said that the existence of the provisions also acts to prevent or repress anti-competitive behaviour.
Compulsory Licensing Regulation
The Regulation implements the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). It was implemented as part of wider European and international action to address public health problems faced by least developed countries and other developing countries1.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Sections 48-54
Section 22 of the Patents, Designs and Trade Marks Act 1883 gave the Board of Trade the power to order the grant of compulsory licence where:
(a) The patent was not being worked in the UK; or
(b) The reasonable requirements of the public with respect to the invention were not satisfied; or
(c) Any person was prevented from working or using the invention of which he was possessed.
The jurisdiction of the Board of Trade was subsequently passed to the Judicial Committee of the Privy Council, and then court by subsequent patent Acts in the early 20th century.
The 1949 Patent Act allowed for the grant of compulsory licences in two categories:
(a) In respect of any patent where there had been inadequate working or oppressive conduct by the patentee
(b) Where the invention was concerned with food, medicine, or surgical or curative device.

The 1977 Patents Act re-enacted the 1949 Act in this area, save for the omission of the provision relating to food, medicine and surgical/ curative devices; however, the European Court held that the UK may not grant compulsory licences where demand for a patented product is satisfied by imports from other European member states. Additionally, it was held that the UK may not grant compulsory licences to permit a licensee to import products from outside the EC if the patentee works the invention in another member State, but not if he works in in the UK. The aim of this being to prevent discrimination against a patentee who decides to manufacture in another member State of the EC.2 Compulsory Licensing Regulation
See http://eur-lex.europa.eu/en/index.htm for further information.

69. If the applicable law provides for the grant of compulsory licenses on the ground of "nonworking" or "insufficient working", please provide the definitions of those terms by citing

1 For further information see Regulation (EC) No 816/2006 which can be found on http://eurlex. europa.eu/en/index.htm.
2 For a fuller discussion of the legislative history see Thorley, S; Miller, R; Burkill, G; Birss, C; Terrell on the law of patents, (2000), Sweet & Maxwell.
legal provision(s) and/or decision(s):

Section 48B(1)(a) refers to whether an invention is being 'commercially worked' or 'so worked to the fullest extent possible'. These terms are not defined in statute but decisions of the UK IPO have provided guidance on how s.48B(1)(a) is to be interpreted.
In Enviro-Spray Systems Inc's Patents [1986] RPC 147, the hearing officer declined to attempt a formal definition of 'commercial working' but saw no reason to depart from its plain and ordinary meaning – 'as far as manufactures are concerned, the expression is... clearly satisfied by the straightforward manufacture of goods for the purposes of trade'. He also observed that working can be commercial and yet not be exploiting the invention to the full, so manufacture on a scale too small to fully meet demand can still constitute commercial working.
In Kamborian's Patent [1961] RPC 403 (also a decision of the UK IPO), the hearing officer considered that the fullest extent to which an invention may be worked can be expressed as 'the highest rate of production which is practicable and necessary substantially to meet the demand'. In order to succeed in showing that this ground applies, the applicant for the compulsory licence must provide 'evidence to show what the demand for the invention might reasonably be expected to be, and how far short, if at all, production under the patent falls, as far as is practicable to supply it'.

70. Does the importation of a patented product or a product manufactured by a patented process constitute "working" of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

In effect, yes, under the conditions set out by s.48B(3), which provides that a compulsory licence cannot be granted in respect of the ground mentioned in s.48B(1)(a) if demand in the UK is being met by importation of the patented invention from a member State of the European Economic Area (EEA) where the invention is being commercially worked.

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?
_ Yes
_ No

If yes, what is the time period?

Three years from the date of grant of the patent (s.48(1)). This time period applies to all applications for a compulsory licence.

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?

_ Yes
_ No

If yes, what are “legitimate reasons”?

Section 48B(2) allows an application on the ground mentioned in s.48B(1)(a) to be stayed to allow sufficient time for the patentee to ‘commercially work’ the invention if ‘it appears to the comptroller that the time which has elapsed since the publication in the journal of a notice of the grant of the patent has for any reason been insufficient to allow the invention to be so worked’.

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

There is no definition of ‘reasonable terms’ in statute but section 48A.03 of the Manual of Patent Practice gives the following guidance:
What constitutes "reasonable terms" depends on a careful consideration of all the surrounding circumstances in each case, eg the nature of the invention, the terms of any licences under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand.
Furthermore, in Brownie Wireless Co Ltd's Applications 46 RPC 457, the court considered the best test of whether a royalty is reasonable is: how much are manufacturers who are anxious to make and deal with the patented article on commercial lines ready and willing to pay?

