

## ANALYSIS OF THE PROPOSAL FOR A REGULATION OF A MANUFACTURING EXCEPTION RELATED TO THE SPC AND AIMED TO MAKE THE EUROPEAN INDUSTRY COMPETITIVE

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On 28 May 2018 the European Commission launched a Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.<sup>1</sup> By means of this regulation the European Commission submitted to the Parliament and the Council the creation of a new exception to the infringement of an intellectual property rights, specifically to the Supplementary Protection Certificate or SPC. The new exception has been known as *manufacturing waiver*, since it would permit manufacturing a protected technology with the exclusive aim of either exporting to third countries or entering into the market right after the expiry date of the SPC.

The Commission explains in its Proposal for a new Regulation that the absence of this exception in the Regulation 469/2009/EC has had two unintended consequences:<sup>2</sup>

- (1) It has prevented manufacturers of generic and biosimilar medicaments established in the Union from manufacturing, even for the exclusive purpose of exporting to third country markets in which such protection does not exist or has expired; and
- (2) It has made more difficult for those manufacturers to enter the Union market immediately after expiry of the certificate, given that they are not able to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.

The European Commission is clear when it concludes that “*This puts manufacturers of generics and biosimilars established in the Union at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection*” and that if the European institutions do not intervene, the viability of the generic and biosimilars industry in the EU could be under threat.<sup>3</sup>

European Union law has already harmonised patent law as to make possible that the pharmaceutical laboratories obtain marketing authorisations for medicinal products before a patent expires. This enables them entering into the market right

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<sup>1</sup> Published as COM(2018) 317 final, 2018/0161 (COD).

<sup>2</sup> See Recital 4 of the Proposal.

<sup>3</sup> Recitals 5 and 6 of the Proposal.

after the expiry of the patent. Some countries, such as Germany, the United Kingdom and Spain, have expressly included in their legislation that the request or award of a marketing authorisation is not to be regarded as patent infringement. This extensive Bolar provision allows companies obtaining marketing authorisations not only in the European countries, but also outside the European Union.

However, this legal framework does not enable an European manufacturer marketing his pharmaceutical product in a certain country once the patent or SPC have expired in that country. If the patent or SPC is still in force in the European country where the manufacturer is going to produce the medicine, the manufacturer will be under risk of patent infringement in that country although the patent has expired in the country of export.

The proposal of Regulation made by the European Commission is a first step to enable European manufacturers to be competitive abroad. Limited to SPCs, this new legislation would allow to produce a medicine for which a marketing authorisation had been obtained in a third country in spite of the existence of an SPC in the country of manufacture.

We will analyse below the contents of the new legislation to verify if it satisfies the objectives that are proposed. Given the case, what aspects should be modified to make the proposal a real and effective instrument to boost the competitiveness of the European pharmaceutical industry of generics and biosimilars in order to compete under equal conditions with manufacturers established in third countries.

## **1. Background and previous proposals to regulate the export manufacturing waiver**

When the European Commission proposed the new Regulation, it aimed (a) to ensure that manufacturers established in the Union are able to compete effectively in third country markets where supplementary protection does not exist or has expired, (b) to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant SPC and (c) to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.<sup>4</sup>

The current proposal of the Commission has not been the first text of a specific exception in this domain that has been discussed in the European Union. However, it is the first time that the Commission boosts an exception to manufacturing

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<sup>4</sup> Recital 7 of the proposed Regulation. For a thorough analysis of previous attempts and the economic and legal background of the manufacture for export exception, see SEUBA, X., GENOVESI, M. AND ROFFE, P, "A Manufacturing for Export Exception", in MERCURIO, B. and KIM, D. (Eds), *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options*, Routledge, 2017. Available at [https://papers.ssrn.com/sol3/Data\\_Integrity\\_Notice.cfm?abid=2745802](https://papers.ssrn.com/sol3/Data_Integrity_Notice.cfm?abid=2745802).

activities within the scope of protection of an European intellectual property right such as the SPC.

In 2003 European institutions proposed for the first that the manufacturing of a pharmaceutical product should not be considered a patent infringement activity in certain circumstances. Only three years before, the Commission had lost its battle against the Canadian Bolar exception. The Commission, through its proposal of modification of Directive 2001/83,<sup>5</sup> included a Bolar-type provision in the text of the Directive<sup>6</sup>. In its revision of the text, the European Parliament included an amendment to the proposal of Directive of the Commission and suggested the inclusion of a new exception to patent infringement as an export clause.<sup>7</sup> The justification given by the European Parliament in 2003 was that it was intended to facilitate exports of generics.<sup>8</sup>

The Commission did not accept the proposal and sent the proposal back to the European Parliament without the export exception. In its second report to the

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<sup>5</sup> Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2001) 404 final — 2001/0253(COD)), published in OJ C 75E, the 26 March 2002, p. 216–233.

<sup>6</sup> The text introduced by the Commission included a new Article 10(4): “*Conducting the necessary tests and trials with a view to application of paragraphs 1, 2 and 3 to a generic medicinal product shall not be regarded as contrary to patent rights or to complementary protection certificates for the medicinal products*”.

<sup>7</sup> Report of the European Parliament of 9 October 2002 on the proposal for a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2001) 404 – C5- 0592/2001 – 2001/0253(COD)). Amendment 39, Article 1, paragraph 7, to Article 10, paragraph 4 of the Directive 2001/83/EC. The text of the proposal was drafted in the following terms as a new Article 10(4) to the Directive 2001/83/EC: “*Conducting the necessary tests and trials [on the active ingredient, submitting an application for marketing authorisation for a generic or biosimilar medicinal product, submitting samples pursuant to Article 19 and granting marketing authorisation for a generic medicinal product] with a view to application of paragraphs 1, 2 and 3, [as well as for export, will not be regarded as contrary] to patent rights or to complementary protection certificates for [the reference] medicinal products [in question]*”

<sup>8</sup> The justification given by the European Parliament (see previous footnote) was as follows: “*This amendment makes the Commission proposal more precise in that it describes exactly what development work may be carried out in connection with the authorisation procedure for a generic medicinal product. This will create legal certainty. Otherwise, generic medicinal products will continue to be developed outside the EU while the original is still under patent, with the consequent loss of jobs, investment and know-how.*

*A provision concerning exportation has been introduced for the following reasons:*

- *to improve access to medicinal products by facilitating exports of generic products so as to meet the health needs in a country which has granted a compulsory licence or which does not have a patents system”.*

Four years later, in 2006, a Regulation on compulsory licenses on patents to generics for export to countries with public health problems was established, thus giving a timid answer to a necessity but not to the competitive interests of the generic and biosimilar industry out of the European Union (Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, published in OJ L 157, 9.6.2006, p. 1–7).

proposal of Directive, the Parliament insisted in the introduction of the exception, now as Article 10(5).<sup>9</sup>

Again, the Commission did not accept to introduce the export clause. Whereas in a common position the European Parliament and the Council reached an agreement pursuant to which the Bolar clause was accepted, the export clause did not make its way into the text.<sup>10</sup>

Fifteen years after that first proposal of the European Parliament, the European Commission has come to accept the export clause, albeit limiting its application to SPCs.

In Spain, a new Patent Act was passed in 2015.<sup>11</sup> Some political parties proposed an amendment to the Act intended to introduce an exception to patent infringement, namely the manufacture for export exception.<sup>12</sup>

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<sup>9</sup> Recommendation for Second Reading, of 2 December 2003, on the common position adopted by the Council with a view to adopting a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (10950/03/2003 – C5- 0464/2003 – 2001/0253(COD)). The text said “*Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2 [and] 3 [to a generic medicinal product] and [paragraph 4] to a [biosimilar] medicinal product and the consequential practical requirements [relating to those provisions, as well as for export,] shall not be regarded as contrary to patent rights or to supplementary protection certificates for those medicinal products*”.

<sup>10</sup> Common Position (EC) No 61/2003 of 29 September 2003 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. In number 11, the Common Position provides that “*11. Amendment 134 relating to the so called Bolar clause on patent protection has been accepted in principle except the part referring to products for exports. In relation to submission of applications and granting of an authorisation, the Council believes that these activities, being of an administrative nature, will not infringe patent protection. The Council and the Commission have underlined this in a joint statement. Thus, it is neither necessary nor appropriate to include those activities in a provision on exemptions from patent protection. As concerns the submission of samples, this will be covered by the addition agreed by the Council: “and the consequential practical requirements”*”. The joint statement foresaw that “*The Council and the Commission consider that the submission and subsequent evaluation of an application for a marketing authorisation as well as the granting of an authorisation are considered as administrative acts and as such do not infringe patent protection*”. This agreement between both European institutions gave green light to the so called bolar clause.

