Questionnaire on Exceptions and Limitations to Patent Rights

The answers to this questionnaire have been provided on behalf of:
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Section 1: General

This section is intended to obtain general information on exceptions and limitations to patent rights that are provided under the applicable laws. For the purpose of this questionnaire, the term "applicable law" refers to relevant national and regional statutory law and, where applicable, case law.

The terms used in the questionnaire are drafted in a general way aiming at providing a broad understanding of each concept used, assuming that the exact wording of these exceptions and limitations might differ under the applicable laws. More detailed explanations of the various exceptions and limitations may be found in the following documents: SCP/13/3, SCP/15/3 and CDIP/5/4.

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The standard for patentability is set out by s.1(1) of the Patents Act 1977 (as amended):

> ***1(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –***
>
> > ***(a) the invention is new;***
> > ***(b) it involves an inventive step;***
> > ***(c) it is capable of industrial application;***
> > ***(d) the grant of a patent for it is not excluded by subsections (2) and (3)or section 4A below;***
> > ***...***

'Invention' is defined by s.125(1) as '*that specified in a claim of the specification of the application or patent... as interpreted by the description and any drawings*'. Section 1(2) defines certain things which are not regarded as inventions. Sections 1(3) and 4A define classes of inventions for which a patent will not be granted.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.

The exclusions from patentability are set out in Sections 1(2), 1(3) and 4A of the Patents Act:

> ***1(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of –***

(a) a discovery, scientific theory or mathematical method;
(b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
(c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
(d) the presentation of information;

but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.

(3) A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

(4) For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.
...

4A(1) A patent shall not be granted for the invention of-

(a) a method of treatment of the human or animal body by surgery or therapy, or
(b) a method of diagnosis practised on the human or animal body.

(2) Subsection (1) above does not apply to an invention consisting of a substance or composition for use in any such method.

(3) In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

(4) In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that specific use does not form part of the state of the art.

<u>Exclusions under s.1(2)</u>

The list of exclusions under s.1(2) is not to be considered exhaustive. Each category has its own legal precedents. However, the preferred method when examining patent applications for excluded matter is to follow the four step test set out by the Court of Appeal in *Aerotel/Macrossan* [2007] RPC 7 which sets out how an examiner should approach the issue and provides a framework for making any decision.

The four steps are:

1 ***Construe the claim*;**

What does the claim mean and what is it's scope?

2 ***Identify the actual or alleged contribution;***

This can be summarised by asking what the inventor has really added to the stock of human knowledge? It will take into account the problem being solved and how the invention works. It will also consider to some extent the common general knowledge though should not be confused with identifying the

inventive step. Any assessment of the contribution must be based on the context of the claim as a whole and not its individual integers.

3 ***Ask whether it falls solely within excluded subject matter;***

Having identified the contribution is it excluded under one or more of the exclusions listed in Section 1(2) of the Act.

4 ***Check whether the actual or alleged contribution is actually technical in nature.***

This step is included to ensure that an invention is technical and not something for which we would not normally grant a patent.

Interpretation of the fourth step should also consider the judgement in *Oneida Indian Nation* [2007] EWHC 954 (Pat). In that case the fourth step does not need to be applied if an application has failed at the third.

Taking each category in turn, the applicable case law is as follows:

Discovery, scientific method

***Hickton's Application* [1909] 26 RPC 339**
***Genentech* [1989] RPC 147**
***Tate & Lyle Technology v Roquette Frères* [2010] FSR 1**

Mathematical Methods

***Gales Application* [1991] RPC 305**
***Vicom/Computer-related invention* [1987] 1 OJEPO 14 (T0208/84)**

Literary, dramatic, musical or artistic work or any other aesthetic creation

***ITS Rubber* [1979] RPC 318**

Scheme, rule or method of performing a mental act

***Fujitsu* [1997] RPC 608**
***Halliburton* [2005] EWHC 1623 (Pat)**
***Halliburton Energy Services Inc's Applications* [2011] EWHC 2508(Pat), [2012] RPC 129**
Practice Notice "Patents Act 1977: Patentability of Mental Acts"

Playing a Game

***Shopalotto* [2006] RPC 7**
***IGT* [2007] EWHC 1341**
Practice Notice "*Patents Act 1977: Patentability of games*"

Method of doing Business

***Merrill Lynch* [1989] RPC 561**
***Aerotel/Macrossan* [2007] RPC 7**
***Halliburton* [2012] RPC 129**

Computer Program

***HTC Europe Co Ltd v Apple Inc* [2013] EWCA Civ 451**
***Protecting Kids the World Over (PKTWO) LTD's Patent application* [2012] RPC 13**
***Aerotel/Macrossan* [2007] RPC 7**
***Symbian* [2009] RPC 1**
***Astron Clinica* [2008] RPC 14**

