

The Legislative Reform (Patents) Order 2014

**Explanatory document by the Intellectual Property Office,
an Executive Agency of the Department for Business,
Innovation and Skills**

Glossary

BRE	Better Regulation Executive
EMA	European Medicines Agency
EU	European Union
EC	European Commission
HTA	Health technology assessment
IA	Impact Assessment
IPO	Intellectual Property Office
IP	Intellectual property
LRO	Legislative Reform Order
LRRA	Legislative and Regulatory Reform Act 2006
MHRA	Medicines and Healthcare products Regulatory Agency
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
RPC	Regulatory Policy Committee
TRIPS	Agreement on Trade Related Aspects of Intellectual Property
UK	United Kingdom

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Introduction

This explanatory document is laid before Parliament in accordance with section 14 of the Legislative and Regulatory Reform Act 2006 (“the 2006 Act”) together with the draft of the Legislative Reform (Patents) Order 2014 (“the draft Order”) which we propose to make under section 1 and section 20 of that Act.

The purpose of the draft Order is to amend section 60 of the Patents Act 1977 to clarify that activities which are carried out for the purposes of obtaining regulatory approval or health technology assessment (HTA) for drugs fall within the scope of section 60(5)(b) of the Patents Act 1977.

Chapter 1: Background to the Order

Legislative background

1.1 The Patents Act 1977 sets out the legal rights and requirements for UK patents and patent applications for the whole of the United Kingdom and Northern Ireland. A patent gives its owner the right to prevent third parties from making, using, selling or importing their invention for up to 20 years in return for disclosure of their invention. If a third party does any of these things without the consent of the patent owner, it is considered to be an infringement of the patent and the owner is entitled to take legal action against the infringer.

1.2 The rights granted by a patent support innovation by helping businesses to protect investments made in research and development. A strong research base is vital both to the competitiveness of our economy and to promote the wellbeing of our society. It is important, however, that the right balance is struck between the freedom to conduct appropriate research and the intellectual property framework.

1.3 In line with international agreements^{1 2}, patent laws in most European countries include an experimental use exception (commonly known as a research exception) which permits the use of a patented invention for experimental purposes without infringing the rights of the holder.

1.4 In the UK the research exception is set out in section 60(5)(b)³ of the Patents Act 1977. It exempts from infringement acts "done for experimental purposes related to the subject matter of the invention". Its extent has been considered by the UK Courts in a number of cases, and judgments have resulted in a narrow interpretation of which acts fall within its scope. Trials carried out to discover something unknown, to test a hypothesis, or to find out whether something will work in specific conditions can be regarded as an experiment, but trials carried out to demonstrate to a third party that a product works, or to amass information to satisfy a third party that it works as claimed, are not regarded as acts done for experimental purposes^{4 5} and are therefore not acts which are exempt from infringement.

1.5 Section 60(5)(i)⁶ of the Patents Act exempts from infringement certain activities performed for the regulatory approval of generic drugs, as set out in European legislation⁷. This exemption, commonly called the Bolar exception, relates only to generic drugs and

¹ Community Patent Convention of 1975. It should be noted that the CPC was never implemented

² Article 27(c) Agreement Relating to Community Patents, 15 December 1989, 89/695/EEC. Signed by twelve states, ratified by Denmark, France, Germany, Greece, Luxembourg, the Netherlands and UK.

³ See Annex A

⁴ *Monsanto v Stauffer* [1985] RPC 515

⁵ *Auchinloss v Agricultural & Veterinary Supplies Ltd* [1999] RPC 397 followed the decision in *Monsanto v Stauffer* (above)

⁶ See Annex A

⁷ EU Directives 2001/83 relating to medicinal products for human use and 2001/82 relating to veterinary medicinal products

implemented EU Directives intended to provide an equivalent in European law to the United States Hatch-Waxman Act⁸. In line with Government policy, the UK fully implemented the Directives, and only acts specifically required to obtain marketing authorisation for a generic drug are exempt; it does not extend to innovative drugs.

1.6 Legislation in this area varies across the EU in accordance with how the Directives were implemented in each jurisdiction and in the light of domestic case law. For example, case law in Germany^{9 10} led to the exemption of all studies and trials necessary to obtain marketing approval of any medicinal product in any country, not just generics, and not just in the EU¹¹. Many other Member States have similarly broad provisions.

1.7 To further complicate the international context, US case law has evolved since the Directives were implemented in the EU, resulting in a broader interpretation of the Hatch-Waxman Act, which exempts from infringement all uses of compounds that reasonably relate to submission of information to the US government under any law regulating the manufacture, use or distribution of drugs.

Problems

1.8 In order to obtain regulatory approval to market a new drug product, companies must undertake trials to demonstrate to the regulatory authorities that the product is safe and effective¹². This is a long and costly process and the success rate for new drugs is low¹³. Clinical trial methodologies usually require a new product to be compared to the current standard-of-care therapy.

1.9 Health technology assessment (HTA) is carried out¹⁴ to assess the benefits and costs of a drug or treatment and how it compares with the available alternatives. HTA often takes place alongside the later stages of the regulatory approval process. In England, the NHS is required by Regulations to fund a drug or treatment which has received a positive HTA from NICE. Although much of the data submitted for the purposes of HTA is the same as that submitted to obtain a marketing authorisation, the authorities may request further information before making a decision.

1.10 The products used as comparators in both clinical trials and HTA may be protected by patents belonging to a third party. As trials and studies for new drugs are not considered

⁸ Section 505(j) 21 U.S.C. 355(j) introduced following *Roche Products v Bolar Pharmaceutical* 733 F.2d 858 (Fed. Cir. 1984)

⁹ [1997] RPC 623 & Case X ZR 99/92 Bundesgerichtshof. X Zivilsenat (Klinische Versuche (Clinical Trials) I)

¹⁰ [1998] RPC 423 and Case Z ZR 68/94 Bundesgerichtshof: X. Zivilsenat (Klinische Versuche (Clinical Trials) II)

¹¹ §11 2b Patentgesetz (see http://bundesrecht.juris.de/patg/_11.html)

¹² In accordance with EU legislation such as Directive 2001/83 relating to medicinal products for human use.

¹³ Average combined success rate has fallen to ~50% in recent years according to The Centre for Medicines Research International. Figures quoted in "Trial watch: Phase III and submission failures 2007-2010", *Nature Reviews: Drug Discovery* 2011, Vol. 10, p1.

¹⁴ E.g. by the National Institute for Health and Care Excellence (NICE) for England, the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC).

exempt from infringement in UK law, stakeholders risk patent infringement if they do this work in the UK. This has been a concern for stakeholders for some time¹⁵.

1.11 Although drugs can be purchased on the open market for use in trials, trial methodology can make their use difficult. For example, the form of a drug on the open market may not be suitable for use in “blind” trials where a participant should not know what product is being taken. Alternatively, the drug on the open market may not provide the particular formulation or dosage needed for the trial. A license could be sought from the patent holder, however there is no guarantee that this would be granted and it would signal commercial intent to a competitor. These circumstances put a third party into the position of potentially infringing a patent during the process of obtaining regulatory approval or carrying out HTA for a new product.

1.12 The risk of patent infringement can also arise when trials or HTA are performed with combination medicines. These medicines combine a number of different drugs into one product. A problem can arise if one or more of the drugs used in the combination is protected by a patent owned by a third party. Stakeholders have specifically listed clinical trials for combination therapies¹⁶ as being a particular area of concern for patent infringement. Although a combination medicine under trial or HTA can involve a new drug, it may be necessary or advantageous to deliver the drug as part of a combination to meet a medical need. This is often the approach taken in anti-viral and cancer treatments.

1.13 Many factors are taken into account by companies when deciding where to locate clinical trials; the risk of patent infringement being one of them. The UK is in direct competition with other countries, both within the EU and internationally, as a location for clinical trials. In its favour, the UK has a good healthcare and scientific infrastructure, world experts in particular conditions, specialised hospitals, good access to patients through the NHS network, and high levels of literacy and ethical standards.¹⁷ However, the narrow exceptions to patent infringement in UK law may put companies at a disadvantage compared to other countries with broader exceptions. Stakeholders have indicated that, everything else being equal, it is likely that trials would be located in a jurisdiction with more generous Bolar or research exceptions¹⁸.

Summary of proposals

1.14 The proposed changes to the Patents Act specify that activities relating to trials for human and veterinary medicines, as well as HTA are acts which fall within the scope of the existing research exception (see paragraph 1.4 above).

¹⁵ Stakeholder raised these concerns in an informal 2008 IPO consultation on the research exception <http://www.ipo.gov.uk/pro-policy/consult/consult-closed/consult-closed-2008/consult-2008-patresearch.htm>

¹⁶ See for example, paragraph 16, Government Response to informal consultation and paragraph 13 Government Response to formal consultation.

¹⁷ Stakeholders listed these factors, and others, in the 2011 informal consultation on patent infringement in clinical trials – see paragraph 30 <http://www.ipo.gov.uk/response-2011-bolar.pdf>

¹⁸ See paragraph 22 (page 7) Government response to informal consultation <http://www.ipo.gov.uk/response-2011-bolar.pdf>

1.15 The Order inserts new paragraphs 6D to 6G into section 60 of the Act. Paragraph 6D specifies that for the purposes of the research exception:

"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."

1.16 Paragraph 6E defines that "medicinal product assessment" means any testing, course of testing or other activity undertaken with a view to providing data to:

- obtain or vary an authorisation for a medicinal product to sell or supply, or offer to sell or supply a medicinal product (whether in the United Kingdom or elsewhere); or
- comply with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation; or
- enable a government or public authority (whether in the UK or elsewhere) to carry out an assessment of suitability of a medicinal product for medicinal use for the purpose of determining whether to use it, or recommend its use, in the provision of health care; or
- enable such assessment to be carried out by a person (whether in the UK or elsewhere) with functions of providing healthcare on behalf of such government or public authority or providing advice to, or on behalf of, such a government or public authority about the provision of health care.

1.17 The term "medicinal product assessment" in the Order is intended to cover both clinical trials for human medicines, field trials for veterinary medicines and activities which fall within the term "health technology assessment".

1.18 Paragraph 6F defines the terms "medicinal product", "medicinal product for human use" and "veterinary medicinal product".

1.19 Post-approval studies to comply with regulatory requirements, studies necessary to amend an authorisation, or to obtain an authorisation for a new indication of an authorised drug will fall within the scope of the new exception. In short, any tests or studies which are required by regulatory bodies will be allowed.

1.20 The new provision is intended to allow clinical trials, field trials and health technology assessment to be carried out without infringing a patent. Commercial use of a patented product after obtaining regulatory approval/HTA recommendation is not covered by the provisions and a licence or other form of agreement from the patent holder would be required before an approved product could be supplied commercially.

1.21 Where the proposed changes go beyond the scope of section 60(5)(i) of the Patents Act (the "Bolar exception"), generic manufacturers will be able to rely on the new provision. Examples include when a generic product manufacturer does not follow the shortened approval route for their product and instead undertakes a full approval process, activities relating to the health technology assessment of a generic product, or where a test or trial is carried out with a view to obtaining regulatory approval or HTA in a country outside of the UK, the EU or EEA.

