

INCEPTION IMPACT ASSESSMENT			
TITLE OF THE INITIATIVE	Optimising the Internal Market's industrial property legal framework relating to supplementary protection certificates (SPC) and patent research exemptions for sectors whose products are subject to regulated market authorisations.		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	DG GROWTH – UNIT F5 INTELLECTUAL PROPERTY AND FIGHT AGAINST COUNTERFEITING	DATE OF ROADMAP	15/02/2017
LIKELY TYPE OF INITIATIVE	Legislative proposal(s)		
INDICATIVE PLANNING	Q4 2017		
ADDITIONAL INFORMATION	-		
<p>This Inception Impact Assessment aims to inform stakeholders about the Commission's work in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options. The Inception Impact Assessment is provided for information purposes only and its content may change. This Inception Impact Assessment does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content.</p>			

A. Context, Problem definition and Subsidiarity Check
<p>Context</p> <p>The Single Market Strategy, adopted in October 2015 (COM(2015)550), announced that the Commission will "consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations". In particular, the Strategy undertook to explore a recalibration of certain aspects of patent and Supplementary Protection Certificate (SPC) protection, and announced that this recalibration could comprise the following three elements: the creation of a European SPC title; an update of the scope of the EU patent research exemptions; and the introduction of an SPC manufacturing waiver.</p> <p>The European Parliament has taken a positive position in relation to the SPC manufacturing waiver, elimination of uncertainties as to how the unitary patent will coexist with national SPCs, and the possible creation of a unitary-SPC (2014/2206(INI) and 2015/2354(INI)). On 17 June 2016, the EPSCO Council (Health) adopted Conclusions on strengthening the balance in the pharmaceutical systems in the EU and invited the Commission to conduct an evidence-based analysis of the impact of the EU's pharmaceutical incentives, including the SPC and the "Bolar" exemption, on innovation and access to medicines.</p> <p>SPCs are a <i>sui generis</i> intellectual property right that constitute an extension (of up to five years) to the term of a patent right (of twenty years). SPCs apply to innovative pharmaceutical and plant protection products that have been authorised by regulatory authorities. They aim to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that products require prior to obtaining regulatory marketing approval. The relevant EU legislation is Regulation (EC) No 469/2009 and Regulation (EC) No 1610/96 on SPC covering pharmaceutical and plant protection products respectively.</p> <p>The Bolar patent exemption aims at speeding up the entry of generic¹ medicines into the market by allowing early preparatory development on generics to obtain pre-market regulatory approval even when the SPC of the reference medicine is still in force². The Bolar exemption is regulated at EU level for the pharmaceutical industry only; this is done through Article 13(6) of Directive 2001/82/EC and Article 10(6) of Directive 2001/83/EC. The scope of the EU Bolar exemption has been updated in some EU MS as explain below, inter alia, to meet new pharmaceutical-related requirement.</p>

¹ "Generic" is as a medicinal (or plant protection) product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference (originator) medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated before getting a fast-track marketing authorization. Proof of bioequivalence requires testing that, in principle, might be patent infringing regarding the reference's (originator) patent/SPC.

² For more details on originators-generics competition, see the Commission pharmaceutical sector inquiry at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>

Patent legislation that applies to all of these sectors is governed at three levels: firstly, the national patent acts of the 28 Member States for national patents; secondly, the European Patent Convention for the granting of European patents, which are granted by the European Patent Office; and thirdly, the Unified Patent package, which will introduce the unitary patent (UP) and Unified Patent Court (UPC). All the actions related to this initiative seek to complement - and enhance the coherence of - the Unitary Patent package for sectors that rely on SPC protection and patent exemptions. Indeed, the Unified Patent Court Agreement includes a cross-reference to Article 13(6) of Directive 2001/82/EC and Article 10(6) of Directive 2001/83/EC above.

The Commission will conduct a back-to-back evaluation and impact assessment of all relevant provisions and options for modernising the SPC Regulations and the provisions of the Directives dealing with the Bolar exemption (the Commission has not conducted so far any evaluation of this legislation).

Problem the initiative aims to tackle

Several issues/problems have been identified:

1. Loss of export markets and lead-time to entry into Member State markets for EU-based generics and biosimilars, resulting in reliance on foreign based supplies of generics and active pharmaceutical ingredients (APIs)

Manufactures of generic and biosimilar medicines based in non-EU countries where SPC protection does not exist (e.g. in Canada, Brazil, Russia, India and China) or where protection is shorter in duration can enter markets in which patent protection has expired up to five years earlier than is possible for EU-based manufacturers. This is because the EU's SPC acquis prevents EU-based generic manufactures from producing for export during the period of SPC protection of the reference medicine. In addition, this situation often gives an unintended lead time advantage to non-EU based operators as regards entering EU Member States generics market immediately upon the expiry of SPC protection within the EU.