AT&T/Cvon **[2009] EWHC 343 (Pat)**
Gemstar v Virgin **[2010] RPC 10**
Vicom/Computer-related invention **[1987] 1 OJEPO 14 (T0208/84)**
HTC v Apple **[2013] EWCA Civ 451**
Really Virtual Co Ltd v UK Intellectual Property Office **[2012] EWHC 1086 (Ch)**
Protecting Kids the World Over (PKTWO) **[2012] RPC 13**
Lantana v Comptroller-General of Patents **[2014] EWCA Civ 1463**

Symbian makes it clear that a computer program may be patentable if it makes a 'technical contribution'.

AT&T sets out five signposts that indicate if a computer program makes the required technical contribution – only one of the signposts needs to be answered in the affirmative. The fourth signpost was revised in HTC v Apple so that the signposts are now:

i) ***Whether the claimed technical effect has a technical effect on a process which is carried on outside the computer;***
ii) ***Whether the claimed technical effect operates at the level or the architecture of the computer; that is to say whether the effect is produced irrespective of the data being processed or the application being run;***
iii) ***Whether the claimed effect results in the computer being made to operate in a new way;***
iv) ***Whether the program made the computer a better computer in the sense of running more efficiently and effectively as a computer;***
v) ***Whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented;***

Presentation of Information

Gemstar v Virgin **[2010] RPC 10**
Autonomy **[2008] EWHC 146 (pat)**
Townsend's Application **[2004] EWHC 482**

Further details of the case law may be found in section 1 of the Manual of Patent Practice.

Medical inventions

Methods of treatment by therapy or surgery, or methods of diagnosis performed directly on the human or animal body are excluded from patentability under s.4A(1), which corresponds to Art.53(c) of the EPC 2000. UK practice in interpreting this exclusion is governed by a variety of decisions of the UK courts (binding on UK practice) and the EPO Boards of Appeal (strongly persuasive). For example, the UK Court of Appeal decision in *Unilever (Davis's) Application* [1983] RPC 21 confirmed that the definition of 'therapy' includes both curative and prophylactic treatments (such as vaccination), and the exclusion applies equally to treatment of humans and veterinary treatment of animals. UK practice on the interpretation of 'methods of diagnosis practised on the human or animal body' is based on the decision of the EPO Enlarged Board of Appeal in G 01/04 *Diagnostic methods* OJEPO 2006, 334. Therefore, methods are only excluded if they include all the steps leading towards the identification of a condition, and thereby make it possible to decide on a particular course of treatment. Moreover, diagnostic methods are only excluded if they are practised on the human or animal body; *in vitro* diagnostic methods (e.g. genetic or immunological tests performed on isolated blood samples) are not excluded.

Section 4A(1) does not prevent the patenting of materials or compositions used in such methods, as stated in s.4A(2).

Unlike s.1(2) of the Act, there is no proviso in s.4A(1) that methods are only excluded "to the extent that a patent or application for a patent relates to that thing as such". UK practice

therefore follows the decision of the EPO Enlarged Board of Appeal in G 01/07 MEDI-PHYSICS/Treatment by surgery [2011] 3 OJEPO 134 which held that any multi-step method which includes a step comprising a method of surgery or therapy is excluded from patentability.

In addition, 'first medical use' claims of the type 'substance X for the use in therapy' are regarded as novel if the substance has not previously been used in any method excluded under s.4A(1); as set out in s.4A(3) (equivalent to Art.54(4) EPC).

Moreover, s.4A(4) (equivalent to Art. 54(5) EPC) allows for the protection of further, specific uses of known substances or compositions; i.e. 'second medical use' claims of the type 'substance X for use in the treatment of disease Y'.

Following the decision of the Court of Appeal in *Actavis v Merck* [2008] RPC 26, a second medical use claim may be distinguished from the prior art solely by a new and inventive dosage regime. However, merely explaining the mechanism which underlies a use already described, or merely discovering a new technical effect or advantage of a known treatment, will not confer novelty. See *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [1999] RPC 253, *El-Tawil's Application* [2012] EWHC 185 and *Actavis UK Ltd v Janssen Pharmaceutica NV* [2008] EWHC 1422, [2008] FSR 35.