1.22 The Unified Patent Court (UPC) Agreement¹⁹ also contains exceptions to patent infringement. In order to implement the UPC the UK must ensure that its laws comply with this Agreement. The infringement provisions in both the Patents Act and the UPC Agreement are currently broadly similar and by clarifying which activities fall within the experimental purposes exception according to UK law we will ensure that this exception continues to be in line with the UPC Agreement

¹⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:175:0001:0040:EN:PDF>

Chapter 2: Consultation

2.1 BIS Ministers have fulfilled the obligations laid down to undertake a full and extensive consultation on the proposals, through the consultation exercises described below.

2.2 The responses to the consultations have been analysed by the Intellectual Property Office and it is appropriate to proceed with the proposals in the draft Order.

Consultation process

Informal consultation

2.4 Following a Government commitment made in “The Plan for Growth Report”²⁰ to ensure that the intellectual property system supports the life science sector, the Intellectual Property Office informally consulted stakeholders for their views on whether current legislation strikes the right balance between the rights granted to a patent holder and the needs of the pharmaceutical industry to carry out clinical and field trials, specifically where the risk of patent infringement may be an issue. The consultation also asked for possible remedies to the problem, should it be established.

2.5 The consultation ran for 8 weeks, from 6 June 2011 to 31 July 2011. It was published on the Intellectual Property Office website at <http://www.ipo.gov.uk/consult-2011-bolar.pdf>. It was circulated to the organisations and individuals listed in Annex B to this document.

2.6 A total of 17 responses to the consultation were received (see Annex B). These comprised five from the IP profession, five from the pharmaceutical industry, four from trade bodies representing the IP and pharmaceutical sectors, one from a trade body representing the generics industry, one from a charitable organisation and one from a clinical research organisation.

2.7 Responses²¹ indicated that the current legislation does not strike the right balance between the rights of a patentee and the need to carry out trials on new products. Stakeholders want to be able to run clinical trials without worrying that they are infringing a third party’s patent. Respondents also expressed concern about the lack of certainty as to which activities are exempt from infringement. There was almost unanimous agreement²² that change is required, and the majority²³ of responses indicated a desire to see the law changed. One response suggested that the current legislation is not causing significant harm. No responses opposed legislative change.

2.8 The Government acknowledged that there was evidence of a need to amend UK patent law in this area, and committed to run a formal consultation on proposals to amend

²⁰ Para 2.207 HM Treasury “The Plan for Growth” March 2011: http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf

²¹ <http://www.ipo.gov.uk/response-2011-bolar.pdf>

²² 15/16 responses agreed that there was a need for change.

²³ 12/16 responses think the law should be changed.

the Patents Act 1977 to exempt from infringement activities involved in clinical or field trials. The full Government Response can be seen at <http://www.ipo.gov.uk/response-2011-bolar.pdf>.

Formal consultation

2.9 A formal consultation ran for 8 weeks, from 24 October 2012 to 19 December 2012. The consultation asked whether the Patents Act should be amended to include a new exception to patent infringement and if so which acts should be included in the new exception and what its geographical scope should be. Stakeholders were asked to comment on the following options for legislative change:

- i. Change UK patent law to exempt from infringement all activities required to secure regulatory approval to market innovative drugs in all countries;
- ii. Change UK patent law to exempt from infringement all activities required to secure regulatory approval to market innovative drugs in the EU and EEA only;
- iii. Change UK patent law to exempt from infringement all activities required to secure regulatory approval to market innovative drugs and also all activities necessary for health technology assessment.

2.10 The consultation was produced in accordance with the Government's Consultation Principles²⁴ and the Legislative Reform Order-Making Powers (Guidance note for officials)²⁵. The consultation document was published on the Intellectual Property Office website at <http://www.ipo.gov.uk/consult-2012-bolar.pdf>. It was circulated to the organisations and individuals listed at Annex C to this document. In addition, subscribers to the IPO alert service were made aware that a new consultation had been issued. The consultation was also publicised on the IPO twitter feed.

2.11 A total of 20 responses were received (see Annex C). These comprised six from the IP profession of which four came from professional bodies, two from the research and development pharmaceutical industry, three from trade bodies representing the pharmaceutical and biotechnology sectors, two from technology transfer organisations, one from a trade body representing the generics industry, a charitable organisation, a licensing organisation, a company employee, a Devolved Administration, a biological contract manufacturing organisation and an active pharmaceutical ingredient manufacturer.

2.12 The overwhelming majority of responses^{26 27} agreed that section 60(5) of the Patents Act should be changed to exempt from patent infringement activities which are carried out when preparing or running clinical or field trials for new drugs. Most

²⁴ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/60937/Consultation-Principles.pdf

²⁵ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/80237/13-563-legislative-reform-orders-guide.pdf

²⁶ The figures indicate the number of responses to particular questions. Where the denominator varies, this shows the different number of responses to a specific question i.e. 20 responses were received to question 1; 16 responses were received to question 2.

²⁷ 19/20 responses agreed that section 60(5) of the Patents Act should be changed to exempt from patent infringement activities which are carried out when preparing, or running clinical or field trials using new drugs.

respondents²⁸ want to see the exemption cover activities carried out to gain regulatory approval of new drugs and a significant majority²⁹ want the exemption to extend to studies required for health technology assessment. The full Government Response can be viewed at <http://www.ipo.gov.uk/response-2012-bolar.pdf>.

2.13 One response, received from an individual, disagreed with the proposed changes to the Patents Act. The response further stated that none of the proposed options were acceptable, disagreed with the impact assessment and with the use of a legislative reform order to make the changes. Whilst the opinions expressed have been fully taken into account, they must be considered in context, namely that all other responses broadly supported the Government's proposals, and these responses come from across the range of stakeholders who would be affected by the changes.

2.14 There was some difference of opinion as to the exact form any changes should take but there was a clear preference for the new exception to include both activities required for regulatory approval as well as those for HTA³⁰. With regard to geographical scope, there was a strong preference for any new exception to extend to all countries³¹. Of the options which specifically indicated a geographical scope, all but two of the responses (13/15) wanted the activities allowed by the new exception to extend to all countries and not be limited to the EU and EEA. Although the option which including HTA did not specifically ask about the scope, several comments were received which stated that this option should extend to all countries.

2.15 In view of the responses received, the Government accepted that the Patents Act should be changed to include an exemption from infringement for activities involved in preparing or running clinical trials or field trials involving innovative drugs for the purpose of gaining regulatory approval in any country, and that the exemption should also cover activities involved in health technology assessment.

²⁸ 15/16 want to see the exemption cover activities carried out to gain regulatory approval of new drugs.

²⁹ 10/16 want the exemption to extend to studies required for health technology assessment.

³⁰ 9/15 responses ranked option (iii) first, 5/15 ranked option (i) first, 1 respondent listed options (ii) and (iii) as joint top and 1 response considered none of the options to be acceptable

³¹ 13/15 responses wanted the activities allowed by the new exception to extend to all countries and not be limited to the EU and EEA.

Chapter 3 - Analysis of Ministerial Responsibilities

Sections 1 and 2 LRRA

3.1 This Order is made under section 1 of the Legislative and Regulatory Reform Act 2006.

3.2 The Order will remove and reduce burdens in accordance with section 1(2) of the Act, namely financial burdens (section 1(3)(a)) and burdens to obstacles to efficiency (section 1(3)(c)).

3.3 We consider the following burdens set out in section 1(3) of the Act will be reduced or removed by the changes contained in the Order:

- The financial burden caused to the pharmaceutical industry by the need to carry out expensive legal assessments of the infringement position in respect of all relevant patents prior to running clinical trials in the UK.
- The financial burden which may result from an injunction granted against a company running a trial in the UK, the result of which prevent them from using any data already generated.
- The financial cost to a company of a delay in getting a product to market, caused by a trial being delayed, either due to legal challenges or the inability to run it abroad.
- The efficiency burdens placed on companies when they locate a trial abroad due to the narrow infringement exceptions in the Patents Act.
- The financial and efficiency burdens on SMEs and academic institutions who may have more limited budgets for assessing infringement risk or locating trials abroad and may therefore be more at risk of infringing a third party patent. This burden affects companies with smaller budgets.
- The financial burden to the UK clinical trials sector and medical institutions when clinical trials are run abroad due to the narrower infringement provisions in UK law compared to most other EU countries.

3.4 Consultation responses confirm that current legislation causes a financial burden to companies running clinical trials, but the evidence suggests that the exact scale of costs varies according to the business model adopted by any particular company. Due to the commercial-sensitivity of the information, very little quantified evidence was provided. One company indicated that 60% of the compounds they are currently developing have potential infringement issues which would affect clinical trials and estimated that the total cost savings to them of a change to the law to exempt clinical trials from infringement would be nearly £7 million. Another company, although unable to provide specific figures indicated that freedom-to-operate studies cost tens of thousands of pounds plus internal costs, and a third company indicated that they spend a week of attorney time a year investigating infringement issues. All these costs would be saved by the current proposals.

3.5 Under section 1 of the 2006 Act, we are seeking to amend the provisions set out in section 60 of the Patents Act 1977 to clarify that certain activities relating to the conduct of clinical trials and health technology assessment are exempt from patent infringement.

Section 3 LRRRA

3.6 The Minister is satisfied that the conditions set out in section 3(2) of the Act are satisfied for the reasons set out below.

3.7 The formal consultation asked stakeholders to comment on the preconditions set out in section 3 of the LRRRA. 12 responses were received, 11 of which agreed with our assessment of these preconditions. Further detail of our assessment and stakeholder comments are given below.

3.8 One response disagreed with our assessment of the preconditions and suggested that the proposals are disproportionate. The response was received from an individual and has been taken into account. However, it should be considered in context, namely that all other respondents agreed that no necessary protection is removed; that these responses came from a broad range of stakeholders representing the innovative pharmaceutical industry, the biological industry, the generic industry as well as the IP legal profession which represents both companies who wish to carry out clinical trials and HTA as well as those who hold patents which may be infringed by such activities.

The policy objective could not be satisfied by non-legislative means (section 3(2)(a))

3.9 We considered two non-legislative options - industry agreements, and clarification of current legislation:

Industry agreements:

The risk of infringement when undertaking trials would be removed if the parties involved agreed not to enforce their patent rights e.g. by using legal agreements of non-infringement which parties would enter into voluntarily. At informal consultation stakeholders indicated that such agreements were unacceptable due to their indefinite and imprecise scope³². Concerns were raised that such agreements could lead to further fragmentation and reduced certainty of the infringement position. It could not be guaranteed that all current and future holders of pharmaceutical patents valid in the UK would sign up to voluntary agreements. Without buy-in from stakeholders, the infringement risk would not be removed and the financial burden on stakeholders would remain the same. As the financial burden would not be reduced or removed, this is not a viable option.

Clarifying current legislation:

Non-statutory guidance could be produced to help stakeholders understand what is exempt according to Court judgments. However, case law is limited in this area, and whilst some activities would clearly be exempt from infringement, it would be difficult to accurately assess and give guidance on the position of all possible acts related to regulatory approval and HTA. In the absence of clear and legally certain guidance, legal uncertainty would remain. It is likely that stakeholders would still undertake their own investigations of the infringement risks associated with their trial or HTA, and the cost would be similar to that which

³² 6/13 responses at informal consultation specifically listed problems with industry agreements. The vast majority of responses preferred legislative change (see paragraphs 34-38 Government response).

stakeholders bear under the current legislation. As the financial burden would not be reduced or removed, this is not a viable option.