Such a situation might incentivise European manufacturers of generic and biosimilar medicines to move their production outside the EU - either via delocalisation or long-term outsourcing contracts (often the only option for SMEs) - to overcome these legal hurdles and to stay globally competitive. EU reliance on foreign-manufactured medicines might be increasing, with the loss of high value jobs in the EU).

2. SPC protection might be not adapted to a changing global trade and innovation model

While the current SPC system is widely used, several issues related to eligibility (should other regulated products a part of pharmaceutical and plant protection products be eligible for SPC protection?), scope or registration process have nevertheless emerged. In particular, the system might be out of tune with recent developments in innovative sectors that are – or will be – subject to marketing authorisation systems (e.g. personalised medicines, chemicals in general, biopharmaceuticals, new uses of patented products, intelligent pills). Gaps in protection and a resulting lack of incentives to invest may lead to these sectors not achieving their full potential in terms of innovation and growth within the internal market.

3. Fragmented implementation of the Bolar and research patent/SPC exemptions

There is a general recognition that the Bolar patent exemption has been instrumental in the development and uptake of generic competition. However, Member States do not always exempt the same innovation and testing practices under these patent exemptions, for example:

- In a number of Member States, there is uncertainty as to whether these exemptions apply to tests conducted by originator, generic and biosimilar manufacturers for the purpose of seeking marketing authorisations in non-EU countries. Therefore, European companies might be duplicating testing in the EU and in third countries.
- There are indications that only certain EU Member States implemented the Bolar exemption to allow pharmaceutical originators to conduct testing to meet new national regulatory requirements on pricing and reimbursement (e.g. health technology assessment, or "HTA", that compare a given medicine with others to show relative cost/efficacy effectiveness). In the absence of such exemption, companies have to spend resources and time to identify potentially infringing patents before conducting such testing.
- Some Member States do not allow the supply of patented active pharmaceutical ingredients (APIs) to EU-based generic manufacturers for the purpose of seeking marketing authorisations under the Bolar patent exemption. EU API suppliers may further increase delocalisation and outsourcing of production to third countries as a consequence. EU reliance on foreign-manufactured APIs could increase, with a corresponding loss of jobs in the EU.

The Bolar exemption might not be available for plant protection products or other regulated products.

4. Fragmentation resulting from the current SPC regime

Existing SPCs, although regulated by EU regulations, are granted autonomously, and enforced, at national level. Approximately 20 000 SPCs had been granted up to the end of 2015. There are cases where some Member States have granted SPC applications, while the very same applications have been refused in other Member States, or else granted but with a different scope. Multiple national SPCs also result in high costs of registration and maintenance. Some Member States' patent offices do not have adequate administrative capacity for the registration of SPCs, and grant them without checking the information provided.

As a first step to address this, the Commission intends to issue in the first semester of 2017 a Communication providing guidance on how the upcoming Unitary Patents will dovetail with national SPCs. However, looking ahead, users of the SPC system may well consider that Unitary Patent protection is less appealing if only national SPCs, and not European SPC titles, are available.

Mapping of affected stakeholders in relation to the four issues described above:

- Some innovative sectors whose products are subject to pre-market regulatory authorisation might not be eligible for SPC protection or Bolar research exemptions.
- Originators in the agrochemical and pharmaceutical sectors, whether universities, start-ups, SMEs or large companies, face additional administrative, testing and management costs associated with the current fragmented SPC systems, and different national approaches to the Bolar exemption.
- The European-based generic medicines industry and API suppliers, and especially SMEs, do not compete on a level playing field vis-à-vis competitors based outside the EU, as explained above. They do not enjoy full business predictability across the internal market due to the opaque or insufficient definition of the SPC and Bolar exemption frameworks in some Member States. They also incur high cost of monitoring national SPCs in 28 jurisdictions in the EU.
- Research is increasingly being carried out by universities, biotechnology firms or contract research organisations (CROs). These bodies also face unnecessary costs associated with identifying potentially infringing patents and national SPCs before conducting clinical trials.
- EU consumers and patients might not enjoy full access to innovative developments if the right incentives are not in place. For their part, Member States' health sectors might not benefit from optimum and timely entry of new innovative drugs and affordable generics. For generics, Member States may become overly dependent on foreign-based production following patent-expiry of the reference medicines. Furthermore, new initiatives of EU Member States' joint purchasing of medicines would meet obstacles if the relevant SPCs in the participating Member States have different scope and duration stemming from existing fragmentation.