<sup>11</sup> Approved by the *Cortes Generales* (Congress and Senate) on 24 July as Act 24/2015

<sup>12</sup> Specifically, the Catalan main party at that time, *Convergència i Unió*, suggested the following draft: “*The rights conferred by the patent shall not extend to the manufacturing or using of the invention or the offering or delivering of the means needed to carry out the invention in Spain, with the aim to dispose of the subject matter of the invention in the market immediately after the expiry date of the patent and/or if the offering or selling has as the final destination a Country where patent protection does not exist*” (Amendment n<sup>o</sup> 79). The whole justification was as follows: “*Competitiveness in the chemical-pharmaceutical sector is such that it is necessary to effectively dispose in the market of the object of the patented invention with prompt immediacy once the protection expires, through the patent or, given the case, the corresponding Supplementary Protection Certificate*”.

Finally, the Spanish Government did not support these proposals and the amendments were rejected. The adoption of an exception allowing the manufacture for export of medicines was under discussion in the European institutions and it was considered that the question should be treated in that context.

One year later, a comprehensive economic and trade agreement was concluded between the EU and Canada. Indeed, that agreement enacted the manufacture for export exception, in quite similar terms to those of the Regulation approved by the Commission on 28 May 2018 to amend the Regulation No 469/2009 concerning the SPC for medicinal products.

### **2. The comprehensive economic and trade agreement with Canada and the studies commissioned by the European Union prior to propose a Regulation to be applied throughout the territory of the Union**

The Comprehensive Economic and Trade Agreement (CETA), signed on 30 October 2016, is a free-trade agreement reached between Canada, the European Union and its member states.<sup>13</sup> The Agreement has been provisionally applied, so the treaty

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*Currently, the Spanish chemical-pharmaceutical industry is in a lower step of business possibilities compared to other foreign companies that can manufacture and supply their product in advance to be marketed, either in our country immediately after the expiry of protection, or in a country where it has already expired. With the proposal filed, the Spanish companies would be on equal terms with the companies located in third countries where there is no patent protection or there is no possibility of extending the protection for the patented invention once the natural term of 20 years of patent has expired.*

*In this way, a Spanish manufacturer of active ingredients may compete on equal terms, providing products to the corresponding pharmaceutical companies for the preparation of the final medicament and its commercialisation immediately upon expiry of the patent protection or its corresponding Supplementary Protection. In the same way, it will be possible that the active ingredient for the preparation of medicines is supplied and commercialised in foreign countries without patent or when it expires even when in our country the corresponding patent is in force or, where appropriate, the Supplementary Protection Certificate. This activity should not in principle diminish the intellectual property right of the company that owns the invention, since currently there are already companies working in foreign countries that can introduce the patented product immediately after the patent expiry”.*

This proposal for the implementation of an exception to infringement contained two provisions that preserved the possibility of manufacturing during the SPC period with two different aims: (a) to satisfy the necessity of export to third countries where there is no patent protection and (b) to allow a medicines manufacturer or laboratory to enter into the market the day one after the expiry date of the SPC. In both cases the exception helps the manufacturer to compete on equal conditions with those located out of the territory of the EU.

Other political parties also supported the approval of an exception to export activities and proposed further amendments in that same sense. In the Congress *Izquierda Unida* and in the Senate, together with that last political party (amendment 11), *Esquerra Republicana de Catalunya* (amendment 38), *Entesa pel Progrés de Catalunya* (amendment 107). Those other amendments proposed were limited to the export manufacturing exception (Published on 3 July 2015 in the BOCG, Serie A, Proyectos de Ley, No. 555, pages 184 to 262).

<sup>13</sup> The European Parliament approved the Agreement on 15 February 2017 (P8\_TA(2017)0030. *EU-Canada Comprehensive Economic and Trade Agreement. European Parliament legislative resolution of*

has abolished customs duties on 98% of the types of product that the EU trades with Canada.<sup>14</sup>

Article 20.27 of CETA establishes the obligation of granting a specific *sui generis* protection for pharmaceuticals. This is a type of protection that in Europe exists since 1992, through the Supplementary Protection Certificate or SPC.<sup>15</sup> In Europe this Certificate was valid for a maximum period of five years, while in Canada there was no regulation on such specific kind of intellectual property rights that permitted the extension of the protection of patents related to medicines.

The parties agreed that the duration of the *sui generis* right of exclusivity would not exceed a period of two to five years, at the choice of each party.<sup>16</sup> It was also agreed that parties could introduce a limitation to that IP right related to the activities carried out with the protected product during the period of protection for the purpose of export.

The Canadian Patent Act was modified through Bill C-30 on October 31, 2016,<sup>17</sup> just one day after the signature of the Agreement with the European Union and the member states. Among other changes, new Articles 104 to 122 were added to regulate the new *Certificate of Supplementary Protection* or CSPs. According to Article 116(3), the term of the Certificate in any event is for a maximum of two years, the minimum term foreseen in the CETA.

In relation to the exception provided to manufacturers during the Certificate's term, Article 115(2), with the title of *No infringement — export*, foresees that "*Despite subsection (1), it is not an infringement of the certificate of supplementary protection for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada*". Subsection (1), on the *Scope of supplementary protection*, contemplates that it grants "*the same rights*,

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15 February 2017 on the draft Council decision on the conclusion of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part (10975/2016 – C8-0438/2016 – 2016/0205(NLE))).

<sup>14</sup> Guide to the Comprehensive Economic and Trade Agreement (CETA), published at [http://trade.ec.europa.eu/doclib/docs/2017/september/tradoc\\_156062.pdf](http://trade.ec.europa.eu/doclib/docs/2017/september/tradoc_156062.pdf).

<sup>15</sup> In 1996 SPCs were also foreseen for plant products through a new Regulation, namely Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (published in OJ L 198, 8.8.1996, p. 30–35).

<sup>16</sup> Article 22.27(6) of CETA establishes that "*without prejudice to a possible extension of the period of sui generis protection by a Party as an incentive or a reward for research in certain target populations, such as children*". In the case of the European SPCs this additional extension is of six months according to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, published in the OJ L 378, the 27 December 2006, p. 1–19.

<sup>17</sup> Passed on First Reading by the House of Commons of Canada as Bill C-30, *An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures*.

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*privileges and liberties that are granted by the patent set out in the certificate, but only with respect to the making, constructing, using and selling of any drug that contains the medicinal ingredient, or combination of medicinal ingredients, set out in the certificate, by itself or in addition to any other medicinal ingredient”.*

In Europe, the DG Internal Market, Industry, Entrepreneurship and SMEs (DG Growth) commissioned a consultancy, Charles River Associates, to conduct a study to assess the economic impacts on the European pharmaceutical industry as well as wider impacts on employment and spending on pharmaceuticals, of a number of changes to exemption provisions during the patent and Supplementary Protection Certificate (SPC) term in Europe on medicines for human use, specifically related to (a) Bolar provisions, (b) exports during the term of protection and (c) stockpiling for granting a day 1 entry into the respective markets of the Member States. The opinion was issued February 2016 and published by the European Commission on 5 October 2017 with the title of *Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe*.<sup>18</sup>

The conclusions of the report were clearly reflected in the Executive Summary of the report.<sup>19</sup> The SPC export waiver and the day one launch would bring clear benefits to the European pharmaceutical industry: *“With respect to the SPC export waiver to third countries, considering the impact on both EU based innovators and generics and biosimilars, we estimate that in our base case scenario, it could result in net additional sales of €7.3 billion to €9.5 billion by 2025 for the EU based pharmaceutical industry. These results translate into an EU manufacturing employment increase of 13% to 16% (20,000 to 25,000 additional jobs), assuming no change in worker productivity. Additional savings to EU spending on pharmaceuticals of 4-8% could materialise from a timelier introduction of generics and biosimilars in European markets following SPC expiry in Europe. These numbers are lower bounds as the effects are estimated on a sample of 117 non-biological and 17 biological molecules”.*

It is also explained that the exemption would result in an increase of exports of the EU pharma industry of 6 to 18% and, if the day one entry launch was introduced, savings on pharmaceutical expenditure of 1 to 4%

### **3. The SPC as a *sui generis* IP right not regulated neither in the TRIPS Agreement nor in most of the countries**

The SPC is an IP right enshrined in some legal orders. The United States were the first country to adopt an extension of the exclusivity of the patent rights to pharmaceuticals as an exchange between the industries of originators and generics after the effects of the *Roche Products, Inc. v. Bolar Pharmaceutical Co.* decision in

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<sup>18</sup> Accessible at <https://publications.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en>.

<sup>19</sup> Pages 2 and 3 of the study.

1984.<sup>20</sup> Shortly after the decision was rendered, declaring that the mere acts carried out to obtain the approval of a marketing authorisation by the competent authorities result in an infringement of the patent right, originators and generics reached a compromise known as the Drug Price Competition and Patent Term Restoration Act or Hatch-Waxman Act,<sup>21</sup> through which an extension of the patent term<sup>22</sup> and a new exception based on the balance agreed in the pharmaceutical industry after the Bolar case (after known as the *Bolar exception*).<sup>23</sup>

a) *The SPC as an extension to the patent exclusivity based on the local effects of the delay in obtaining a market authorisation to a medicament*

It is not the object of this article analysing the legal nature of the supplementary protection certificate in depth, but only in relation to the exception that has been proposed by the Commission.