3.10 The overwhelming majority³³ of responses at formal consultation agreed with our assessment that the identified non-legislative options were not a viable way of achieving the policy objective.

3.11 We therefore consider that there is no non-legislative solution which would achieve the aim of reducing the burden on industry.

The effects of the provisions are proportionate to the policy objective to be achieved (section 3(2)(b))

3.12 The Patents Act already contains limited exceptions to patent infringement. The change made by the Order specifies that certain activities are in-scope of the experimental purposes exception in section 60(5)(b). The amendment will only apply to activities carried out in the course of obtaining regulatory approval and health technology assessments of new drugs. We are not seeking to exempt any other acts. The amendment is limited to the pharmaceutical sector to enable companies to innovate and comply with regulatory requirements and provide data for health technology assessments.

3.13 In the absence of acceptable non-legislative options, the proposed limited amendments to the Patents Act is the most proportionate way to remove the cost burdens placed on the pharmaceutical industry by current legislation. 11/12 formal consultation responses agree with our assessment of proportionality.

The provisions of the proposed order will strike a fair balance between the public interest and the interest of any person adversely affected by them (section 3(2)(c))

3.14 The balance to be struck is between the holders of patent rights and the public interest in new drugs being available on the market.

3.15 At formal consultation 11/12 responses agreed that the proposed changes strike a fair balance. Specific comments included:

- "a trial itself has little impact on a patentee's interest and earlier entry of a new drug onto market is in the public interest. The balance between patent rights and immediate post-patent expiry entry of products onto the market in the interests of public health already exists for generics".
- "it is in the public interest to exempt trials in order to promote development and marketing of innovative medicines and inexpensive generics."

3.16 We received anecdotal evidence that current legislation encourages companies to run some trials abroad, even when the disease to be treated is more prevalent in the UK and, all things being equal, it would be easier to run the trial here. When this happens, trial participants are not selected from the UK population, and for late stage trials this means that a large number of people may not have access to experimental treatments which may cure

³³ 11/12 responses agreed with our assessment of the available non-legislative options (see page 18, Government Response to formal consultation).

or alleviate their condition. In this situation, it may also be difficult to recruit a sufficient number of participants which could ultimately delay a trial and thus delay entry of a successful drug onto the market. Furthermore, at the other extreme, sufferers of rare diseases may be affected by a decision to locate a trial abroad as they would not have access to an experimental treatment and alternative treatments are likely to be scarce as products to treat such conditions are less commercially viable.

3.17 For these reasons, there is a clear public interest in having access to both experimental trial drugs and approved new medicines at the earliest opportunity which current UK patent legislation does not encourage.

3.18 A further consequence of trials being forced abroad is the potential loss to the UK economy of skilled jobs in the clinical research sector and of pharmaceutical manufacturing sites which are often located where a trial has been run (use a quote to support from consultation). It is in the public interest to encourage these highly-skilled sectors to remain in the UK.

3.19 Some concern was raised at formal consultation that unlicensed use of a compound by third parties in clinical trials may negatively affect the safety profile of the product. This would be the case, for example, where a trial participant suffered an adverse reaction to a product during the trial. As there is a requirement to report such results to the regulatory authorities, the use of a third party's product in a trial could in the worst case scenario result in regulatory approval being withdrawn for the product. However, this needs to be set against the public interest not to expose individuals to potentially harmful drugs.

3.20 For these reasons, we are satisfied that the proposals strike a fair balance between the public interest and the interests of patent holders.

The provisions do not remove any necessary protection (section 3(2)(d))

3.21 Although the patent regime grants a limited monopoly to an individual or company in return for full disclosure of an invention, the decision whether to apply for a patent lies with an individual and is therefore optional. Furthermore, patent protection is not absolute and legislation sets out exceptions to it.³⁴ The World Trade Organisation (WTO), of which the UK is a member, allows for the provision of limited exceptions to the exclusive rights conferred by a patent³⁵ in its Agreement on Trade Related Aspects of Intellectual Property (TRIPS). Subject to this agreement, infringement provisions may be amended in line with changes to policy. For example the Bolar exception was introduced into EU law³⁶ in 2004 to allow generic manufacturers to obtain regulatory approval for a product prior to expiry of associated patents.

3.22 The provisions of the Order are in keeping with the existing exceptions to patent infringement as they clarify that certain specific acts relating to clinical trials and health

³⁴ Section 60(5) of the Patents Act sets out exceptions to patent infringement. See Annex A.

³⁵ TRIPS Article 30 "Exceptions to the Rights Conferred" - *Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*

³⁶ See Annex A

technology assessment fall within the existing research exception. The changes do not exempt commercial activities which a patentee could reasonably expect to continue exercising and do not remove any necessary protection as a third party will still require a licence from the patent holder in order to use a patented product for commercial activities.

3.23 On a practical level, the laws of most EU Member States exempt clinical trials from patent infringement. These broader provisions mean that a trial can be run abroad, and the results of it can be used to obtain regulatory approval for a new drug in the UK. This was confirmed by stakeholders at formal consultation. As UK legislation can be so easily side-stepped and as patent protection is an optional as opposed to an absolute right, we consider that the ability to prevent someone from using a patented product in trials is not necessary. 11/12 formal consultation responses agreed with our assessment that the proposed provision will not remove any necessary protection.

The provisions of the proposed order do not prevent a person exercising any right or freedom that they might reasonably expect to continue to exercise (section 3(2)(e))

3.24 The factors outlined above in respect of necessary protection are also relevant here. Although patentees currently have the right in UK law to prevent another party using their product in a trial, a company wishing to eliminate this risk may do so by running it abroad, therefore no practical benefit flows from this right and the expectation of exercising it is frustrated by legislation in other jurisdictions. Furthermore, any third party seeking to use a patented product commercially would still require a licence from the patentee. The proposals do not prevent anybody from exercising a right which they might expect to continue exercising, namely the commercial exploitation of a patent.

For these reasons, we consider this precondition is met. 11/12 formal consultation responses agreed with our assessment of this precondition.

The provisions in the proposed order are not constitutionally significant

3.25 The proposals are not constitutionally significant. Formal consultation responses did not suggest otherwise.

Other issues

Devolved administrations/Territorial extent

3.26 The proposed Order will amend the Patents Act 1977 which applies to the whole of the UK. Intellectual property is not a devolved matter and there are no specific implications for the devolved administrations. Isle of Man officials have agreed that the changes will apply there.

Compatibility with the Convention on Human Rights

3.27 The Minister does not believe that any human rights issues arise with regard to this draft Order. It is therefore compatible with the Convention on Human Rights.

Compatibility with the obligations arising from membership of the European Union

3.28 The draft order is compatible with any obligations resulting from membership of the European Union.

Impact assessment

3.29 A full, final stage impact assessment has been published and is included in this document at Annex D.

Minister's recommended Parliamentary process

3.30 The Minister recommends that the draft Order and the Explanatory Document should be laid in Parliament under the affirmative resolution procedure.

3.31 The proposed amendment of the Patents Act enacts a change to Government policy. The change is a straightforward legislative reform which has widespread support from interested parties.

Annex A: Extracts from relevant UK and EU legislation

Section 60(5) Patents Act 1977

s.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;
- b) it is done for experimental purposes relating to the subject-matter of the invention;
- 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;
- 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.
- 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;
- 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.
- (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.

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use (extract from consolidated text)

Article 10

1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

2. For the purposes of this Article:

(a) 'reference medicinal product' shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8;

(b) 'generic medicinal product' shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

3. In cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided.

4. Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

5. In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

6. Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Article 10a

By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the test and trial results shall be replaced by appropriate scientific literature.

Article 10b

In the case of medicinal products containing active substances used in the composition of authorised medicinal products but not hitherto used in combination for therapeutic purposes, the results of new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with Article 8(3)(i), but it shall not be necessary to provide scientific references relating to each individual active substance.

Article 10c

Following the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to veterinary medicinal products (extract from consolidated text)

Article 13

1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 5 for not less than eight years in a Member State or the Community.

A generic veterinary medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply when the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit, within a period of one month, confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

However, the 10-year period provided for in the second subparagraph shall be extended to 13 years in the case of veterinary medicinal products for fish or bees or other species designated by the Commission.

That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).

2. For the purposes of this Article:

(a) 'reference medicinal product' shall mean a product authorised within the meaning of Article 5 in accordance with the provisions of Article 12;

(b) 'generic medicinal product' shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information intended to provide proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

3. In cases where the veterinary medicinal product does not fall under the definition of a generic medicinal product set out in paragraph 2(b) or where bio-equivalence cannot be demonstrated through bioavailability studies or in the case of changes to the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, the results of the appropriate safety and residue tests and pre-clinical tests or clinical trials shall be provided.

4. Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

5. In the case of veterinary medicinal products intended for one or more food-producing species and containing a new active substance that has not been authorised in the Community by 30 April 2004 the ten- year period provided for in the second subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another food-producing species, if it is authorised within the five years following the granting of the initial marketing authorisation.

This period shall not, however, exceed a total of 13 years, for a marketing authorisation for four or more food-producing species.

The extension of the ten-year period to 11, 12, or 13 years for a veterinary medicinal product intended for food-producing species shall be granted only if the marketing authorisation holder also originally applied for determination of the maximum residue limits established for the species covered by the authorisation.

6. Conducting the necessary studies, tests and trials with a view to the application of paragraphs 1 to 5 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products.

Article 13a

1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law on the protection of industrial and commercial property, the applicant shall not be required to provide the results of safety and residue tests or of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the veterinary medicinal product have been in well-established veterinary use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the applicant shall provide appropriate scientific literature.

2. The assessment report published by the Agency following the evaluation of an application for the establishment of maximum residue limits in accordance with Regulation (EEC) No 2377/90 may be used in an appropriate manner as literature, particularly for the safety tests.

3. If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies in accordance with Regulation (EEC) No 2377/90, together with further clinical trials, it shall not

be permissible for a third party to use such studies or such trials pursuant to Article 13, for a period of three years from the grant of the authorisation for which they were carried out.

Article 13b

In the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products but not hitherto used in combination for therapeutic purposes, the results of safety and residue tests, if necessary, and new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with point (j) of the first subparagraph of Article 12(3), but it shall not be necessary to provide scientific references relating to each individual active substance.

Article 13c

After the marketing authorisation has been granted, the marketing authorisation holder may allow use to be made of the pharmaceutical, safety and residues, pre-clinical and clinical documentation contained in the file for the veterinary medicinal product with a view to examining a subsequent application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

Article 13d

By way of derogation from point (j) of the first subparagraph of Article 12(3), and in exceptional circumstances with respect to immunological veterinary medicinal products, the applicant shall not be required to provide the results of certain field trials on the target species if these trials cannot be carried out for duly substantiated reasons, in particular on account of other Community provisions.