The UK IPO no longer allows 'Swiss-type' second medical use claims of the form 'the use of substance X in the manufacture of a medicament to treat substance Y', following the EPO Enlarged Board of Appeal decision in G 02/08 ABBOTT RESPIRATORY/*Dosage regime* [2010] 10 OJEPO 456.

Further details of the case law may be found in section 4A of the Manual of Patent Practice and the Examination Guidelines for Patent Applications relating to Medical Inventions in the Intellectual Property Office.

Biotechnological inventions

Schedule A2 to the Patents Act 1977 (which implements articles 1-11 of EC Directive 98/44/EC on the legal protection of biotechnological inventions) states that an invention is not excluded from patentability solely on the grounds that it concerns either a product consisting of or containing biological material, or a process by which biological material is produced, processed or used. However, Sch.A2 states that the following are not patentable inventions:

- **(a) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;**
- **(b) processes for cloning human beings;**
- **(c) processes for modifying the germ line genetic identity of human beings;**
- **(d) uses of human embryos for industrial or commercial purposes;**
- **(e) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;**
- **(f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.**

Schedule A2 also states that inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. Moreover, notwithstanding part (a) above, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial

sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. Where the invention resides in a whole or partial gene sequence, the industrial application of the sequence must be disclosed in the application as filed.

Further details may be found in the Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office.

Following the decisions of the Court of Justice of the European Union (CJEU) in C-34/10 ("*Brustle*") and C-364/13 ("*International Stem Cell Corporation*"), the UK IPO issued a Practice Notice dated 25 March 2015 setting out our practice on the patentability of inventions involving human embryonic stem cells. The UK IPO will not grant patents for processes of obtaining stem cells from human embryos, for human totipotent cells or for inventions whose implementation requires the use of cells originating from a process which requires the destrunction of a human embryo. Patents will be granted for inventions concerning human stem cells that are not derived from human embryos, such as induced pluripotent cells and adult stem cells. The Office will continue to grant patents for inventions that are for therapeutic or diagnostic purposes that are applied to and useful to the human embryo.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Rights granted with a patent

Infringement is covered by sections 60 to 71 of the Patents Act. The acts that constitute infringement of a patent are set out by s.60(1) and (2):

> ***60(1) Subject to the provision of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say –***
>
> > ***(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;***
> > ***(b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;***
> > ***(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.***
>
> ***(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.***

Sections 60(1) and (2) correspond to articles 25 and 26 of the Community Patent Convention.

Section 61 gives the proprietor of a patent the right to bring civil proceedings in the court in respect of any act alleged to infringe the patent. The claims that may be made in such proceedings are set out by s.61(1):

61(1) Subject to the following provisions of this Part of this Act, civil proceedings may be brought in the court by the proprietor of a patent in respect of any act alleged to infringe the patent and (without prejudice to any other jurisdiction of the court) in those proceedings a claim may be made –

> ***(a) for an injunction or interdict restraining the defendant or defender from any apprehended act of infringement;***
> ***(b) for an order for him to deliver up or destroy any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;***
> ***(c) for damages in respect of the infringement;***
> ***(d) for an account of the profits derived by him from the infringement;***
> ***(e) for a declaration or declarator that the patent is valid and has been infringed by him.***

Section 61(2) provides that the court cannot both award damages and order an account of profits in respect of the same infringement.

If the proprietor and the alleged infringer agree to do so, they may refer the question of infringement to the Comptroller to be determined in proceedings before the UK IPO (s.61(3)). However, the powers of the Comptroller are more limited than those of the court and the proprietor may only claim the reliefs mentioned in s.61(1)(c) and (e) in such proceedings.

<u>Rights conferred by publication</u>

Section 69(1) provides that, from publication of the application until grant, the applicant has the same right to bring proceedings for an act of infringement as he would have had if the patent had been granted on the day of publication. However, the right is subject to the following conditions set out in s.69(2):

69(2) The applicant shall be entitled to bring proceedings by virtue of this section in respect of any act only –

> ***(a) after the patent has been granted; and***
>
> ***(b) if the act would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent, but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Patent Office.***

Section 69(3) requires the court or the comptroller to reduce the amount of damages awarded if it is considered that it would not have been reasonable to expect from the application as published that a patent conferring protection against the infringing act would be granted.

Section 69 corresponds to article 34 of the Community Patent Convention.

<u>Rights of co-owners and exclusive licensees</u>

Where there are two or more joint proprietors, each of the proprietors has the right to bring proceedings under sections 61 and/or 69 without the concurrence of the others, although the others must be made parties to the proceedings (s.66(2)).