The SPC is an intellectual property right based on a general premise established in the Recitals of the EC Regulation No. 1768/92:<sup>24</sup> *“at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research”*. Based on this, the European Community proposed *“the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary”*.

As the CJEU has reminded in a recent Judgement of 25 July 2018,<sup>25</sup> the objective of the SPC is *“to re-establish a sufficient period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on*

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<sup>20</sup> United States Court of Appeals for the Federal Circuit, 733 F.2d 858 (1984), Judgement of April 23, 1984.

<sup>21</sup> Drug Price Competition and Patent Term Restoration Act. Public Law 98-417, of September 24, 1984.

<sup>22</sup> 35 U.S.C. 156, *Extension of patent term*. Not contemplated as a sui generis right, but as an extension of the term of exclusivity granted to the patent.

<sup>23</sup> 35 U.S.C. §271(e)(1) states that *“it shall not be an act of infringement to [...] use [...] a patented invention [...] solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs”*.

<sup>24</sup> Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, published in the OJ L 182, 2.7.1992, p. 1–5 and repealed by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

<sup>25</sup> Teva, Accord, Lupin and Generics (UK) v Gilead Sciences Inc., Case C- 121/17.



*which the first MA in the European Union was granted*".<sup>26</sup> So, the effect of the SPC is local, based on the specific circumstances of delays provoked by the necessity of obtaining a marketing authorisation in Europe prior to launching a pharmaceutical product in a country of the European Union.

The CJEU also reminds that Article 4 of Regulation No 469/2009 provides that the protection granted by the SPC extends only to the product covered by the MA granted for the corresponding medicinal product and for any use of the product as a medicinal product that has been authorised before the expiry of the SPC, exclusively '*[w]ithin the limits of the protection conferred by the basic patent*'. And the same happens regarding Article 5 of Regulation No 469/2009, under which the SPC is bound to the content of the basic patent.<sup>27</sup>

The SPC is thus a new and different IP right that can be subject to revocation according to the provisions contained in the SPC Regulation.

### *b) Non-applicability of the TRIPs Agreement to the SPC*

The Agreement on Trade-Related Aspects of Intellectual Property Rights, commonly known as TRIPS, was approved as Annex 1C of the Agreement establishing the World Trade Organisation (WTO) and is mandatory for all WTO members. All the member states of the European Union and the EU itself have signed the WTO Agreement and have to give effect to the provisions of TRIPS.<sup>28</sup>

It is established in the TRIPS Agreement that the term "intellectual property" refers to the categories that are the subject of Sections 1 through 7 of Part II.<sup>29</sup> These categories are: (1) Copyright and Related Rights, (2) Trademarks, (3) Geographical Indications, (4) Industrial Designs, (5) Patents, (6) Layout-Designs (Topographies) of Integrated Circuits and (7) Protection of Undisclosed Information.<sup>30</sup> SPCs are not the object of regulation in the TRIPs Agreement. Therefore, they are not subject to the TRIPS Agreement.<sup>31</sup>

An extension of the patent term for pharmaceutical products based on the time needed to obtain a marketing authorization has only been adopted in some states. The first country to adopt a Bolar type legislation was the United States through the Patent Term Restoration Act of 1985.<sup>32</sup> Other countries that approved an extension

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<sup>26</sup> Idem, para. 39 of the decision.

<sup>27</sup> Idem, paras. 44 and 45.

<sup>28</sup> See Article 1.1 of the Agreement.

<sup>29</sup> See Article 1.2 of the Agreement.

<sup>30</sup> Articles 9 to 39 of the TRIPS Agreement.

<sup>31</sup> In that same sense see SEUBA, X., GENOVESI, M. AND ROFFE, P, "*A Manufacturing for Export Exception*", op cit. at footnote 4.

<sup>32</sup> See above, footnote 21.

of the patents are South Korea in 1987,<sup>33</sup> Japan in 1988,<sup>34</sup> Australia in 1990,<sup>35</sup> Taiwan in 1994,<sup>36</sup> Ukraine in 2000,<sup>37</sup> Belarus in 2002,<sup>38</sup> Russia in 2003<sup>39</sup> and CEI countries, Singapore in 2004.<sup>40</sup> All these countries have approved a possible extension of the patent term up to a period of five years. Canada accepted an extension of the patent term up to a maximum of 2 years in 2016, after the trade agreement negotiated with the EU was signed. Apart from those states and the European Union, other states do not foresee in their domestic legislations the possibility of extending the patent term.

Thus, the TRIPS Agreement does not extend to SPCs or patent restoration terms and the member states are free to decide on whether they are regulated or not and in what terms and limitations.

*c) An exception justified and consistent with Article 30 of TRIPS, even when this is only applicable to patents and do not cover other intellectual property rights*

With the title of *Exceptions to Rights Conferred*, Article 30 of the TRIPS Agreement establishes the principles for the application of an exception to patent infringement: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”.

Apart from what it has been mentioned above about the application of the exception to the exclusive rights conferred by a patent, which does not include the SPCs (indeed, as it has already mentioned above, SPCs are not a subject of the regulation of TRIPS), Article 30 of TRIPS is a translation to the realm of patents of the three steps test of the Berne Convention for the Protection of Literary and Artistic Works.<sup>41</sup>

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<sup>33</sup> Article 90 of the Korean Patent Act.

<sup>34</sup> Article 67 (2) of the Japanese Patent Act

<sup>35</sup> Section 70 of the Patents Act 1990 provides for patent term extensions of up to 5 years in appropriate circumstances

<sup>36</sup> Article 53 of the Taiwanese Patent Act.

<sup>37</sup> Article 6 of the Ukraine Law on the Protection of Rights to Inventions and Utility Models.

<sup>38</sup> Article 1(3) of the Belarus Patent Law.

<sup>39</sup> Article 1363(2), Part IV of the Civil Code of the Russian Federation

<sup>40</sup> Sections 36A of the Singapore Patents Act.

<sup>41</sup> Adopted in 1886, the Berne Convention deals with the protection of works and the rights of their authors Article 9(2) on *Right of Reproduction*. Possible exceptions states that “It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author”. See *Declaration on Patent Protection. Regulatory Sovereignty under TRIPS*, published by the Max Planck Institut at <https://www.mpg.de/8132986/Patent-Declaration.pdf>: “Article 30 of the TRIPS Agreement constitutes an indivisible entirety. The ‘three steps’ are to be considered together and as a whole in a comprehensive overall assessment”.

According to Article 30 of TRIPs, an exception to the exclusive rights conferred by a patent should comply with three conditions: (a) it has to be “*limited*”, (2) it should not “*unreasonably conflict with a normal exploitation of the patent*” and (3) it should not cause “*unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties*”.

During the negotiation of the TRIPs Agreement, some countries tried to include specific exceptions that could be comprised within that article. Finally, the text approved was open to the inclusion of any circumstance that might comply with the three conditions established in that article.<sup>42</sup> The text adopted in the case of patents is similar to that approved for the exceptions on trademarks and copyrights.<sup>43</sup>

It has been interpreted that Article 30 of the TRIPS Agreement does not require exceptions to be interpreted narrowly, but they are to be interpreted according to their objectives and purposes set forth in TRIPS Articles 7 and 8.<sup>44</sup> They do not unreasonably conflict with a normal exploitation of the patent if “*they are based on important competing public policy considerations or have the effect of countering unreasonable impediments to the operation of markets (notably secondary markets)*”.<sup>45</sup>

The exception proposed by the Commission is intentionally addressed to comply with the conditions of Article 30, although it is not applicable to SPCs<sup>46</sup>. The

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<sup>42</sup> It can be tracked through the different statements formulated by the different countries during the long negotiations that resulted in the final text approved by the States. It is interesting to note the differences with the initial proposal of 29 March of 1990 of the European Communities: “*Limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as rights based on prior use, acts done privately and for non-commercial purposes and acts done for experimental purposes, provided that they take account of the legitimate interests of the proprietor of the patent and of third parties*” (MTN.GNG/NG11/W/68, p. 10, Art. 24(2)).

<sup>43</sup> Though there are important differences. Article 13 on copyrights states that “*Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder*”. Article 17, on trademarks, establishes that “*Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties*”.

<sup>44</sup> See *Declaration on Patent Protection. Regulatory Sovereignty under TRIPS*, page 15, mentioned at footnote 41. Cfr with *Canada – Patent Protection of Pharmaceutical Products*, of 17 March 2000 (WT/DS114/R) where the report of the group ad hoc interpreted the word “limited” restrictively. The interpretations of special groups, as it was the case in the opinion that has been cited, are not binding for the interpretation of the WTO and are not juridical precedents for subsequent cases (see Matsushita, Schoenbaum and Mavroidis, at *The World Trade Organization*, Oxford, Oxford University Press, 2nd ed. 2006, p. 112).

