Title:	Impact Assessment (IA)			
Unified Patent Court implementation: Alignment of exceptions to				
infringement	Date: 17/03/2014			
IA No: BISIPO003	Stage: Consultation			
Lead department or agency:	Source of intervention: International			
BIS - Intellectual Property Office	Type of measure: Secondary legislation			
Other departments or agencies:	<b>Contact for enquiries:</b> Katherine Evans katherine.evans@ipo.gov.uk			
Ministry of Justice				

#### **Summary: Intervention and Options**

#### **RPC Opinion: Amber**

#### 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, Two-Out?	Measure qualifies as
£m 0	£m 0	£m 0	No	

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

Currently the exceptions to patent infringement in UK patent law do not completely agree with those in the Unified Patent Court (UPC) Agreement. UK exceptions do not extend as far as those provided by some other Member States and are more limited than outlined in the Agreement. To leave the exceptions as they are in UK law would create the scenario where a patent in the UK may or may not be considered to have been infringed depending on whether it was a GB patent, a European bundle or a unitary patent. This would create doubt and uncertainty for patent-holders and users of patented products. An amendment to UK law would bring certainty on these specific matters.

#### What are the policy objectives and the intended effects?

The overall objective is to improve legal certainty surrounding infringement of patents for parties with an interest in the development of plant varieties and computer programs in the UK. This is part of the package of changes relating to the Unified Patent Court Agreement; part of which provides the two additional infringement exceptions (Article 27 of the Agreement) to those that currently exist in UK law. The new infringement exceptions will benefit some of those involved in the development of plant varieties and computer programming as it will ensure that patents do not unduly inhibit innovation in these sectors. It will also put UK law on a level playing field with much of Europe.

# 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 – make changes to implement the UPC Agreement and also align infringement laws applied to the UK national patents with those of the UPC Agreement.

Our preferred option is Option 2 as this means that all patents valid in the UK are subject to the same infringement exceptions as under the UPC Agreement, providing legal certainty for users and bringing cost savings for research & development in the field.

# Will the policy be reviewed? It will be reviewed. If applicable, set review date: 7 years from entry into force of the UPC Agreement

Does implementation go beyond minimum EU requirements? No								
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	<b>Small</b> Yes	II Medium Yes		<b>Large</b> Yes				
What is the $CO_2$ equivalent change in greenhouse gas emission (Million tonnes $CO_2$ equivalent)	<b>Traded:</b> N/A	1	Non-tr N/A	aded:				

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: \_\_\_\_\_ Date: \_\_\_\_\_

## Summary: Analysis & Evidence

**Description:** No Change

#### FULL ECONOMIC ASSESSMENT

Price Base	PV Bas	е	Time Period	Net Benefit (Present Value (PV)) (£m)				
Year 2014 Year 2		014	Years	<b>Low:</b> 0	High: 0 Bo	est Estimate: N/A		
COSTS (£m)			Total Tra		Average Annual			
		(0	Constant Price)	Years	(excl. Transition) (Constant Price)	(Present Value)		
Low			0		0	0		
High			0	-	0	0		
Best Estima			0		0	0		
Description and scale of key monetised costs by 'main affected groups' No Change								
Other key non-monetised costs by 'main affected groups'								
BENEFITS	6 (£m)	(	<b>Total Tra</b> Constant Price)	nsition Years	Average Annual (excl. Transition) (Constant Price)			
Low			0		0	0		
High			0	-	0	0		
Best Estima	te		0		0	0		
Description and scale of key monetised benefits by 'main affected groups' No Change Other key non-monetised benefits by 'main affected groups'								
Key assumptions/sensitivities/risks       Discount rate (%)       3.5								
BUSINESS ASSESSMENT (Option 1)								