74. If the applicable law provides for the grant of compulsory licenses on the ground of anticompetitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

Sections 50A and 51 of the Patents Act allow the Competition Commission, the Secretary of State or a Government Minister to apply for a compulsory licence if patent abuse is a factor contributing to an anti-competitive situation. Section 50A allows the Competition Commission or the Secretary of State to apply to the comptroller to take action following a merger or market investigation to remedy, mitigate or prevent a competition matter that cannot be dealt with in any other way under the Enterprise Act. Section 51 makes provision for Government Ministers to apply to the comptroller to take action in response to a report by the Competition Commission ‘that a person was engaged in an anti-competitive practice which operated or may be expected to operate against the public interest’ or ‘that a person is pursuing a course
of conduct which operates against the public interest’ (s.51(1)). Applications under s.50A or 51 must involve ‘conditions in licences granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licences’, or ‘a refusal by the proprietor to grant licences on reasonable terms’ (s.50A(1)(c) and 51(3)).

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

The conditions are set out in s.48A(1)(b)(i) and s.48B(1)(d)(ii) (see answer to question 67).

76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:

Different provisions apply for WTO and non-WTO proprietors. For WTO-proprietors, s.48A(6)(c) entitles the proprietor to ‘remuneration adequate in the circumstances of the case, taking into account the economic value of the licence’ whereas s.50(1)(b) provides that non-WTO proprietors are entitled to ‘reasonable remuneration having regard to the nature of the invention’.

In the decision of the UK IPO in Montgomerie Reid's Application (BL O/145/83) (decided under the 'reasonable remuneration' criterion) it was held that the royalty to be paid for a compulsory licence under s.48 should be one which would be negotiated between a willing licensor and a willing licensee.

77. If the applicable law provides for the grant of compulsory licenses on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

N/A

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

No compulsory licences have been issued under sections 48-54 in the last 10 years. Very few applications for compulsory licences are received (estimated to be less than one per year on average since the Patents Act 1977 came into force). Similarly, the UK IPO has received no applications for EU compulsory licences.

79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

No amendments to the law are foreseen.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

We are not aware of any significant challenges.

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):

Sections 55-59 of the Patents Act concern Crown use of patented inventions. Section 122 concerns the Crown's right to sell forfeited articles.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

_ Non-working or insufficient working of the patented invention
_ Refusal to grant licenses on reasonable terms
_ Anti-competitive practices and/or unfair competition
_ Public health
_ National security
_ National emergency and/or extreme urgency *(s.59)*
_ Dependent patents
_ Other, please specify:

Section 55(1) provides that certain acts are exempt from infringement if they are done in the UK by a government department, or any person authorised in writing by a government department, 'for the services of the Crown'. According to s.56(2), 'for the services of the Crown' includes –

(a) the supply of anything for foreign defence purposes;

(b) the production or supply of specified drugs and medicines; and
(c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Secretary of State thinks necessary or expedient.
Section 122 provides that nothing in the Patents Act affects the Crown's right to dispose of or use articles forfeited under the customs and excise laws. The Crown is therefore exempted from infringement for the sale or use of goods seized under the customs and excise laws.

84. (a) What are the public policy objectives for providing government use in your country?

Government departments should not be fettered by the existence of patents in the discharge of their functions.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Powers to use a patented invention, without the permission of the proprietor of the patent go back to 1883. Proposals to limit the powers were rejected by the Banks Committee (1970).

85. If the applicable law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", please explain how the applicable law defines those two concepts and their scope of application, and provide examples:

Section 59 has the effect of extending the Crown use provisions under s.55 'during any period of emergency'. Section 59(3) defines the meaning of 'period of emergency' as follows': any period beginning with such date as may be declared by Order in Council to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section.
Section 59(4) requires that the draft of an Order under s.59(3) must be approved by each House Of Parliament. To date, no Order under s.59(3) has ever been made.

86. Please indicate how many times and in which technological areas government use has been issued in your country:

We do not keep records of this as the UK IPO does not generally get involved in Crown use matters - the relevant government department negotiates directly with the proprietor of the patent. However, it is our understanding that the Crown use provisions are invoked very rarely because the government prefers to negotiate a licence like any other party would. It seems likely that the need to determine and pay compensation for Crown use is a factor in deciding to take a conventional licence.

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

We have not consulted our users about the Crown use provisions recently but we are not aware of any problems with the provisions.

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

See 87.

Section 10: Exceptions and limitations related to farmers' and/or breeders' use of patented Inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 60(5)(g) of the Patents Act:
60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –
...
(g) it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent for agricultural use;

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

The exception originates from EU Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. For further information see Directive 98/44/EC which can be found on http://eur-lex.europa.eu/en/index.htm.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

See http://eur-lex.europa.eu/en/index.htm for further information.