<sup>45</sup> *Idem*. The *Declaration on Patent Protection* was signed by 37 scholars, cited at page 19 of the document mentioned at footnote 41.

<sup>46</sup> See the text of Recital 11 of the proposed Regulation: “*By limiting the scope of the exception to making for the purpose of export outside the Union and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not unreasonably conflict with normal exploitation of the product in the Member State where the certificate is in force, nor unreasonably prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties*”.

exception proposed by the Commission through its proposal of Regulation is *limited* as the SPC right is only restricted to making and other related acts with the only purpose of exporting to third parties or prepare the launch in the same conditions as other makers producing in third countries. The exception proposed *does not conflict with the normal exploitation of the patent* as it will not have an impact in the country where the production is to be carried out during the period of exclusivity. The *legitimate interests of the patent owner* will not be unreasonably prejudiced either. On the contrary, the legitimate interests of third parties, the competitors and consumers, are appropriately protected through an exception that provides certainty to the pharmaceutical industry producing in the European Union<sup>47</sup>.

In any case, the limitation established in the exceptions established in the TRIPs Agreement are only applicable to the rights specifically regulated in that Agreement, specifically on patents in its Article 30 and not to SPCs, an IP right that is not the object of that Agreement.

#### **4. Non-infringing activities. The making and related acts to export to third countries**

The main objective of the legislation proposed is the adoption of a specific exception to the exclusivity conferred to the certificate regulated by the EC Regulation 469/2009. The subject matter of the SPC is defined in Article 4 of the Regulation<sup>48</sup>. It is not an extension of the patent to which it refers, but only of the protection conferred to the product covered by an administrative authorisation to place it on the market as a medicinal product and within the limits of the patent. The extension of the duration of the protection conferred by an SPC has a local effect in the European Union, derived from the compromise acquired among the European countries in 1992<sup>49</sup>.

The title of Article 4, now "*Subject matter of protection*", is modified to "*Subject matter of protection and exceptions to rights conferred*" in order to include a reference to the specific exception that is now proposed. The current text is numbered as (1) of that article and four further paragraphs are added.

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<sup>47</sup> See Recital 6 of the Regulation proposed, where it is said that "*Without any intervention, the viability of the manufacture of generics and biosimilars in the Union could be under threat, with consequences for the Union's pharmaceutical industrial base as a whole*".

<sup>48</sup> Its current wording, contained in a single paragraph, is that "*Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate*".

<sup>49</sup> In this sense, see the recitals of the Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, where it is explained that "*a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market*".

The title proposed refers to “*exceptions*”, in plural, and not to “*exception*”. This would suggest that the Commission was thinking about introducing more than one exception to export acts as it has been finally proposed the 28 May 2018 and in consistence with the recitals of the Regulation. The content of Recital 7 also points towards that direction.<sup>50</sup>

The specific acts under the exception that fall out of the infringement of an SPC are included in paragraph (2), letter (a), of article 4 of the Regulation. Article 4(2) introduces the exception in a first sentence that states that “*The certificate referred to in paragraph 1 shall not confer protection against a particular act against which the basic patent conferred protection if, with respect to that particular act, the following conditions are met*”. The conditions established in the article are four, the first (letter (a)) defining the specific activities that are subject to the exception and the other three (letters (b) to (d)) establishing specific requirements of notifications, labelling and communications to third parties that the maker has to carry out in order to benefit of the exception proposed by the regulation.

Paragraph (a) states that the acts comprise: (i) making for the exclusive purpose of export to third countries; or (ii) any related act that is strictly necessary for that making or for the actual export itself. It implies not only that the acts carried out by the maker are included in the exception, but also those acts carried out by the maker itself or by third parties that are required either to enable the making possible or the export of the product made.

‘*Making*’ is the expression used in Article 29 of the Community Patent Convention as one of the acts falling within the scope of exclusivity of a patent,<sup>51</sup> Article 7 of the Proposal for a Council Regulation on the Community patent<sup>52</sup> and Article 25 of the Agreement on a Unified Patent Court.<sup>53</sup> In the same sense, Article 28(1) of the TRIPS

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<sup>50</sup> Cfr. Recitals 7 (the exception “*is intended to complement the efforts of the Union’s trade policy to ensure open markets for Union-based manufacturers of medicinal products. Indirectly, it is also intended to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate. It would also help to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate*”) and 8 (“*is appropriate to restrict the protection conferred by a supplementary protection certificate so as to allow making for the exclusive purpose of export to third countries and any related acts strictly necessary for making or for the actual export itself*”) of the proposed regulation.

<sup>51</sup> Convention for the European Patent for the Common Market (Community Patent Convention 76/76/EEC), published in the OJEC of 26 January 1976, No. L 17 1-28: “*A Community patent shall confer on its proprietor the right to prevent all third parties not having his consent: ( a) from making, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking the product for these purposes*”.

<sup>52</sup> Proposal for a Council Regulation on the Community patent, published as /\* COM/2000/0412 final - CNS 2000/0177 \*/ in the OJ C 337E, of 28 November 2000, p. 278–290. The text of that article are the same as those of the Community Patent Convention.

<sup>53</sup> Agreement on a Unified Patent Court, published in the OJ C 175, of 20 June 2013, p. 1–40. The content of the article is the same as the articles cited in the preceding footnotes.

Agreement, on the rights conferred by a patent<sup>54</sup>. The exception would cover therefore the activity of making the product, “*which corresponds to the medicinal product protected by a supplementary protection certificate in the territory of a Member State, for the exclusive purpose of export to third countries*”<sup>55</sup>. This means that the making is limited to a specific purpose, that of exporting the manufactured product to a third country.

A second category of the acts included in the exception are those “*strictly necessary for that making or for the actual export itself*”. The proposal of Regulation understands these acts as “*any upstream or downstream acts by the maker or by third parties in a contractual relationship with the maker, where such acts would otherwise require the consent of the certificate-holder, and are strictly necessary for making for the purpose of export or for the actual export itself*”.<sup>56</sup> Specific activities that would be covered by the exception are:

- (i) Supply and import of active ingredients for the purpose of making the medicinal product
- (ii) Temporary storage of the product
- (iii) Advertising

These acts, carried out for the exclusive purpose of export to third country destinations, are cited explicitly in Recital 9 of the proposed Regulation. They are included as examples of activities that would be considered as “*related acts*” in the expression used in the legislative text. So, these are not the only acts included in the exception. Other acts that are also comprised within the exception whenever they are referred to that exclusive purpose of exporting to third countries, would be for instance possessing or offering the product made (which comprises advertising) or the active ingredients for making the product or packaging and labelling the finished medicinal product.

There are some limits that Recital 10 clarifies that are not covered by the exception. Contrary to the above list of acts included in the exception, the negative list is a *numerus clausus* list. The acts included are as follows:

- (i) Placing the product made for the exclusive purpose of export on the market in the Member State where a supplementary protection certificate is in force, either directly or indirectly after export.
- (ii) Reimportation of the product to the market of a Member State in which a certificate is in force.
- (iii) Any act or activity for the purpose of import of medicinal products, or parts of medicinal products, into the Union merely for the purposes of repackaging and re-exporting.

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<sup>54</sup> This articles states that “1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product”.

<sup>55</sup> Recital 9 of the Regulation.

<sup>56</sup> Idem.

The first limitation has to be interpreted in the sense that export to a member state is permitted whenever an SPC has not been extended or is not in force in that country. Therefore, exporting to a third country means any country out of the European Union and any EU country where an SPC is not in force. Reimportation is equally tolerated if it is carried after the expiry of the patent. In the same sense, reimportation is accepted whenever carried out after the expiry date of the patent.

Finally, it is not permitted that a medicinal product not made in the European Union is imported into the states of the European Union just to be repackaged or re-exported. Undertaking those downstream activities during the SPC lifetime is only permitted in relation to a medicinal product that has been made within the European Union.

### **5. Manufacturing to entering into the EU market immediately after expiry of the relevant supplementary protection certificate**

The Regulation proposed by the European Commission explains that *“A further unintended consequence is that the protection conferred by the certificate makes it more difficult for those manufacturers to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired”*.<sup>57</sup> This constraint places the European manufacturers of generics and biosimilars *“at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection”*.<sup>58</sup>

In effect, as the Commission explains, the industry established in the European Union is not only prevented from manufacturing within Europe to export to third countries, but also to enter in the European Union right after the expiry of the SPC, in the same conditions as manufacturers established beyond the European borders. This harms the competitiveness of the European industry and, as dramatically highlighted in the text of the Commission, *“the viability of the manufacture of generics and biosimilars in the Union could be under threat, with consequences for the Union’s pharmaceutical industrial base as a whole”*.<sup>59</sup> In this sense, *“Indirectly, it is also intended to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate. It would also help to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate”*.<sup>60</sup>

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<sup>57</sup> Recital 4 of the Regulation.