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

## Summary: Analysis & Evidence

### Description: Align UK exceptions to infringement laws with UPC agreement

#### FULL ECONOMIC ASSESSMENT

Price Base	PV Bas	se	Time Period	Net Benefit (Present Value (PV)) (£m)				
Year Year			Years	Low: 0 Hig		gh: 0 I	Best Estimate: 0	
COSTS (£m)		Total Tra	ansition		Average Annua			
			(Constant Price)	Years	(excl. Transit	ion) (Constant Price)	(Present Value)	
Low		0			C	0		
High			0	0		C	0	
Best Estima			0			C	0	
Description and scale of key monetised costs by 'main affected groups' We are unable to fully monetise the costs at this stage. We will be asking questions at consultation which should help inform us.								
Other key non-monetised costs by 'main affected groups' The new rules will affect 500 GB plant breeders patents (less than 0.5% of GB patents and approximately 0.05% of all UK patents.) Some patent holders may find that their inventions may be used in instances where previously licenses may have been required, resulting in loss of income. The legal sector may also face reduced demand for licensing services. These losses of income are intermediate costs for other firms.								
BENEFITS	6 (£m)		<b>Total Tra</b> (Constant Price)	n <b>sition</b> Years	(excl. Transit	Average Annual		
Low			0			C	0	
High			0	0		C	0	
Best Estimat	te		0			C	0	
Description and scale of key monetised benefits by 'main affected groups' We are unable to fully monetise the benefits at this stage, we hope to gain greater insight into the benefits at consultation stage.								
Other key non-monetised benefits by 'main affected groups'         The ability to undertake R&D activities which may already be done in other parts of Europe will be of benefit to UK businesses and may attract foreign research activity. Those performing R&D will have reduced licensing fees and reduced legal and administrative costs. The legal certainty provided by having a single coherent structure for infringement exceptions, rather than a dual system, will benefit both patent holders, and those using patents.         Miscount rate (%)         3.5								
We will solicit estimates of the costs and benefits of the proposed changes in the consultation. At present, we are assuming that the costs will roughly balance benefits within existing affected groups. We are also assuming that the lower costs to research and development and greater certainty will encourage additional innovation. There is a risk that we will not receive sufficient evidence at consultation.								
BUSINESS AS	SESSM	ENT (O	Option 2)					
Direct image	tonhus	inces	/Equivalant Ann			In coope of OlO(	2 Mossuro qualifios as	

Direct impact on bus	iness (Equivalent Annua	In scope of OIOO?	Measure qualifies as	
Costs: 0	Benefits: 0	Net: 0	No	

# **Evidence Base (for summary sheets)**

#### Problem under consideration

Patent systems within Europe are fragmented which creates uncertainty for firms and increases transaction costs. In response to this, a number of changes are being made across Europe to harmonise European patent law. Two main changes under consideration are the development of a Unitary Patent and an associated Unified Patent Court (UPC) (covered in separate IAs nos BISIPO005 and BISIPO006.)

In addition, there currently exist subtle but significant differences in national laws when it comes to determining what constitutes an infringement of a European patent, i.e. those acts that a patent owner can prevent others from doing without their permission. National patent laws also vary when it comes to defining exceptions to infringement, i.e. certain limited acts which would otherwise be considered infringing if it were not for the fact that an exception exists. An example of a common exception to patent infringement is the research exception which permits some experiments on patented inventions, and so allows the creation of new knowledge building on existing patented knowledge, without having to compensate the existing patent owner.

The Government would like to extend the existing exceptions to patent infringement to align with those set out in the UPC Agreement. This will reduce uncertainty and transaction costs for firms because it will mean that all patents valid in the UK will subject to the same exception to infringement and are thus on an equal footing no matter whether the patent is enforced through the national courts or the UPC. This will mean fewer occasions where legal advice is required. Introducing these exceptions will help UK remain a desirable location for research & development activities as it will more closely align the exceptions to infringement in UK law with those of other major EU countries such as Germany and France.