Annex B: Informal consultation

Organisations consulted

The American Pharmaceutical Group (APG)

Amgen UK

The Association of the British Pharmaceutical Industry (ABPI)

Association for University Research and Industry Links (AURIL)

AstraZeneca

Biotechnology Industry Organisation (BIO)

BioIndustry Association (BIA)

Bird & Bird

British Generic Manufacturers Association (BGMA)

Bristol-Myers Squibb

BTG plc

BUSINESSEUROPE

Cancer Research Technology (CRT)

Cancer Research

Chartered Institute of Patent Attorneys (CIPA)

Clinical Contract Research Association (CCRA)

The Confederation of British Industry (CBI)

Covance Eisai Ltd

Lilly

Ethical Medicines Industry Group (EMIG)

European Federation of Pharmaceutical Industries and Associations (EFPIA)

European Generic Medicines Association (EGA)

Fédération Internationale des Conseils en Propriété Industrielle (FICPI)

GlaxoSmithKline (GSK)

Hikma

ICON

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

IP Institute

Intellectual Property Lawyers Association (IPLA)

International Association for the Protection of Intellectual Property (AIPPI)

Institute of Knowledge Transfer (IKT)

Japan Pharmaceutical Manufacturers Association (JPMA)

Janssen-Cilag

Johnson & Johnson

Linklaters

Lonza

MSD

Mitsubishi Pharma Europe Ltd

MRC Technology (MRCT)

National Office of Animal Health (NOAH)

Novartis UK

Orion Pharma

Pfizer

ProPharma Partners Limited

Quintiles

Reckitt Benckiser (RB)

Research Councils UK (RCUK)

Royal Veterinary College (RVC)

Sanofi

Sandoz

UCB

UNICO Pharmaceuticals

Universities UK

Wellcome Trust

Respondees

Association of the British Pharmaceutical Industry (ABPI)

BioIndustry Association (BIA)

Bird & Bird

Boehringer-Ingelheim

Cancer Research UK

Chartered Institute of Patent Attorneys (CIPA) (Life Sciences Committee)

Clinical research organisation personal response – confidentiality requested

Eli Lilly

European Generic Medicines Association (EGA)

FICPI-UK (International Federation of Intellectual Property Attorneys)

IP Federation

Interpat

Japan Intellectual Property Association (JIPA)

Japan Pharmaceutical Manufacturers Association (JPMA)

Johnson & Johnson

Merck

Novartis

Annex C Formal consultation

Organisations consulted

The American Pharmaceutical Group (APG) Amgen UK

Arnold & Porter LLP

The Association of the British Pharmaceutical Industry (ABPI)

Association for University Research and Industry Links (AURIL)

Association of Medical Research Charities (AMRC)

AstraZeneca

Avidity

Biotechnology Industry Organisation (BIO)

BioIndustry Association (BIA)

Bird & Bird

Bristol-Myers Squibb

British Generic Manufacturers Association (BGMA)

British In Vitro Diagnostic Association (BIVDA)

BTG plc

BUSINESSEUROPE

Cancer Research Technology (CRT)

Cancer Research UK

Chartered Institute of Patent Attorneys (CIPA)

Clinical Contract Research Association (CCRA)

The Confederation of British Industry (CBI)

Covance

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Lilly

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European Federation of Pharmaceutical Industries and Associations (EFPIA)

European Generic Medicines Association (EGA)

Fédération Internationale des Conseils en Propriété Industrielle (FICPI)

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International Association for the Protection of Intellectual Property (AIPPI)
Institute of Knowledge Transfer (IKT)
Japan Pharmaceutical Manufacturers Association (JPMA)
Janssen-Cilag
Johnson & Johnson
Linklaters
Lonza
MSD
Mitsubishi Pharma Europe Ltd
MRC Technology (MRCT)
National Institute for Health and Clinical Excellence (NICE)
National Office of Animal Health (NOAH)
Northern Ireland Executive
Novartis UK
Orion Pharma
Pfizer
ProPharma Partners Limited
Quintiles
Reckitt Benckiser (RB)
Reddie & Grose
Research Councils UK (RCUK)
Royal Veterinary College (RVC)
Sanofi

Sandoz

Scottish Parliament

UCB

UNICO Pharmaceuticals

Universities UK

Wellcome Trust

Welsh Assembly Government

Respondees

The Association of the British Pharmaceutical Industry (ABPI)

BioIndustry Association (BIA)

British Generic Manufacturers Association (BGMA)

Chartered Institute of Patent Attorneys (CIPA)

Eli Lilly

Ethical Medicines Industry Group (EMIG)

Fujifilm Diosynth Biotechnologies

GlaxoSmithKline

Intellectual Property Lawyers Association (IPLA)

IP Federation

ISIS (University of Oxford Technology Transfer Company)

Japan Intellectual Property Association (JIPA)

Licensing Executives Society (LES)

Patents Judges

Pharmaceutical Life Cycle Management Solutions

Polpharma

PraxisUnico

Individual employee of a pharmaceutical company

Wellcome Trust

Welsh Assembly Government

Annex D: Impact Assessment

Title: Experimental use and Bolar exception IA No: BIS0402 Lead department or agency: Intellectual Property Office (IPO) Other departments or agencies:	Impact Assessment (IA)
	Date: 13/06/2013
	Stage: Final
	Source of intervention: Domestic
	Type of measure: Secondary legislation
	Contact for enquiries: Fiona Warner (IPO)

Summary: Intervention and Options

RPC Opinion:

Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Measure qualifies as One-Out?
£0m	£0m	£0m	Yes
			Zero Net Cost

What is the problem under consideration? Why is government intervention necessary?

UK law puts the pharmaceutical industry at greater risk of patent infringement when running clinical trials and health technology assessment than most EU countries as the provisions in UK law are more narrowly drafted than in most other Member States. This is a problem because a) there is a cost to industry of assessing this risk; b) it makes the UK a less attractive location in which to do this work which has economic implications. Government intervention is required to address this issue as the industry considered the non-statutory options of industry agreements of non-infringement and guidance would not provide legal certainty and hence the risk of infringement would remain. Legislative change would provide certainty.

What are the policy objectives and the intended effects?

UK law should be changed to exempt from infringement activities involved in clinical trials, field trials and health technology assessment (HTA) for innovative drugs/therapies or drug/therapy combinations.

Changing the law will reduce the cost to industry as it will no longer be necessary to assess the infringement position prior to carrying out trials. Additionally, this will make the UK a more attractive location for clinical/field trials which may bring economic benefits to the UK.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1- do nothing

Option 2- changing UK legislation to exempt from infringement activities involved in clinical trials, field trials and HTA for innovative drugs/therapies or drug/therapy combinations;

Option 3- clarify current legislation through non-statutory guidance;

Option 4- change EU legislation to exempt from infringement activities involved in clinical and field trials for innovative drugs/therapies or drug/therapy combinations;

Option 5- encourage industry agreements

Option 2 is the chosen option as it will allow the policy objective to be achieved in a shorter timescale.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 10/2018					
Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes	< 20 Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded:	Non-traded:	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible
SELECT SIGNATORY:

Date

..... :

Summary: Analysis & Evidence Policy Option 1

Description: Do nothing

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period	Net Benefit (Present Value (PV)) (£m)			
			Low: 0	High: 0	Best Estimate: 0	
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)	
Low	0		0		0	
High	0		0		0	
Best Estimate	0		0		0	
Description and scale of key monetised costs by 'main affected groups'						
Zero						
Other key non-monetised costs by 'main affected groups'						
Zero						
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)	
Low	0		0		0	
High	0		0		0	
Best Estimate	0		0		0	
Description and scale of key monetised benefits by 'main affected groups'						
Zero						
Other key non-monetised benefits by 'main affected groups'						
Zero						
Key assumptions/sensitivities/risks					Discount rate (%)	3.5
Zero						

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	No	NA

Summary: Analysis & Evidence Policy Option 2

Description: Change UK legislation to exempt from infringement activities involved in clinical trials, field trials and health technology assessment for innovative drugs/therapies and drug/therapy combinations

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	High: 0	Best Estimate: 0
COSTS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)	
Low		0	0	0	
High		0	0	0	
Best Estimate		0	0	0	

Description and scale of key monetised costs by 'main affected groups'

It has not been possible to monetise costs despite running two consultations on the issue and asking stakeholders for this information.

Other key non-monetised costs by 'main affected groups'

i) Loss of income from licence - indications are that companies do not pay much to licence a drug for trial use due to low success rates, hence losses are probably not significant. ii) Earlier reduction in market share for the patent-holder - assumes trials are not currently run abroad when in reality they probably are and hence cost of change is minimal iii) Impact on product safety data profile through unlicensed use - however greater safety data will prevent harmful drugs reaching market.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
	Low	0	1	0
High	0	0		0
Best Estimate	0	0		0

Description and scale of key monetised benefits by 'main affected groups'

We have not been able to monetise the benefits. Although stakeholders provided some figures (shown below), no real indication of the frequency of the non-monetised benefits was given. Without this information it is not possible to estimate the monetised benefits.

Other key non-monetised benefits by 'main affected groups'

Savings: freedom-to-operate investigations (£3K-£135K per study); full revocation actions (costing up to £1.5m per case); licensing negotiations (£10K-£15K)

Other benefits: makes UK more attractive location for trials; makes UK law more consistent with the majority of EU Member States; more clinical trials run in the UK and run earlier - participants will have access to experimental drugs and clinicians will improve knowledge by involvement in trials.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
-------------------------------------	-------------------	-----

Assumptions:

- That more trials would be run in the UK if infringement risk is removed;
- That some companies license or sell their patented products for use by third parties in clinical trials.
- That clinical trials are not currently run until there is no risk of infringement i.e. at patent expiry.
- We expect this to be a regulatory OUI as benefits should outweigh costs. It is deregulatory.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	Yes	Zero net cost

Summary: Analysis & Evidence Policy Option 3

Description: Clarifying legislation using non-statutory guidelines

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)			
			Low: 0	High: 0	Best Estimate: 0	
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)	
Low	0	1	0	0	0	
High	0		0	0	0	
Best Estimate	0		0	0	0	
Description and scale of key monetised costs by 'main affected groups'						
Zero cost - worst case scenario is that industry will continue to assess the infringement risk as they currently do.						
Other key non-monetised costs by 'main affected groups'						
There would be a cost to Government of producing guidance and alerting interested parties to it. The costs would therefore be in time spent by officials doing this work. It is expected that the costs would be negligible.						
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)	
Low	0	1	0	0	0	
High	0		0	0	0	
Best Estimate	0		0	0	0	
Description and scale of key monetised benefits by 'main affected groups'						
We have not been able to monetise the benefits. Although stakeholders provided some figures (shown below), no real indication of the frequency of the non-monetised benefits was given. Without this information it is not possible to estimate the monetised benefits.						
Other key non-monetised benefits by 'main affected groups'						
Firms will no longer need to undertake freedom-to-operate investigations (£3000-£135 000 per study). Savings from full revocation actions to undertake research (costing up to £1.5m per case). Quicker than changing legislation. More clinical trials run in the UK and run earlier - participants will have access to experimental drugs and clinicians will improve knowledge by involvement in trials.						
Key assumptions/sensitivities/risks					Discount rate (%)	3.5
Assumptions: i) that more trials would be run in the UK if the infringement risk is removed, ii) that some companies license or sell their patented products for use by third parties in clinical trials, iii) that clinical trials are not currently run until there is no risk of infringement i.e. at patent expiry. Risks: i) limited case law in this area will make it difficult to provide useful and legally certain guidance to stakeholders, leading to a lack of confidence.						