Subsidiarity check (and legal basis)

The EU actions envisaged tackle internal market barriers covered by Article 114 of the Treaty on the Functioning of the EU (TFEU). Action at EU level is justified to ensure the smooth functioning of the internal market for innovative products subject to marketing authorisations, and to permit the benefits of an efficient industrial property framework to be reaped in the relevant product markets. Both existing rules on SPCs and the Bolar patent exemption are regulated by secondary EU legislation based on Article 114.

The first paragraph of Article 118 TFEU, covering measures for the creation of European intellectual property rights, is the legal basis for Regulation 1257/2012 implementing unitary patent protection and therefore, it would be an additional legal basis for the creation of an EU SPC title.

Some Member States have considered the idea of introducing the SPC manufacturing waiver via amendments to their national patent law, but those amendments would not apply to SPCs granted for unitary patents. Amendments to the SPC Regulations can only be adopted by the EU legislator. A few EU Member States have introduced amendments to their national patent exemptions rules that might not be followed by the Unified Patent Court as this Court relies on the EU rules on Bolar exemptions. A system of mutual recognition of EU SPCs granted by national authorities or a centralised/virtual grant authority could only be tackled at EU level.

B. Objectives and Policy options

This initiative aims to support this Commission's mandate to deepen and make the internal market fairer, thus stimulating sustainable jobs, growth and investments, with a special positive impact on innovative SMEs. The objectives of the initiative also support the sustainability of public health budgets, as well as access to medicines in the EU and in third countries.

Specific policy objectives :

1. Create a level playing field for EU-based manufacturers of generic and biosimilar medicines by comparison with firms based in non-EU countries (both for export and for EU-market entry purposes), while keeping a high level of SPC protection in the EU. This in addition would lessen reliance on imports of products that are essential to public health.
2. Increase business predictability, legal certainty and potentially provide additional incentives for innovation, in the EU for companies dealing with regulated products in the context of additional regulatory requirements, new business models and new forms of innovation. It would help these innovative sectors to be globally more competitive and increase the attractiveness of Europe as a hub for innovation and manufacturing.
3. Maximise certainty and benefits of the Bolar patent exemptions, including a reduction of the fragmentation in the internal market that is associated with the current Bolar system; provide the upcoming Unified Patent Court with clear provisions reflecting best practice developed in Member States in relation to patent exemptions. This can also reduce unnecessary duplication of clinical trials.

4. Increase the reliability – and reduce the cost and burden – of the registration and enforcement of SPCs in the EU. Maximise the benefits of the Unitary Patent system to those sectors relying on SPC protection, including a reduction of the fragmentation in the internal market that is associated with the current SPC system; and provide the upcoming Unified Patent Court with clear provisions reflecting best practice developed in Member States for these sectors.

To achieve the policy objectives set out above, the Commission is considering the following **options**:

1. Baseline scenario: no policy change.
2. Non-legislative instruments aiming at improving implementation of existing EU legislation related to SPC protection and patent exemptions.
3. Legislative changes:
 - 3.1 Introduction of an SPC manufacturing waiver for export purposes to allow EU based manufacturers of generics/biosimilars manufacturing their products during the EU SPC term of the reference medicine to export their products to countries with no SPC protection.
 - 3.2 Modernisation of the existing SPC Regulations (in combination, or not, with option 3.1) to update the existing framework (e.g., amendments to the SPC-eligibility, scope of protection, registration procedures, etc.) with a view to new challenges faced by the pharmaceutical industry.
 - 3.3 Clarification and recalibration of the scope of patent Bolar and research exemptions in the EU to cover the situations describes in the problems-point 3 in section A above (testing for foreign approval and health technology assessment, and for supply to active ingredients), or to be extended to other industries like the agrochemical one (in combination, or not, with option 3.1 or 3.2).
 - 3.4 Creation of a European SPC title (in combination, or not, with option 3.1, 3.2 or 3.3).

Under the baseline scenario, the SPC regime would continue to rely on existing EU and national rules on patent exemptions and SPCs, and on court rulings, including rulings by the Court of Justice of the EU (CJEU). Member States might continue in a unilateral and uncoordinated manner to move forward recalibrating their national patent/SPC rules and practice, with different approaches persisting across the internal market. While the upcoming Unified Patent Court would eventually forge jurisprudence, it would take a considerable amount of time and could depart from best practices developed in some EU Member States. The problems identified in section A above would by and large continue.