The patents valid in the UK once the UPC Agreement is ratified will be GB Patents<sup>1</sup> (granted by the IPO), a European bundle patent validated in the UK (granted by the EPO and valid in a 'bundle' of countries including the UK) or a unitary patent (granted by the EPO and valid across up to 25 states where the Unitary Patent Regulation applies). During the transition period, those holding European bundle patents will be able to 'opt out' of the UPC for the lifetime of that patent, meaning that their patents would be considered under national jurisdictions rather than the UPC (this IA refers to these as 'opted out EP(UK)s'). It will also be possible to withdraw an 'opt out', meaning that those patents would then go to the UPC. The transition period will be 7 years from the opening of the court, but there is the possibility that it could be extended for an additional 7 years.

The UPC Agreement infringement provisions only apply for European bundle patents subject to the jurisdiction of the UPC and for Unitary Patents. The Agreement makes no provision for GB patents or European bundle patents which have opted out and are subject to the jurisdiction of national courts. The UPC Agreement includes two exceptions to infringement which do not currently exist in UK patent law; these are described in more detail below. It is proposed that the two new exceptions to infringement shall apply to patents falling under UK jurisdiction (GB patents and opted out EP(UK)s) as well those patents under the jurisdiction of the UPC in order to ensure that all patents valid in the UK are subject to the same legal regime.

There also will be minor changes to UK infringement provisions required to take account of the fact that the territory of the unitary patent is wider than the territory of the other patents valid in the UK, which are just valid in the UK. These changes will mean that the right to prevent indirect infringement (e.g. supplying a patented product to a third party) of a unitary patent will need to include the right to prevent indirect infringement for the whole territorial extent of a Unitary Patent and not just the UK. Similarly, current UK exceptions to patent infringement which allow use of patented inventions on ships, aircraft, hovercraft and vehicles temporarily or accidently in the territory of the United Kingdom will need to ensure that they take account of the wider territory of the unitary patent.

<sup>1</sup> In this usage, the term 'GB' does not solely refer to England, Wales and Scotland; it also includes Northern Ireland. This is in accordance with the WIPO country codes list.

Two other proposed changes to the UK Patents Act will have a wider impact, and are the focus of this IA. The UPC Agreement contains two exceptions to infringement which do not currently exist in UK law and will apply to unitary patents and European bundle patents within the UPC's jurisdiction. The Government wishes to align UK law on patent infringement with the UPC Agreement by introducing these two new exceptions for all European bundle patents (irrespective of which court has jurisdiction), unitary patents and national GB patents. This will mean introducing two limited exceptions to the exclusive rights of patent holders: for the use of biological material for the purposes of breeding, discovering or developing other plant varieties (throughout the rest of this IA, this will be referred to as the plant breeders exception) and also an exception for inventions involving computer programs – permitting the making of back-up copies, limited decompilation and restricted copying and adaptation by lawful users (later referred to as the computer programs exception).

In the UK, new plant varieties can be the subject of Plant Breeders' Rights as provided for by the Plant Varieties Act 1997 and Regulation (EC) 2100/94. Plant Breeders' Rights enable rights holders to prevent others from selling or reproducing the plant variety without permission. Plant Breeders' Rights cannot prevent third parties from using a protected plant variety in the development of a new variety. However as patent law stands in the UK breeders would not be able to make use of patented biological material in the development of new varieties as this risks infringement of a patented product. While the number of patent applicants for GB plant breeding patents affected is small (500 since 2000), British applicants comprise 60% of these applicants<sup>2</sup> and therefore this change is important for the sector. The proposed exception would remove the barrier to use patented biological material in the development of new varieties, and ensure that the terms of the Patent Act are not in conflict with spirit of Plant Breeders' Rights legislation in the UK.

Across Europe, computer programs as such are not able to be patented. This is set out in the European Patent Convention with which all EU Member State national patent laws (including our own) are aligned. This means that although it is possible to get patents in the UK for some inventions involving computer programs, it is not possible to get patents for innovations that are solely computer programs such as an improved word processing program. The program itself is protected under the Copyright Designs and Patents Act 1988. There are certain exceptions to copyright which were introduced through the computer programs Directive (2009/24/ EC), and the UPC Agreement makes reference to that Directive in Article 27(k). There may be a small subset of activities currently allowed by the exceptions to copyright law that would potentially be restricted by patent law. The proposed new exception ensures that patent law does not prevent actions allowable under copyright law. There are no other references to computer programs in the Agreement, and it makes no changes to what subject matter is considered patentable.