<sup>58</sup> Recital 5 of the Regulation.

<sup>59</sup> Recital 6 of the Regulation.

<sup>60</sup> Recital 7 of the Regulation.

The report issued for the Commission explains in Section 3.6 that “A stockpiling exemption is likely to benefit the European generic and biosimilar pharmaceutical industry by allowing domestic producers to enter timely in markets where the SPC term of the reference product has expired, putting them on an equal footing to compete in these markets with generic and biosimilar producers located in markets without SPC protection (within as well as outside the EU)”.<sup>61</sup> Specifically in relation to biosimilars, it is stated that “A stockpiling exemption is likely to benefit EU-based biosimilars given the complexity of moving from manufacturing pilot batches to advance manufacture. [...] As discussed in section 4.5.3, the delay to enter markets following protection expiry is currently well in excess of 6 months for biosimilars”.<sup>62</sup> Not having such exception provokes that “manufacturers located in countries where the protection has expired earlier or did not exist in the first place have an advantage in entering first upon protection expiry compared to e.g. domestic producers”.<sup>63</sup>

The consequence is clear: “the combined effects of an SPC export waiver and a stockpiling exemption are likely to be mutually reinforcing, as domestic generic and biosimilar producers that have already set up large scale production to supply export markets will also be able to prepare stocks for timely entry upon domestic SPC protection expiry”.<sup>64</sup> Additionally, it is also stressed that “a stockpiling exemption can be expected to result in a reduction in pharmaceutical expenditures by reducing delays in entry”.<sup>65</sup>

Despite these explanations and logic explained by the Commission, the text of the Regulation surprisingly does not include in the proposal any specific provision that will permit the European industry to produce in the European Union “to enter the Union market immediately after expiry of the certificate”.

It is a paradox that the Commission has taken care of the interests of third companies to which the products are given for the actual export so that they can reimport the medicaments exported once the SPC has expired<sup>66</sup> but not of the producers themselves or the companies that can acquire the product in the European Union to introduce it in the market on that same date. The medicines can therefore be exported with the aim of being reimported after the expiry of the SPC,

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<sup>61</sup> Pages 18 and 167.

<sup>62</sup> Pages 19 and 173. It is also mentioned that the longer delay for biosimilars is “in large part due to the complexity of developing biosimilar products, however the delay has reduced over time” and that “ramping up production is more difficult for biosimilar producers due to the complexity of the production process”.

<sup>63</sup> Page 18.

<sup>64</sup> Pages 19 and 181.

<sup>65</sup> Idem.

<sup>66</sup> Article 4(4) of the Regulation proposed by the Commission establishes that “The maker shall ensure, through appropriate means, that persons in a contractual relationship with the maker who perform acts falling within paragraph 2(a)(ii) [any related act that is strictly necessary for that making or for the actual export itself] are fully informed and aware [...] (b) that the placing on the market, import or re-import of the product might infringe the certificate referred to in that paragraph where, and as long as, that certificate applies”.



but they cannot be stored in the European Union to be placed onto the European market after the certificate lapses? This is contradictory.

The solution would be as simple as providing at paragraph 4(2)(a)(i) that the Certificate does not confer protection not only to the “*making for the exclusive purpose of export to third countries*”, but also “*to enter the Union market immediately after expiry of the certificate*”. These additional words make use of the same terms contained in the Considerations of the proposal of Regulation abovementioned.

The proposal of the Commission can be amended as to complete the scope of the exemption during the parliamentary procedure.<sup>67</sup>

### **6. Unnecessity and deterring effects of the communication and publication of the commercial intentions of the manufacturer foreseen in the Regulation**

The proposal of Regulation not only establishes the exception to the acts of manufacture for export. It establishes a specific regimen of safeguards, “*in order to increase transparency, to help the holder of a supplementary protection certificate to enforce its protection in the Union and to reduce the risk of illicit diversion onto the Union market during the term of the certificate*”.<sup>68</sup> In this regard, the text introduces up to three types of safeguards: (a) a special labelling of the product manufactured for export, (b) an obligation to inform clients and (c) the obligation to make a communication to the corresponding patent offices with certain information of the maker that will be published.

We analyse each of these safeguards, whether they are appropriate to achieve the objectives of the Regulation and what are their effects on the manufacturers that will benefit from the exception.

#### *a) Labelling to export*

The proposal of Regulation imposes labelling requirements on the maker “*in order to facilitate, by means of a logo, identification of the product as a product exclusively intended for the purpose of export to third countries. The making and related acts should only fall outside the protection conferred by a supplementary protection certificate if the product is labelled in this manner. This labelling obligation would be without prejudice to labelling requirements of third countries*”<sup>69</sup>. In this sense, the letter (c) of Article 4(2) foresees that “*the maker ensures that a logo, in the form set*

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<sup>67</sup> The preliminary conclusions of the Max Planck Institute for Innovation and Competition in their final Report on their *Study on the Legal Aspects of Supplementary Protection Certificates in the EU*, p. 311, are that “Manufacturing waivers in the form of export or stockpiling waivers are not precluded by TRIPS if they only apply to SPCs” (published by the European Commission at [file:///dataserver/Users/mvq/Downloads/MPI%20Study%20\(2\).pdf](file:///dataserver/Users/mvq/Downloads/MPI%20Study%20(2).pdf) and consulted the 3 August 2018).

<sup>68</sup> Recital 12 of the Regulation.

<sup>69</sup> Recital 15 of the Regulation.

out in Annex -I, is affixed to the outer packaging of the product or, if there is no outer packaging, to its immediate packaging” as a condition of the exception to making for the exclusive purpose of export to third countries. The logo, included in Annex 1 to the proposed Regulation, to be affixed to the outer packaging of the product, would be inserted in this form:



This condition, as noticed from the corresponding Recital mentioned above, has the aim of facilitating the identification of the product as covered by the exception. This provision entails a presumption that every product including the logo should fall outside the SPC protection. Other products not labelled as indicated in the Regulation will in principle not fall under the exception, unless an appropriate reason is given by the manufacturer (for instance, if the product has not been packaged yet or the outer packaging is commissioned to a third company).

*b) Obligation to inform clients*

The Regulation establishes that the manufacturers (shall) “*inform persons within its supply chain, through appropriate means, in particular contractual means, that the product is covered by the exception introduced by this Regulation and is intended for the exclusive purpose of export. A maker who failed to comply with these due diligence requirements would not benefit from the exception, nor would any third party performing a related act in the same or a different Member State where a certificate conferring protection for the product was in force, and the holder of the relevant certificate would therefore be entitled to enforce its rights under the certificate*”.<sup>70</sup>This means that the persons that is bound contractually with the maker in its supply chain will have to inform the person receiving the product. In the case that it did not comply with that obligation the exception will not be applicable.

As explained above, persons having a contractual relationship with the maker can be suppliers, clients, or subcontractors. A supplier of the manufacturer could be the manufacturer of the active pharmaceutical ingredient or API or of an intermediate of that API; a client, a manufacturer of the medicament or a distributor of the medicament; and a subcontractor, the person or company that carries out activities such as storage, packaging or transport.

The obligation of information established in the Regulation is aimed at informing those within the supply chain of the maker or in the downstream. The maker of a

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<sup>70</sup> Recital 14 of the Regulation.

pharmaceutical product does not have to inform the API manufacturer as the first receives the product from the second or from a trader. If the API was protected by the SPC, the API manufacturer or trader will have to inform its client or clients in the territory of the SPC. The subcontractors who carry out any related act not included in the supply chain (packaging or storage) or who cannot dispose of the product (transporter or customs brokers) do not seem to be the recipients of the information. The subcontractors in this case will not have the capacity of placing the medicament on the market, importing or reimporting it. Therefore, there is no need that these subcontractors are informed that those acts might infringe the SPC. They will not be in conditions of carrying out any of the activities that are the object of the limits established in the Regulation.