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net:	Yes	Zero net cost

Summary: Analysis & Evidence Policy Option 4

Description: Changing EU legislation to exempt from infringement activities involved in clinical and field trials for innovative drug/therapies or drug/therapy combinations.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)			
			Low: 0	High: 0	Best Estimate: 0	
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)	
Low	0	1	0		0	
High	0		0		0	
Best Estimate	0		0		0	
Description and scale of key monetised costs by 'main affected groups'						
It has not been possible to monetise costs despite running two consultations on the issue and asking stakeholders for information on the costs to them of changing the law. This option was not consulted on formally, but information of the costs and benefits of changing EU law would be similar to those for changing UK law.						
Other key non-monetised costs by 'main affected groups'						
As for option 2 and additionally: This route will take longer to achieve legislative change than changing UK law and therefore stakeholders would bear these costs for a longer period of time.						
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)	
Low	0	1	0		0	
High	0		0		0	
Best Estimate	0		0		0	
Description and scale of key monetised benefits by 'main affected groups'						
We have not been able to monetise the benefits. Although stakeholders provided some figures (see option 2), no real indication of the frequency of the non-monetised benefits was given. The exact figures and frequency are dependent on commercial decisions and business models of individual companies. For these reasons we are unable to assess whether the figures provided are major, minor or unjustified.						
Other key non-monetised benefits by 'main affected groups'						
As for option 2 and additionally: Cost of assessing infringement risk in other EU countries would be saved. Law will be consistent throughout the EU; ease of understanding of legislation for the Rest of the World. Consistent law will give stakeholders more choice of where to run trials without risking infringement.						
Key assumptions/sensitivities/risks					Discount rate (%)	3.5
Assumptions: i) that more trials would be run in the UK if the infringement risk is removed, ii) that some companies license or sell their patented products for use by third parties in clinical trials, iii) that clinical trials are not currently run until there is no risk of infringement i.e. at patent expiry. Risks: i) EU-wide consistency might mean a greater share of clinical trial being located in other countries which currently have a narrow research exception.						

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	No	NA

Summary: Analysis & Evidence Policy Option 5

Description: Encouraging industry agreements

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	High: 0	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0	0	0
High	0	0	0
Best Estimate	0	0	0

Description and scale of key monetised costs by 'main affected groups'

It has not been possible to monetise the costs.

Other key non-monetised costs by 'main affected groups'

Legal costs associated with drafting agreements.

Agreements may not be legally certain so will be open to challenge with associated legal costs.

Costs of assessing who owns patents and who needs to sign any particular agreement.

Voluntary - difficult to get everyone to sign up/participate; a company may choose not to participate in the scheme and hence lose competitive advantage.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0	0	0
High	0	0	0
Best Estimate	0	0	0

Description and scale of key monetised benefits by 'main affected groups'

Monetised benefits would in theory be the same as option 2.

Other key non-monetised benefits by 'main affected groups'

Possibly quicker than changing legislation.

Voluntary code - companies can choose to participate with the industry agreements and therefore maintain their competitive advantage.

No legislative change - zero cost.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

Assumptions:

- that the agreements would be appropriate and create the same outcomes as previous options.

- that the agreements would receive appropriate backing and support in drafting.

BUSINESS ASSESSMENT (Option 5)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	No	NA

Evidence Base (for summary sheets)

Problem under consideration

The problem under consideration is the impact that current patent law has on stakeholders carrying out clinical trials, field trials and health technology assessments (HTA) for drugs. Specifically, the problem is the risk to a company of infringing a patent owned by somebody else when carrying out these trials and assessments.

To be able to sell a drug product, it is necessary to obtain regulatory approval, or a marketing authorisation, for the product from the relevant authorities³⁷. Data from human clinical trials or animal field trials is submitted to the authorities to demonstrate that the drug is safe and effective. Clinical trial methodologies often require a new product to be compared to the current standard-of-care therapy, which may be protected by a patent. Activities that are necessary to conduct clinical and field trials on new drugs are not currently exempt from patent infringement in the UK. Therefore, if a company uses a patent-protected product in their trials, they risk being sued for infringing the patent.

Health technology assessments are often carried out³⁸ to assess, amongst other things, if a new product works and how it compares with the available alternatives, which may be patented products. HTA often takes place alongside the later stages of the regulatory approval process (i.e. before a market authorisation has been obtained for a product) and is required before a drug can be recommended for use by the NHS. Although much of the data submitted for the purposes of HTA is the same as is submitted to obtain a marketing authorisation, the authorities may request further information before they make a decision. The activities carried out in order to provide this additional information are outside the scope of the current exceptions to patent infringement allowed by UK law.

For these reasons, a company may legitimately need to use a drug which is protected by a patent held by somebody else.

Similar considerations apply to clinical trials, field trials and HTA carried out for combination therapies i.e. those which combine the use of a new drug and an existing, patented drug.

Current UK patent law only exempts from patent infringement trials and studies carried out to get regulatory approval of generic, or "copy", drugs using a particular route set out in European law³⁹. Clinical and field trials carried out on new, or innovative, drugs and activities done for the purposes of HTA, which involve the use of a patented product e.g. as a comparator, are therefore considered patent infringement. This discourages stakeholders from locating these trials and studies in the UK.

³⁷ Such as Medicines and Healthcare products Regulatory Agency (MHRA), European Medicines Agency (EMA)

³⁸ E.g. by the National Institute for Health and Clinical Excellence (NICE)

³⁹ Directives 2004/27/EC and 2004/28/EC relating to human and veterinary medicinal products respectively.

Rationale for intervention

“The Plan for Growth”⁴⁰ report (published in March 2011) states that the Government is committed to ensuring that the Intellectual Property (IP) system supports the life science sector. This is, in part, a response to stakeholder concerns that the current regulatory framework puts them at a risk of patent infringement when carrying out clinical and field trials for non-generic products, resulting in an unwillingness to conduct such trials in the UK⁴¹.

As discussed above, UK law⁴² exempts from infringement certain activities performed for the regulatory approval of generic drugs (commonly known as the “Bolar exception”). This exception comes from EU law⁴³ which in turn was intended to provide an EU equivalent to the Hatch-Waxman Act in the US⁴⁴. The UK fully implemented the Directives and they were not gold-plated. As such the only acts exempt from infringement according to this area of UK law are those which are specifically required to obtain marketing authorisations for generic drugs. The exception does not cover new drugs.

Different national case law in Member States led to the Directives being implemented differently throughout the EU. The German provisions in this area are much broader than in the UK, and specifically exempt from infringement all studies and trials necessary to obtain marketing approval of any medicinal product in any country, not just generics, and not just in the EU⁴⁵. The UK is currently one of only 8 Member States in which clinical and field trial activities for new drugs may infringe a patent⁴⁶.

The pharmaceutical sector operates internationally and the UK competes with countries worldwide as a location for clinical trials. Within the EU, Germany is often cited by stakeholders⁴⁷ as a more industry-friendly regime. US case law⁴⁸ has also evolved since this

⁴⁰ “The Plan for Growth”, available at http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf (paragraph 2.207)

⁴¹ The Research and Bolar Exceptions: An informal consultation on patent infringement in pharmaceutical clinical and field trials (response document) <http://www.ipo.gov.uk/response-2011-bolar.pdf>

⁴² Section 60(5)(b) and (i) of the Patents Act 1977

⁴³ EU Directives 2004/27/EC and 2004/28/EC which amend earlier Directives 2001/82/EC and 2001/83/EC

⁴⁴ Section 505(j) 21 U.S.C. 355(j) introduced following *Roche Products v Bolar Pharmaceutical* 733 F.2d 858 (Fed. Cir. 1984)

⁴⁵ §11 2b Patentgesetz (see http://bundesrecht.juris.de/patg/___11.html)

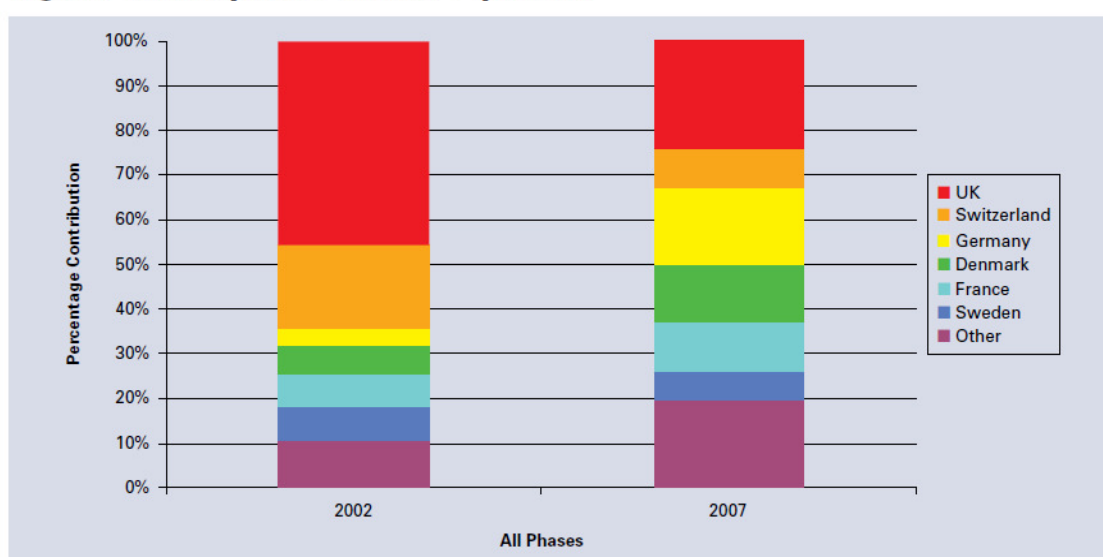
⁴⁶ See table at para 6.5 <http://www.avidity-ip.com/assets/pdf/BolarJun12.pdf>

⁴⁷ 6 responses from 17 to the informal consultation specifically mentioned German law as a better regime in which to run clinical trials.

change in EU and UK law, resulting in a broader interpretation of the Hatch-Waxman Act which exempts from infringement all uses of compounds that reasonably related to submission of information to the US government under any law regulating the manufacture, use or distribution of drugs⁴⁹.