It is important to recognise that these limited changes to UK infringement exceptions represent no change to what is considered patentable – national laws on patentable subject matter have been aligned across Europe through the European Patent Convention of 1973 which also established the European Patent Office (EPO). Furthermore, there is no change to the meaning of infringement as detailed in section 60(1) - (3) of the Patents Act 1977 as this area of the law is already considered to be consistent with the equivalent provisions of the UPC Agreement. The proposed changes affect no other infringement exceptions.

#### Rationale for intervention

The rationale for intervention comprises of two points. The primary reason is to make clear that all patents valid in the UK (GB, EP(UK), and Unitary Patents) provide patent owners with the same rights to prevent others from using their patent without permission. Complexity and uncertainty place a burden on businesses in terms of both time and money. This measure will ensure that all patents valid in the UK will have the same infringement provisions applied irrespective of which court has jurisdiction. The second is to shape the patent system to allow sufficient use of patented plants and acts required to allow necessary copying, loading or correction of errors and interoperability of software so as not to discourage innovation via research & development.

<sup>2</sup> Since 2000, there have been 500 successful applicants for GB plant breeding patents. Of these applicants, 60% are deemed British. Source: IPO data.

Legally, the UK is not required to align national law on infringement relating to national (GB) patents or opted out EP(UK)s with the provisions of the UPC Agreement as the Agreement only relates to European patents within its jurisdiction and Unitary Patents. However, if the law relating to GB patents is not aligned, this will result in different patents valid in the UK being subject to different infringement laws. This would be undesirable as it would increase the uncertainty of the patent regime in the UK. It is the Government's view that it is desirable to bring the exceptions to infringement in the Patents Act 1977 into line with the equivalent provisions in the UPC Agreement.

The second purpose for intervention is to introduce exceptions to patent infringement which allow UK based users to have greater freedom to develop plant varieties or use software in ways that accord with the Software Directive (Directive 2009/24/EC) without running the risk of legal proceedings on grounds of infringement.

These uses do not entirely fall within the current patent infringement exceptions in UK law. The introduction of this exception would allow for the use of the patents in certain limited instances; this could decrease the cost of research and development, thereby increasing spending in this area and lead to increased innovation in the UK. In the absence of making these changes, research & development activities may go to other European countries where the exceptions are in place. This is important as expenditure on R&D in the UK by foreign owned businesses constituted 51% of total expenditure<sup>3</sup>.

#### Policy objective

The overall objective is for all patents valid in the UK to be subject to the same exceptions to infringement. This will improve legal certainty surrounding infringement of third party patents for companies involved in research into plant varieties and computer programs in the UK. It will allow for research & development activities using these patents to take place without the need to seek permission from patent owners.

This is part of the package of changes which will implement the UPC Agreement, and will extend further than the other proposed changes to UK law (detailed in accompanying Impact Assessment) as it will also apply to (GB) patents and opted out EP(UK)s. The positive impact on UK innovation should be noted by increased investment in research & development activities in the UK. Furthermore, the UK will maintain its status as a desirable place to conduct research. These measures will only affect patents, including existing patents, during the duration of their patent protection.

A plant breeders' exception permitting the breeding, discovering or developing of new plant varieties will reduce the potential disadvantages faced by plant breeders if the UK does not incorporate these exceptions into UK law. So far, the UK has taken a more restrictive approach to infringement exceptions than other European countries. France, Germany and the Netherlands have such an exception in their national law, but the UK does not. Responses to the 2008 public consultation on the patents research exception (<u>http://www.ipo.gov.uk/response-patresearch.pdf</u>) suggested that the UK regime for researchers in the field of plant breeding was perceived as more restrictive than in other European countries such as Germany. The UK considered action at national level but there was no consensus between the plant breeders and the patent holders as to whether regulation was appropriate. The industry across Europe were at that time attempting to reach a solution that would not require legislation but were unable to reach a consensus and further discussion about action at a national level was halted as negotiations for the UPC Agreement signalled a possibility that it may be included in the Agreement.

