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) 01633 814892 fiona.warner@ipo.gov.uk

Summary: Intervention and Options

RPC Opinion: Green

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, One-Out?**	**Measure qualifies as**
£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 Minister: Younger of Leckie Date: 9th April 14

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing

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'

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	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 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	**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 OUT 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**
High	0		0	**0**
Best Estimate	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**
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'

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 commerical 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 triial being located in other countries which currently havw 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	1	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 authorities[1]. 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 out[2] 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 law[3]. 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.

Rationale for intervention

"The Plan for Growth"[4] 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

[1] Such as Medicines and Healthcare products Regulatory Agency (MHRA), European Medicines Agency (EMA)

[2] E.g. by the National Institute for Health and Clinical Excellence (NICE)

[3] Directives 2004/27/EC and 2004/28/EC relating to human and veterinary medicinal products respectively.

[4] "The Plan for Growth", available at http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf (paragraph 2.207)

for non-generic products, resulting in an unwillingness to conduct such trials in the UK[5].

As discussed above, UK law[6] exempts from infringement certain activities performed for the regulatory approval of generic drugs (commonly known as the "Bolar exception"). This exception comes from EU law[7] which in turn was intended to provide an EU equivalent to the Hatch-Waxman Act in the US[8]. 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 EU[9]. The UK is currently one of only 8 Member States in which clinical and field trial activities for new drugs may infringe a patent[10].

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 stakeholders[11] as a more industry-friendly regime. US case law[12] has also evolved since this 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 drugs[13].

There is evidence to suggest that the UK is the European market leader with respect to number of drugs undergoing clinical trials[14] [15] 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 share[16]:

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[5] 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

[6] Section 60(5)(b) and (i) of the Patents Act 1977

[7] EU Directives 2004/27/EC and 2004/28/ EC which amend earlier Directives 2001/82/EC and 2001/83/EC

[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] §11 2b Patentgesetz (see http://bundesrecht.juris.de/patg/__11.html)

[10] See table at para 6.5 http://www.avidity-ip.com/assets/pdf/BolarJun12.pdf

[11] 6 responses from 17 to the informal consultation specifically mentioned German law as a better regime in which to run clinical trials.

[12] Merck KGaA v Integra Lifesciences Ltd, 545 U.S. 193 (2005)

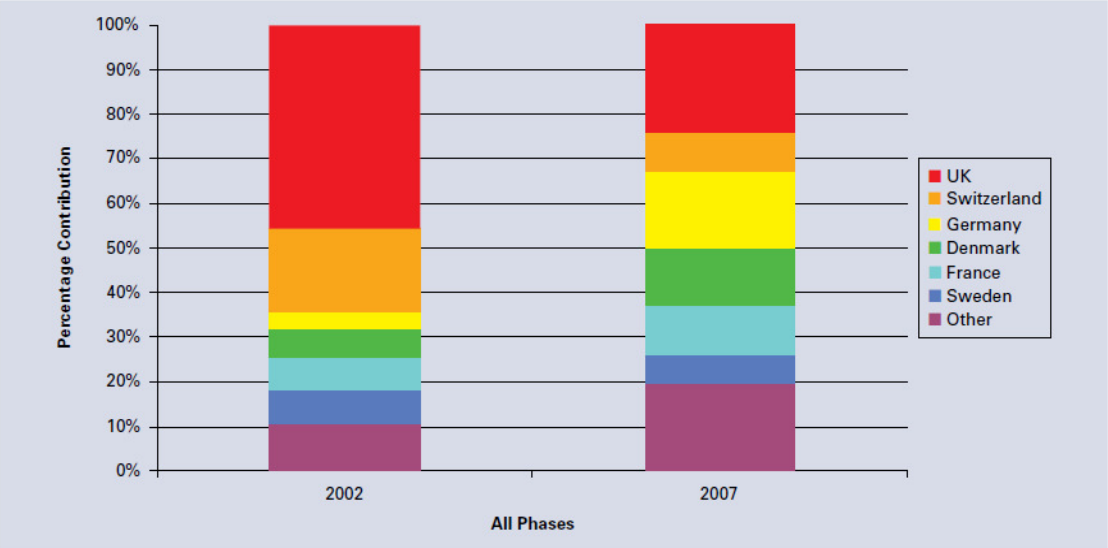
[13] http://www.law.cornell.edu/uscode/text/35/271

[14] 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.