There is evidence to suggest that the UK is the European market leader with respect to number of drugs undergoing clinical trials^{50 51} We have also found evidence which shows that, whilst remaining in top position for clinical trials in Europe between 2002 and 2007, the share of trials run in the UK shrank in the same period whilst Germany and France increased their share⁵²:

Figure 1: European Product Pipelines



Data: Ernst & Young

⁴⁸ Merck KGaA v Integra Lifesciences Ltd, 545 U.S. 193 (2005)

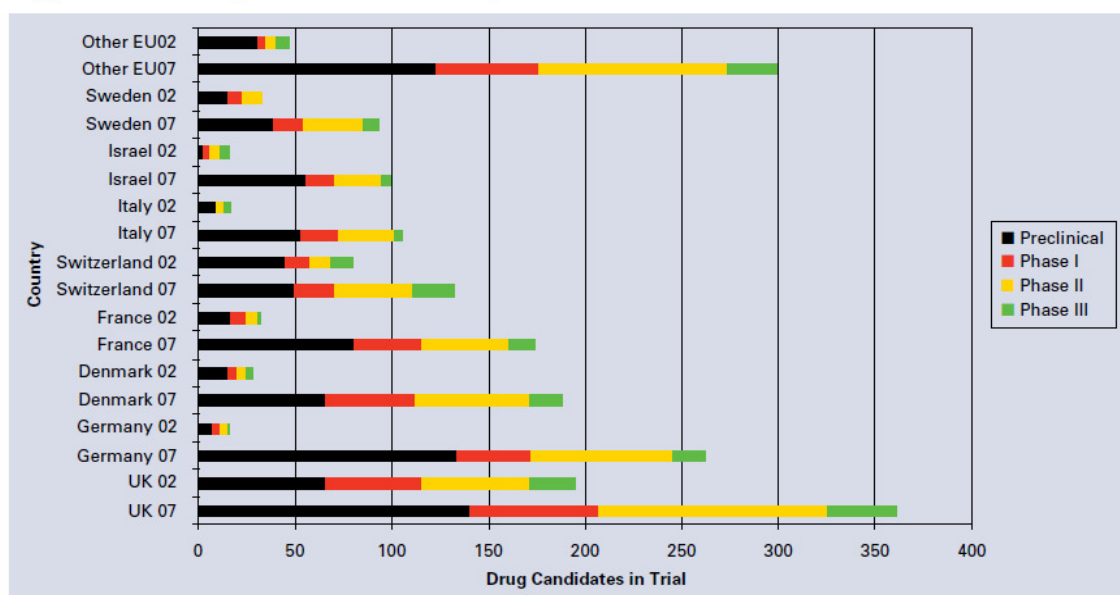
⁴⁹ <http://www.law.cornell.edu/uscode/text/35/271>

⁵⁰ <http://www.bis.gov.uk/assets/biscore/economics-and-statistics/docs/10-541-bis-economics-paper-02.pdf> BIS, 2010, "Life Sciences in the UK " Economics Paper no.2, p.35 shows biotechnology drugs in development in Europe, 2007.

⁵¹ [http://www.ey.com/Publication/vwLUAssets/Beyond_borders_2012/\\$FILE/Beyond_borders_2012.pdf](http://www.ey.com/Publication/vwLUAssets/Beyond_borders_2012/$FILE/Beyond_borders_2012.pdf) - see page 80 "European Clinical Pipeline by country, 2011" relates to biotechnological drugs in development

⁵² <http://www.berr.gov.uk/files/file49805.pdf> - see "The UK Pipeline" page 6, figures 1 and 2.

Figure 2: European Product Pipelines 2007 vs 2002



Data: Ernst & Young

Source: "The Review and Refresh of Bioscience 2015: A Report to Government by the Bioscience Innovation and Growth Team" (page 7). <http://www.berr.gov.uk/files/file49805.pdf>

We have been told by stakeholders that UK law is unclear, and that they incur costs due to this lack of clarity as they need to assess whether they are likely to infringe somebody's patent before deciding where to run a clinical trial. A decision is sometimes made to run trials in countries where the law in this area is clearer e.g. Germany. The UK is therefore losing out on some clinical trials which might be run here if this area of the law provided greater legal certainty for companies performing trials.

A company wanting to carry out a clinical trial which uses another company's patented drug risks being sued for infringing that patent. Arguably, this may be seen as unfairly preventing a competitor from demonstrating that their product is safe and effective until after the expiry of the patent. As the trial process is lengthy, this may give a patent-holder a significant advantage over competitors.

It should be noted that UK law already includes an exception to patent infringement (the Bolar exception) which allows trials and studies needed to get a marketing authorisation for generic versions of patented products to be carried out before expiry of the patents for the relevant drugs. This allows the generic version to be put on the market as soon as the patent expires. A similar rationale can be applied to new products i.e. the law should allow the regulatory process to be completed in order for a new product to be available for sale as soon as the relevant patent expires; to not do so would extend the effective period of patent protection beyond the maximum 20 years.

It is possible for a company running a clinical trial to buy a product on the open market and use it in the trial. However, there are a number of issues with this. Firstly, the quantity of product required to perform a trial could signal commercial intent to competitors, which is not

desirable. Secondly, in order to run a meaningful trial, all drugs (including comparators and placebos) given to participants need to look the same. This can be difficult to achieve using a commercial product, and it may therefore be necessary for a company to produce the drug themselves in order to obtain it in the required form. Thirdly, it is possible that the required product may not be available on the open market, in which case the only option is to make it. If carried out in the UK, the second and third options would infringe a patent, even though the activities are limited to producing a product for use in a trial, and not for commercial purposes.

The IPO has undertaken two consultations on this issue, one informal prior to the impact assessment process, and the other formal, in line with the impact assessment process. Both showed that stakeholders agree that the law needs to be changed to allow companies to carry out tests and trials on new drugs without the risk of them infringing somebody's patent.

Across the two consultations^{53 54}, we received comments from a wide range of stakeholders, including the IP profession, the research and development pharmaceutical industry, trade bodies, the generics industry, charitable organisations, a technology transfer company, a licensing organisation, a company employee, a Devolved Administration, a biological contract manufacturing organisation and an active pharmaceutical ingredient manufacturer and a clinical research organisation. This diverse sample has allowed an appropriate all round understanding of the needs and wants across the industry.

More details of the two consultations are set out briefly below:

Informal consultation

The informal consultation⁵⁵ investigated the impact of current UK legislation on pharmaceutical clinical and field trials in the UK. Responses⁵⁶ showed that stakeholders

⁵³ Informal consultation: Formal responses were received from: Association of the British Pharmaceutical Industry (ABPI), BioIndustry Association (BIA), Bird & Bird, Boehringer-Ingelheim, Cancer Research UK, Chartered Institute of Patent Attorneys (CIPA) Life Sciences Committee, a clinical research organisation (confidentiality requested), Eli Lilly, European Generic Medicines Association (EGA), FICPI-UK (International Federation of Intellectual Property Attorneys), IP Federation, Interpat, Japan Intellectual Property Association (JIPA), Japan Pharmaceutical Manufacturers Association, Johnson & Johnson, Merck, Novartis.

⁵⁴ Formal consultation: responses were received from ABPI, BIA, British Generic Manufacturers Association (BGMA), CIPA, Eli Lilly, Ethical Medicines Industry Group (EMIG), Fujifilm Diosynth Biotechnologies, GlaxoSmithKline (GSK), Intellectual Property Lawyers Association (IPLA), IP Federation, ISIS, JIPA, Licensing Executives Society (LES), Patents Judges, Pharmaceutical Life Sciences Management Solutions, Polpharma, PraxisUnico, Wellcome Trust, Welsh Assembly Government (WAG), an individual employee of a pharmaceutical company.

⁵⁵ The Research and Bolar Exceptions: An informal consultation on patent infringement in pharmaceutical clinical and field trials - <http://www.ipo.gov.uk/consult-2011-bolar.pdf>

⁵⁶ <http://www.ipo.gov.uk/response-2011-bolar.pdf>

were of the opinion that current legislation does not strike the right balance between the rights of a patentee and the need to carry out trials on new products. Stakeholders stated that they want to be able to run clinical trials without worrying that they are infringing a third party's patent. Responses also indicated a lack of certainty as to which activities are exempt from infringement, which cause problems for stakeholders. There was almost unanimous agreement⁵⁷ that change is needed, and the majority⁵⁸ of responses specifically indicated that this should be done by changing the law.

In response to the informal consultation⁵⁹, the Government accepted that there was evidence of a need to amend UK patent law to remove the risk of patent infringement for activities relating to clinical or field trials and agreed to run a formal consultation on proposals to amend the Patents Act.

Formal consultation

The formal consultation⁶⁰ asked whether the Patents Act should include an exception to infringement for activities involved in preparing or running clinical or field trials which use new drugs and, if so, asked what the change should look like. Stakeholders were asked to rank, and comment on, the following three options to change the law:

- i. Change UK patent law to exempt from infringement all activities required to secure regulatory approval to market innovative drugs in all countries;
- ii. Change UK patent law to exempt from infringement all activities required to secure regulatory approval to market innovative drugs in the EU and EEA only;
- iii. Change UK patent law to exempt from infringement all activities required to secure regulatory approval to market innovative drugs and also all activities necessary for health technology assessment e.g. data to support assessment by the National Institute for Health and Clinical Excellence (NICE).

Stakeholders were also asked:

- to provide evidence of the cost savings and losses which would be incurred if activities relating to clinical and field trials were exempt from infringement;
- for information about why stakeholder may be put into the position of risking patent infringement when running clinical trials for new drugs;
- to comment on the partial impact assessment, the definitions used, whether micro-businesses should be included in the proposed measures,
- to comment on the suitability of using a legislative reform order (LRO) to make the

⁵⁷ 15/16 responses agreed that there was a need for change.

⁵⁸ 12/16 responses think the law should be changed.

⁵⁹ <http://www.ipo.gov.uk/response-2011-bolar.pdf>

⁶⁰ <http://www.ipo.gov.uk/consult-2012-bolar.pdf>

changes and LRO preconditions⁶¹.

The overwhelming majority of responses (19/20⁶²) agreed that section 60(5) of the Patents Act should be changed to exempt from patent infringement activities which are carried out when preparing, or running clinical or field trials using new drugs. Most respondents (15/16) want to see the exception cover activities carried out to gain regulatory approval of new drugs and a significant majority (10/16) want the exception to extend to studies required for health technology assessment⁶³.

The Government accepted that the Patents Act should be changed to include an exception to patent infringement for activities involved in preparing or running clinical or field trials involving innovative drugs for the purpose of gaining regulatory approval in any country. The Government also accepted that this exception should cover activities involved in health technology assessment⁶⁴.

It should be noted that the European legislation from which the Bolar exception comes was deregulatory in its effect as it exempts firms making generic drugs from part of third party patent protection when they want to undertake studies to obtain regulatory approval. The consultations have therefore allowed us to identify a further opportunity for deregulation and to level the playing field for stakeholders by changing UK law in the manner outlined in the next section.

Policy objective

As previously discussed (see "Problem under consideration" above), current UK law exempts from patent infringement certain activities performed for the regulatory approval of generic drug products. Tests or trials carried out to get marketing authorisations for new, or innovative, drugs; or for the purposes of HTA, fall outside its scope. Stakeholders have indicated that this causes them problems and want to see the law changed (see "Rationale for Intervention" above for more details).

The policy objective is to improve the legal certainty of the status of clinical trials, field trials and health technology assessment in respect of patent infringement. We propose doing this by amending the Patents Act to provide an exception to infringement which covers:

- all activities required to obtain regulatory approval of all drugs;

⁶¹ LRO preconditions are: proportionality, fair balance, necessary protection, rights and freedoms, constitutional significance.

⁶² The figures indicate the number of responses to particular questions. Where the denominator varies, this shows the different number of responses to a specific question i.e. 20 responses were received to question 1; 16 responses were received to question 2.

⁶³ HTA relates e.g. to the studies required by the National Institute for Health and Clinical Excellence (NICE) in order for a drug to be approved for use by the NHS.

⁶⁴ <http://www.ipo.gov.uk/response-2012-bolar.pdf>

- trials and studies necessary for HTA of all drugs;
- the activities listed above when carried out for the purpose of obtaining regulatory approval or HTA in all countries.