The Government's public consultation on the patent research exception identified a desire amongst the UK plant breeders and seed industry for a specific exception to infringement which would allow the use of biological material for the purpose of breeding, discovering & development of a new plant variety. This exception is similar to that already included in German Patent law. This sector was particularly concerned with the situation where a breeder uses a plant variety including patented gene for cross breeding but selects out the patented gene so that it does not appear in the final variety. It is not clear that the current patent research exception (Section 60(5)(a) Patents Act 1977) would apply in such a case, and as a result some research into developing new plant varieties may be restricted because of the risk of patent infringement. The introduction of the proposed exceptions would address this issue.

<sup>3</sup> ONS Business Enterprise Research & Development, 2012, available at <u>http://www.ons.gov.uk/ons/rel/rdit1/bus-ent-res-and-dev/2012/stb-berd-2012.html</u>

The computer programs exception would reflect an aspect of Directive 2009/24/EC (the Software Directive, which provides for the protection of computer programs) allowing for the back-up, de-compilation, correction of errors or study and testing, of a program insofar as it may relate to patents. This change would complement the way the Directive has been interpreted in the Copyright Designs and Patents Act 1988 which makes reference to the "lawful use" of a computer program in the specific circumstances listed in Sections 50A, 50B, 50BA and 50C. Currently, if some aspect or technical effect which the software implemented were patented, others could be prevented from any of the acts permitted under copyright law as it may be considered that the act was unlawful. The proposed exceptions would make these acts lawful and bring software in line with similar copyrighted materials for the specified acts.

#### Description of options considered (including do nothing)

#### Option 1 – do nothing

To do nothing would mean making no changes to the infringement provisions in the Patents Act 1977. This would result in the exceptions to infringement applicable in national law (S60(5) of the Patents Act 1977) being different to those in the UPC Agreement (Article 27) because UK law currently does not include the two exceptions to infringement which are present in the UPC Agreement (Article 27(c) and Article 27(k).

Option 2 – make changes to give effect in national law to the infringement provisions in the UPC Agreement and align infringement laws applied to UK national patents with those of the UPC Agreement

The Government introduces two new exceptions to patent infringement to give effect to Article 27(c) and 27(k) of the UPC Agreement which will apply to all patents valid in the UK whether they are national patents, European patents or European patents with unitary effect.

The proposal is to make it clear in UK law that the infringement exceptions comply with those in the UPC Agreement. This will mean adding an exception for the use of biological material for the purposes of breeding, discovering or developing plant varieties and also an exception for the acts permitted in Articles 5 and 6 of the Software Directive. This proposal also aligns the infringement provisions for national patents with those of the UPC Agreement ensuring that the same exceptions apply to all patents valid in the UK irrespective of which authority (IPO or EPO) had granted the patent. The proposal will also make some minor changes to reflect the wider territory of the unitary patent. This includes ensuring that the right to prevent indirect infringement is for the whole of the unitary patent's territory and that the exceptions for the use of inventions on ships, aircraft, hovercraft and vehicles temporarily taken into the UK take account of the wider territory of the unitary patent.

An alternative to regulation could include creating voluntary licensing schemes in which patent owners license to researchers. However, this is essentially the current system and would not meet the policy objectives to bring UK patents in line or improve the research & development environment for plant varieties and software.

Option 2 is the preferred option as this achieves the policy objectives of ensuring national law gives effect to the provisions of the UPC Agreement and aligning the law on infringement for all patents valid in the UK. It also achieves the policy objective of creating a desirable research & develop environment.

#### Costs and benefits

We are unable to monetise all costs at this stage but we will seek further information at consultation to allow us to quantify them.