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The exception under s.60(5)(g) applies where plant propagating material has been sold to a farmer by the proprietor of the patent, or with his consent, for agricultural use. It allows the farmer to subsequently use the product of his harvest from such material for further propagation or multiplication of the plant on his own land without infringing the patent.
Section 60(6A) imposes restrictions on the exception and sets out conditions which apply when an otherwise infringing act falls within the scope of s.60(5)(g). These restrictions and conditions are set out in Schedule A1 to the Patents Act. Paragraph 2 of Schedule A1 provides that s.60(5)(g) applies only to certain specified varieties of plant species and groups. The conditions which apply where an otherwise infringing act falls within the scope of sub-section (5)(g) include (i) the requirement that a farmer (other than a 'small farmer') must pay equitable remuneration to the proprietor (which must, however, be less than the farmer would have paid for buying more plant propagating material from the proprietor); and (ii) certain specified information must be supplied by the farmer and by the proprietor, on request from the other.
Schedule A1 is not reproduced here but may be viewed on the UK IPO's website here. The scope of 'sale' in s.60(5)(g) is clarified in s.60(6C): 60(6C) In paragraphs (g) and (h) of subsection (5) "sale" includes any other form of commercialisation.

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
No amendments to the law are foreseen.

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

We are not aware of any significant challenges.

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):
Section 60(5)(h) and of the Patents Act:

60(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –
...
(h) it consists of the use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

The exception originates from EU Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. For further information see Directive 98/44/EC which can be found on http://eur-lex.europa.eu/en/index.htm.

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

See http://eur-lex.europa.eu/en/index.htm for further information.

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

The exception under s.60(5)(h) applies where breeding stock or other animal reproductive material has been sold to a farmer by the proprietor of the patent, or with the proprietor's consent. The farmer may subsequently use the animal or animal reproductive material for an agricultural purpose without infringing the patent. There is no equivalent to Schedule A1 for s.60(5)(h) and thus the exception applies to all varieties of animal. However, s.60(6B) makes clear that the farmer is not allowed to sell any animals or animal reproductive material derived from his 'agricultural use' of the original animal or material as part of a commercial reproduction activity:
60(6B) For the purposes of subsection (5)(h), use for an agricultural purpose –
(a) includes making an animal or animal reproductive material available for the purposes of pursuing the farmer's agricultural activity; but
(b) does not include sale within the framework, or for the purposes, of a commercial reproduction activity.
The scope of 'sale' in s.60(5)(h) is clarified in s.60(6C):
60(6C) In paragraphs (g) and (h) of subsection (5) "sale" includes any other form of commercialisation.

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The UK Government is proposing to introduce a new exception for plant breeders. This forms part of the proposals for implementation of the Unified Patent Court (UPC) Agreement into UK law.

The intention of the proposal is for the UK exceptions to infringement to be in line with those found in Article 27 of the UPC Agreement. The policy behind this is to ensure that, when the UPC is brought

in, all patents valid in the UK will be subject to the same infringement exceptions. This will give patent owners, and potential users of patents, clarity over which infringement exceptions will apply to patents in the UK. The proposed change will be in the form of an addition to the exceptions to infringement listed in Section 60(5) of the Patents Act.

The UK Government will be consulting on the proposed new exception over the summer of 2014. The consultation will seek views from plant breeders on the impacts that this exception may have upon their research, and business.

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

We are not aware of any significant challenges.

Section 11: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

Section 60(3) provides an exception from contributory infringement for those who supply or offer to supply a staple commercial product.

102. In relation to each exception and limitation, please indicate:
(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

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. Subsection (2) relates to contributory infringement and subsection (1) relates to primary infringement.

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

Section 60(3) corresponds to paragraph 2 of article 26 of the CPC.

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

There is no definition of 'staple commercial product' but in Pavel v Sony BL CC/14/93 the Patents County Court construed the term as a product of the kind needed every day and generally obtainable. It was also noted that the product should be one generally available when the specification was published.

In addition, in relation to each exception and limitation, please explain:
(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

No amendments are foreseen to the above exception.

However, the UK Government is proposing to introduce a new exception relating to the use of software. This forms part of the proposals for implementation of the Unified Patent Court (UPC) Agreement into UK law.

The intention of the proposal is for the UK exceptions to infringement to be in line with those found in Article 27 of the UPC Agreement. The policy behind this is to ensure that, when the UPC is brought in, all patents valid in the UK will be subject to the same infringement exceptions. This will give patent owners, and potential users of patents, clarity over which infringement exceptions will apply to patents in the UK. The proposed change will be in the form of an addition to the exceptions to infringement listed in Section 60(5) of the Patents Act.

The UK Government will be consulting on the proposed new exception over the summer of 2014. The consultation will seek views on the impacts that this exception may have upon research and business.

(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

We are not aware of any significant challenges.

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

Articles 101 and 102 of the EU Treaty provide prohibitions on anti-competitive practices within the EU which place limitations on the scope of licensing agreements.

The Competition Act 1998 provides similar prohibitions applicable within the UK.

References

The Manual of Patent Practice (April 2014 update)

Examination Guidelines for Patent Applications relating to Medical Inventions in the Intellectual Property Office (May 2013)

Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office (2013)

The CIPA Guide to the Patents Act 7th Ed, 2011, Sweet and Maxwell, London.

Thorley, S; Miller, R; Burkill, G; Birss, C; *Terrell on the law of patents*, (2000), Sweet & Maxwell, London.

[End of Questionnaire]