The distributors or the clients of the maker with the capacity of placing on the market, importing or reimporting the medicament are the subjects of the supply chain that are the addressees of the duty of information foreseen in the Regulation. In this case, the maker of the product protected by the SPC will have to inform the distributor or client that the medicament is exclusively for export to third countries and that that should it be placed, imported or reimported to the country where, and as long as, the SPC applies, the SPC might be infringed.<sup>71</sup>

c) *Once-off duty to provide certain information to the authority of the state where the making is to take place and publication of the communication*

The last condition established as a safeguard in the Regulation proposed by the Commission consists in providing certain information of the activity that the maker intends to carry out. The Commission explains that *“this Regulation should impose a once-off duty on the person making the product for the exclusive purpose of export, requiring that person to provide certain information to the authority which granted the supplementary protection certificate in the Member State where the making is to take place. The information should be provided before the making is intended to start for the first time in that Member State. The making and related acts, including those performed in Member States other than the one of making in cases where the product is protected by a certificate in those other Member States too, should only fall within the scope of the exception where the maker has sent this notification to the competent industrial property authority (or other designated authority) of the Member State of making. The once-off duty to provide information to the authority should apply in each Member State where making is to take place, both as regards the making in that Member State, and as regards related acts, whether performed in that or another Member State, related to that making”*.<sup>72</sup>

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<sup>71</sup> An example of a clause valid in this context could be: *“The Client is informed of the existence of the Supplementary Protection Certificate No. [NUMBER] in [COUNTRY] and that the Medicament has been manufactured with the exclusive purpose of export to third countries. Placing the Medicament on the market, importing or re-importing it might infringe that SPC”*.

<sup>72</sup> Recital 13 of the Regulation.

Articles 4(2) establishes in its letter (b) that “*the authority referred to in Article 9(1) of the Member State where that making is to take place (‘the relevant Member State’) is notified by the person doing the making (‘the maker’) of the information listed in paragraph 3 no later than 28 days before the intended start date of making in that Member State*”<sup>73</sup>.

The interest in the communication does not lie on the mere fact that the patent office is informed. It is established in a new paragraph 4 of Article 11<sup>74</sup> that “*The notification sent to an authority as referred to in Article 4(2)(b) shall be published by that authority within 15 days of receipt of the notification*”. This implies that the notification is published and therefore disclosed to third parties, the SPC holder and the competitors will have knowledge of the intentions of the maker at least two weeks before it begins to make the medicament protected by the SPC (the communication is made 28 days prior to the making, less 15 days in which it has to be published).

The proposal of Regulation foresees that the authority that receives the communication is required “*to publish that information, in the interests of transparency and for the purpose of informing the holder of the certificate of the maker’s intention*”.<sup>75</sup> It is at least questionable that the effect of the publication fulfils the necessities derived from those two interests and there is no explanation at all on what those interests consist of and what kind of necessity fulfils the communication. There is no evaluation at all of the necessity or the pros and cons of the communication in terms of competitiveness.

The information required in the communication is of a confidential nature.<sup>76</sup> The identity of the manufacturer and the sites of manufacture is protected by the EU law and is expressly contemplated as confidential by the Health authorities of the European Union.<sup>77</sup> It is established that the names of manufacturers or suppliers of

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<sup>73</sup> The information listed in paragraph (3) of Article 4 consists in: the name and address of the maker; the address of the premises where the making is to take place; the number of the SPC and identification of the product; the number of the authorisation granted for the manufacture of the corresponding medicinal product; the intended start date of making in the relevant Member State; and an indicative list of the intended third country or countries where the product is to be exported.

<sup>74</sup> Article 11 of Regulation 469/2009/EC establishes the regimen of publication of an SPC. This new paragraph 4 would be added to the three already existing.

<sup>75</sup> Recital 13 of the Regulation, i.f.

<sup>76</sup> The Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, states in its Recital 2 that “*Businesses, irrespective of their size, value trade secrets as much as patents and other forms of intellectual property right. They use confidentiality as a business competitiveness and research innovation management tool, and in relation to a diverse range of information that extends beyond technological knowledge to commercial data such as information on customers and suppliers, business plans, and market research and strategies*” [Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (Text with EEA relevance), OJ L 157, 15.6.2016, p. 1–18].

<sup>77</sup> The HMA/EMA recommendations on transparency. Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on

the active substance or the excipients are accepted as commercially confidential, unless disclosure is necessary for public health reasons, as well as those of other manufacturers involved in the procedures.<sup>78</sup> It is an information that is known by the health authorities but kept confidential to third parties as commercially sensitive and valuable. The principle of transparency has indeed been alleged in the past to approve rules in Europe compelling the member states to suppress unnecessary administrative barriers in the course of trade.<sup>79</sup>

On the other hand, there is no need to take such safeguards as there is no risk of an SPC infringement since a medicament cannot be placed into the European market without previously having obtained a marketing authorisation from the corresponding national or European health authorities. A medicament that is manufactured in the European Union necessarily must obtain a previous administrative approval where there will be information of the applicant as well as of the identity of the manufacturer of the medicament if it is located in the European Union. If a medicament that had been manufactured in the European Union was to be introduced or reimported in the territory of one of the member states, it would be known by the SPC holder as the marketing authorisation would inform of this fact.<sup>80</sup> There is therefore no risk that the medicament is placed in the European

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granting of a marketing authorisation [published in November 2010, EMA/484118/2010] establish that “*EMA and National Competent Authorities should have a common approach on what should be considered as commercially confidential, in particular whilst procedures to assess marketing authorisation applications are ongoing. In view of the lack of a legal definition and for the purpose of harmonisation ‘commercial confidential information’ shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information*”. The HMA/EMA Guidance Document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application - release of information after the granting of a marketing authorization [HMA/EMA Working Group on Transparency, adopted in principle by HMA on 23rd February 2012, formally adopted by written procedure on 9 March 2012, and edited on 14 March 2012] states clearly that the manufacturers of (a) the medicinal products and (b) the active substances and the sites of manufacture are Commercially Confidential Information.

<sup>78</sup> HMA/EMA Working Group on Transparency, Sections 1, 3.1.1, 3.4, and HMA/EMA Guidance Document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application, sections 1.2.5.2, 1.2.5.3, 1.5.6, 1.5.8, 1.5.10, 1.5.22, 1.9, 3.2.S.2, 3.2.P.3 [both cited in the previous footnote].

<sup>79</sup> The *Bolkestein Directive* (Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ L 376, 27.12.2006, p. 36–68) compels the Member States to eliminate restrictions on cross-border provision of services while at the same time increasing transparency and information for consumers would give consumers wider choice and better services at lower prices (Recital 2 of the Directive). The communication contemplated in the proposed Regulation does not provide transparency within the meaning of the interests of consumers, but on the contrary it damages the interests of the makers in relation to their competitors and orders the disclosure of specially sensitive commercial information of their business plans to direct competitors of third countries that are not obliged to provide that information.

<sup>80</sup> According to article 2 of the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [published in the OJ L 136, on 30 April 2004, p. 0001-0033], “*The holder of a marketing authorisation for medicinal products covered by this Regulation must be established in the Community. The holder*

market or reimported as given the case this information would necessarily be public and known by the SPC holder beforehand<sup>81</sup>.

In fact, none of the exceptions that have been recognised to third parties in the patent laws requires any communication to the patent office from the person that carries out acts falling within the scope of the patent claims. There is no link between the patent holder and the person that benefits from the application of an exception. The mere obligation of disclosing information that will be communicated to the patentee about the acts that the competitor intends to carry out implies the exercise of a control on the independent activity of a competitor. The request of a communication about the commercial intentions of the non-infringer is not foreseen in relation to any of the following exceptions: (a) private and non-commercial use, (b) experimental use; (c) pharmacists preparations; (d) prior use; (e) farmer privilege; (f) Bolar clause; (g) parts of transport means –vehicles, trains, ships, aircrafts. Different to those exceptions is the situation of persons linked to the patentee by (a) a commercial license; (b) a compulsory license; or (c) exhaustion of right or parallel commerce.

In conclusion, the introduction of the safeguards as they have been proposed will harm the competitiveness of the European generic and biosimilar manufacturers compared to manufacturers established in third countries where the identity of the manufacturers and the site of manufacture, the date of manufacture of the APIs or medicines, as well as the countries where the manufacturer has the intention to

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*shall be responsible for the placing on the market of those medicinal products, whether he does it himself or via one or more persons designated to that effect*". Article 9 of the Regulation (EC) No 726/2004 remits to Title V of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [published in the OJ L 311, 28.11.2001, p. 67–128] in what concerns the contents of the labelling and package leaflet. Article 8(2) of Directive 2001/83/EC establishes that "A marketing authorization may only be granted to an applicant established in the Community" and Article 26(3) that "The applicant or the holder of a marketing authorisation shall be responsible for the accuracy of the documents and the data submitted". Article 8(3) of Directive 2001/83/EC establishes that the application of a marketing authorization of a medicament shall be accompanied among other particulars by the name or corporate name and permanent address of the applicant and the qualitative and quantitative particulars of all the constituents of the medicinal product, including the reference to its international non-proprietary name (INN) recommended by the WHO or a reference to the relevant chemical name. According to Article 59(1), the package leaflet shall be drawn up in accordance with the summary of the product characteristics and shall include the name and address of the manufacturer. It is understood by manufacturer in Europe importers of medicinal products coming from third countries that are able to carry out manufacture in compliance with the particulars supplied pursuant to Article 8(3)(d) – description of the manufacturing method, and/or to carry out controls according to the methods described in the particulars accompanying the application in accordance with Article 8(3)(h) – description of the control methods employed by the manufacturer.