#### Option 1

This option does not meet the policy objective of giving clarity over what acts are considered exceptions to infringement of a patent within the UK. It would in effect create two parallel systems because there would be two different sets of infringement exceptions within the territory of the UK: one which applied to European patents valid in the UK (EP(UK)) which have been opted-out of the UPC and (GB) patents; and another which applied to unitary patents and EP(UK)s which had not been opted out. It would be unclear whether the infringement provisions of the UPC, or of the UK would apply to a particular patent until the alleged infringer faced court proceedings.

#### Option 2

The new plant breeders' exception would bring the 500 successful applications for GB plant breeders patents<sup>4</sup> under the same proposed exceptions regime as the 2,200 successful applicants for EPO patents validated in the UK<sup>5</sup>. GB plant breeders' patents account for less than 0.5% of GB patents and approximately 0.05% of all UK patents<sup>6</sup>. As such, the changes will have a small impact overall to GB patents and an even smaller impact relative to all patents in force in the UK.

We will be looking at the extent to which licensing takes place at consultation, and will be asking about the burden it places on those who may become subject to the exception. We will solicit evidence on the level of licensing for both patent owners and researchers and the costs associated with this licensing.

Patents including a component for software cannot be counted as the UK does not grant patents for software explicitly, as noted earlier. We are collecting data on litigation to gain a better understanding of the levels of litigation associated with infringement that might be affected by the proposed changes.

The changes to infringement provisions of the unitary patent territory will reflect the unitary patent and therefore do not have separate costs and benefits associated with them.

#### Costs

#### Costs to those who receive income from licensing patented products

Currently, patent owners are able to charge a licence fee for researchers to use a patented product for the purposes of research. Those who hold patents in either the plant breeding field or in computer programs may have concerns that people may be exploiting their invention without due compensation. The loss of licensing income will have an impact on those businesses holding patents in plant products, and those with patents in computer program implemented inventions is not quantified at present. The consultation will solicit will solicit further views and evidence.

As these exceptions apply only to research & development, and not to the commercialisation of the product, we believe that the impact on patent owners will be limited.

#### Costs to the legal services

Those providing legal services to facilitate existing licenses for patented products may lose some income as they face decreased demand for their services in the long run. There would be decreased demand for licensing services and potentially decreased demand for litigation of infringement disputes. However, these are intermediate costs and do not affect UK GDP.

#### Administrative Costs

Existing license agreements may have to be renegotiated or redrafted to reflect the new exceptions. This may result in transitional costs as these agreements are updated. This cost will be borne by both patent owners and licensees.

#### Other Costs

We do not anticipate any significant administrative, policy or enforcement costs. There may be some initial familiarisation costs as those using patented products and patent owners adapt to the new exceptions. However, these exceptions are standalone exceptions which do not have an impact on others.

#### **Benefits**

The proposed changes will mean that some acts relating to research and development currently considered to be infringing will no longer be considered infringing acts for patents valid in the UK (GB, EP(UK) or the new Unitary Patent). The two specific exceptions which would be introduced under this proposal will affect plant breeders and those working with computer programs.

Both these exceptions will provide greater clarity for users and researchers as well as patent owners over what acts can and cannot be carried out without the patent owner's permission.

GB patents granted since 1994 as of March 2014. Source: Internal IPO data. 4

EPO patents validated in the UK, by those who paid post grant fee, since 1994 as of March 2014. Source: PATSTAT data. 5 6

GB and UK patent totals above compared to UK IPO Facts and Figures and EPO estimates.

#### Savings for licensees

The loss of licensing income for patent holders would represent a saving for those who would not be required to pay a license fee to commence research. This means that there is simply a transfer of costs from one party to another resulting in no net cost or benefit. However, the lower costs faced by researchers could result in increased investment in research & development. We will solicit evidence of these savings in consultation.

#### Administrative savings

The introduction of these two exceptions means that both patent holders and those considering research may find savings because of a reduction in administrative costs. This is because the exception removes the need to seek a license/permission to use the patented product. We assume that each time someone seeks permission to use a patented invention there must first be negotiations. The addition of these new exceptions removes the need to do this, so reducing the level of administration required resulting in a net saving for businesses. As noted before, these are intermediate savings and will not affect UK GDP. The estimates we are collecting on litigation, and evidence sought during the consultation period, should give us a better idea of these costs.