Policy option 2 best reflects these objectives. Further details of all the policy options which have been considered are given in the next section.

The proposed change amounts to extending the exception to infringement which is currently available, in terms of a) the types of products which are exempt; b) the types of tests, trials and studies which are exempt; and c) the location in which the data generated by these tests, studies and trials may be used whilst still being in scope of the exception.

It is not envisaged that the exception will include any other activities.

The intention is that, subject to drafting considerations, the new exception will replace the current, narrow, Bolar exception⁶⁵ and will cover both new and generic drugs. This will provide a coherent exception to patent infringement for activities related to authorisation of all drugs both for marketing and HTA purposes by removing the existing inconsistency in UK law between generic and innovative products.

This in turn should make the UK a more attractive location in which to run clinical and field trials and in which to carry out HTA. It will allow stakeholders to carry out clinical or field trials without risking patent infringement, bringing the UK into line with the broadest exceptions in respect of clinical trials currently available in other EU Member States. Including HTA will allow any additional tests required to approve any drug for NHS use to be carried out and will allow companies to carry out HTA studies for use abroad.

Making these changes will encourage stakeholders to run clinical trials in the UK rather than countries with broader exceptions. This in turn should encourage growth in the UK by supporting jobs in the clinical trial sector and associated industries as well as maintaining expertise in these areas in the UK. Stakeholders will also save the money they currently spend assessing the risk of infringement.

Description of options considered (including do nothing) and costs/benefits

The policy options we have considered are 1) do nothing, 2) change UK legislation, 3) clarify current legislation and issue guidance, 4) change EU legislation, 5) encourage industry agreements. Further details of all these options are given below.

⁶⁵ s.60(5)(i) Patents Act 1977

Option 1 - do nothing

Maintaining the *status quo i.e.* keeping the exception as it currently stands. Only activities carried out for achieving authorisation of generic drugs or biosimilar drugs using the generic route will be exempt from infringement.

Costs/Benefits

The “do nothing” option is compared against itself and therefore its costs and benefits are necessarily zero, as is its Net Present Value.

This option will not meet the policy objective.

Informal consultation responses overwhelmingly rejected this option⁶⁶. Given the majority of stakeholders indicated that there is a problem, and that it also does not achieve the policy objective, doing nothing is not considered a viable option.

At formal consultation we asked if stakeholders agreed that the law should be changed to exempt clinical and field trials from patent infringement. The overwhelming majority⁶⁷ agreed, representing a rejection of the “do nothing” option. We did not formally ask stakeholders whether we should “do nothing” at formal consultation as it was specifically and overwhelmingly rejected at the informal consultation stage.

Option 2 – changing UK legislation to exempt from infringement activities involved in clinical and field trials for innovate drugs/therapies or drug/therapy combinations;

This option involves amending UK law to exempt certain activities from being infringing acts and is our preferred option.

We specifically want to change the law to exempt from patent infringement activities involved in preparing or running:

- clinical trials and field trials for the purposes of gaining regulatory approval in all countries;
- health technology assessments for use in all countries.
- It will meet the policy objective in a reasonable timescale and responses from the informal consultation indicate a clear desire for legislative change. Specific options

⁶⁶ 15 from 16 responses to the informal consultation indicated that there is a need for change in the legal framework surrounding clinical trials.

⁶⁷ 19/20 responses to the informal consultation agreed the law should be changed in this way.

for legislative change were consulted on at formal stage (see “Rationale for intervention, pages 9-10 above).

Stakeholders indicated that there are costs and benefits associated with the proposed measures (see below). However, as discussed above, stakeholders have also expressed a strong desire to see the law changed to allow them to carry out clinical trials, field trials and HTA without the risk of patent infringement. As such, we are of the opinion that they perceive the benefits of the proposed changes to outweigh the costs.

Costs

We asked stakeholders to provide evidence of the losses which would be incurred if the law was changed. Respondents to the formal consultation indicated that deciding where to run trials is not straightforward, and that many factors need to be considered when choosing a location. This makes quantification of the costs directly associated with the proposed changes to the law very difficult and consequently very little monetised evidence was provided. However, results from both consultations indicate a clear desire from stakeholders to see the law changed.

Stakeholders were able to provide information of the non-monetised costs. These are listed below:

- Loss of licensing fees or loss of sales revenue for patent holders when their drug is used in a trial. This assumes that patentees currently licence or sell their products to third parties for use in clinical trials. However, it was noted by one stakeholder that trial sponsors are unlikely to be prepared to spend much licensing a product for trial-use when there is a) a low chance of trial success and b) the patent will expire before commercialisation of a successful trial product. A further comment indicated that loss of licensing fees for trial work would be outweighed by licensing fees or royalties obtained for the patented component of a combination product by earlier approval and marketing of a new product which contains it. Furthermore, the impact on sales revenue should not be extensive as the proposed change only relates to use in clinical trials, field trials and health technology assessment, and not to the final marketed product.
- Earlier reduction in market share for the patent holder after patent expiry. This assumes that third parties seeking to produce a competitor drug either do not run a clinical trial until there is no risk of infringement *i.e.* after patent expiry, or that they do not currently run clinical trials while the patent is still in-force. Anecdotal evidence, however, suggests that clinical trials are being run before expiry of a competitor's patent, either in the UK or another country. It is therefore likely that the real cost caused by changing the law to allow clinical trials to be exempt from infringement would have a negligible effect.

- Losses to academics, SMEs and technology transfer companies looking to commercialise their product to pharmaceutical companies for further development, and loss of control of IP rights for drugs used in trials. On the other hand, positive results in trials could encourage larger pharmaceutical companies to invest in smaller entities;
- Companies are responsible for reporting safety information generated for their drug products, even if they do not generate the information themselves. Concern was raised that unlicensed use of a product e.g. by third parties in clinical trials could adversely impact the safety profile of a product. Another, related point is that adverse results during a third-party trial could deter larger pharmaceutical companies from developing a product in conjunction with an originating SME or academic. However, both of these issues need to be balanced against public health, and arguably greater trial-use of a product would enable adverse reactions to drugs to be identified more quickly and would prevent drugs with harmful side-effects reaching market.

Benefits

The main benefit of this option to stakeholders would be a more certain legal position for clinical trials in patent law. This would remove the time and costs of assessing infringement risk and thus reduce the regulatory burden currently placed on them.

It is stated above that the cost to a company due to earlier reduction in market share may be negligible if third parties run clinical trials abroad in countries with broader exceptions to patent infringement. Therefore the benefits of this option to these companies may not be significant. However, this ignores the less tangible benefits to the UK economy resulting from implementation of this policy option. Specifically allowing clinical trials, field trials and HTA to be carried out in the UK would remove the risk of patent infringement when carrying out these activities. This in turn will encourage companies to do tests and trials in the UK, supporting the clinical trial and pharmaceutical sectors and should benefit the UK economy by supporting jobs in the clinical trial sector and associated industries as well as maintaining expertise in these areas in the UK. It may also specifically benefit SMEs and academics by who do not have large budgets and consequently have limited ability to locate trial work abroad.

Some limited evidence of the cost of the current legislation was obtained during the informal consultation.

- Company A indicated that they have at least one query a year relating to patent infringement when running clinical trials. This requires considerable analysis of the infringement risk by their legal department, taking up approximately a week of attorney time, at a cost of around £3000. This is set against a company background

of over 100 clinical trial protocols run across over 500 sites in the UK, with more than 10 000 patients involved. In the example provided, the decision was taken to run the trial in a country with a broader Bolar provision, and thus may be considered a loss to the UK economy.

- The legal activities carried out by company B relate to drug development and clinical trials include freedom-to-operate studies, European Patent Office opposition proceedings and revocation actions in the UK courts. They estimate the cost of in-house Freedom-to-Operate (FTO) studies ranges from £90K to 135K, and EPO oppositions range from £100K to £250K, depending on the importance of the case. Revocation proceedings may cost up to £1.5 million.
- These two companies clearly operate very different strategies and it is therefore difficult to give a best estimate of the average benefit to stakeholders based on the information provided. It seems reasonable to assume, however, that the proposed law change would save companies the legal and administrative cost burden associated with assessing infringement risk prior to running clinical trials. Based on the evidence provided, the benefits range from £3000 at the lower end to £135K for Freedom-to-Operate studies, and from £100K to £1.5 million for challenging the validity of a patent.
- Company B provided some updated information at formal consultation stage. They indicated that approximately 60% of the molecules they have in clinical development have potential infringement issues in respect of clinical trials only i.e. where a patent will expire before commercialisation. The estimate that the costs associated with opposition or revocation of these patents could be in excess of £5.6 million, with internal costs of approximately £1.35 million. The total benefit to company B of a change in legislation could therefore be nearly £7 million.
- Company C estimated the cost of FTO searches as being in the region of tens-of-thousands of pounds, plus the drain on a company's internal resources; licensing negotiations and costs may be £10 000 to £15 000 per licence; costs of challenging validity or defending an infringement action are difficult to quantify but are significant. They indicated that all these costs would be saved if the proposed changes were implemented.
- Anecdotal evidence was provided that company D, a medium-sized biotechnology company has lost business due to the narrow exception to infringement currently available in the UK, however no quantification of the loss was given. The implication is that if the infringement exceptions had been broader these losses would not have occurred.

Further, more general, comments were received regarding the cost savings which would be brought about if the law is changed. These are difficult to quantify and include:

- Freedom-to-operate searches and follow-on costs where an infringement risk is identified.
- The delay of a trial and subsequent commercialisation of a product due to an uncertain infringement position.
- Obtaining FTO searches, validity opinions and funding EP oppositions to ensure that trials are not disrupted by third parties.
- In the technology transfer sector, simplification of the negotiation procedure would mean no assessment of infringement risks would be required prior to collaboration with other companies resulting in cost savings. Costs would also be saved in the following areas: clinical trial agreements, material transfer agreements, retained IP rights.
- The outlay, often from a limited budget, for SMEs assessing infringement risks.

Stakeholders also cited the following as benefits associated with the proposed change to legislation:

- Stakeholders who have previously been given legal advice against running trials in the UK due to the current risk of infringement, or who will currently not consider locating a trial in the UK due to this risk; would be more likely to locate trials here.
- Extending HTA assessment to the generic industry should increase the growth in the biosimilars and generics market in the UK.
- A more favourable legislative provision should prevent the loss of clinical research jobs to other countries, which currently impacts the UK economy.
- Opportunities are lost to the UK and to patients when trials are run elsewhere, leading to a loss of expertise and revenue for UK institutions. This would be prevented if the clinical trial environment was more favourable in the UK.
- Improved commercialisation success rate as more safety data would be generated through others' use of a drug in a trial environment. This would have a public health benefit. This would be of particular benefit to SMEs and academic researchers with limited budgets. This is would be a positive outcome of adverse results in a trial which are listed against the "costs" of the proposed changes above.

Although not mentioned by stakeholders, under the current regime, costs could be incurred where a patent-holder aggressively prevents a competitor from using their patent-protected product in a clinical trial e.g.by threatening infringement action. This could significantly delay the entry of a new drug to the market, which would have associated costs. These costs would be saved if this policy option comes into effect.