[15] 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

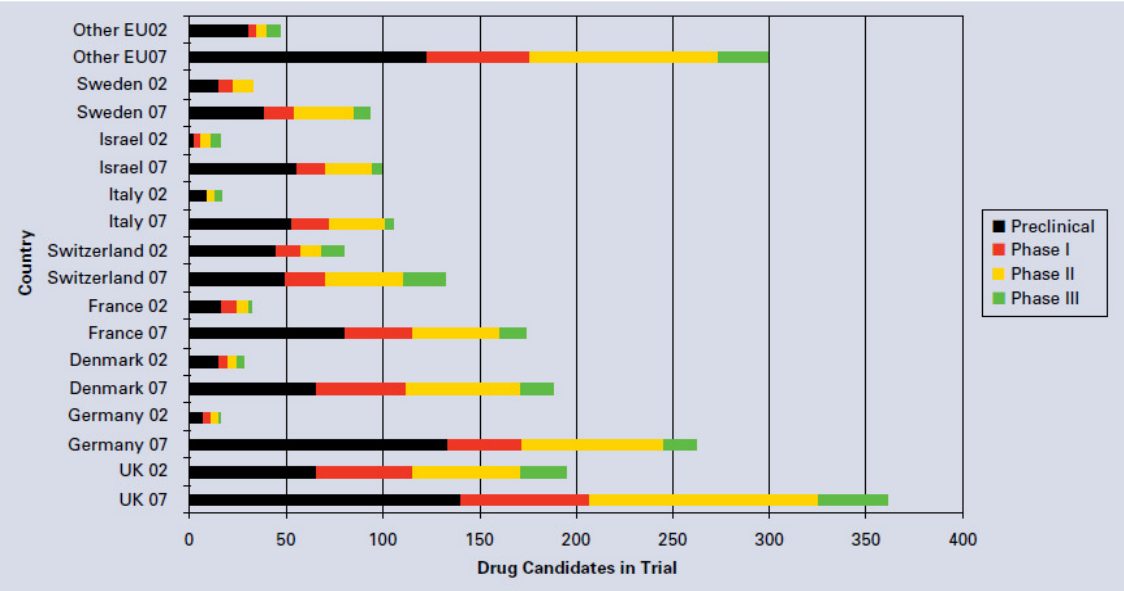
[16] http://www.berr.gov.uk/files/file49805.pdf - see "The UK Pipeline" page 6, figures 1 and 2.

Figure 1: European Product Pipelines



Data: Ernst & Young

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 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[17] [18], 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 consultation[19] investigated the impact of current UK legislation on

[17] 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 (Internation Federation of Intellectual Property Attorneys), IP Federation, Interpat, Japan Intellectual Property Association (JIPA), Japan Pharmaceutical Manufacturers Association, Johnson & Johnson, Merck, Novartis.

[18] 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.

[19] 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

pharmaceutical clinical and field trials in the UK. Responses[20] showed that stakeholders 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 agreement[21] that change is needed, and the majority[22] of responses specifically indicated that this should be done by changing the law.

In response to the informal consultation[23], 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 consultation[24] 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 changes and LRO preconditions[25].

The overwhelming majority of responses (19/20[26]) 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

[20] http://www.ipo.gov.uk/response-2011-bolar.pdf
[21] 15/16 responses agreed that there was a need for change.
[22] 12/16 responses think the law should be changed.
[23] http://www.ipo.gov.uk/response-2011-bolar.pdf
[24] http://www.ipo.gov.uk/consult-2012-bolar.pdf
[25] LRO preconditions are: proportionality, fair balance, necessary protection, rights and freedoms, constitutional significance.
[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.

health technology assessment[27].

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 assessment[28].

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;
- 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 exception[29] 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.

[27] 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.

[28] http://www.ipo.gov.uk/response-2012-bolar.pdf

[29] s.60(5)(i) Patents Act 1977

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.

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 option[30]. 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 majority[31] 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.

[30] 15 from 16 responses to the informal consultation indicated that there is a need for change in the legal framework surrounding clinical trials.

[31] 19/20 responses to the informal consultation agreed the law should be changed in this way.

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 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 the exception to outweigh the costs.

Costs/Benefits

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 limited[32]. 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 times[33] 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.

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

[33] 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 States[34], 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.

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.

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

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 do 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 innovate 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.