An exclusive licensee has the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence, although the proprietor must be made a party to the proceedings (s.67).

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

☑ Private and/or non-commercial use;
☑ Experimental use and/or scientific research;
☑Preparation of medicines;
☑ Prior use;
☑ Use of articles on foreign vessels, aircrafts and land vehicles;
☑ Acts for obtaining regulatory approval from authorities;
☑ Exhaustion of patent rights;
☑ Compulsory licensing and/or government use;
☑ Exceptions and limitations related to farmers' and/or breeders' use of patented Inventions

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".
Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

Section 2: Private and/or non-commercial use

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

Section 60(5)(a) 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 –***
>
> > ***(a) it is done privately and for purposes which are not commercial;***

Section 60(5)(a) corresponds to article 27(a) of the Community Patent Convention (CPC) of 1975 (which never came into force).

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

N/A

6. (a) What are the public policy objectives for providing the exception?

It should be possible to carry out minor activities without hindrance by the threat of patent infringement.

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

The Patents Act 1977 was intended (inter alia) to implement the CPC and s.60(5)(a) implements article 27(a) of the CPC.

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

These terms are not defined in statute but there is case law providing guidance on their interpretation. In *Smith, Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] FSR 513, the court considered that the word ‘privately’ in s.60(5)(a) includes commercial and non-commercial situations; is not synonymous with ‘secret’ or ‘confidential’; and is used as the opposite of ‘publicly’, denoting an act done for the person’s own use. In interpreting the meaning of ‘purposes which are not commercial’, the purposes of the act must be considered: there would be infringement if the purposes include any commercial ones in addition to the non-commercial ones. Experiments done for legal proceedings in the High Court or the UK IPO are not considered to be done for a ‘commercial’ purpose.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

Section 60(6) provides that a person who does an act falling within the exception under s.60(5)(a) is not treated as a ‘person entitled to work the invention’ for the purposes of s.60(2). It follows that acts of contributory infringement under s.60(2) do not fall within the exception under s.60(5)(a). It may therefore be an infringing act under s.60(2) to supply a person with material for carrying out an act falling within the scope of s.60(5)(a).

9. 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 framework is considered adequate and there are no plans to change it.

10. Which challenges, if any, have been encountered in relation to the practical

implementation of the exception in your country? Please explain:

In *Smith, Kline & French Laboratories Ltd v. Evans Medical Ltd* [1989] FSR 513 and *McDonald v. Graham* [1994] RPC 407 at 431 it was considered that where there is a dual purpose to the activities carried out and one of these activities is commercial in nature then the defence of private use will not apply.

Section 3: Experimental use and/or scientific research

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

Section 60(5)(b) 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 –***
> ***...***
>
> > ***(b) it is done for experimental purposes relating to the subject-matter of the invention;***

Section 60(5)(b) corresponds to article 27(b) of the Community Patent Convention.

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

N/A

13. (a) What are the public policy objectives for providing the exception?

Scientific progress should not be hindered by the threat of patent infringement.

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

The origin of the UK experimental use exception lies in the CPC. Section 60(5)(b) of the Patents Act 1977 is almost identical to the equivalent provisions in Article 27 of the CPC.

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

There is no distinction concerning the nature of the organisation in statute or case law. In *Monsanto Co v Stauffer Chemical Co and another* [1985] RPC 515, the Court of Appeal considered that the exception may cover acts which have a commercial end in view. It follows that the exception may apply to commercial organisations.

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

The statute contains no definition of ‘experimental purposes’ but there is case law providing guidance on its interpretation.

In *Monsanto Co v Stauffer Chemical Co and another* (above) it was held that trials carried out in order to discover something unknown, or to test a hypothesis, or in order to find out whether something which is known to work in specific conditions will work in different conditions can fairly be regarded as experiments. However, trials carried out in order to demonstrate to a third party that a product works or in order to amass information to satisfy a third party, whether a customer or a body regulating the safety etc of such products, that the product works as its maker claims are not to be regarded as acts done “for experimental purposes”’.

In *Auchincloss v Agricultural & Veterinary Supplies Ltd* [1997] RPC 649 and [1999] RPC 397 it was held that making (and experimenting) merely for the purposes of getting an official approval is not a defence under s.60(5)(b).

In *CoreValve v Edwards Lifesciences* [2009] EWHC 6 Pat Ct, the court applied the principle established by the German Supreme Court in *Klinische Versuche (Clinical Trials) I* [1997] RPC 623:

An act for experimental purposes which is related to the subject-matter of the invention and therefore legitimate can exist if a patented pharmaceutically active substance is used in clinical trials with the aim of finding whether and, where appropriate, in what form the active substance is suitable for curing or alleviating certain other human diseases.