<sup>81</sup> On the contrary, if the medicament is the API is manufactured for export, this information will remain confidential in third countries, where the information of the suppliers of the pharmaceutical company that will market the product in the country will not have to have to be disclose. If this information has to be communicated to the patent office and it is published, this will have a negative effect in the possibilities of the European manufacturers, as their intentions will be exposed to the originator and to the competitors, either generics or biosimilars.

export is information that is respected as confidential and is not disclosed to the SPC holder or competitors.

## **7. Entry into force of the Regulation. Necessity that the manufacturing waiver is applied to the non-infringing activity rather than to the granted SPC rights**

The proposed Regulation establishes that only certificates granted on or after the date of the first day of the third month that follows the month in which this amending Regulation is published.<sup>82</sup> As currently worded, the applicability of the manufacturing waiver is linked to the fact that the SPC had not been granted in a specific date after the entry into force of the Regulation. This means that the exception would not be applicable to any SPC already granted. Therefore, the manufacturing exception would not accrue the benefits identified in the studies presented the Commission have calculated.

In other words, the expectations of the European industry of generics and biosimilars would be frustrated during several years and the threat on the viability of the manufacture of generics and biosimilars in the Union, with consequences for the Union's pharmaceutical industrial base as a whole, would not be dissipated.

The reasons for this delay in the application of the Regulation are explained at Recital 19: (a) not to deprive the SPC holders of their acquired rights, (b) to allow the applicants a reasonable time to adjust to the changed law context and to make appropriate investment and manufacturing location decisions in a timely way and (c) to allow sufficient time for public authorities to put in place appropriate arrangements to receive and publish notifications.

*a) Inconsistency of the Proposal of regulation in relation to its applicability. It is not true that the SPC holders will be deprived of their acquired rights or that they need time to adjust to the changed law context or to make appropriate investment and manufacturing location decisions*

None of the reasons provided in the text of the proposed Regulation are supported by any study or data. On the contrary, as it has already been mentioned, these assertions contradict the fact that the application of the exception will not unreasonably conflict with normal exploitation of the product in the Member State where the certificate is in force, nor unreasonably prejudice the legitimate interests of the certificate-holder.<sup>83</sup>

The only practical consequence of the proposed Regulation for the SPC applicant is that it will have to face competition from European producers located in the EU in

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<sup>82</sup> A new Article 4(5) is introduced in Regulation (EC) No 469/2009 in terms of establishing to which certifications the exception will be applicable: "*Paragraph 2 shall apply in the case only of certificates granted on or after [OP: please insert the date of the first day of the third month that follows the month in which this amending Regulation is published in the Official Journal]*".

<sup>83</sup> Recital 11 of the proposed Regulation.

non-European countries and given the case in European countries once the exclusivity rights expire in such countries. The exception will not have an impact during the exclusivity period. On the contrary, it will make the European industry competitive in the pharmaceutical sector in relation to its direct competitors, mainly Asian and American.

The assertion that the SPC holders need time “*to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions*” is a mere sentence void of support in the text of the Regulation and contrary to the real effects that the exception will have. What does it mean with *appropriate investments*? In what is thinking the European Commission? What kind of *manufacturing location decisions* would the SPC holders have to make?

The situation on the contrary, as the Commission contends in the Recitals of the proposed Agreement, is that the absence of such an exception will put in risk the pharmaceutical industry located in the European Union. As it is explained in the Recital 7 of the proposed Regulation, this is aimed: (a) to ensure that manufacturers established in the Union are able to compete effectively in third country markets where supplementary protection does not exist or has expired, (b) to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant SPC and (c) to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.

The proposal for a new Regulation also mentions that it will “*allow the applicants a reasonable time to adjust to the changed law context and to make appropriate investment and manufacturing location decisions in a timely way*”. The meaning of this sentence lacks an explanation in the text of the proposal. Indeed, the exception proposed will not change anything, but the capacity to compete of the European generic and biosimilar industry. The Commission does not explain what the applicant has to adjust or what kind of “*appropriate investment and manufacturing location decisions*” is it referring to. There is no indication at all in the documents provided by the Commission, if there is any.

*b) The different criteria applied to the entry into force of other exceptions to patents introduced by the European Union in the past, even to the SPCs themselves*

If we revise the EU legislation that has been approved in the past in relation to the application of exceptions to patent law, we realise that the regime of delay in the application of the manufacturing waiver in the proposed of Regulation is strange and inconsistent with the implementation of exceptions or limitations to patents. The exceptions foreseen so far are intended to overcome limitations that are detrimental to the interests of the individuals affected. This is the case of the Bolar provision, the farmer privilege, compulsory cross-licensing between plant variety



holders and patent holders or compulsory licenses on patents to generics for export to countries with public health problems.

When the *Bolar provision* was approved in Europe in 2004 through Article 10(6) of the Directive 2004/27/EC,<sup>84</sup> it applied to the activities to obtain the corresponding authorisations to place generic or biosimilar products in the market. That European Directive did not subject the application of the exception to patents or SPCs that were approved after the entry into force of the Directive. The exception was applicable to the activities carried out by third parties and foreseen by that exception. Countries implemented the Directive in their corresponding patent laws and none of them delayed the application of the exception to intellectual property rights that were granted until the entry into force of the exception. If this had been the case, the Bolar provision would not have been applicable until recent times.

In 1998 the European Communities approved a Directive on biotechnological inventions.<sup>85</sup> One of situations that was a novelty in the European law of the member states was the exception to patent infringement known as the *farmer privilege*. It had been strongly debated during the discussions before the European Parliament and finally approved as an authorisation to use the product of his harvest for further multiplication or propagation on his own farm although this activity objectively falls within the scope of the patent and entails an infringement.<sup>86</sup> The Directive did not delay the entry into force of that exception in the law of the member states. The applicability of such exceptions was the same as the other provisions established in that regulation.

In the same regulation of biotechnological inventions, *compulsory cross-licensing between plant variety holders and patent holders* was foreseen in the field of exploitation of new plant characteristics resulting from genetic engineering or use

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<sup>84</sup> Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, published in the OJ L 136, 30.4.2004, p. 34–57. Article 10(6) of the Directive foresees that “*Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products*”.

<sup>85</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, published in the OJ L 213, 30.7.1998, p. 13–21.

<sup>86</sup> Article 11 of the Directive 98/44/EC states as follows: “*1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94. 2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity. 3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices*”.

of plant varieties in genetic engineering, in order to guarantee access through a compulsory licence and subject to a fee. The EC Directive did not establish either any limitation in relation to rights already granted. As in the case of the farmer privilege, the limitation to the patent rights was established to any existing patent or plant variety.

Finally, in relation to patents, in 2006 the European legislative bodies established through a EU Regulation the possibility of obtaining *compulsory licenses on patents to generics for export to countries with public health problems*<sup>87</sup> Once again, the applicability of this limitation was not constrained to patents that had not been granted when the Regulation entered into force. Otherwise, even today, after twelve years of the approval of that Regulation, the possibility of obtaining a compulsory license would still not be applicable in the territory of member states.

Even if we consider the creation of the SPC, the fact that the patent offices must put in place appropriate arrangements to receive, examine, grant and publish the SPCs was not considered a problem for the immediate application of the Regulation.

Article 23 of the *SPC Regulation* approved in 1992<sup>88</sup> established that the Regulation would be applicable six months after its publication and was binding in its entirety and directly applicable in all Member States. The SPC Regulation did not include any provision that the SPCs would only be granted on the basis of patents obtained after the date the regulation entered into force.<sup>89</sup>

When *paediatric extensions* were created in 2006 through an amendment of the EC Regulation 1768/92 on SPCs,<sup>90</sup> the legislator did not establish any limitation to the application of t in relation to SPCs already granted. On the contrary, a specific regimen for the entry into force of the Regulation was established to allow SPCs already granted to benefit of paediatric extensions and special provisions were approved to allow the SPC holders to apply for such extensions in extended terms after the entry into force of the Regulation of 2006.<sup>91</sup>

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<sup>87</sup> Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, published in the OJ L 157, 9.6.2006, p. 1–7.

<sup>88</sup> Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products), published in the OJ L 182, 2.7.1992, p. 1–5.

<sup>89</sup> The Regulation only provided a delay in certain States whose laws had introduced the patentability of pharmaceutical products only recently before the Regulation was passed. Art. 21 provided that “*In those Member States whose national law did not on 1 January 1990 provide for the patentability of pharmaceutical products, this Regulation shall apply five years after the entry into force of this Regulation*”.

<sup>90</sup> Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use mentioned above, footnote 16.