Regarding options of improving implementation and enforcement of existing legislation or doing less/simplifying existing legislation:

- The Commission is expected to issue, in the first semester of 2017, a Communication providing guidance on how to articulate the upcoming Unitary Patents and the existing national SPCs.
- The Commission would continue to work to improve the implementation and enforcement of the SPC Regulations by participating at the annual SPC national expert meetings and providing inputs to the CJEU in the context of the latter's preliminary rulings.
- The Commission could promote guidelines highlighting best practices adopted by Member States and/or encouraging the establishment of a group of national experts on Bolar and research exemption provisions.

These options would improve the outcome of the baseline scenario (option 1).

Further to the non-legislative approaches described above, alternative policy approaches would entail EU legislative intervention to implement options 3.1 to 3.4 above. The policy objectives sought by options 3.2, 3.3 and 3.4 could be partially achieved by the non-legislative options described above. Regarding the creation of a European SPC title, several features provide for sub-options which will be further assessed in the Impact Assessment process: choosing the legislative procedure (see below), setting the administrative fees, the language of the proceedings (ranging from English-only to EPO, EUIPO or European Medicine Agency regimes), the designation of the granting authority (variations on this option could be: mutual recognition between national patent offices, creation of a virtual grant authority involving Members States and the Commission, creation of a EU authority, EPO, EUIPO or the European Medicine Agency etc), and legal actions against the decision to grant or refuse an SPC application.

A mix of non-legislative and legislative instruments could be considered. Several regulatory instruments could be considered for any EU legislative intervention: a stand-alone Regulation recasting and amending the existing SPC Regulations (potentially including the introduction of a European SPC title) and the EU provisions about the Bolar patent exemption; or amendments to existing EU legislation through separate legislative instruments for each of the actions discussed above. Another option could be a specific Regulation creating a European SPC title.

The options under consideration take into account the needs of all types of affected stakeholders identified above, and are adapted in particular to the increasing number of SMEs and of producers of generic and biosimilar medicines present in these innovative sectors. The options under consideration take account of trends in innovation and new regulatory requirements. One of the options under consideration is the creation of a "virtual authority" to European SPCs that could be possible thanks to digital technology.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

The global spending in medicines is expected to grow significantly and shift toward generic medicines. Generics and biosimilars could represent 80% of the volume of medicines by 2020. Within this context, an SPC manufacturing waiver for export purposes to non-EU countries could allow EU based medicines manufacturers to seize net export opportunities of several billion Euros in the coming years. This in turn would generate increased investment in manufacturing activities in the EU and create new jobs. In addition, an SPC manufacturing export waiver for EU Member States could result in speedier entry of European generics and biosimilars within the EU following the expiry of protection in EU markets, with saving some billion Euros over the same period. This could generate significant savings in the health budget depending on generic entry and facilitate availability and accessibility of medicines. Any potential negative effect of such measure on innovations will be also considered.

Continuous investments in innovation in sectors already covered by the existing SPC acquis are necessary in a context of increasing demand for new health treatments, and safer and sustainable food supply. The innovative pharmaceutical and biotechnology sectors are the most R&D intensive industries, spending an estimated EUR 30.5 billion in R&D in the EU in 2014. Another relevant industry is the innovative agrochemical industry which invests over 7% of its revenue in research and development with over 5,500 staff on technical support in Europe. Within these industries, innovative SMEs play an essential role for maintaining the innovative character of the pharmaceutical sector (EC pharma sector inquiry, 2008). Patents in first place but also SPCs, together with data and market exclusivity, provide incentives for pharmaceutical companies to invest heavily in innovation. On the importance of SPC in Europe, statistics show that approximately 1,650 SPC applications were filed in Member States in the sole 2014. Approximately 19,000 SPC were filed in Europe over the period 1991 to 2014, confirming the importance for the pharmaceutical industry of this protection right. Considering the actual innovation and budgetary challenges faced by the pharmaceutical industry, a recalibration of certain rules may provide additional certainty and reduce costs and burdens for market players and authorities.

A broad and up-to-date Bolar and research patent exemption could impact economically in terms of keeping the European pharmaceutical sector as a hub for clinical trials and bringing market opportunities to EU-based suppliers of APIs. It is difficult to quantify the full extent of its impacts, as the Bolar exemption is one among a number of factors influencing the location of clinical trials. For instance, extending the Bolar to cover medicines could result in cost savings for patent screening of up to several millions of Euros. Its extension across Europe would also reduce the risk of infringements in Member States, due to stricter rules, and it could have positive effects on incentives to innovate by increasing freedom to operate. It would also have positive effects on the creation of additional skilled jobs. In the case of biosimilar medicines, it would support the reduction of duplication in clinical trials for innovators as well as the subsequent reduction of bioequivalence tests for generic producers in obtaining market authorisation.