However, the court in *CoreValve v Edwards Lifesciences* considered that there must be an outward limit to that principle, and held that application of the principle should involve the consideration of whether the immediate purpose of the transaction is to generate revenue. The clinical trials in question were not considered to be exempted under s.60(5)(b) since one of the purposes of the trials was to 'generate immediate revenue of a substantial character'. It follows that commercial factors must be considered in determining whether the exception applies.

In *Smith, Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] FSR 513, it was held that experiments for the purposes of litigation are exempted under s.60(5)(b) if they relate to the subject matter of the invention found in the claims of the patent alleged to be infringed, in the sense of having a real and direct connection with it.

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

☐ determine how the patented invention works
☐ determine the scope of the patented invention
☐ determine the validity of the claims
☐ seek an improvement to the patented invention
☐ invent around the patented invention
☑ other, please specify: **The law does not require the purpose of the experiment to fall into any specific category. The relevant case law is set out in answer to question 15.**

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

☐ Research and/or experimentation must be conducted on or relating to the patented invention ("research on")
☐ Research and/or experimentation must be conducted with or using the patented invention ("research with")
☐ Both of the above

Please explain by citing legal provision(s) and/or decision(s):

Section 60(5)(b) requires that the act must be done for experimental purposes '*relating to the subject matter of the invention*'. Beyond that, the law contains no requirement to consider the above criteria in determining the scope of the exception.

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:

☐ A non-commercial purpose
☐ A commercial purpose
☑ Both of the above
☐ The commercial intention of the experimentation and/or research is not relevant

In *Monsanto Co v Stauffer Chemical Co and another* (above)) it was held that the exception can cover experimental work having a commercial purpose, but not all trials for a commercial

purpose fall within the exception. Furthermore in *CoreValve v Edwards Lifesciences* (above) it was held that the exception did not apply since one of the purposes of the experiments was to 'generate immediate revenue of a substantial character'

19. If the applicable law makes a distinction between "commercial" and "non-commercial" purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

There is no distinction in statute. The case law sets out no clear distinction but requires commercial factors to be considered in determining whether the exception applies. For a discussion of the case law see answers to questions 14, 15 and 18.

20. 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):

Section 60(6) provides that a person who does an act falling within the exception under s.60(5)(b) is not treated as a 'person entitled to work the invention' for the purposes of s.60(2). It follows that associated acts of contributory infringement under s.60(2) do not fall within the exception under s.60(5)(b). It may therefore be an infringing act under s.60(2) to supply a person with material for carrying out the experimental work.

21. 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 experimental use provision was the subject of a 2008 UK consultation by the UK IPO. The purpose of this consultation was to seek evidence on the effect of the patent research exception and to identify the extent of stakeholder concerns on this aspect of UK patent law. This consultation was in response to a number of reports that concluded that clarification or restructuring of the research exception was needed. In particular it was noted that the lack of case law in this area leads to uncertainty over the scope of the experimental use exception. No conclusive evidence was provided in the consultation responses to indicate that the experimental use exception was restricting research in the UK. The absence of clear evidence did not support a change of legislation. The consultation did provide evidence in two areas which do not strictly concern the experimental use exception in the UK:- risk of patent infringement during clinical trials and use of patented plant material by plant variety breeders; these issues are the subject of further investigation and monitoring, consecutively, in the UK.

The case law discussed above has resulted in a situation where acts carried out for the purposes of obtaining regulatory approval (e.g. clinical trials) are not covered by the experimental use exception. Furthermore, the UK implemented the Medicinal Products Directive 2001/83/EC and the Veterinary Medicinal Products Directive 2001/82/EC by read-out to the text of those Directives (see Q.51 below). Therefore trials and studies are only specifically exempt from infringement when they are carried out on generic drugs (section 60(5)(i) Patents Act 1977). The UK IPO consulted on this issue in 2011 and 2012. Responses to those consultations supported a change to the law in this area.

The UK IPO is consequently in the process of making this change, which will exempt from infringement (i) all activities required to obtain regulatory approval of all drugs, (ii) trials and studies necessary for health technology assessment of all drugs. These activities, trials and studies will be exempt from infringement when carried out for the purpose of obtaining regulatory approval and HTA in all countries. The change is expected to come into effect in April 2014.

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

See 21.