Option 3 – clarify current legislation

Clarification of current legislation would involve assessing current case law to produce non-statutory guidelines as to what is understood to be exempt according to any relevant judgments. However, case law in this area is limited⁶⁸. Some acts would clearly be exempt, but it would be difficult to accurately assess and give guidance on the position of all possible acts related to clinical trial activities. Without clear guidance, the infringement position for many acts would still be uncertain.

There is also a risk with this option that the Government would be seen to be interpreting the law, which is the job of the Courts.

It should be noted that this option was not specifically included in the informal consultation. However, lack of legal certainty with respect to clinical trials was commented on several times⁶⁹ and this option would not address those concerns. As the Government response to the informal consultation accepted that there was a need to change the law rather than clarifying it, we did not include this option in the formal consultation.

Although this option would be quicker and easier to achieve than legislative change, it would not meet the policy objective of providing legal certainty for stakeholders. For this reason we do not consider clarification of legislation a viable option.

Costs

The difficulty in clarifying which acts are exempt or infringing may result in stakeholders not having confidence in the guidance provided by Government and would therefore undertake their own investigations of the infringement risks, with associated legal costs. These costs would be the same, or similar, to those which stakeholders have under existing legislation so the net cost to stakeholders of this option would be zero.

There would be a cost to Government in terms of time spent analysing case law, producing guidance and alerting interested parties to its existence. As this option would not meet the policy objective, no further investigation of the exact costs to Government was undertaken. It is, however, expected that the costs of this option would not be significant.

⁶⁸ Main identified cases are *Monsanto v Stauffer* [1985] RPC 515 and *Auchinloss v Agricultural & Veterinary Supplies Ltd* [1999] RPC 397

⁶⁹ 6 responses from 16 to the informal consultation specifically mentioned the lack of certainty or clarity of the current legislation

Benefits

If it were possible to adequately define all acts which are not infringing in this area under the current law, and if stakeholders had confidence in this clarification, the potential benefits would be similar to those of changing UK legislation.

A more certain legal position of clinical trials in patent law would remove the costs to stakeholders of assessing the infringement risk and will thus reduce the regulatory burden currently placed on them. These benefits are outlined on pages 13-14, under the benefits of option 2.

No further questions were asked about this option at formal consultation stage and no comments were received which provide any further information on this option.

Option 4 – change EU legislation to exempt from infringement activities involved in clinical trials and field trials for innovative drugs/therapies or drug/therapy combinations.

This option would involve changing EU law to specifically exempt clinical trial activities from being infringing acts. This would involve lobbying other Member States to re-open Directives, followed by negotiations, in order to achieve the necessary changes.

Many EU Member States⁷⁰, including Germany, implemented the original EU legislation more broadly than the UK and therefore do not have the same legal uncertainties as the UK. It seems unlikely, therefore, that a sufficient number of Member States would be willing to commit the time and effort required to make a change which would only affect a minority of Member States. It would also impact on any competitive advantage which certain Member States currently have over others in the field of clinical trials.

The responses to the informal consultation indicate a clear desire for legislative change, either domestically or at EU level. With sufficient support from other Member States, this option would achieve the policy objective, but it would be a lengthier process than making the same change to domestic law. Without support from other Member States, we would not be able to achieve the policy objective. We consider it unlikely that we would receive sufficient support from other Member States to make this change for the reasons discussed above i.e. the infringement positions in many other countries already allow trials to be carried out without risk of patent infringement. For these reasons, this policy option is not considered viable.

⁷⁰ The UK is currently one of only 8 Member States which implemented the Directives very narrowly.

Costs/Benefits

Costs and benefits for option 4 are the same as outlined for option 2 on pages 13-14. However an additional cost to be considered is that due to the slower process of option 4, the impact of the change would be slower impact and have greater administrative costs. There would also be an additional cost due to the longer time taken to achieve legislative change in the EU compared with the UK.

This policy option also has the risk of having dissimilar implementation across member states, as happened with the European legislation from which the Bolar exception originates. Therefore, this policy option may not result in a level playing field across the UK.

For these reasons, this option is not considered viable.

No further questions were asked about this option at formal consultation stage. No comments were received which provide any further information on this option.

Option 5 – encourage industry agreements.

There are a number of possible alternatives for this option: i) providing a draft agreement of non-infringement for stakeholders to use; ii) encouraging stakeholders to draft their own agreements; iii) sector-wide agreements; iv) bi-lateral agreements; and v) agreement between members of trade bodies not to sue each other.

This policy option requires no legislative change and would therefore be quicker than changing the law. Although we did not consult on specific options, it is clear from responses to the informal consultation that stakeholders consider the concept of industry agreements an unacceptable way of achieving the policy objective. They are of the opinion that this option is an indefinite and imprecise tool which would further fragment an already uncertain infringement position. Without the participation of stakeholders the policy objective would not be achieved and hence is not considered a viable option. We did not consult stakeholders further on this option in light of the negative responses received at informal stage.

Costs

We are unable to monetise costs for this option.

We consider the likely costs to stakeholders would be in time spent negotiating and drafting legal agreements, assessing who owns relevant patents and who needs to sign an agreement.

Furthermore, there could be difficulty in ensuring high enough participation levels. Businesses may lose their competitive advantage as a result of choosing not to participate.

Benefits

The benefits, if this were to be successful across the sectors, are again the same as proposed in option 2 on page 13-14.

No further questions were asked about this option at formal consultation stage. No comments were received which provide any further information on this option.

Risks and assumptions

Assumptions

The policy options presented in this assessment are based on feedback from informal and formal consultations into the issues. A diverse range of stakeholders responded to the consultations and we therefore consider that the feedback is representative of the views of stakeholders who may be impacted, directly or indirectly, by amending UK legislation to remove the risk of patent infringement when carrying out clinical trials, field trials or HTA on drugs.

We have also made the following assumptions:

- That some stakeholders involved are “straddling the fence”, i.e. that pharmaceutical companies both manufacture patented drugs which others want to use in clinical trials, and also wants to use drugs patented by other companies in their own clinical trials, either as part of a combination therapy, or as a comparator. Therefore, on some occasions a particular company would benefit from the proposed change by being able to use another company’s product in clinical trials, and on other occasions they would “lose” as another company could use the first company’s product in their own trials. We received no evidence at consultation to suggest that there would be a disproportionate impact on any particular group.
- That if the risk of patent infringement when carrying out clinical trials was removed, companies would choose to conduct more clinical trials in the UK. Some companies indicated at consultation that such a change would make the UK a more attractive location in which to run trials, but we are aware that a large number of factors are considered by companies when choosing a location for clinical trials, of which patent infringement is just one.
- That some companies currently licence or sell their patented products for use by third parties in clinical trials. Anecdotal evidence suggests that this is not the case for all companies, and some provide their products free of charge to third parties.
- That clinical trials are only run when there is no risk of patent infringement *i.e.* after patent expiry. Again, anecdotal evidence suggests that this is not the case with companies either running their trials abroad, or running them in the UK when the infringement position is not certain.

- That we would not receive sufficient support from EU Member States to successfully introduce EU legislation to remove infringement risk.

Risks

The consultations undertaken indicate that there is little risk associated with amending UK law to remove the risk of patent infringement when performing drug trials in the UK. There was little call to retain the status quo.

The following risks have been identified for specific policy options:

- In respect of policy option 3 (clarification of legislation), limited case law exists which would make it difficult to provide useful and legally certain guidance to stakeholders. This could lead to a lack of confidence. There is also the risk that legal challenges of its content could be brought.
- In respect of policy option 5 (changing EU law to give all Member States a broad infringement exception in this area), there is a risk that pharmaceutical companies could locate clinical trials in other countries which currently have a narrow research exception e.g. the Netherlands and Spain, and not use the UK for this work.

Direct Costs and Benefits to Business Calculations (following OITO methodology)

Under the “One In, Two Out” rule, a measure that has a net cost to business must have a measure or measures of twice the equivalent cost removed in order to be implemented. Preferred policy option 2 would exempt firms from part of third party patent protection when they want to undertake clinical trials and is therefore de-regulatory. We expect the benefits to outweigh the costs for UK firms, and so expect the policy to be an OUT. We have been unable to fully monetize the costs and benefits due to the many factors which need to be considered by stakeholders when making a decision as to where to locate trials. For the purposes of this impact assessment we therefore consider the policy to be a ZERO NET COST measure.

Wider impacts

Economic/Financial

The following economic and financial impacts have been identified:

- Small businesses and academic groups have limited budgets for performing clinical trials. Large multinational pharmaceutical companies have large budgets for this work. Large companies are able to locate their trials in countries where they do not risk patent infringement, whereas smaller companies are unlikely to be able to. The proposed change to the law will level the playing field, allowing both large and small companies to locate trials in the UK without risking infringement.

- The wider economic impact of the proposed changes would be making the UK a more attractive location in which to perform clinical trials. This should increase the number of trials run here which would bring economic benefits in the clinical trial, and related sectors.

Microbusinesses

The “Guidance on Moratorium on New Domestic Regulation for Micro-Businesses and Starts-Ups” aims to minimise the burden placed on the smallest business by regulatory changes by exempting them from such changes. However, if micro-businesses are exempt from the current proposals they will be at risk of being sued by a patent holder, which will put them at a competitive disadvantage compared to larger pharmaceutical and biotechnology companies. We therefore consider that micro-businesses should be included in the scope of our proposals so they do not infringe a third party’s patent when carrying out clinical trials, and hence will not be at risk of legal action being taken against them. This will enable micro-businesses and start-ups to compete on a level playing field with other companies in these sectors.

We requested a microbusiness exemption from the Economic Affairs and Reducing Regulation Sub-committee when seeking clearance for the formal consultation. This was granted and the letter is attached at Annex A.

Social

The proposed changes, and possible increase in the number trials run in the UK may have the following public health impacts:

- Experimental drugs are often a last resort for very ill patients, and any increase in the number of trials run in the UK will increase the number of experimental treatments available to them.
- It will be more likely that trials for drugs for diseases which have a higher incidence in the UK than other countries will be run in the UK. Due to the greater number of potential trial participants, it is hoped that the trials would be shorter and new drugs for these diseases will reach the market more quickly.

We do not envisage that the proposals will have any other social impacts.

Environmental

We do not envisage that the proposals will have any environmental impacts.

Summary and preferred option with description of implementation plan

Our chosen option is option 2 – changing UK legislation to exempt from infringement activities involved in clinical and field trials for innovative drugs/therapies or drug/therapy combinations. More specifically, we want to amend the Patents Act to provide an exception to infringement which covers:

- all activities required to obtain regulatory approval of all drugs;
- trials and studies necessary for HTA of all drugs;
- the activities listed above when carried out for the purpose of obtaining regulatory approval or HTA in all countries.

This option will meet the policy objective in a reasonable timescale. Responses from both consultations indicate a clear desire for legislative change and we are therefore confident it has stakeholder backing.

Evaluation of preferred option

The proposed change is being introduced as part of a package of changes to the Patents Act 1977. The IPO will monitor and evaluate the impact of these changes on an on-going basis through regular discussions with stakeholder groups, monitoring of customer complaints and consideration of any legal decisions which make specific reference to the changes introduced and the impact they have had. A post implementation review will also take place to pull together any information gathered in respect of the changes and this is currently scheduled for 2018.