#### Wider benefits to innovation

British companies may currently be inhibited from taking some actions using patented plant material or software products relating to the limited exceptions to infringement in UK law and so may be disadvantaged compared to competitors in other European countries. Our consultation will be asking specific questions of those in the plant breeding and software industries to gauge this. The benefits of broadening these infringement exceptions will help stimulate innovation as researchers may find that any fear for of being sued for infringement will be reduced. As of next year, R&D will be capitalised in UK national account and will become part of GDP, thus any measure, such as the proposed exceptions, to help locate research in the UK will ultimately impact growth and GDP.

#### Greater legal certainty through creating a single regime

If UK patent law were not amended this would produce a two-tier system, where some EP(UK) patents held within the UK would be covered by UPC law which provides two additional exceptions to infringement, whilst for others, UK law would apply meaning that these exceptions would not apply. This would create greater uncertainty amongst the research community as it would not be clear whether a product intended for research would be covered by the exceptions in the UPC Agreement, or those in the Patent Act 1977. This uncertainty could inhibit research & development of new products in the two technology sectors affected.

By making the proposed changes, third parties navigating the field would find it easier than at present as they would not have to determine which infringement laws applied in order to know if current or planned research would carry a risk of infringing a patent.

#### **Risks and assumptions**

The positive impact of the introduction of these exceptions is that it may result in increased research & development leading to innovation in the UK. As the proposed exceptions will increase the availability of research materials, no negative impact on the research environment is anticipated.

Many of the costs savings or income losses by various groups detailed earlier are intermediate costs and the net effect will be neutral. The analysis here also assumes that the exceptions result in a reduction in licensing and litigation. Were the infringement exceptions to cause confusion, their introduction could result in increased litigation as patent owners and researchers use the courts to clarify the exceptions. However, there is an established body of existing exceptions of patent use; therefore, existing legal practices and research process should be easily expanded to include the additional exceptions.

This impact assessment assumes that other European countries will also align their infringement provisions to those of the UPC. As noted, the plant breeders exception already exists in France, Germany, and the Netherlands and therefore the introduction of this exception would put the UK plant breeding community on par with their regimes. However, if other countries chose not to align with the UPC Agreement, then the benefits of being on par with other regimes are reduced.

#### Wider impacts

The main impacts from the proposed changes will be positive incentives to innovate and are thus mostly financial and economic. As the proposed exceptions pertain to plant breeding rights, the changes could lead to increased innovation in biological material that could create positive impacts such as generating pest-resistant crops and have positive environmental and food supply impacts. However, these are indirect impacts and the case laid out here relies on the economic impacts.

#### Distributional impacts

The three main directly affected groups are patent owners, legal services and researchers. Patent owners engaged in research & development activities may find that a reduction in license fee collection is offset by reduced license fee payments for research and development activities. The legal sector may find decreased demand for their services.

#### Impact on Micro Enterprises

Micro enterprises and SMEs are those which are most adversely affected by legal complexity and cost, and the need to take external legal advice. The innovative firms among them are also most directly affected by limits to their ability to develop new products and methods, and by differences in national regimes. A single exceptions regime, which is consistent with the Unitary Patent Court, is likely to benefit micro enterprises, so there is no reason to exclude them from this change

#### Summary

Option 2 is the preferred option as it ensures that the legal framework for infringement exceptions in UK patent law is equivalent to that of the UPC. This puts all patents in the UK on an equal footing, and ensures that the system is not unduly hard to navigate for users. The introduction of the exceptions should also have positive impacts on innovation as it reduces the costs to research and development.

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

As part of the implementation of an international agreement, this is out of scope of OITO.

#### Evaluation

The UPC Agreement will be reviewed after 7 years, or 2000 cases (whichever is first). As set out in Article 87 of the Agreement there will be a broad consultation with users about the functioning of the UPC. Depending on the outcomes of this review, the details of the Agreement may be reconsidered.