Section 4*: *Preparation of medicines

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

Section 60(5)(c) 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 –***
> ***...***
>
> > ***(c) it consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;***

Section 60(5)(c) corresponds to article 27(c) of the Community Patent Convention.

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

N/A

25. (a) What are the public policy objectives for providing the exception? Please explain:

Pharmacists should be free to make individual medical preparations as prescribed by a doctor without threat of patent infringement.

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

The Patents Act 1977 was intended (inter alia) to implement the CPC and s.60(5)(c) implements article 27(c) of the CPC.

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

There is no relevant case law but the wording of the statute indicates that the exception covers pharmacists.

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

☐ Yes
☑ No

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

N/A

28. 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):

Section 60(6) provides that a person who does an act falling within the exception under s.60(5)(c) is not treated as a 'person entitled to work the invention' for the purposes of s.60(2). It follows that associated acts of contributory infringement under s.60(2) do not fall within the exception under s.60(5)(c). It may therefore be an infringing act under s.60(2) to supply a person with material for preparation of a medicine.

29. 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 framework is considered adequate and there are no plans to change it.

30. 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 5: Prior use

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

Section 64 of the Patents Act:

> ***64(1) Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention –***
>
> > ***(a) does in good faith an act which would constitute an infringement of the patent if it were in force, or***
> > ***(b) makes in good faith effective and serious preparations to do such an act, has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act.***
>
> ***64(2) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (1) may –***
>
> > ***(a) authorise the doing of that act by any partners of his for the time being in that business, and***
> > ***(b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.***
>
> ***64(3) Where a product is disposed of to another in exercise of the rights conferred by subsection (1) or (2), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent****.*

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

N/A

33. (a) What are the public policy objectives for providing the exception? Please explain:

The exclusion exists to ensure prior users are treated fairly with respect to patent holders.

Section 2(1) of the Patents Act 1977 states that '*An invention shall be taken to be new if it does not form part of the state of the art*'. When the Act came into force it deprived a secret prior user of his right to sue a patent holder for grounds of invalidity. To counter this deprivation it was thought only just to accord a right to continue his use, thus a secret prior user may continue his use without being sued on grounds of infringement subject to Section 64.

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

The 1949 Act granted no protection to a prior user whose prior use began before the priority date of the invention; however, secret prior use was grounds for revocation, and was thus protected.

34. How does the applicable law define the scope of "use"? Does the applicable law provide for any quantitative or qualitative limitations on the application of the "use" by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 64 protects a person who in the UK before the priority date of the invention does in good faith an act which would constitute infringement of the patent or who makes in good faith effective and serious preparations to do such an act (s.64(1)). Therefore, in order for the prior use exception to apply, the act in question must constitute infringement of the patent.

The recipients of products disposed of in exercise of rights conferred by s.64(1) or (2) are protected under s.64(3).

In *Lubrizol Corporation v Esso Petroleum Co. Ltd.* [1998] RPC 727 the Court of Appeal affirmed (at page 770) that the protection afforded by s.64 to the prior user is not strictly limited to acts identical to those which were performed before the priority date but 'cannot be a right to manufacture any product, nor a right to expand into other products'. The Court of Appeal upheld the view of the Patents Court that 'if the protected act has to be exactly the same (whatever that may mean) as the prior art then the protection given by the section would be illusory. The section is intended to give practical protection to enable a man to continue in substance what he was doing before'. In the event, two customer trials by the defendant in the UK of small samples imported from the US with a view to possible later manufacture in the UK but with no decision yet made, were held, although serious, not to be 'effective' preparations to do an infringing act. The Court of Appeal amplified (at page 785) that it is not 'sufficient to show that the serious preparations, if pursued to finality, will have the requisite effect'.

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

No.

36. According to the applicable law, can a prior user license or assign his prior user's right to a third party?

The right may not be licensed but, if the act of prior use or preparations therefore occurred in the course of a business, the prior user may assign or transmit the right, or authorise the doing of the act, under the specific conditions set out by s.64(2).

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

Yes.

If yes, please explain what those conditions are:

The conditions are set out by s.64(2) (see answer to question 31).

38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

Yes – these situations are covered by similar provisions in sections 20B and 28A of the Patents Act.

If yes, please explain the conditions under which such use can continue to apply:

Where a terminated application has been reinstated under s.20A following termination of the application, the rights of third parties are as set out under s.20B:

> ***20B(4) If the application has been published under section 16 above before its termination and, after the termination and before publication of notice of the request for its reinstatement, a person –***
>
> > ***(a) began in good faith to do an act which would have constituted an infringement of the rights conferred by publication of the application if the termination had not taken place, or***
> > ***(b) made in good faith effective and serious preparation to do such an act,***
> > ***he has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the reinstatement of the application and the grant of the***

patent; but this right does not extend to granting a licence to another person to do the act.