<sup>91</sup> New paragraphs were added to Art. 7 of the SPC Regulation: “*4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate*” and “*5. Notwithstanding paragraph 4, for five years following the entry into force of*

The precedents of the legislative initiatives of the European Union show that it has never been considered to delay the applicability of a certain limitation or exception to a patent right. Even the application of the SPCs was not postponed to patents that had not been granted yet. The SPCs could be granted based on any existing patent.

It does not seem that a different criterion should be applied, especially if, as is the case, the general interests of the countries of the European Union and patients and consumers are affected.

*c) Whose interests serves a delayed effectiveness of the Regulation and the application of the exception of at least 10 years?*

The prohibition of retroactivity just means that laws should not take effect before they are published. As we have seen, this has not have been the criteria applied to other exceptions approved in the European Union. Legal certainty means that the application of law must be certain, in the sense that it has to be clear and precise, and its legal implications foreseeable. The general principle of legal certainty prohibits that laws take effect before they are published, or have a retroactive effect.<sup>92</sup>

The proposed amendment does not affect the content of the SPC right, its granting, existence or scope of protection of the intellectual property right created by the Regulation 469/2009/EC.<sup>93</sup> The proposed amendment addresses indeed, as it is explained in the Recitals of the Regulation proposed, the unintended practical consequences of the SPC system.<sup>94</sup> These unintended effects have a practical nature in the manufacturing activities of the European industry of generics and biosimilars. The entry into force of the new Regulation should affect therefore the activity that is the object of the exception, i.e. the making of medicaments that falls within the scope of a certificate.

If the entry into force was not applicable to certificates already granted, the efficacy of the new Regulation would in fact be delayed 10 to 12 years.<sup>95</sup> The application of

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*Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate”.*

<sup>92</sup> The ECJ established in *European Commission v Moravia Gas Storage AS* (Case C-596/13 P), para 32, that “A new rule of law applies from the entry into force of the act introducing it, and, while it does not apply to legal situations that have arisen and become definitive under the old law, it does apply to their future effects, and to new legal situations. It is otherwise, subject to the principle of the non-retroactivity of legal acts, only if the new rule is accompanied by special provisions which specifically lay down its conditions of temporal application”.

<sup>93</sup> As it has already been mentioned, this is acknowledged in Recital 11. See above, footnote 46.

<sup>94</sup> As indicated in Recitals 4, 5, and 6.

<sup>95</sup> The extension of an SPC needs that the patent expires in order to be effective. Article 13 of EU Regulation 469/2009 provides that “The certificate shall take effect at the end of the lawful term of the basic patent”. When an SPC is granted to a patent in force, it is because a marketing authorisation

an SPC can be made within six months of the date on which the marketing authorisation to the medicinal product has been granted.<sup>96</sup> Depending on the Member State, the publication of the SPC and its granting takes less or more time.<sup>97</sup> If the Regulation proposed is finally approved with the regimen of entry into force that has been included in the new Article 4(5) of the Regulation 469/2009, it will imply that the European producers of generics and biosimilars will not benefit of the application of the manufacturing waiver exception for at least 10 years.

That enormous delay in the application of the new exception cannot be understood if we take into consideration that the manufacturing waiver does not affect indeed the exclusive rights of the SPC holders but that the only effect of the exception foreseen in the proposed Regulation is to boost the competitiveness of the EU generic and biosimilar industry abroad, what is the aim of the proposed Regulation as explained in its Recitals 4 to 7, as we have had the occasion of analyse above. It is a regulation that has been awaited for a long-time by the European industry in order to be competitive out of the European Union, even inside.

The SPC is granted exclusively to compensate the delay in the launch of a medicament derived from the necessity of obtaining an administrative to place the product on the market in the Community. Accordingly, the SPC Regulation is linked to that local effect and should not affect the activity of the EU producers with regards to other territories. As we have already seen, the manufacturing waiver has no impact in the exclusivity rights granted to the SPC holder in the territories where an SPC has been granted and is in force. The manufacturing waiver does not elude the application of the enforcement directives in case of infringement.<sup>98</sup> On the contrary, if the application of the proposed Regulation was delayed, the impact in the generic and biosimilar industry would be enormous.<sup>99</sup>

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has been granted to a medicinal product. Usually for a new product 8 to 10 will have passed. So, a period of 10 to 12 years will still be left to the patent. After the patent has lapsed the SPC will then be effective and the possibility of invoking the application of the exception provided by the Regulation.

<sup>96</sup> This is the normal situation under Article 7(1) of the EU Regulation 469/2009. If the basic patent was granted after that date, according to article 7(2) the applicant will be allowed to apply for a certificate within six months of the date on which the patent is granted.

<sup>97</sup> The granting of a certificate is national and the election of the date when the proposed amendment will enter into force will create distortions within the EU market as the date of granting of an SPC is not the same in the different EU markets. If a country had granted an SPC on the basis of a certain medicine after the entry into force of the proposed Regulation, the exception would not be applicable there while it could be applicable in a country where the SPC would not have been granted yet at that date. Depending on the country, the SPC can be granted in some months (as in Germany) or in some years (as in Spain or Italy).

<sup>98</sup> See Recital 17 of the proposed Regulation.

<sup>99</sup> *Medicines for Europe* published a document titled '*Comparison of expiry dates of protection worldwide*', where it compared the situation of the protection conferred to 109 products in the EU, USA, Korea, China, India and Canada. In all the cases the protection conferred in Europe expired later than in Canada, India and China. It expired in Europe later than in the USA in 88% of the cases (97 against 12) and Korea in 94% of the cases (103 against 6) [consulted online on August 3, 2018, at <file:///Users/mvq/Documents/2.%20Note%20on%20SPC%20manufacturing%20waiver%20Oct%202017.pdf>]. In a non-published study carried out by *AESEG* considering the difference between

## 8. Conclusions

The proposed Regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products introduces an exception to overcome the limitations of the European pharmaceutical industry to be in equal conditions to compete with companies located beyond the European Union borders. Nonetheless, the exception is restricted to SPCs. The manufacturing exception as it has been proposed complements the Bolar provision approved in 2004 and includes, limited to the SPCs, the exemption that the European Parliament proposed in 2002 for patents and SPCs. Member states will have to decide whether they introduce a similar exception in their domestic patent laws.

The exception that is under study explains that it has two main objectives: to ensure open markets for Union-based manufacturers of medicinal products and to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate. Unfortunately, the text passed by the Commission contemplates the possibility of exporting to third countries (even to companies that will reimport the medicaments into the European markets after the expiry of the corresponding SPCs), but does not regulate the possibility that the European producers introduce themselves their own production into the European market without exporting it to third parties. A first day launch provision is missing in the text. It can be solved easily by providing that the making falling under the exception is not only that aimed to the exclusive purpose of export to third countries, but also that aimed to enter the Union market immediately after expiry of the SPC.

Perhaps the most important aspect that will make the Regulation proposed ineffective for at least ten years is paragraph 5 of Article 4, which would make the legislation proposed inapplicable to SPCs already granted. All studies carried out by the Commission, and concerning the effects of the exception, would be useless. The opportunity for the European manufacturers would be lost for all of those products, what includes SPCs that will lapse even after 2030. This delay has never been foreseen in other patent exceptions, such as the Bolar provision or the farmer's privilege, and would frustrate the expectations of the European manufacturing industry, thus risking the pharmaceutical industrial base of the European Union as a whole. Article 4(5) should therefore be suppressed in order to make the text consistent with the aims and goals of the Regulation.

In what concerns the safeguards, inexistent in other exceptions established in the law in relation to patents, the impression is that the Commission did not carry out a thorough analysis of the real risks that might arise if the manufactured products

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the expiry date in Europe and in the United States in non-biological medicines that in 2017 had sales over USD 400 million (in a number 25 molecules), the market that will not be accessible to the European generic manufacturers if the exception for exports is not applicable, rises to USD 109.29 billion.

were launched or reimported in the SPC countries before the expiry of the SPC and has overreacted. The communication and publication of strategical commercial information of the European manufacturer is not justified in a highly regulated sector such as pharma. The reasons pointed out in the text, such as transparency or reduction of illicit diversion of medicaments onto the European Union market, are not supported by facts and arguments. On the contrary, it harms competitiveness and potential business opportunities of European manufacturers of generics and biosimilars.

With the arrangements in the text that have been the proposed in this study, the metes and bounds of the exception proposed in the text of the Regulation would meet the expectations placed on that important exemption, key in the future of the EU based generic and biosimilar industry.

In general the conclusions of this analysis can be summarised in that the manufacturing waiver should extend to the possibility that the EU manufacturers were able to make before the expiry date not only to export to third countries but also to launch immediately after the expiry of the SPC in the EU member states; it should not include any requirement different to other exceptions that would be detrimental to the competitiveness of the EU industry; and the application of the exception should benefit the manufacturer as soon as possible once the Regulation is approved. Otherwise the objectives set out in the Regulation will be jeopardised.

In Barcelona, 13 September 2018