Today, SPCs are a national title; with the introduction of the unitary patent, a European SPC title would create a number of advantages to the SPC users, which tend to operate across borders in terms of research and development, licensing and commercialisation activities. A European SPC title would bring savings in terms of costs with only one competitive fee for the whole EU, reduction of attorney costs, litigation in only one court for the entire EU territory (i.e. the UPC), higher legal certainty and predictability, less discrepancy on SPCs' expiry dates, etc. This would be of interest to all market players, and especially to SMEs operating across borders. National patent offices might lose some administrative fees related to national SPCs; this would be offset by a reduction in administrative tasks and redistribution of part of the European SPC fees. The cost for the EU of creating and running a SPC grant authority also needs to be considered.

Overall, the modernisation of the SPC framework and Bolar exemption would increase legal certainty, facilitate research and clinical trials, support internationalisation and the marketing of medicines across Europe and further afield. Regarding international trade and investment, a European SPC title, and more certainty on the SPC and Bolar and patent research exemptions, might benefit users from non-EU countries, increase manufacturing in Europe, and attract international investment into the EU in the relevant innovative hi-tech and R&D-intensive sectors. The impact assessment will analyse whether an SPC manufacturing waiver would improve the EU's trade-balance for generics, biosimilars and medicines in general.

Likely social impacts

Depending on the option(s) chosen, these initiatives aim to encourage innovation, meaning more and better products and services for citizens. Innovative sectors provide large numbers of highly qualified jobs (researchers, doctors, engineers, etc.) and pay high salaries in Europe. Considering the current economic context and the increasing use of automation and big data, additional support to such sectors will secure existing jobs, create new ones and maintain stable working conditions.

In the field of pharmaceuticals, improved incentives and greater legal certainty would bring timely access to both innovative and generic/biosimilar medicines for patients. The timely entry of generics/biosimilars is instrumental for the sustainability of public health budgets in the context of an ageing population in the EU. Indeed, national expenditure in medicines corresponds to 15-20% of public health budgets in Europe.

Likely environmental impacts
Not applicable
Likely impacts on fundamental rights
It is unlikely that this initiative will have negative impact on fundamental rights.
Likely impacts on simplification and/or administrative burden
Better-defined and up-to-date Bolar and research patent exemptions would reduce the cost of unnecessary litigation. A European SPC would bring both simplification and a reduction of administrative burden for SPC users (which currently must be filed in 28 Member States), Member States' patent offices and national courts.
D. Data Collection and Better Regulation Instruments
Impact assessment
The IA will assess the detailed options above in order to determine the most cost-efficient mix of options which should be retained. Drafting of the impact assessment (IA) would start in 2017, aiming at submission to the Regulatory Scrutiny Board by the end of the year. A Commission inter-service steering group is monitoring this initiative, involving the following Directorates General: DG Internal Market, Industry, Entrepreneurship and SMEs, DG Health and Food Safety, DG Research and Innovation, DG Trade, DG Competition, the Legal Service, and the Secretariat-General.
Data collection
The Commission has contracted the following studies to analyse the economic and legal angles of the issues above that can be used as the basis for impact assessment: <ul style="list-style-type: none"> - Study-1: study on the economic impact of an SPC export waiver and recalibration of the Bolar patent exemption, terminated in 2016. - Study-2: evaluation of the Paediatric Regulation, terminated in 2016. - Studies-3-4-5: three studies evaluating the legal and economic aspects of the SPC system in the EU, due in 2017. Additional targeted studies may be commissioned for in-depth analysis of specific issues. Any eventual new legislation as a result of this initiative will be further evaluated five years after its entry into force.
Consultation strategy
A formal open online public consultation on the issues, objectives and policy options set out above will be launched in the first half of 2017. This consultation will be announced on the Your Voice in Europe website: http://ec.europa.eu/yourvoice/consultations/index_en.htm The public consultation will cover both the assessment/evaluation of the EU SPC and Bolar framework, and the assessment of all options and their potential impacts. Furthermore, targeted consultation activities will also be organised, including a conference/workshop for broad set of stakeholders' groups as identified in the stakeholder-mapping above. Member States' patent offices were consulted in 2013 on a European SPC and the Commission participates in the annual meeting of the Member States' SPC experts. Additional consultations and presentations to national patent offices and relevant Member State authorities are planned. The EU associations of pharmaceutical industries have issued position papers on several aspects of this initiative (notably on the European SPC and the manufacturing waiver).
Will an Implementation plan be established?
An implementation plan will be established for all relevant new or altered legal instruments arising from this initiative.