(5) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (4) above may –

(a) authorise the doing of that act by any partners of his for the time being in that business, and
(b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

(6) Where a product is disposed of to another in exercise of a right conferred by subsection (4) or (5) above, that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the applicant.

(6A) The above provisions apply in relation to the use of a patented invention for the services of the Crown as they apply in relation to infringement of the rights conferred by publication of the application for a patent (or, as the case may be, infringement of the patent).

Similar provisions exist under s.28A to cover the situation where a lapsed patent has been restored under s.28:

28A(4) If after it was no longer possible for the patent to be so renewed, and before publication of notice of the application for restoration, a person –

(a) began in good faith to do an act which would have constituted an infringement of the patent if it had not expired, or
(b) made in good faith effective and serious preparations to do such an act, he has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the restoration of the patent; but this right does not extend to granting a licence to another person to do the act.

(5) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (4) may –

(a) authorise the doing of that act by any partners of his for the time being in that business, and
(b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.

(6) Where a product is disposed of to another in exercise of the rights conferred by subsection (4) or (5), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent.

(7) The above provisions apply in relation to the use of a patent for the services of the Crown as they apply in relation to infringement of the patent.

39. 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

40. 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 framework is considered adequate and there are no plans to change it.

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

See explanation of *Lubrizol Corporation v Esso Petroleum Co. Ltd. [1998] RPC 727* in answer to question 34.

Section 6: Use of articles on foreign vessels, aircrafts and land vehicles

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

Section 60(5)(d)-(f) 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 –***
> ***...***
>
> > ***(d) it consists of the use, exclusively for the needs of a relevant ship, of a product or process in the body of such a ship or in its machinery, tackle, apparatus or other accessories, in a case where the ship has temporarily or accidentally entered the internal or territorial waters of the United Kingdom;***
> >
> > ***(e) it consists of the use of a product or process in the body or operation of a relevant aircraft, hovercraft or vehicle which has temporarily or accidentally entered or is crossing the United Kingdom (including the air space above it and its territorial waters) or the use of accessories for such a relevant aircraft, hovercraft or vehicle;***
> >
> > ***(f) it consists of the use of an exempted aircraft which has lawfully entered or is lawfully crossing the United Kingdom as aforesaid or of the importation into the United Kingdom, or the use or storage there, of any part or accessory for such an aircraft;***

Section 60(7) defines the terms used in s.60(5)(d)-(f):

> ***60(7) In this section –***
>
> > ***"relevant ship" and "relevant aircraft, hovercraft or vehicle" mean respectively a ship and an aircraft, hovercraft or vehicle registered in, or belonging to, any country, other than the United Kingdom, which is a party to the Convention for the Protection of Industrial Property signed at Paris on 20 March 1883 or which is a member of the World Trade Organisation; and***
> >
> > ***"exempted aircraft" means an aircraft to which section 89 of the Civil Aviation Act 1982 (aircraft exempted from seizure in respect of patent claims) applies.***

Section 60(5)(d)-(f) corresponds to article 27(d)-(f) of the Community Patent Convention.

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

N/A

44. (a) What are the public policy objectives for providing the exception? Please explain:

The movement of foreign vessels, etc, should not be hindered by the threat of patent infringement.

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

The Patents Act 1977 was intended (inter alia) to implement the CPC and s.60(5)(d)-(f) implement article 27(d)-(f) of the CPC.

45. The exception applies in relation to:

☑ Vessels **(the statute refers to 'ships' rather than 'vessels')**

☑ Aircrafts
☑ Land Vehicles **(the statute refers to 'vehicles' rather than 'land vehicles')**
☐ Spacecraft

Hovercraft are also specifically mentioned in s.60(5)(e)

46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Yes – the words 'temporarily' and 'accidentally' are used in section 60(5)(d) and (e). These terms are not defined in statute but the meaning of 'temporarily' was considered by the courts in *Stena Aktiebolag v Irish Ferries Ltd* [2002] RPC 50 and [2003] RPC 36 CA. The case concerned a high-speed catamaran used to provide a regular ferry service between Eire and the UK, with three or four crossings being made each day. The vessel's home port was in Dublin, but it spent around three hours in UK territorial waters on each crossing. The vessel's superstructure was found to fall within the scope of the claimant's patent, and the claimant argued that the vessel's regular and frequent crossings took it outside the scope of s.60(5)(d) because 'temporarily' should be interpreted as 'on isolated occasions or casually'. The court rejected this argument, stating that the primary purpose of the word 'temporarily' was to distinguish between vessels which were engaged in essentially internal operations, and those which travelled between countries. Regard was to be had for the intention of the vessel's operator; on each crossing, the intention was for the vessel to enter and then leave UK territorial waters, and the fact that each crossing was repeated frequently did not alter the fact that each entry into UK waters was designed to be short-lived. The court therefore held that s.60(5)(d) applied and so infringement had not occurred.

47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):

Section 60(5)(d) specifies that the use must be 'exclusively for the needs of a relevant ship'. In *Stena Aktiebolag v Irish Ferries Ltd* (above), the court rejected an argument that the defence in s.60(5)(d) was restricted only to 'machinery, tackle, apparatus or other accessories' associated with the vessels and held that a purposive construction made clear that s.60(5)(d) applied as much to vessels as a whole as to any parts used on them.

48. 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

49. 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 framework is considered adequate and there are no plans to change it.

50. 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 7: Acts for obtaining regulatory approval from authorities

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

On 1 October 2014, section 60(5)(b) of the Patents Act was amended by new subsections 60(6D),(6E), (6F) and (6G) to clarify the research exception:

> ***Section 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) ...***
>
> ***(6D) For the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention.***
>
> ***(6E) In subsection (6D), "medicinal product assessment" means any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes—***
>
> ***(a) obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);***
>
> ***(b) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;***
>
> ***(c) enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of—***
>
> ***(i) providing health care on behalf of such a government or public authority, or***
>
> ***(ii) providing advice to, or on behalf of, such a government or public authority about the provision of health care,to carry out an assessment of suitability of a medicinal product for human use for the purpose of determining whether to use it,***
>
> ***(6F) In subsection (6E) and this subsection—***
> ***"medicinal product" means a medicinal product for human use or a veterinary medicinal product;***
> ***"medicinal product for human use" has the meaning given by article 1 of Directive 2001/83/EC(2);***
> ***"veterinary medicinal product" has the meaning given by article 1 of Directive 2001/82/EC(3).***
>
> ***(6G) Nothing in subsections (6D) to (6F) is to be read as affecting the application of subsection (5)(b) in relation to any act of a kind not falling within subsection (6D).***

Section 60(5)(i) of the Patents Act 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 –***
>
> ***(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.

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:

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 recent 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 exception 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:

No further amendments to the law are foreseen.

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 8: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

☑ National
☑ Regional
☐ International
☐ Uncertain, please explain..……

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

A regional exhaustion doctrine applies within the EEA under articles 34 and 36 of the Treaty on the Functioning of the European Union (the 'EU Treaty').

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

The UK also has a doctrine of implied licence, which functions as an exhaustion doctrine. This doctrine was established in *Betts v Willmott* (1871) LR 6 Ch App 239 where it was held that, on selling a patented product, the patentee transfers with the goods a licence for the purchaser to sell or use the article. The principle applies regardless of whether the first sale is made in the UK or elsewhere.

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

Balancing patent holders' rights with freedom of trade.

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

See 60.

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

☑ Yes **(National law)**
☑ No **(Regional law)**
☐ Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

The regional exhaustion doctrine cannot be overridden since it derives from article 28 of the EU Treaty which prohibits restrictions on imports between Member States.

Since the national exhaustion doctrine is one of implied licence, it can be overridden if the patentee imposes conditions on the use/re-sale of the product when it is first sold. Such conditions place a limitation on the grant of the licence to deal with the patented product and apply to all those who buy the product with knowledge of them. These principles were set out in *National Phonograph Company v Menck* (1911) 28 R.P.C. 229 Pat Ct ; *Incandescent Gas Light v Brogden* (1899) 16 R.P.C. 179 ; and *Dunlop v Longlife Battery* [1958] R.P.C. 473.

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

Yes.

64. Which challenges, if any, have been encountered in relation to the practical

implementation of the applicable exhaustion regime in your country? Please explain:

We are not aware of any significant challenges.

Section 9: Compulsory licenses and/or government use

Compulsory licenses

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.

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:

<u>Sections 48-54</u>

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 countries[1].

(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.

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[1] For further information see Regulation (EC) No 816/2006 which can be found on http://eur-lex.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.

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 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 (1 October 2015 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 (July 2012)

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]